Long term outcomes following percutaneous dilatational tracheostomy in the critically ill

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctor of Medicine by

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Contents

Abstract

Background: Percutaneous procedures are now the predominant tracheostomy technique within the critical care setting. Complication rates for various techniques appear to be equivalent to those achieved with surgical tracheostomy. There is a paucity of data when comparing percutaneous procedures, particularly when considering late complications (tracheo-innominate artery fistulae (TIF), tracheo-oesophageal fistulae (TOF) and tracheal stenosis (TS). Given the severity of illness and associated mortality in many of these patients the incidence of these complications remains difficult to define. Confounding factors present in survivors of critical illness may present difficulties in diagnosis such that underlying tracheal pathology may go undiagnosed.

Aims: To determine:

- The incidence of common early and late complications of percutaneous dilatational tracheostomy (PDT) in relation to surgical tracheostomy (ST).
- The role of peri-operative events that may contribute to the aetiology of late complications of TS, TIF and TOF.
- The incidence of early and late complications in relation to percutaneous tracheostomy to define the safest percutaneous technique.
- The utility of adjunctive techniques (bronchoscopy & ultrasound scanning) in reducing complications of PDT.
- The prevalence of sub-clinical TS following PDT using the single tapered dilator technique (STD).
- Aetiological factors for sub-clinical TS.
- Whether sub-clinical TS may present atypically in critical illness survivors.

Methods: We have conducted a systematic review of all prospective studies reporting late complications after tracheostomy performed in the critically ill. We have also extracted data to assess the role of peri-operative events and monitoring in causing or preventing late complications. We have undertaken an eleven-year review of all PDTs performed within our unit to define the incidence of complications arising within our own population. Finally, a prospective study to identify the prevalence of sub-clinical

TS and identify atypical presenting features in survivors of critical illness has been performed.

Results: All surgical and percutaneous techniques are broadly similar in terms of early and late complications. There is a higher incidence of wound infection when comparing ST to the multiple dilator PDT. There are few studies assessing late complications between percutaneous techniques. The TS rate varies from 2.8 to 0.6% for ST and the STD technique respectively. Due to limited data we were unable to identify peri-operative events that may lead to late complications. There is a very low rate of complications attributed to the STD technique with only 9 significant late adverse events. The rate of sub-clinical TS is low with doubtful clinical significance.

Conclusions: We have not found a significant difference in the incidence of TS between PDT and ST. Our pooled proportions meta-analysis may indicate a tendency toward a higher rate of stenosis for ST. The reported complication rates presented within our cohort study may indicate that the STD PDT is one of the safer techniques available. The rate of sub-clinical stenoses following STD PDT is low and of doubtful clinical significance. Further work is required to define the role for percutaneous tracheostomy outside the critical care setting and to gather qualitative data to assess the patient's perception of tracheostomy in the critical care setting.

Dedication

To my mother Maureen who, sadly, did not survive long enough to see this project finished**.**

Acknowledgements

As with any significant body of work I would have been unable to complete this text without the collaboration and support from a myriad of individuals.

Amongst these I would like to acknowledge the assistance of Drs Becky Hanlon, Paul Jeanrenaud, Richard Pugh, Eoghan O'Callaghan, Carl Wright and Eoin Young without whom the MRI study would not have reached conclusion.

Similarly, the systematic review would have not reached fruition without the hard graft of Drs Ben Morton and Clare Hammell and the statistical expertise of Catrin Tudor-Smith and Lisa Williams.

The prolonged and ongoing review of percutaneous tracheostomy outcomes at Aintree University Hospital would not have been possible without the diligent reporting of all of my critical care consultant colleagues.

I would also like to thank Professor Simon Rogers for his review of the manuscript and constructive comments prior to submission.

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Ultimately, without the initial support of both of my parents I would never have had the opportunity to undertake this study. Their foresight and ability to see the value of an education, regardless of how long it takes, will always leave me in their debt.

Finally, I would like to thank my wife and children. Cheryl has probably been the individual who has suffered the most throughout this period. Her support and encouragement through my unpredictable moods and general negativity have been remarkable.

Declaration

I hereby declare that the content of this thesis "Long term outcomes following percutaneous dilatational tracheostomy in the critically ill" from inception to execution has been my own work.

This has been supported by Drs O'Callaghan, Wright and Young who assisted with patient recruitment and questionnaires for the MRI study. Dr Becky Hanlon provided radiological review of the MRI scans performed.

Drs Ben Morton and Clare Hammell assisted with data extraction for the systematic review, whilst Catrin Tudor-Smith and Lisa Williams provided statistical advice and support.

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APACHE	Acute physiology and chronic health evaluation
AUH	Aintree University Hospital NHS Foundation Trust
BD	Balloon dilator
CCU	Critical Care unit
CI	Confidence intervals
CPDT	Ciaglia percutaneous dilatational tracheostomy
CT	Computed tomography
CXR	Chest x-ray
DNA	De-oxyribonucleic acid
EI	Empey Index
ETT	Endotracheal tube
FEV_1	Forced expiratory volume in one second
FVC	Forced vital capacity
GWDF	Guide wire dilating forceps
IL-1	Interleukin-1
IL-6	Interleukin-6
IQR	Inter-quartile range
MRI	Magnetic resonance imaging
NICE	The National Institute for Health and Care Excellence
nTS	Non-tracheal stenosis (group)
PACS	Picture archiving and communications system
PDT	Percutaneous dilatational tracheostomy
PEFR	Peak expiratory flow rate
PNR	Prospective non-randomised (study)

PO	Prospective observational (study)
RCT	Randomised controlled trial
RD	Risk difference
RNA	Ribonucleic acid
SD	Standard deviation
SE	Standard error
SSRD	Single step rotational dilator
ST	Surgical tracheostomy
STD	Single tapered dilator
TCSA	Tracheal cross sectional area
TGF-β	Transforming growth factor β
TIF	Tracheo-innominate artery fistula
TLT	Trans-laryngeal tracheostomy
TNF- α	Tumour necrosis factor α
TOF	Tracheo-oesophageal fistula
TS	Tracheal stenosis

Chapter 1

A history of tracheostomy and mechanical ventilation within the critical care setting

A history of tracheostomy

The earliest possible use of a tracheostomy may date as far back as the Bronze Age description of a healing throat incision described in the book of Hindu medicine, the Rig Veda[1]. Later examples of its use have been attributed to the Imhotep (c 2650–2600 BC)[2], an Egyptian polymath who lived in the 27th century BC, Alexander The Great (356–323 BC) and the Greek physician Aretaeus of Cappadocia who practiced in the first century AD[1-4]. The procedure may have been relatively common place around 100BC with reports continuing until the second century when Galen of Pergamon (AD 129 – c.200) credited Asclepiades of Bithynia (129 – 40BC) as the originator of the operation[5].

From the second century onwards little further is reported on the procedure. At this point it appeared to fall in to disrepute partly from a belief that incised cartilaginous tissue does not heal. It was referred to variously as a scandal of surgery, semi-slaughter[4] and a futile and irresponsible idea[5].

At the height of the Renaissance, interest was renewed in airway surgery. In 1543 Andreas Vesalius (1514 – 1564), professor of surgery and anatomy at the University of Padua and imperial physician to Emperor Charles V, passed a reed in to the trachea of a dying animal and maintained respiration by blowing in to it[4]. The significance of this intervention was not, however, appreciated for many years. In 1546 the first description of a successful tracheostomy performed in a human and described by the operating surgeon was recorded by Antonio Brasavola (1500-1555) in a patient with a tracheal abscess[5]. In 1620 Nicholas Habicot (1550-1624), surgeon to the Duke of Nemours, who had previously documented the first tracheostomy for the removal of a foreign body and the first procedure in a paediatric patient, published the first book solely for the description of the procedure[6]. From the sixteenth to nineteenth centuries

frequent descriptions of the operation continue to be made but it was still regarded as a useless and dangerous procedure. During this period Goodall found evidence of only twenty eight successful operations in the literature all but three of which were performed in adult patients[6].

At the onset of the nineteenth century tracheostomy was used cautiously for upper airway obstruction resulting from diphtheria. In 1851 Armand Trousseau (1801-1867), a French physician from Tours, reported the first large series of tracheostomies inserted for diphtheria related upper airway obstruction[7]. From 215 procedures he reported the survival of forty seven patients[3]. Consequently the process of acceptance of tracheostomy as a legitimate surgical procedure had begun. Descriptions of the use for upper airway obstruction due to diphtheria, croup and foreign bodies increased. Indications also widened to include cases of laryngeal syphilis and tuberculosis[3]. The mortality remained high, however, and the procedure remained feared and its use was largely attempted only for hopeless cases.

At the beginning of the twentieth century the issues of timing and technique of tracheostomy were largely resolved by Chevalier Jackson (1865-1958). Jackson was an American laryngologist who studied at the Jefferson Medical College in Philadelphia and was later at professor of laryngology at the same institution. He is frequently referred to as the "father of endoscopy". In 1909 he reported a series of one hundred tracheostomies of which eighty six patients survived, ten died from non-tracheostomy related causes with four dying as a direct result of the procedure[8]. Jackson detailed the important factors in this significant improvement on previous outcomes. He advocated the avoidance of general anaesthesia or any sedative agent to allow preservation of spontaneous respiration and the cough reflex. Similar to Trousseau[7], he advocated an earlier operation than had previously been commonplace

thus avoiding the extreme dangers of hypoxia and hypercarbia when the procedure is performed in patients in extremis. He also outlined the importance of meticulous attention to detail during the operation itself (a luxury not afforded if the patient is in extremis) with particular reference to a midline dissection and careful haemostasis. He also suggested standards for post-operative management and cannula care.

In a later paper Jackson outlined the aetiological factors related to the development of tracheal stenosis namely, high tracheostomy (cricothyroidostomy), damage to the cricoid cartilage and ill-fitting cannulae[9]. Lessons that had to be re-learnt by intensivists some sixty to eighty years later[10].

1.1. Terminology

According to Goodall's detailed history the earliest descriptions of tracheostomies referred to by Galen and Aretaeus in the second and third centuries AD were described using the phrases "cut to the larynx" and "make an incision in the artery"[6]. At this time the "artery" and "bronchus" both referred to the trachea including the larynx. Around this time Antyllus (second century AD) refers to the procedure as a pharyngotomy. Later descriptions of the operation by Caelius Aurelianus in the fifth century and Paul of Aegina in the seventh century refer to laryngotomy. In 1620 Habicot described the operation as a bronchotomy. Goodall considered the first use of the term "tracheotomy" was by Thomas Feyens (or Fienus)(1567-1631), professor of medicine at the University of Leuven, in the "Libri Chirurgiae XII" published in 1649[6]. However the term was not adopted and laryngotomy and bronchotomy remained in common use. In 1718 Lorenz Heister (1683-1758) published his best-known work, "Institutiones Chirurgie". In this text he re-introduced the word "tracheotomy" to describe the procedure and also gave his opinion that the other

terms should be discarded. Following Heister's work the usage of tracheotomy to describe the procedure became increasingly common place[6]. After Armand Trousseau's paper, detailing the use of tracheostomy in a series of diphtheria patients, the term tracheotomy largely replaced the other terms[7].

1.2 Development of tracheal cannulae

Early non-human descriptions of the use of tracheostomies highlight that rudimentary cannulae in the form of reeds were most likely utilised (see below)[11]. None of the documented descriptions of tracheostomy prior to that of Fabricius of Aquapendente (1537-1619), also a professor of anatomy and surgery at the University of Padua, detailed the use of a tracheal cannula, leading Goodall to conclude that none of the earliest operators used them[12]. At the beginning of the seventeenth century Fabricius described the use of a small straight cannula with two wings to prevent it entering the trachea[12]. Fabricius stated that the tube should be short to prevent trauma to the posterior tracheal wall and not too wide to prevent too much air entering the lungs. Following this description, cannula use appears to have become accepted and more widespread. Fabricius' pupil and successor as professor of anatomy at Padua, Julius Casserius (1561-1616) later introduced a curved tube with tapes to secure it in-situ although these were not adopted at the time and the straight tube remained in use (fig 1). Casserius' tube was made of silver, although other operators also recommended gold and lead as alternatives. Later, in 1620, Habicot developed a slightly curved flattened tube designed to fit between the tracheal cartilages. Following this the use of curved rather than straight tracheal cannulae came in to favour[12].

The first suggestion of the utility of a dual lumen cannula, in an attempt to keep the tube clear of bronchial secretions without the need to remove it from the trachea, was

described by George Martin (1702-1743), a Scottish ship's doctor, in 1730 – a modification that was suggested to him by a lay person. Goodall, however, was unable to find any evidence that Martin had actually used such a tube[12]. By the beginning of the nineteenth century around the time of Trousseau's work the cannula had the curve of a quarter circle. However, Robert W Parker, surgeon to the East London Hospital from 1876 – 1902, noted in 1880 that such a tube did not conform to the anatomical relation of the trachea and the skin of the anterior neck[12]. As a consequence of this the tip of the tube tended to impinge on the anterior tracheal wall causing ulceration. Parker therefore modified the design of the tube to allow the tracheal portion of the cannula to pass posteriorly and inferiorly within the tracheal lumen without impinging upon the tracheal wall. Interestingly, the tube designed by Parker had the same configuration as that proposed by Julius Casserius much earlier[12].

1.3 Changing indications

From the earliest descriptions of the use of tracheostomies to the middle of the nineteenth century the overwhelming indication for the procedure was the presence of upper airway obstruction. This was largely due to the acute infectious causes prevalent at the time and foreign body impaction. In the late nineteenth century Friedrich Trendelenberg (1844-1924), surgeon in chief at the University of Leipzig, reported twenty five tracheostomies using a cuffed tube inserted to facilitate operations on the jaw, mouth and larynx[4]. In Jackson's series of one hundred patients described above there were eleven laryngectomies and other major operations[8].

Isolated reports advocating the use of tracheostomy for the resuscitation of drowning victims, along with the use of intermittent positive pressure ventilation (see below), were published as early as 1769 by Scottish physician William Buchan (1729-

1805)[4,13]. In the first edition of his book "Domestic Medicine" Buchan advocated mouth-to-mouth ventilation with expired air or tobacco smoke along with insufflation of tobacco smoke in to the intestines. In 1880 Karl Heuter (1838-1892), professor of surgery at the University of Greifswald, suggested the use of a tracheostomy for tracheal toilet and artificial respiration following its use in two patients with bronchial catarrh[14]. However, despite such reports, the use of tracheostomy for lower airway pathology at this time remained uncommon with the majority of procedures still being performed for upper airway obstruction.

In one of the earliest descriptions of tracheostomy use for lower airway disease Wilson described its use for patients with bulbar poliomyelitis[15]. In his report of seventy patients with pharyngeal paralysis he states that a tracheostomy was performed in `a few cases`. As a result of this he claimed there was an improved ability to remove tracheal secretions, a reduction in the aspiration of said secretions and improvements in ability to provide nutrition. Although Wilson did not use intermittent positive pressure ventilation in any of his patients he clearly documents the importance of positioning, pressure area and bowel care, fluid administration and glucose control some sixty to seventy years before the introduction of care bundles in to critical care practice. Following on from Wilson's report, Figi reported the use of tracheostomy for myasthenia gravis (one case in a series of 206 tracheostomies)[16]. Although the initial insertion was because of upper airway obstruction its utility for secretion clearance and muscular weakness became evident later.

Through the 1940s and 50s bulbar poliomyelitis became an increasingly accepted indication for the use of tracheostomies. Its use was said to improve respiration, allow secretion clearance and facilitate positive pressure respiration (see below). Following Henry Lassen's report on the 1952 polio epidemic in Copehagen[17] the indications for

tracheostomy expanded significantly to incorporate trauma patients, poisonings, thoracic and neurosurgical patients.

1.4 Positive pressure ventilation

Similar to tracheostomy the oldest references to the use of artificial respiration date back to Egyptian times when Isis is said to have resurrected Osiris with the breath of life[18]. The relevance of this and other biblical references though remain unclear.

Some of the earliest work using artificial respiration was conducted by Galen who used a bellows to inflate the lungs of a dead animal via the trachea but failed to realize the significance of his findings. In 1472 Paolo Bagellardo (c.1410-1492), also a professor at the University of Padua, appeared to have appreciated the importance of mouth to mouth artificial respiration when he advised midwives to blow in to the mouths of newborns they found to be warm but with no respiration. The insightful advice, however, has to be viewed in context when considering his succeeding comment "or into its anus"[18].

In 1543 Vesalius published an account detailing a mechanism to keep an animal alive whilst its thoracic contents were examined[11]. Up to this point, progress in relation to cardio-respiratory anatomy and physiology had been hampered by the fact that as soon as the thoracic cavity was opened the animal's lungs collapsed and death inevitably followed. By performing a basic tracheostomy (using a reed inserted in to the trachea) on an animal whose thorax had been opened Vesalius found that he was able to keep the animal alive by blowing intermittently through the reed. He thus described lung inflation and the associated improvement in cardiac output that this action caused in the near dead animal whilst simultaneously noting the relationship between lung collapse and diminution of cardiac activity.

In a similar experiment the English polymath Robert Hooke (1635 – 1703) demonstrated the beneficial effects of artificial respiration at the Royal Society in 1667[18]. He performed a tracheostomy in a dog and kept the animal alive, after its thorax and abdomen had been opened, by ventilating the lungs with a bellows. Despite these advances showing that the heart's movements and those of respiration were independent, the use of artificial respiration was not accepted for human use. The most likely reasons for the failure to pursue or accept these ideas were probably in part due to fear of infectious diseases being transmitted by mouth to mouth respiration and that of public or religious reprisals that would follow human experimentation.

Perhaps the most startling failure to realise the utility of artificial respiration came with the experiments of the Scottish Surgeon and Fellow of the Royal Society John Hunter (1728-1793) in 1755[19]. He exposed the thorax of dogs by removing the sternum. He then performed artificial respiration with a dual chambered bellows – one for inspired air the other for expired. He noted that when he stopped moving the bellows the heart became gradually weaker until movement ceased. On resumption of movement of the bellows the heart began to move again. He repeated this experiment ten times on the same dog stopping ventilation for varying time periods up to ten minutes at a time. Each time the heart beat returned with the resumption of movement of the bellows. The lack of application of Hunter's findings to clinical practice at this time is evidenced by the failure to publish his findings for twenty-one years. When presenting his findings to the Royal Humane Society, Hunter suggested that a similar situation of reduced cardiac activity as a result of hypoventilation may exist in victims of drowning and that all that may be required to restore cardiac activity and life was the restoration of breathing. Hunter also suggested that the use of dephlogisticated air

(oxygen) might be more efficacious at resuscitating these drowning victims, that a trial of electricity to stimulate the heart when other methods have failed may be worthwhile and the injection of stimulating substances in to the veins.

During the eighteenth century, drowning became a major public health issue with several societies founded to promote the recovery of such individuals with subsequent reports of successful resuscitation using mouth to mouth respiration (of an apparently dead Scottish miner James Blair)[20]. The use of a bellows or tracheostomy was advocated by William Cullen (1710-1790), professor of Medicine and President of the Edinburgh College of Physicians (1773-1775), in a letter to the then Lord Cathcart President of the Board of Police[21]. Cullen describes the experience and preferences of Alexander Munro (1733-1817), Professor of Anatomy and Surgery at Edinburgh, in resuscitating victims of drowning. Within the letter are described techniques to achieve mouth to mouth ventilation, alleviate upper airway obstruction, perform tracheal intubation using a male catheter and perhaps the first description of cricoid pressure to prevent gastro-oesophageal reflux.

By the end of the eighteenth century, books by Edward Coleman (1765-1839)[22] and the Danes John Herholdt (1764-1836) and Carl Rafn (1769-1808)[23] demonstrated the advances in the practice of resuscitation at this time. Coleman had attended the lectures by John Hunter at the Royal Society and was interested in models of asphyxia following his work with dogs and cats. Coleman's suggestions for resuscitation included the use of a gullet occluder and an endotracheal or tracheostomy tube for lung inflation. It was suggested that the latter might be best used with a bellows and oxygen if available. Following institution of artificial respiration an electric current could be passed through the heart by placing electrodes over the apex and base. This was over a century before Prevost and Battelli published their account of reversal of

ventricular fibrillation using electric shocks[24]. Herholdt and Rafn also advocated the use of chest compressions and recognized the difficulties posed by upper airway obstruction from either the tongue or inhaled foreign bodies. In 1793 the Dutch Humane Society published their results of attempted resuscitations describing 990 successful cases over twenty five years[25].

However, in 1827 the French physician, Jean Jacques Leroy d'Etiolles (1798-1860), in reports that predated the ARDSnet* investigation[26] by 173 years, demonstrated the ill effects of over vigorous bellows ventilation of drowned dogs in inducing emphysema and pneumothorax[27,28]. Following this report, positive pressure ventilation was largely abandoned and would not re-emerge as a therapeutic modality for many decades.

**The ARDSnet investigation was a landmark critical care randomised controlled trial published in 2000. Patients requiring mechanical ventilation for acute lung injury / acute respiratory distress were randomised to receive tidal ventilation at either 12ml or 6ml/kg predicted bodyweight. The trial was stopped early, after recruiting 861 patients, due to a lower mortality in the lower tidal volume group (31 versus 39.8 percent).*

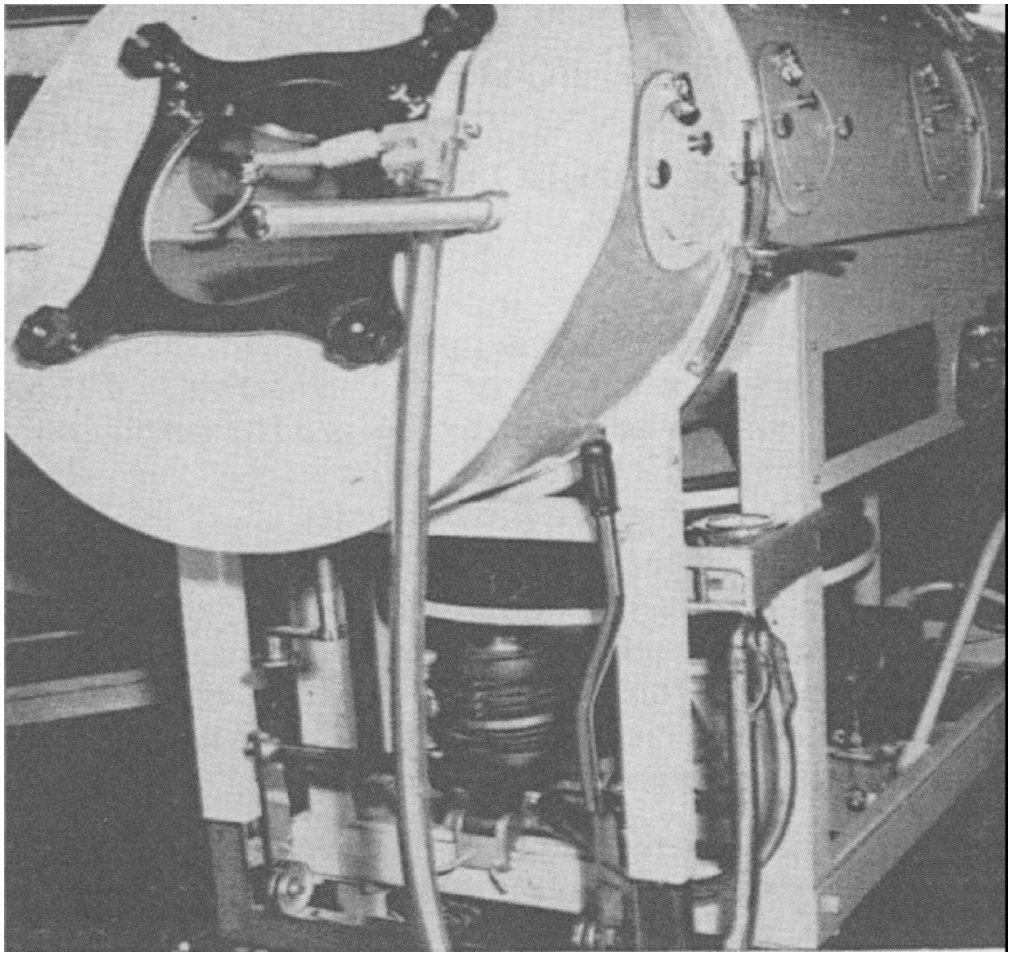
1.5 Tracheostomy and positive pressure ventilation

Although the usage of tracheostomy and positive pressure ventilation had many associations through their development from antiquity onwards, their combined utility in the clinical setting outside the operating theatre was not realised until the poliomyelitis epidemics of the 1940s and 50s.

The first use of tracheostomy and positive pressure ventilation for poliomyelitis on a large scale was reported by Albert Bower (1890-1960), Professor of Medicine at the University of Southern California, and Ray Bennett a biomedical engineer[29]. During the Los Angeles polio epidemic of 1948-49 Bower noted that a respiratory acidosis was a frequent finding despite the use of Drinker-Collins negative pressure

respirators. Bennett, therefore, developed a positive pressure respirator attachment, which enabled the Drinker-Collins respirator to provide intra-tracheal positive pressure respiratory support either via a facemask or a tracheostomy (figures 1.1 & 1.2). Using the positive pressure respirator attachment, Bower and Bennett were able to demonstrate a significant reduction in polio mortality for those cases requiring ventilatory assistance from 78.9% in 1946 to 16.3% in 1949.

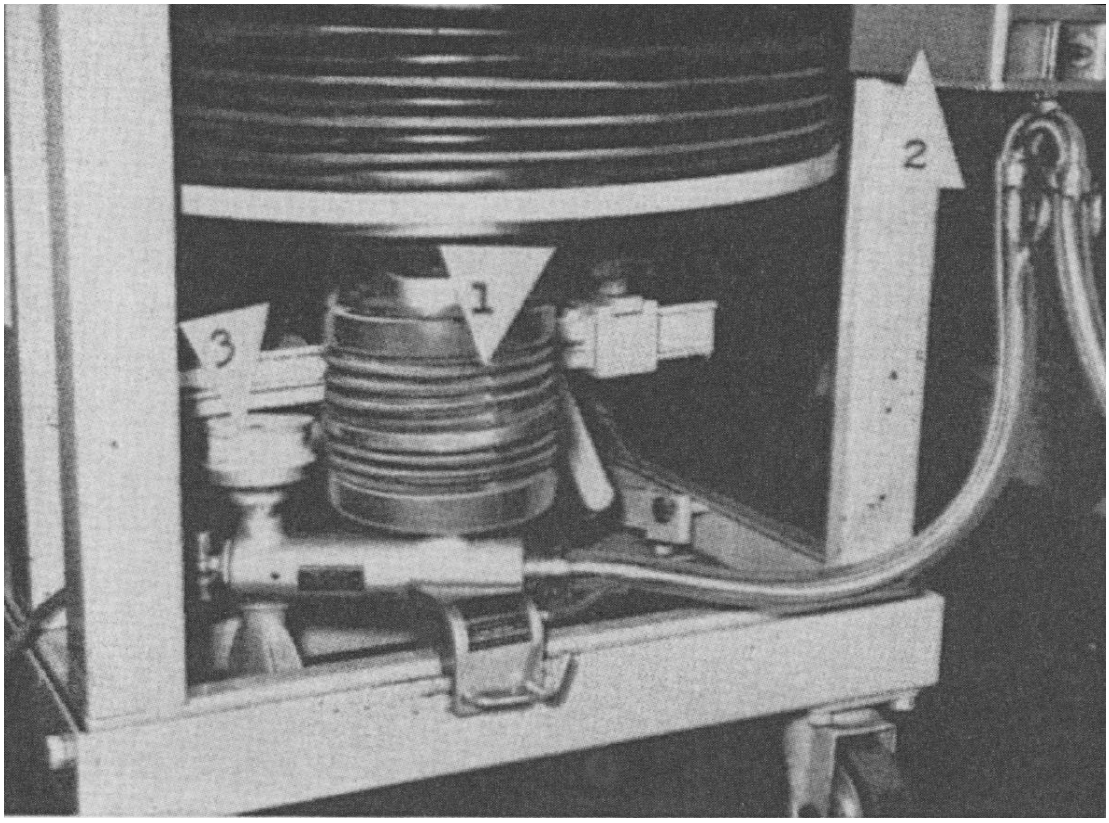
Figure 1.1. *The Bennett positive pressure respirator attachment mounted to a Drinker–Collins respirator*



Front view of the (Bennett) positive pressure respirator attachment mounted to a Drinker–Collins respirator. The bellows providing positive pressure ventilation via face mask or tracheostomy can be seen on the base of the respirator.

From: Bower AG, Bennett VR, Dillon JB.[29] *Reproduced with due acknowledgement to V Ray Bennett, Albert Bower and their publisher.*

Figure 1.2. *Bennett positive pressure respirator attachment: Shows installation of auxillary bellows unit(1), pressure control box (2) and air filter (3).*



From: Bower AG, Bennett VR, Dillon JB.[29] *Reproduced with due acknowledgement to V Ray Bennett, Albert Bower and their publisher.*

Despite the work of Bower and Bennett, the outcome from poliomyelitis requiring respirator support in Northern Europe remained decidedly poor. In August of 1952, twenty seven out of thirty one cases admitted to the Blegdam hospital in Copenhagen with respiratory paralysis died[30]. At this time in Copenhagen, up to seventy patients were requiring respiratory assistance at any one time with fifty new patients being admitted each day, of whom ten per cent were exhibiting signs of bulbar dysfunction. When faced with this bleak scenario, Henry Lassen (1900-1974), chief physician at the hospital, requested the assistance of Bjorn Ibsen (1915-2007) a freelance anaesthetist. Ibsen had spent time at the Massachusetts General Hospital and was aware of Bower and Bennett's earlier work[31]. He embarked upon a similar strategy using positive pressure ventilation and tracheostomy during the Copenhagen epidemic

of 1952. From 26th August, ultimately using a team of thirty five to forty medical staff, 600 trained nurses and 250 medical students working in relays, 321 patients with respiratory insufficiency were treated. Of these 265 patients had a tracheostomy and 232 had positive pressure ventilation. Over this period the mortality reduced from eighty seven per cent in July / August to twenty two per cent in November / December[30]. This episode is now felt to be the beginning of modern intensive care practice. Ibsen was later offered a position at Copenhagen's Kommunehospital where he set up what is widely regarded as the world's first dedicated intensive care unit in 1953[31]. Lassen and Ibsen also provided an insight in to the future problems of critical care with their description of an increased mortality in those patients presenting with shock, renal failure and pulmonary oedema.

1.6 Percutaneous tracheostomy

The Italian surgeon Sanctorio Sanctorious (1561-1636), using a technique described and condemned by Trousseau[7] as the expeditious method, has been suggested as the first surgeon to have described a percutaneous technique in 1626. Although the procedure described used a small dagger-like ripping needle and a silver perforated cannula it is doubtful that it was ever performed by Sanctorious[32]. These same instruments were also used at this time for the tapping of hydrocoeles and ascites. Using the needle, the cannula was inserted in to the tracheal lumen and the needle was withdrawn in a manner that appears remarkably similar to Shelden's description in 1957 (see below)[33]. Although similar methods were later described by Dekker and Heister it is unclear how often a percutaneous technique was used by such luminaries if at all[7]. The French physician, Bauchot, has been credited as the first to perform a percutaneous procedure in the mid eighteenth century using a bronchotome (with a cutting edge) fitting in to the lumen of a flattened silver cannula[32]. Bauchot reportedly

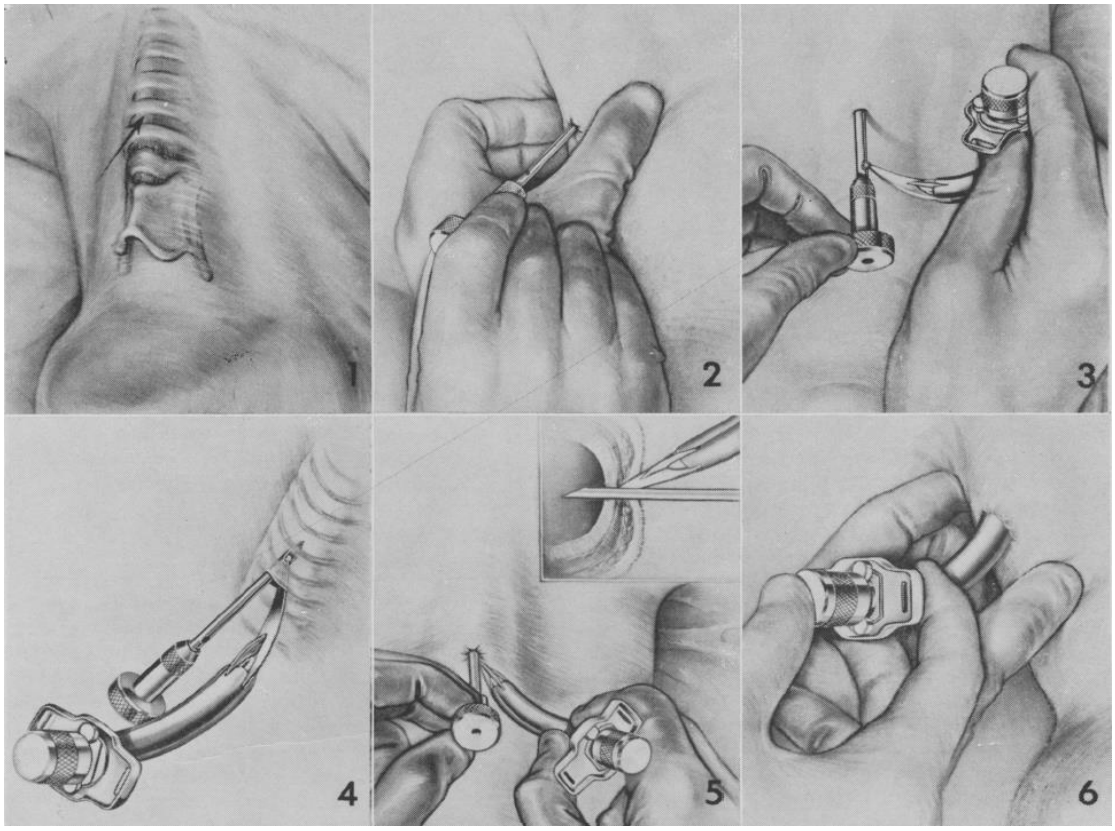
used this technique successfully on two patients[12]. Gerard van Swieten (1700-1772) of Leyden Austria, who had used a percutaneous technique on a large number of live animals and human cadavers, considered the procedure to be extremely difficult and not without risk[7]. Subsequent to this, largely because of Trousseau's recommendation for a large incision and Jackson[8] standardising the open surgical tracheostomy, little more was heard of the percutaneous procedure until the 1950s.

Arguably the first step towards the safe performance of a percutaneous tracheostomy was not related to airway surgery at all. In 1953 Sven Seldinger (1921-1998), a Swedish radiologist, published his technique of catheter insertion over a guidewire[34]. In the 1940s interest in arteriography was increasing although catheter insertion to facilitate this was problematic – usually requiring surgical exposure of the relevant artery. With the advent of flexible guide-wires and polyethylene catheters Seldinger was able to demonstrate the use of percutaneous puncture of a vessel followed by guide-wire and then catheter insertion over the wire. He described this technique in forty procedures all performed under local anaesthetic. In thirty-seven out of the forty procedures arterial puncture and catheter insertion were achieved at the first attempt with no significant haemorrhagic complications.

The first modern description of a percutaneous tracheostomy was described by Shelden in 1955[35]. Despite this being after Seldinger's description of his guide-wire technique Shelden did not employ it. Shelden described the use of a slotted needle and a cutting blade with a ball like tip (figure 1.3). The needle was inserted into the trachea below the cricoid cartilage. The ball like tip of the cutting blade was inserted into the spherical slot on the needle and the ball passed down the needle lumen in to the trachea. With the cutting blade in-situ the needle is removed, the cutting blades and attached tracheostomy tube are then advanced in to the trachea. Once in place the

cutting blades were removed and the tracheostomy tube left in situ. Shelden had used this device for four years at the time of a later publication and claimed use by many other neurosurgeons throughout the world[33]. Despite this it is unclear how many patients underwent this procedure. Even though the device was commercially available and used extensively by Shelden it appears not be have been widely adopted perhaps in part due to reported posterior tracheal wall and oesophageal perforation[36,37].

***Figure 1.3**. Shelden's percutaneous tracheostomy*



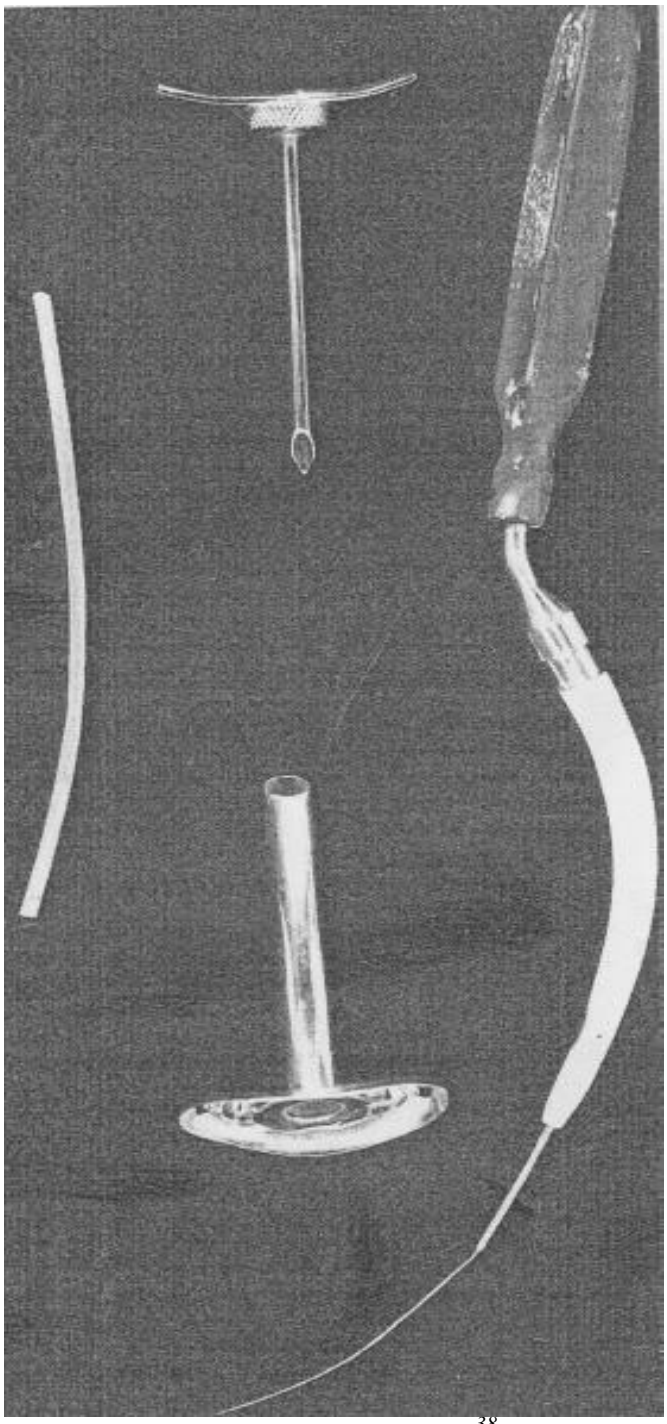
***1.** With the patient's head extended, puncture site is palpated either above or below first tracheal ring. **2.** Needle is angulated through skin and subcutaneous tissue and into lumen of trachea. **3.** Ball like tip of cutting blade is placed within lumen of needle through the spherical opening. **4.** Cutting action of horizontal blade. **5.** Horizontal blade slides along slot in needle. **6**. Tracheostomy tube being inserted into trachea after needle has been removed*

Reproduced with permission from Shelden CH et al. Percutaneous tracheotomy. J Am Med Assoc. 1957;165(16):2068-2070. Copyright© (1957) American Medical Association. All rights reserved.[33]

The first description of a bedside surgical tracheostomy was provided by Roe in 1962 and suggested to be of use predominantly in the emergency setting[37]. In a series of forty patients with post-operative respiratory compromise he described what might now be referred to as a minimally invasive tracheostomy. Using a small incision, that admitted the tip of the finger, followed by blunt dissection of the subcutaneous tissues the cricoid and tracheal cartilages were initially palpated. Complete exposure of the tracheal cartilage was felt to be unnecessary. The procedure had to be abandoned in only one patient.

In 1969 Toy and Weinstein described the first guide assisted percutaneous tracheostomy using a modified Seldinger technique[38]. They described the insertion of a five-millimetre tracheostomy tube over a guiding bougie that had been placed via a needle inserted in to the trachea. Using a handled bougie (figure 1.4) with recessed blade the entire device was thrust in to the trachea. Of the six patients they described, five had successful tracheostomy tube insertion and one had a para-tracheal placement. Despite the potential for use within a critical care setting the authors did not envisage this and suggested its principal uses would be in the emergency setting and elective cases where a bleeding diathesis may be present or a concern for the cosmetic results was present.

Figure 1.4. *Toy and Weinstein's percutaneous tracheostomy device. Illustrated are the guiding catheter (left), percutaneous needle, tracheostomy tube and handled bougie with recessed blade.*



First published in: A percutaneous tracheostomy device. Toy FJ, Weinstein JD. *Surgery*. 1969;65(2):384-389.[38] Copyright (1969) with permission from Elsevier.

From: Toy FJ, Weinstein JD.[38]

Concerns regarding the risk of later tracheal stenosis following damage to the cricoid cartilage persisted following Jackson's early papers until Brantigan and Grow published a series detailing 655 crico-thyroidostomies some of which were performed

at the bedside[39]. Of these patients eight developed sub-glottic stenosis and seven had sub-glottic granulomas. Pre-existing laryngeal injury was felt to be present in thirteen of these fifteen patients due to prolonged trans-laryngeal intubation. The authors therefore concluded that there was little risk of tracheal stenosis following cricothyroidostomy if the larynx was normal but that it should not be performed after prolonged trans-laryngeal intubation.

The first description of a dilatational percutaneous tracheostomy was provided by the thoracic surgeon Pascquale Ciaglia (1912-2000) working in St. Elizabeth Hospital and St. Luke's Memorial Hospital Center, Utica, New York[40]. Following on from Brantigan's work[39] and the minimally invasive bedside surgical tracheostomy described by Roe[37] Ciaglia set about reforming the critical care tracheostomy procedure. Initially he undertook twenty-six fingertip sub-cricoid tracheostomies during which a small incision was made to allow the index finger to palpate the cricoid cartilage. A small incision was made through the crico-tracheal membrane and the withdrawal of the tracheal tube was also palpated. As the trans-laryngeal tube was withdrawn the tracheostomy tube was inserted. After twenty-six procedures Ciaglia concluded the whole process could be accomplished percutaneously. Using a modified percutaneous nephrostomy set he then performed a further twenty-six tracheostomies (one cricothyroidostomy, one through the second to third tracheal rings and twenty four sub-cricoid) with no significant intra-operative complications other than one difficult dilatation in a patient who had previously had a surgical tracheostomy. There were no instances of para-tracheal placement, pneumothorax, subcutaneous emphysema or oesophageal injury. There was one case of sub-glottic stenosis that was felt to be related to prolonged trans-laryngeal intubation. Ciaglia subsequently reported the outcome of fifty two decannulated patients who had

undergone his dilatational tracheostomy in 1992[41]. There were mild voice changes in one patient, one patient had a stomal infection and there no recorded cases of tracheal stenosis or cosmetic problems. Despite this apparent lack of tracheal stenosis reported at this point Ciaglia suggested in this paper that a lower insertion point might be preferable if feasible. In 1994, McFarlane reported on a series of 121 Ciaglia tracheostomies in which there were four cases of sub-glottic stenosis[10]. This was postulated to be due to the high placement of the tracheostomy tube and subsequent damage to the cricoid cartilage with its resultant peri-chondritis and necrosis, a finding in keeping with Jackson's earlier assertions[9]. From this time onwards, most operators have attempted to avoid crico-tracheal placement aiming for a lower insertion point.

Subsequent to Ciaglia's report, further modifications of the percutaneous dilatational technique were proposed and a number of varying approaches have been developed over the ensuing years. In 1990 William "Bill" Griggs (Adelaide, Australia) described the use of guide-wire dilating forceps[42], Antonio Fantoni (Milan, Italy) described the trans-laryngeal tracheostomy in adults in 1996[43] and the single tapered dilator modification of Ciaglia's original procedure was reported in 2000[44]. At the present time, the single tapered dilator appears to be the most frequently used percutaneous technique[45,46]. Subsequently lesser-used techniques have also been described[47,48].

1.7 Modifications to the percutaneous tracheostomy technique

In 1989 Andreas Paul (Montreal, Canada) described the first percutaneous endoscopic dilatational tracheostomy[49]. After initial testing in five anaesthetised dogs (including post mortem examination of tracheal damage) a technique using the fibre-optic bronchoscope to visualise the tracheal lumen during the procedure was described in four human subjects. In one patient they identified a guide-wire misplacement thus

preventing para-tracheal placement. They also postulated that bronchoscopic deployment would reduce posterior tracheal wall and oesophageal injuries whilst allowing precise tracheostomy tube placement. He also hinted at a possible future use of ultra-sound scanning for percutaneous tracheostomy to reduce bleeding complications.

This latter idea was later taken up by Hatfield and Bodenham (Leeds, UK) who undertook a study of thirty patients undergoing percutaneous tracheostomy[50]. In all patients, the thyroid cartilage, carotid arteries and internal jugular veins were easily identified, as was the mid-line and approximate level of puncture. They identified eight patients in whom an anterior jugular vein was considered vulnerable (at or near the mid-line). Two patients had vessels ligated and two had minor bleeding episodes. Additionally, four patients had vulnerable arterial structures (two carotid and two brachio-cephalic arteries). The authors concluded use of ultra-sound scanning may reduce bleeding complications especially in patients with difficult to identify surface anatomy.

1.8 Tracheostomy outcomes

Despite widespread adoption of percutaneous techniques from the late 1980s onwards the outcomes, particularly long term ones, when compared to surgical tracheostomy and amongst the percutaneous techniques themselves were the subject of some discussion and debate.

1.8.1 Percutaneous tracheostomy versus surgical tracheostomy

The outcomes of percutaneous techniques compared to surgical tracheostomy have been the subject of three systematic reviews dating from 2006 – 2007. In the first such

review, Delaney evaluated randomised controlled trials comparing surgical tracheostomies with any percutaneous technique in the critical care setting[51]. He identified seventeen trials, including 1212 patients, the commonest percutaneous procedure evaluated being the original Ciaglia technique[40]. The principal findings were equivalence for bleeding, major short and long-term complications with a significant reduction in stomal infections for the percutaneous procedures. Oliver later identified fourteen prospective trials (of which eight were randomised controlled trials) comparing surgical tracheostomy with a percutaneous technique performed in the critical care unit or the operating theatre[52]. They found no difference in major complications but a greater incidence of minor complications with percutaneous techniques along with a greater incidence of early complications for percutaneous techniques when compared to surgical tracheostomy performed at the bedside. Higgins[53] assessed fifteen randomised controlled trials (incorporating 973 patients) all but two of which were incorporated in Delaney's review[51]. They found percutaneous techniques resulted in fewer wound infections and cosmetic problems with no difference in major complications. When pooled complications were analysed they found in favour of the percutaneous procedures.

1.8.2 Percutaneous versus percutaneous procedures

For many years there appears to be an assumption of equivalence across the percutaneous techniques described. In an attempt to address this Cabrini undertook a systematic review of randomised controlled trials comparing two or more percutaneous techniques[54]. They identified thirteen trials, incorporating 1030 patients, the most studied techniques being the original Ciaglia multiple dilator method, guide-wire dilating forceps and the single tapered dilator. They found that the Ciaglia and single tapered dilator techniques appeared to have the fewest complications. There

appeared to be an increase in minor complications with the guide-wire dilating forceps along with higher failure rates for both trans-laryngeal and rotational dilator techniques (PercuTwist®). They expressed some surprise at the paucity of randomised controlled trials when considering how widespread the use of percutaneous tracheostomy has become. Overall it was felt that the most reliable technique for safety and success was the single tapered dilator. In a later review Cabrini also assessed the complication rates of the two most commonly used percutaneous techniques, the single tapered dilator and guide wire dilating forceps[55]. Having identified five eligible randomised controlled trials comprising 363 patients they concluded that the guide wire dilating forceps technique is associated with a higher incidence of intra-procedural bleeding and technical difficulties when compared with the single tapered dilator. There were no differences in mid and long-term outcomes.

After many centuries of evolving surgical approaches along with advances in our knowledge of physiology and anatomy, percutaneous procedures have become established as the predominant tracheostomy techniques within the critical care setting. Complication rates across the various techniques appear to be at least as low as those achieved with surgical tracheostomies. It is possible that the single tapered dilator method is now the most frequently used procedure with the lowest associated complication rate. However, the paucity of data when comparing percutaneous procedures, particularly when considering long-term outcomes, is somewhat surprising. It is clear, at present, that equivalence between procedures in this respect has not been fully established.

The meta-analyses described above have included only randomised controlled trials (RCTs)[51,53]. The only exception to this was the analysis by Oliver which also included non-randomised prospective studies[52]. The largest single study incorporated into the

previous analyses comprised 346 patients[56]. It is perhaps unsurprising, therefore, that none of the previous meta-analyses have reported differences in late complication rates. The exact incidence of long term complications following tracheostomy procedures in the critically ill is difficult to quantify due to the associated mortality of critical illness, the sub-clinical nature of many tracheal stenoses and the difficulty maintaining follow up of these cohorts. Given this associated morbidity and the cost associated with the management of TS a clearer picture of the risk associated with each tracheostomy technique performed within the critical care setting is required.

1.9 Aims

- To determine the utility of adjunctive techniques (bronchoscopy & ultrasound scanning) in reducing complications of percutaneous tracheostomies percutaneous tracheostomy technique and hence determine the safest percutaneous technique
- To determine the incidence of common early and late complications and outcomes of PDT techniques in relation to surgical tracheostomy.
- To determine the relative indices of early and late complications in relation to percutaneous tracheostomy technique and hence determine the safest percutaneous technique
- To determine the role of early complications that may be postulated to play a part in the genesis of the late complications of tracheal stenosis, tracheo-innominate artery fistula and tracheo-oesophageal fistula
- To determine long term survival following percutaneous tracheostomy

Chapter 2

Major late complications following tracheostomy

Both surgical and percutaneous tracheostomies are associated with a number of well-defined early complications that may occur intra-operatively or over a variable length of time in to the post-operative period[57-59]. The most common of these early complications are haemorrhage, malpositioning of the tracheal cannula, displacement of the tracheal tube, pneumothoraces and subcutaneous emphysema. Assessing the relative frequency for each of these outcomes following surgical and percutaneous techniques has been relatively well defined and the subject of a number of meta-analyses[51-55].

Late complications leading to significant morbidity and potentially mortality (tracheo-innominate artery fistulae, tracheomalacia and tracheal stenosis) may occur after the tracheal cannula has been removed. Given the severity of illness occurring in many of these patients with its associated mortality, the relative incidences of each of these complications remains difficult to define. Additionally, confounding factors present in survivors of critical illness may present additional difficulties in diagnosis. Many survivors will have significant residual muscle weakness, associated with underlying parenchymal lung diseases either predating their critical care stay or as a result of it. Consequently, a reduction in exercise capacity and shortness of breath are commonly found in this population. Such complaints can often be attributed to the after effects of critical illness and underlying tracheal pathology may go undiagnosed.

2.1 The normal trachea

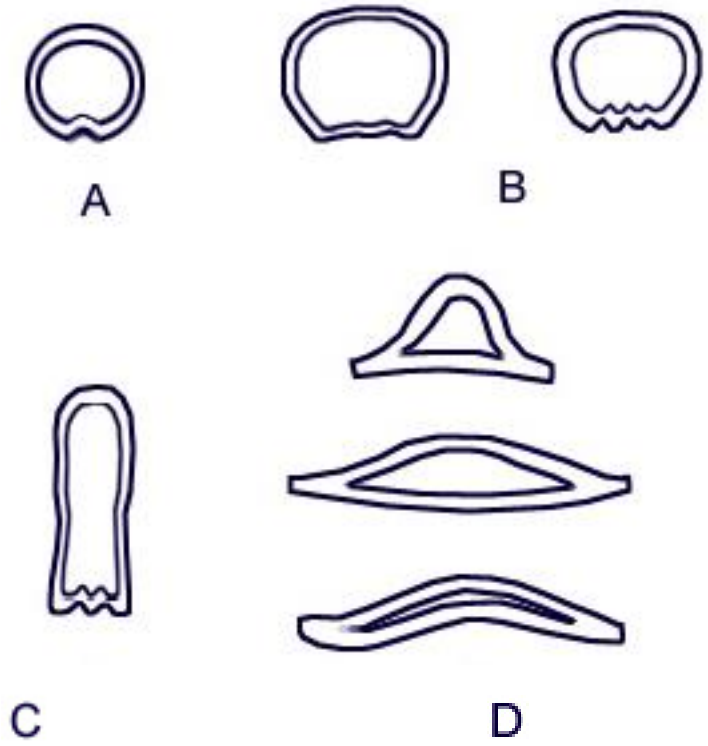
2.1.1 Tracheal anatomy

The trachea lies in the midline of the neck and upper mediastinum. It begins at the lower border of the cricoid cartilage at the level of the sixth cervical vertebra and extends to its bifurcation in to right and left main bronchi at the carina. It is composed

of C shaped rings of cartilage that form the anterior and lateral walls and a musculo-membranous posterior wall. The smooth muscle in the musculo-membranous portion of the tracheal wall contains both transverse and longitudinal fibres. The transverse fibres make up the trachealis muscle connecting the ends of the tracheal cartilages. Tracheal size is related to the size of the individual but in the adult male there are approximately 18-22 tracheal rings extending inferiorly from the cricoid to carina for 11-12 cm. The lateral diameter is approximately 2.3 cm coronally and 1.8 cm sagitally[60,61].

The shape of the tracheal lumen varies with age and in the presence or absence of disease states. The lumen in the child is almost circular reaching its usual adult D shape at adolescence (figure 2.1). Luminal shape also alters dynamically in response to changes in intra-luminal pressure during respiration, coughing and mechanical ventilation. During forced expiration the trachealis muscle approximates the ends of the tracheal cartilages creating an elongated antero-posterior tracheal diameter. In the presence of ageing or significant chronic obstructive pulmonary disease, this reduction in lateral diameter may result in a sabre sheath or scabbard trachea. Chronic obstructive airways disease may also result in a softening of the tracheal cartilage and a widening of the lateral diameter and an antero-posterior narrowing (figure 2.1). This conformational change may ultimately lead to luminal obstruction during coughing and active expiration.

Figure 2.1. *Cross sectional tracheal morphology – normal and common variants.*



A; *Juvenile circular trachea.* ***B;*** *Adult D-shaped trachea.* ***C;*** *Sabre sheath or scabbard trachea.* ***D;*** *Tracheal changes seen in chronic obstructive pulmonary disease.*

Image reprinted with permission from Medscape Drugs & Diseases (http://emedicine.medscape.com), 2015, available at http://emedicine.medscape.com/article/1949391-overview#a3

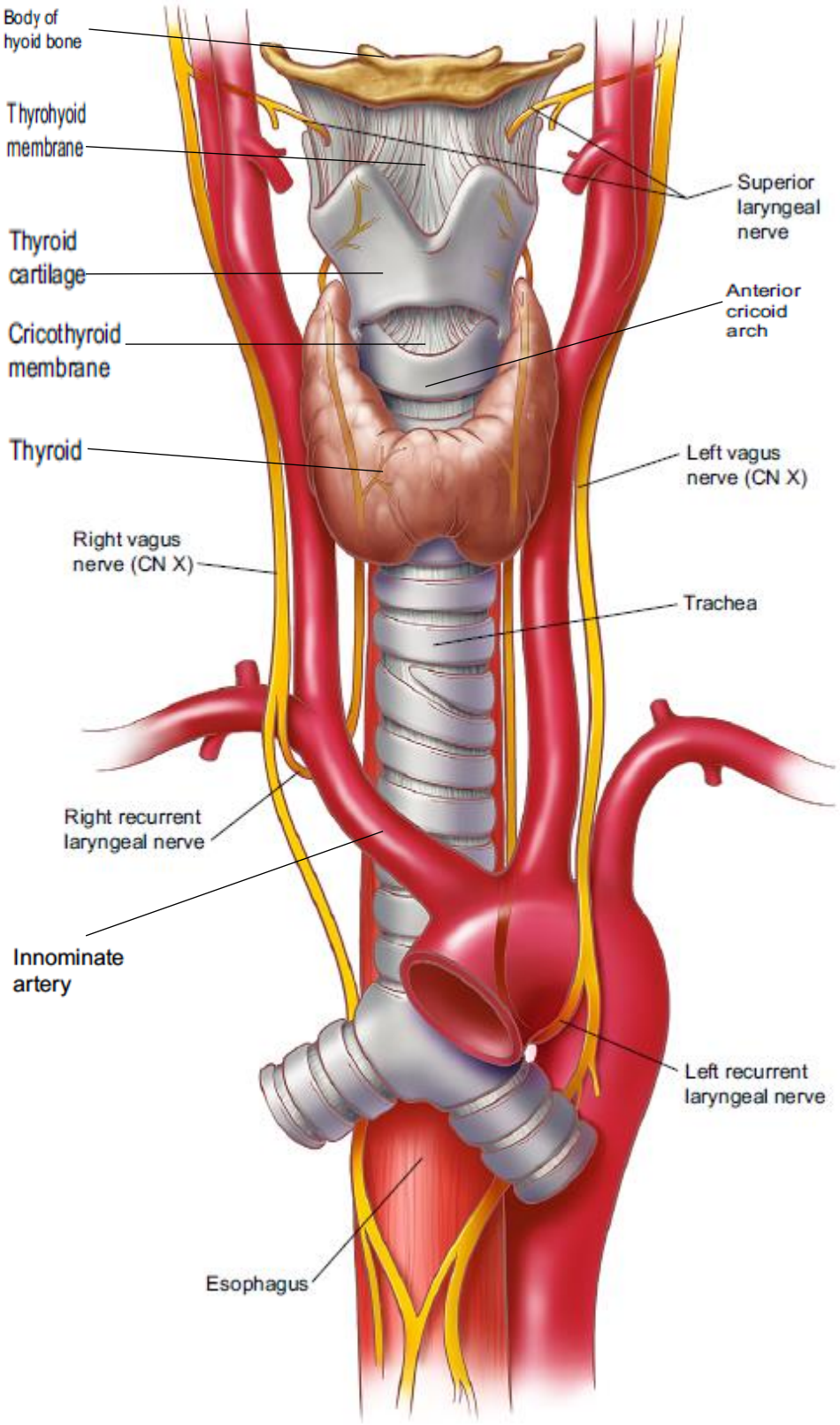
The tracheal wall is lined by a ciliated pseudo-stratified columnar epithelium that also contains Goblet cells and mucous glands. Also present within the epithelium are "brush cells" with surface microvilli and neuroendocrine cells, the function of both cell types is not entirely clear. Mucosal irritation may result in cilia damage and squamous metaplasia resulting in an increased dependence upon coughing to clear secretions. As a result of such injury the tracheal mucosa must be able to regenerate. This occurs from a sub-population of basal stem cells in the columnar epithelium which are able to develop in to ciliated surface cell and Goblet cells[62].

The trachea receives its blood supply segmentally via the lateral walls. The cervical trachea is supplied predominantly from the inferior thyroid artery most frequently via three tracheo-oesophageal vessels. The mid to lower trachea receives its arterial supply from the superior, middle and inferior bronchial arteries. At the segmental level each artery to the trachea will branch superiorly and inferiorly over several tracheal rings forming a series of longitudinal anastomoses. Additionally anterior and posterior braches will run in the inter-cartilaginous space to eventually anastomose with contralateral vessels. The posterior vessels also anastomose with oesophageal arteries[60,61].

2.1.1.1 Anatomical relations

The anatomical relations of the trachea explain many of the early and late complications seen following tracheostomy (figure 2.2). The oesophagus lies posteriorly and slightly to the left of the trachea from the level of the cricoid cartilage with the pre-vertebral fascia and vertebral bodies lying posteriorly to the right. The isthmus of the thyroid gland is anterior to the second to fourth tracheal rings with the inferior thyroid artery supplying the proximal trachea as well as the thyroid gland itself. Lateral to the cervical part of the trachea lie the lobes of the thyroid gland, carotid artery, internal jugular vein, vagus nerve and cervical lymph nodes within the carotid sheath.

Figure 2.2. *Anatomical relations of the trachea including major vessels, thyroid and nerves. Modified from: Deslauriers.*[61]



*Reprinted from Thoracic Surgery Clinics 2007;**17(4)**:529-547. Deslauriers J. Anatomy of the neck and cervicothoracic junction. Copyright (2007), with permission from Elsevier.*

As the trachea descends in to the superior mediastinum anteriorly lies the thymus, the brachio-cephalic (innominate) artery and vein and the aortic arch. The tracheo-innominate artery arises as the first branch of the aortic arch. It ascends obliquely and posteriorly to cross the trachea at the level of the ninth tracheal cartilage (range from sixth to thirteenth). There is however, a degree of variability in the course of the tracheo-innominate artery with passage across the trachea being possible as high as the second – third tracheal ring[63]. Posteriorly lie the oesophagus, pre-vertebral fascia and recurrent laryngeal nerves in the tracheo-oesophageal grooves. Laterally lie the vagus and phrenic nerves, the superior vena cava on the right, left common carotid and left subclavian vessels with the thoracic duct on the left and azygous vein on the right.

2.1.2 Tracheal physiology

The trachea is designed to:

- Conduct air from the larynx to the main bronchi
- Exchange heat and moisture with cold, dry inhaled air
- Remove particulate debris and secretions from the tracheo-bronchial tract.

2.1.2.1 Movement of air

Under normal circumstances for gas to flow through the trachea a pressure gradient has to exist to overcome the resistance of the respiratory system. Conventionally, laminar flow through tubes is represented by the Hagen-Poiseuille Law where flow is inversely proportional to the fourth power of the radius of the tube:

$$\Delta P = Q8L\mu/\pi r^4$$

Where:

ΔP = pressure change across tube

Q = flow rate

L = length of the tube

μ = gas viscosity

r = radius of the tube.

However, when considering the Reynolds number (ratio of inertial forces to viscous forces) for flow through a given tube:

$Re = \rho QL/ \mu$

Where:

Q = flow rate

L= length of tube

ρ = density

μ = viscosity

The transition to turbulent flow occurs at a Reynolds number of around 2300. Thereafter, flow becomes completely turbulent when the Reynolds number exceeds 4000 – conditions found within the trachea. In this situation resistance across the trachea becomes directly proportional to the gas flow rate squared and inversely proportional to the fifth power of the radius[64].

$\Delta P = Q^2 \rho f L / r \pi^2 r^5$

Where:

ρ = density of gas

f = frictional factor

Consequently, a reduction in airway calibre produced by mucosal swelling, endoluminal tumours, tracheal stenosis and tracheal tubes will all considerably increase resistance to airflow.

2.1.2.2 Heat and moisture exchange

During inspiration the upper airways warm and humidify the inspired gas. During quiet breathing, air is completely warmed to 37^0 centigrade and fully humidified at around the level of the tracheal bifurcation – the isothermal saturation point[62]. The drier and colder the inspired air the more distal this point becomes thus increasing heat and moisture losses. This situation is further exacerbated when the upper airway is bypassed with a tracheal or tracheostomy tube where, in addition to heat and moisture loss, mucosal injury may result unless inspired gases are heated and humidified.

2.1.2.3 Removal of particulate debris

Tracheo-bronchial Goblet cells produce a mucin rich secretion that protects the underlying epithelium. The rate and volume of secretions produced is controlled by the autonomic nervous system and inflammatory mediators. The resultant mucous collects debris and micro-organisms and is transported in a cephalad direction by cilial action and exhaled air with expiratory airflow becoming more prominent in the larger central airways.

2.2 Tracheal pathology

2.2.1 Tracheal stenosis

Benign tracheal stenosis (TS) is a progressive narrowing of the tracheal lumen most commonly seen after tracheal intubation and tracheostomy insertion. Pooled data from a number of studies has shown reported incidences of TS of 0.6 – 2.8% (See Chapter 4). Such data, should however, be interpreted with caution. The reported rates are invariably expressed as percentages of tracheostomies performed and not of survivors who have presented for follow up[58,59].

2.2.1.1 Histopathology

Despite a plethora of studies investigating the management of TS the actual mechanisms involved in its initiation remain unclear. It is postulated that hyper-granulation, cuff induced ischaemic mucosal injury, direct tracheal wall injury, infection, gastro-oesophageal reflux and a genetic predisposition may all play a role[65-69]. Why this reaction presents in only a small subset of patients undergoing intubation and tracheostomy remains unknown.

Of the above factors, tracheal mucosal pressure induced necrosis seems to be of prime importance. If the pressure within the cuff of the tracheal tube is above that of the mucosal capillary perfusion pressure the potential result is ischaemic ulceration. As the blood supply of the trachea is segmental with vessels perforating the tracheal wall through the inter-ring spaces pressure on the mucosa can lead to cartilaginous ischaemia and necrosis. Additional hypoperfusion associated with systemic hypotensive states is not uncommon in the critically ill.

Normal wound healing progresses through three phases[70]:

c) Inflammatory phase

Tissue trauma leads to bleeding and clot formation with the release of inflammatory mediators (prostaglandins, interleukin-1 (IL-1), interleukin-6 (IL-6), tumour necrosis factor α and transforming growth factor β (TGF-β)) that increase vessel permeability enabling the migration and accumulation of inflammatory macrophages.

d) Proliferative phase

This phase is characterised by re-epithelialisation and new vessel formation along with fibroblast migration. These processes are largely under the control of platelet-derived growth factor, endothelial derived growth factor, IL-1, IL-6, TGF-β and fibroblast growth factor. Along with fibroblasts there is also proliferation of macrophages, keratinocytes and endothelial cells. New connective tissue is laid down (granulation tissue)

e) Maturation phase

This phase is predominantly controlled by epidermal growth factor and TGF-β. As the new connective tissue matures, collagen becomes the main component.

A number of authors[66,69,71] have postulated the role of infection in generating the abnormal tissue reaction to trauma. Bacterial contamination leads to an infected peri-chondritis and ultimately enhanced fibroblast activity. Whilst the incidence of stomal infection following surgical tracheostomy has been shown to be higher than that associated with percutaneous tracheostomy[51] there is no definitive proof that the incidence of TS differs between the two techniques. Furthermore, there are no studies that demonstrate a protective effect of antimicrobials in the prevention of TS.

The host inflammatory reaction to this mucosal ulceration leads to healing by secondary intention. An inflammatory cascade is initiated that results in the up-regulation of TGF-β which promotes the growth of fibroblasts[70]. It is also possible that fibroblasts may be activated as a result of tissue hypoxia leading to expression of hypoxia inducible factor with a resultant proliferation of fibroblasts and myofibroblasts within the tracheal mucosa[72]. The end result is a proliferation of granulation tissue and subsequent fibrous scar tissue. In some patients the proliferation of granulation tissue may lead to difficulties with decannulation although progression to tracheal stenosis is not always seen[73]. The abnormal healing process responsible for tracheal stenosis results in an imbalance of cell types leading to an excess of scarring and granulation tissue. The fibroblasts present release collagen and an extra-cellular matrix forms, containing types 1 and 3 collagen fibres, fibronectin and a significantly reduced number of elastic fibres, obstructing the normal patent airway[70,72]. The increase of collagen over elastic tissue makes the scarred segment rigid and relatively avascular. The mature tracheal stenosis eventually forms within three to six weeks of decannulation. The later accumulation of submucosal fibrous tissue can lead to contraction, reduction and distortion of the tracheal lumen. The abnormal inflammatory process is not usually confined to the tracheal mucosa but also involves the deeper tracheal structures such as the peri-chondrium and cartilage[69]. Tracheal patency in the presence of weakened or fractured tracheal cartilages becomes compromised, particularly during forceful respiration and coughing, leading to a dynamic central airway collapse.

There may be a number of additional co-factors associated with this abnormal inflammatory cascade. A number of authors have noted a preponderance of female patients with benign tracheal stenosis[74,75] but this is by no means uniform, with other

studies reporting a higher incidence in males[69,71]. Idiopathic tracheal stenosis is also more frequently seen in female patients[76]. It has been postulated that oestrogen has an effect whereby it increases levels of TGF-β increasing collagen production and extra-cellular matrix formation. Additionally, diabetes mellitus[77], obesity and cardio-vascular disease have been noted in up to 30% of TS patients[75]. It is possible that small vessel disease present in such patients may worsen the effects of regional ischaemia induced by the cuff of the tracheal tube. There may also be an effect of tracheo-oesophageal reflux in promoting abnormal healing both in idiopathic and post-intubation stenoses[78].

2.2.1.2 Types of tracheal stenosis

A number of variants of normal tracheal morphology occur that must be excluded when the diagnosis of TS is being considered. In addition to the usual adult D shaped lumen a juvenile circular appearance may persist into adult life. A sabre sheath or scabbard trachea may be seen in the elderly with lateral narrowing and anterior-posterior widening and can be defined as a transverse / sagittal diameter <0.6. In patients with chronic obstructive pulmonary disease a number of states of dynamic tracheal collapse may occur without overt stenosis (figure 2.1).

TS can be simply defined as an abnormal narrowing of the tracheal cross sectional lumen. A degree of stenosis is common after all tracheostomies but intervention for symptomatic disease is only required in a minority. A number of studies investigating the incidence of sub-clinical tracheal stenosis after percutaneous tracheostomy have used a reduction in tracheal cross sectional area (TCSA) of ≥10 per cent narrowing as a definition and found incidences in the region of 10-30%[79,80]. Symptomatic TS is unlikely with reductions in TCSA of ≤50% with severe symptoms being present with

reductions in excess of 75%[81].

Tracheal stenosis may be grouped according to a number of defining characteristics related to the underlying disease process.

a) Benign / Malignant

Benign TS may present following a number of tracheal injuries and diseases. The most frequent cause being post-intubation or post-tracheostomy discussed herein. It may also follow from direct tracheal trauma, chemical irritation, granulomatosis with polyangiitis (Wegener's) and rarely be idiopathic.

Malignant stenoses result from direct infiltration of the trachea from tumours of the oesophagus, thyroid and lung or by malignant lymph node compression. Primary tracheal malignancies are unusual.

b) Functional behaviour

A stenosis can be further defined by its functional behaviour[82]. Most commonly seen is a fixed stenotic, scarring stricture in relation to the original trauma. Less commonly a malacic segment may follow on from the initial injury and result in a functional stenosis with dynamic airway collapse during the respiratory cycle. Such "dynamic stenoses" are perhaps most commonly seen in the patient with chronic obstructive pulmonary disease.

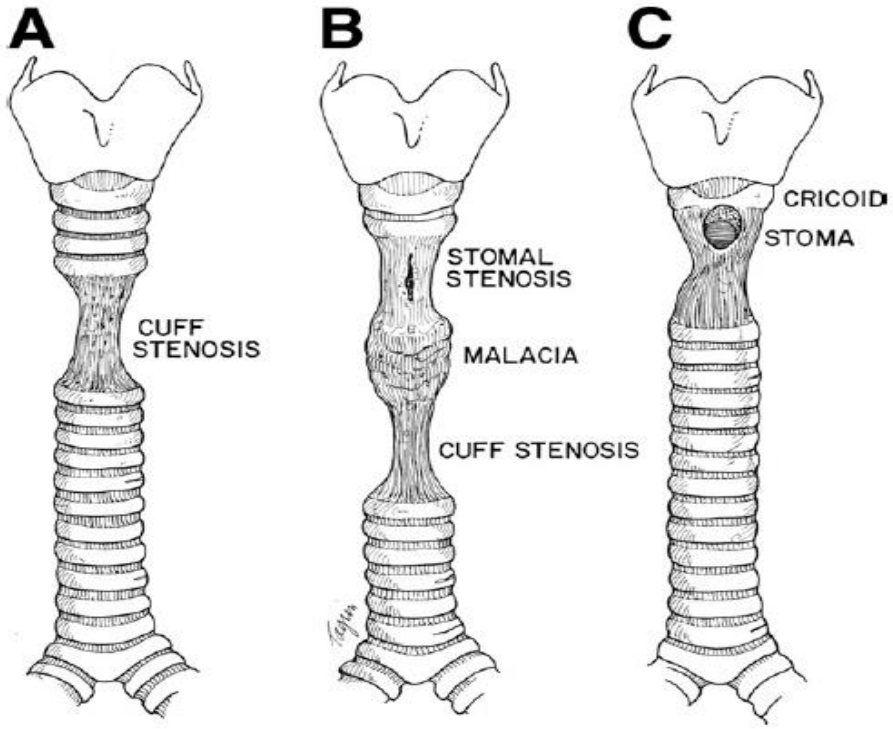
c) Anatomical features of stenosis

Further definition of a stenotic segment is given via an anatomical description of its nature. Lesions may be long or short, stomal or cuff related or subglottic (see below)[82].

d) Sites of tracheal stenosis

Mature tracheal stenoses may occur at a number of sites in relation to the tracheostomy tube (figure 2.3).

Figure 2.3. *Site of post-intubation tracheal stenosis lesions*



A: Cuff related stenosis

B: Cuff related stenosis with associated stomal stenosis

C: Laryngo-tracheal (sub-glottic stenosis) related to cricoid cartilage damage

Reprinted from Seminars in Thoracic and Cardiovascular Surgery 2009;21(3):284-289. Wain JC. Post-intubation tracheal stenosis. Copyright (2009), with permission from Elsevier.[65]

a) Stomal stenosis

Most commonly TS develops at the site of the tracheal stoma. Epstein[73] considered that secondary bacterial infection develops in the traumatised trachea to weaken the anterior and lateral walls.

b) Cuff related stenosis

Stenosis can develop in the region of the tracheostomy tube cuff in response to ischaemic necrosis of the tracheal wall when the pressure within the cuff exceeds the mucosal capillary perfusion pressure. A number of animal[67,68] and human studies[83] have detailed the effects of cuff pressure on capillary mucosal perfusion. At around 22mmHg, there is impairment of mucosal blood flow. Above 37mmHg, there is total obstruction of blood flow to the mucosa overlying the tracheal rings and the stretched posterior muscular wall. Pressures over 50 mmHg for 15 minutes can cause epithelial destruction which can lead to tracheitis, ulceration, persistent inflammation, chondritis, fibrosis and stenosis[83].

Cuff related problems associated with TS were first identified following the poliomyelitis epidemics in the late 1940s and 50s. Between 1947 and 1959 there was a fifteen fold increase in tracheostomies performed at the Massachusetts General Hospital[84]. In 462 reported cases there were two tracheal stenoses. Reports of TS rates in the late 1960s were in the region of 20% in some studies [85,86] although up to 50% of these patients were asymptomatic. At this time the importance of the tracheostomy tube cuff and associated circuitry were being appreciated in the aetiology of stenosis. Andrews demonstrated a reduction in stenosis from 17.5% to 6.9% with the introduction of a lightweight ventilator circuit[85]. They attributed the reduction

to diminished pressure on the lateral walls of the trachea thus preventing stomal pressure necrosis.

The first report of a high volume low pressure cuff of the tracheostomy tube was presented by Grillo[87]. In a randomised trial they detailed the management of 45 patients who had undergone a tracheostomy in the critical care setting comparing those with the new cuff versus with a standard rubber one. Follow up of the patients was by fibre-optic bronchoscopy of survivors or post mortem examination of the trachea in non-survivors. Rating tracheal damage on an objective scale from 0-4 (increasing score indicating increasing mucosal damage) they found significantly less tracheal wall damage with the new cuff. Average intra-cuff pressures reported were 33mmHg for the low pressure and 270 mmHg for the standard rubber cuffs. Following Grillo's work and the use of high volume, low-pressure cuffs along with improvements in tracheostomy care, ventilator circuitry and tube manufacture the incidence of TS following tracheostomy has continued to decrease.

c) Subglottic stenosis

The first recognition that stenoses after percutaneous procedures may be different to those following surgical tracheostomy was highlighted by McFarlane[10]. They described four cases of supra-stomal subglottic stenosis following the original Ciaglia multiple dilator technique. They postulated that damage to the cricoid cartilage was the important aetiological factor. Despite work by Jackson[9] illustrating the dangers of damage to the cricoid cartilage early attempts to develop minimally invasive approaches to tracheostomy predominantly used the space between the cricoid cartilage and first tracheal ring[39,40]. When initial reports of TS were made in relation to these procedures

it was felt that the problems were related to prolonged trans-laryngeal intubation rather than the tracheostomy. Only when reviewing long term outcomes did Ciaglia later suggest that damage to the cricoid cartilage should be avoided[41].

2.2.1.3 Stenosis related to trans-laryngeal intubation versus tracheostomy

There is little published in the literature to define the relative risks of TS as a result of trans-laryngeal intubation or tracheostomy alone. This is confounded by the fact that the majority of patients undergoing tracheostomy within the critical care setting have previously been intubated trans-laryngeally prior to tracheostomy. Even those who undergo early tracheostomy are likely to have had their tracheas intubated for a minimum of four to five days, which may be long enough to institute a stenotic process.

In an early report addressing the relative risks of both interventions, Stauffer reviewed 150 adult critical care patients undergoing tracheal intubation and surgical tracheostomy[74]. They recorded high complication rates in relation to tracheostomy for stomal infection (36%), haemorrhage (36%) and subcutaneous emphysema or mediastinal air (13%). Follow up of survivors revealed a prevalence of TS of 65% in relation to tracheostomy and 19% following tracheal intubation alone. Non-survivors who underwent post mortem examination revealed a high incidence of laryngo-tracheal injury (91-95%). Those patients who had undergone prolonged tracheal intubation prior to tracheostomy were more likely to develop TS. In a more recent report, Zias describes thirty one patients with TS after tracheal intubation or tracheostomy treated at the Lahey clinic in Massachusetts[75]. Of the thirty-one patients, eleven had undergone tracheal intubation alone; the remaining twenty had both

tracheal intubation and tracheostomy (mean of 5.5 days tracheal intubation prior to tracheostomy). Of the twenty stenoses associated with tracheostomy, seventeen were stomal in origin, whilst the predominant feature of post-intubation lesions was a web like stenosis at the level of the cuff. In contrast, Herrak reported a retrospective series of 174 patients in whom 55% had undergone tracheal intubation alone with only 45% having an additional tracheostomy[88].

2.2.1.4 Grading of tracheal stenosis

A number of grading systems for assessment of TS have been developed. Perhaps the first attempt to stratify the degree of obstruction associated with a TS was described by Cotton in relation to paediatric laryngo-tracheal stenosis following prolonged trans-laryngeal intubation[81]. In his original paper Cotton described four grades of luminal obstruction ranging from < 70% (grade 1) to complete obstruction (grade 4) (table 2.1). In an era prior to the widespread use of computed tomography, no reference was made as to how assess such reductions in tracheal diameter. In a later modification of the Cotton scale, Myer described the use of an endotracheal tube (ETT) to better define this[89]. The percentage reduction in airway calibre was calculated by measuring the external diameter of the largest tracheal tube a given stenosis could accommodate and comparing this with the age appropriate tracheal tube size. Despite widespread use of the Cotton scale it makes no reference to the site of the tracheal narrowing, its length or cause. In an attempt to address these issues subsequent authors have addressed these perceived deficiencies. In a retrospective report of paediatric TS, in addition to describing the airway diameter, Grundfast added a description of the length of the stenosis as well as a subjective assessment of its consistency[90].

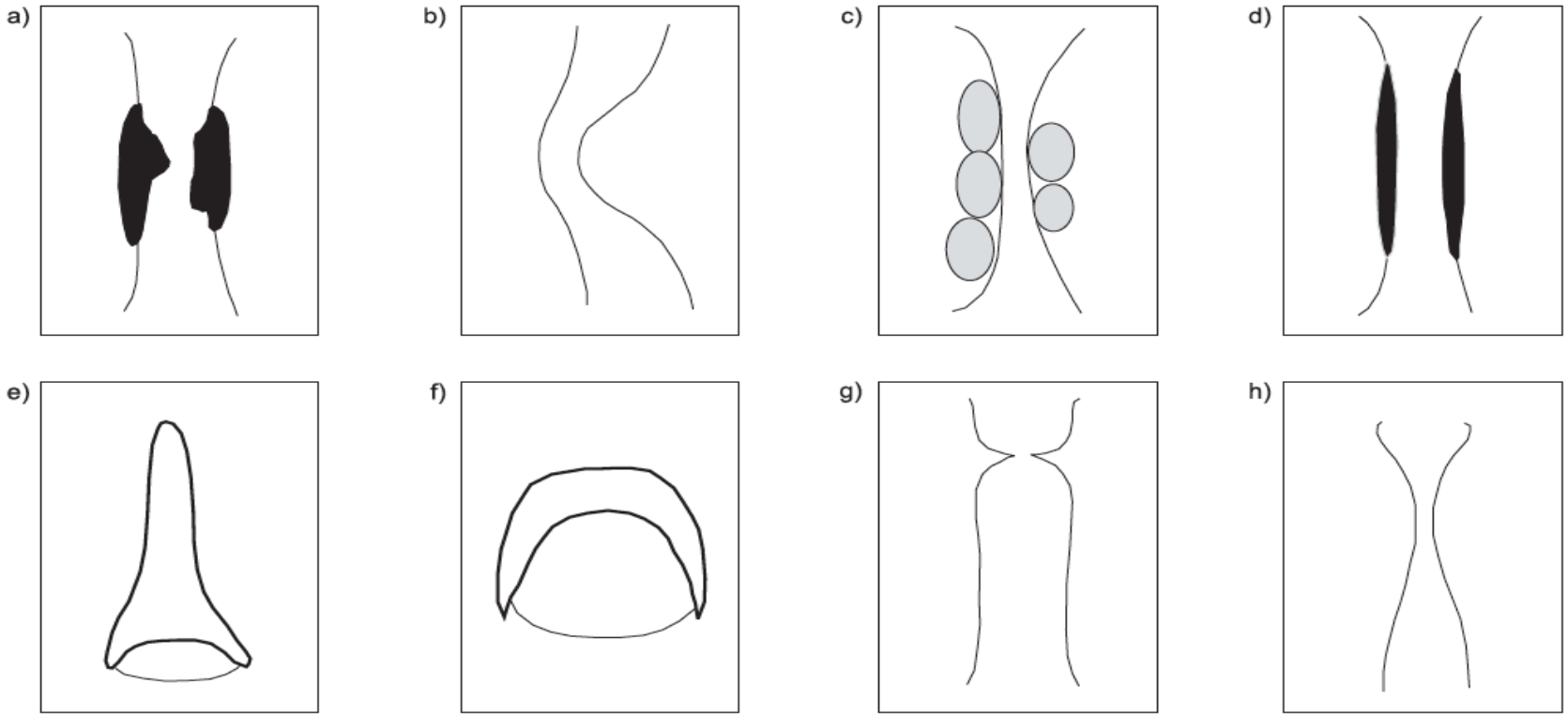
Table 2.1. *Degrees of tracheal stenosis according to Cotton classification*[81]

	Degree of tracheal narrowing
Grade 1	< 70%
Grade 2	70-90%
Grade 3	> 90%
Grade 4	Complete obstruction

Further development related to grading of stenosis was described more recently by Freitag et al[82]. They first described the stenosis as either structural or functional. Structural lesions may be further defined as intra-luminal, extrinsic compression, stricture or distortion. They describe functional or dynamic stenoses as those that vary during the respiratory cycle and are frequently due to malacic disease. Within this category are the sabre-sheath or scabbard trachea and the commoner inward bulging of the posterior musculo-membranous portion of the tracheal wall. Thereafter the reduction in cross sectional area is defined and graded from no appreciable obstruction (0) to complete obstruction (5). The location of the stenotic segment is then described extending from the upper third of the trachea to the right and left main bronchi. Finally the abruptness of transition from a normal calibre airway to the stenotic segment is described (figure 2.4). In a pilot study to validate this scoring system, Freitag found a strong precision and agreement between observers. The most recent scoring system was described by Ghorbani et al, in relation to post intubation TS[91]. They described a four point scale for tracheal calibre, type of stenosis and clinical symptoms giving a possible score of 0-12 – the more severe the stenosis the higher the score. Tracheal measurements and description of stenosis were undertaken during rigid bronchoscopy. When assessing the performance of the grading system in pre-operative assessment for patients presenting for tracheal resection there was a significant association between a score ≥ 8.5 and the need for surgery. Additionally, when assessed against a surgeon blinded to the score obtained there was a 78%

agreement between the score and the surgeon's opinion regarding the need for surgery.

Figure 2.4. Classification of tracheal stenosis. From Freitag et al[82].



[a]Intraluminal tumour or granulation tissue
[b]External distortion or buckling
[c]Extrinsic compression
[d]Scarred stricture
[e]Scabbard trachea (in cross section)
[f]Floppy membrane (in cross section)
[g]Abrupt transition
[h]Tapered transition

2.2.1.5 Diagnosis of tracheal stenosis

2.2.1.5.i Clinical assessment

As long as a high index of suspicion is maintained, the diagnosis of TS can largely be made from a history suggestive of airflow obstruction following on from a period of prolonged intubation or tracheostomy. In the earlier phases of presentation the patient may report an increase in cough associated with difficulty expectorating secretions. With more severe stenosis, the most frequent symptoms reported will be increasing shortness of breath associated with inspiratory stridor. With severe stenosis, dyspnoea at rest is present. At this point the airway diameter is likely to be <5mm. It is not uncommon that, the presence of stridor may be mistaken for lower airway wheeze and thereby treated as asthma[92,93]. In survivors of critical illness, in whom function may be limited due to critical illness associated neuromuscular disease or ongoing respiratory pathology, a typical presentation with stridor and shortness of breath may not be seen. Such patients may merely report a reduction in exercise tolerance the causes for which may be multiple and complex.

Clinical examination may note findings of tachypnoea, use of accessory respiratory muscles, inspiratory stridor a persistently patent stoma and an abnormal voice.

The time course for presentation after intubation may be variable. Most patients will present within two months although a small cohort may present very late. It is in this group of patients where misdiagnosis as lower respiratory tract pathology may be problematic.

2.2.1.5.ii Investigation

a) Radiological imaging

Most patients will undergo radiological imaging either via computed tomography (CT) or magnetic resonance imaging (MRI) prior to formal evaluation of the stenotic segment under general anaesthesia.

Computed tomography with reformatted sagittal and coronal images can produce an accurate representation of the underlying stenosis allowing definition of site, length, reduction in cross sectional area and character of the lesion. Recent advances utilising multi-detector CT imaging to produce three dimensional images of both internal and external segments of the distorted airway allowing a virtual endoscopy have been described[94]. A number of authors have demonstrated a high degree of correlation between such images and the findings at rigid bronchoscopy[94-96]. Such findings suggest that these techniques may have an important role in defining the lesion and planning treatment options.

b) Spirometry

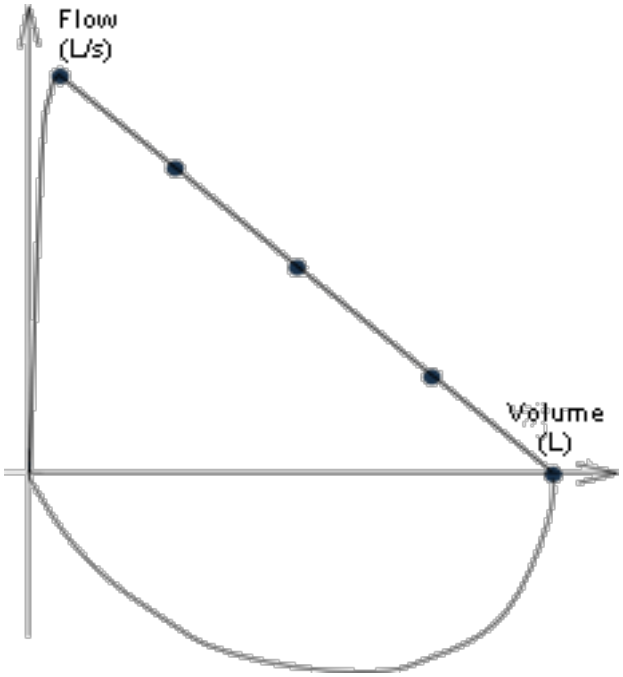
Although spirometry is one of the simpler techniques used to identify upper airway obstruction the typical changes seen occur relatively late in the disease progression. Typically a reduction of TCSA of more than 50% must be present for changes to be evident. With fixed TS there is a characteristic limitation of inspiratory and expiratory flow producing the typical rhomboid curve (figure 2.5). For those lesions that are malacic and show dynamic flow limitation the curve may be more variable with either inspiratory or expiratory abnormalities depending upon the site of the lesion. They are of limited use in assessment

and planning of therapeutic intervention. A lack of correlation between spirometry findings and both clinical symptoms and radiological findings has been noted. In an attempt to address some of the limitations of spirometry, Verbanck and colleagues described a forced oscillation test that was able to define a level of critical TS that was not confounded by the presence of co-existing peripheral airway obstruction[97].

c). Diagnostic bronchoscopy

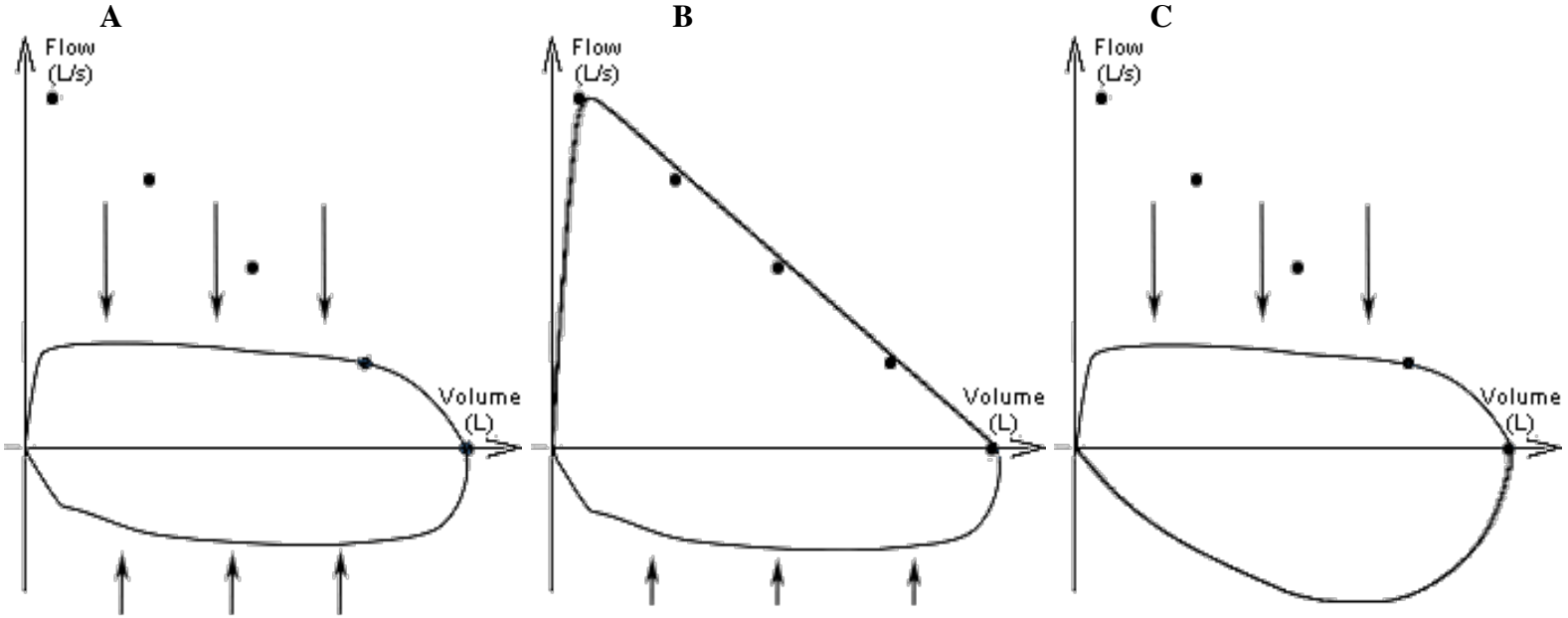
The principal role for bronchoscopy in the setting of TS is for assessment for further surgical intervention, as it is able to define the site, length and character of the lesion and allow planning for operative repair. It may also be utilised with balloon dilatation to temporarily relieve symptoms prior to more definitive treatment. However, recent National Institute for Health and Clinical Excellence (NICE) guidance documented instances of tracheo-bronchial rupture, tracheal laceration, laryngeal injury and bleeding as possible cause for concern. Consequently, balloon dilatation for TS is not recommended by NICE[98].

Figure 2.5: Normal flow-volume loop:



The normal Flow-Volume loop begins on the X-axis (Volume axis): at the start of the test both flow and volume are equal to zero. After the starting point the curve rapidly mounts to a peak: Peak (Expiratory) Flow. After the PEF the curve descends (=the flow decreases) as more air is expired. A normal, non-pathological F/V loop will descend in a straight or a convex line from top (PEF) to bottom (FVC). The forced inspiration that follows the forced expiration has roughly the same morphology, but the PIF (Peak Inspiratory Flow) is not as distinct as PEF. Copyright spirometry.guru (http://www.spiromtery.guru/fvc.html)

Figure 2.6. *Spirometry in upper airway obstruction*



A; Fixed large airway obstruction

Can be both intrathoracic and extrathoracic. The flow-volume loop is typically flattened during inspiration and expiration.

B; Variable Extrathoracic Obstruction

The expiratory part of the flow volume loop is normal: the obstruction is pushed outwards by the force of the expiration. During inspiration the obstruction is sucked into the trachea with obstruction and flattening of the inspiratory limb.

C; Variable Intrathoracic Obstruction

An obstruction near the intrathoracic part of the trachea is sucked outwards during inspiration with a normal inspiratory part of the flow volume loop. During expiration the lesion is pushed into the trachea with partial obstruction and flattening of the expiratory part of the flow volume loop.

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2.2.1.6 Management of tracheal stenosis

i. Interventional bronchoscopy and laser therapy

A number of authors have reported successful outcomes following combination therapy of balloon dilatation in association with laser resection[75,99,100]. Such interventions frequently require multiple procedures for a successful outcome. Early work suggested that this therapy was less effective for complex and longer stenoses and those affecting the cricoid cartilage. Gallucio, in a study of 209 patients (mean number of interventions per patient of 1.56-3.27) with two year follow up, reported successful outcomes, with a combination of balloon dilatation, laser resection and stenting, in 96% of simple stenoses and 69% of complex lesions[99]. Similarly Zias, in a report of 31 cases of TS undergoing an average of 2.4 procedures per patient, described the need for operative intervention in only one patient[75]. It is possible that dynamic stenoses, particularly those involving a degree of tracheomalacia, may be more problematic. In a series of sixty patients undergoing combination therapy of laser resection and stenting, Plojoux described a fifty one per cent success rate with a stent migration rate of 31%[101].

It would appear, from the literature, that the lesions most suitable for endo-luminal therapy are simple web like stenoses. There may also be a role in more complex lesions for symptom relief prior to definitive surgery.

ii. Stenting

Traditional use of tracheal stenting has been for patients with malignant strictures where there is a limited life expectancy[102]. When used for benign

disease with associated longer survival stent related complications become more problematic. Whilst early results achieve relief of obstruction in up to 95% of patients long-term complications can be debilitating[103,104]. Long term problems associated with tracheal stents include formation of granulation tissue, re-stenosis, bleeding, migration, fracture and erosion. The formation of granulation tissue and re-stenosis are two of the more problematic issues related to stent use for benign airway strictures particularly when used in the proximal (sub-glottic) airway. Metallic stents appear to cause more significant problems in this region[105]. Additionally, the sub-cricoid area is not distensible like the proximal trachea. Consequently, a rigid metallic stent placed here is prone to significant shear forces generating formation of significant amounts of granulation tissue, a propensity toward stent fracture and re-stenosis. The resultant granulation tissue makes stent removal more difficult which may be particularly problematic for airway management if these patients present with upper airway obstruction with a stent in-situ.

Whilst a number of small case series published in the literature frequently report satisfactory early symptom relief, the long term complications are frequently excessive, with some authors suggesting that the incidence of late complications is more related to the length of time the stent is deployed rather than the material it is made from[103]. Consequently, the Food and Drug Administration in the United States issued a series of recommendations related to metallic stenting in benign airways disease in 2005 suggesting their use should be avoided[106].

The principal role for tracheal stenting in benign TS appears to be as a bridge to more definitive therapies[107]. It should, therefore, be largely confined to

patients with significant co-morbidities in whom the risk of operative repair is deemed unacceptable, those with a limited life expectancy, those who refuse surgery, those with long complex stenoses that are deemed inoperable and to provide symptom relief prior to definitive surgery.

Potential for an enhanced role for stenting in the future has been suggested with the use of drug eluting stents aimed at reducing the tissue reaction and production of granulation tissue[108]. Stents eluting drugs targeting the mammalian target of rapamycin (mTOR) pathway (sirolimus, everolimus, zotarolimus and paclitaxel) may have local immuno-modulatory effects reducing new vessel formation and production of granulation tissue.

iii. Surgical management

Despite reports detailing the use of tracheostomy in pre-biblical times and intermittent use through the ages tracheal surgery per se was hampered by the belief that cartilaginous tissue heals poorly[5]. This opinion was stated by, amongst others, Hippocrates and Aretaeus and persisted well in to the twentieth century. The first description of a healing tracheal anastomosis in dogs was reported by Gluck and Zeller who felt the technique may have a role in humans[109]. The first reported human tracheal resection for post-traumatic TS was described by Kuster in 1886[110]. Despite these early advances the full utility of tracheal resection for stenotic lesions was not realised until the late 1960s and 70s with the pioneering work of Grillo[111] and Pearson[112]. Currently the treatment of choice for most tracheal stenoses is segmental tracheal resection with primary anastomosis. Pre-operative assessment includes multi-planar CT evaluation with three-dimensional reconstruction, virtual and rigid

bronchoscopy as detailed above. Surgical dissection is limited to preserve the lateral segmental blood supply but segments in excess of six centimetres may be resected in the case of complex lesions[113].

Surgical outcomes have been superior to alternative non-operative procedures with good to satisfactory results reported in excess of 90% of patients[114-116]. Mortality is in the region of 0-2% with the most frequent late complications being anastomotic failure, formation of granulation tissue and laryngeal dysfunction[114]. For long complex and sub-glottic lesions the success rate appears to be around 80-90%[65]. The highest failure rate is seen in patients requiring more than one procedure to correct the defect[117]. Success rates may also be compromised in patients who have previously undergone laser resection and stenting which may damage the cricoid or lead to extension of the length of the stenotic segment[118].

Where the stenosed segment extends beyond a length that is primarily resectable surgical management becomes decidedly more complex requiring reconstruction of the trachea itself. A reconstructed trachea requires lateral rigidity with longitudinal flexibility. Anastomoses need to be airtight and any prosthetic material should ideally not provoke an antigenic tissue reaction. Simple tracheal transplantation is not possible due to the segmental nature of its blood supply. Additionally, prolonged use of immuno-suppressants poses risks of graft infection and breakdown. Currently approaches used have involved tracheal allografts, aortic allografts and tracheal allografts with tissue engineered host stem cells[119]. Cryopreserved and decellularised grafts appear to reduce their antigenicity and potentially improve long-term outcome. Despite this, reports of such cases are few in number predominantly being small cases series and isolated case reports[119,120].

iv. Adjuvant therapy

Adjuvant treatments have been targeted at the three phases of wound healing detailed above in an attempt to diminish the abnormal healing process responsible for TS. Examples of strategies used include:

Inflammatory phase

Corticosteroids, antibiotics, hyperbaric oxygen.

Proliferative phase

Antibiotics, corticosteroids, mitomycin-C, 5 fluorouracil / triamcinolone, hyperbaric oxygen.

Maturation phase

Colchicine, penicillamine, N-acetyl cysteine.

All phases

Anti-reflux therapy

Many of the potential agents have limited evidence particularly in humans with the most studied being corticosteroids (topical, inhaled and systemic), mitomycin-C (topical) and anti-reflux medication (proton pump inhibitors)

Corticosteroids

Theoretically corticosteroids could be expected to affect both inflammatory and proliferative phases of wound healing.

In relation to airway injury, a number of studies have assessed the role of dexamethasone in reducing laryngeal oedema and reducing the need for re-intubation. A Cochrane review, of six studies in adults totalling 1953 patients, found that

prophylactic use of corticosteroids reduced the risk of post-extubation stridor in those patients at high risk but did not reduce the re-intubation rate[121]. Although a number of studies have shown some beneficial effects in paediatric patients there is limited evidence for the role corticosteroids in the setting of adult post-intubation TS – studies being confined case reports or small case series.

Mitomycin-C

Mitomycin-C is an antimicrobial agent as well as having anti-metabolite and anti-proliferative properties. It inhibits de-oxyribonucleic acid (DNA) synthesis and in higher concentrations suppresses ribonucleic acid (RNA) and protein synthesis. Consequently it has been used as a chemotherapeutic agent for solid tumours. When administered topically it has been shown to inhibit fibroblast proliferation possibly by inducing apoptosis. Whilst mitomycin is amongst the most frequently studied adjuvant agents for the management of TS data relating to human use is largely confined to retrospective studies and case reports[122-124].

Two randomised studies have, however, attempted to evaluate the role of mitomycin-C in the treatment and prevention of TS. Hartnick reported a paediatric study of 24 patients undergoing a single mitomycin application after laryngotracheal reconstruction[125]. Thereafter development of granulation tissue was graded on a scale of 0-4. After recruitment of 13 patients to the intervention group and 11 to the control group the study was stopped early, as the outcome in both groups was almost identical (Granulation grade 3-4: placebo treated 1 patient, mitomycin treated 3 patients. Granulation grade 0-2: placebo treated 10 patients, mitomycin treated 11 patients). More recently Smith and Elstad reported the findings of a randomised controlled trial comparing a one or two applications of mitomycin-C in association with endoscopic

laser treatment[126]. Twenty-six patients were recruited with idiopathic, post-intubation and polyangiitis (Wegener's) stenosis. All patients received mitomycin-C at the first procedure. One month later a second endoscopic intervention was undertaken at which patients were randomised to receive either a second application of mitomycin-C or a saline placebo. Follow up for five years revealed an increase in the median interval to relapse from 2.4 years in the single application group to 3.8 years in the two application group. Relapse rates at five years, however, were identical in both groups. Leading the authors to conclude mitomycin-C delays rather than prevents re-stenosis.

In a review of adjuvant therapies for upper airway stenosis Hirshoren identified 11 human studies (181 patients) assessing the effects of mitomycin-C[70]. Only one was randomised[125], eight had no control group and six were retrospective. Of these trials, nine claimed a positive outcome.

Mitomycin-C clearly has an effect on wound healing however optimal timing for application remains unclear. Its efficacy for treating established stenoses is questionable.

Treatment for gastro-oesophageal reflux disease

Initial data suggesting gastro-oesophageal reflux may play a role in the development of TS came from case reports by Little and Bain[127,128]. Further work suggested that those with reflux disease were over-represented in sub-glottic stenosis populations particularly those with idiopathic disease[129,130]. A number of studies have described less successful outcomes for surgical reconstruction in patients with uncontrolled reflux disease[131-133]. However, this was not supported by the findings of a large single blind observational study[134]. In an prospective, single blind observational study of 74

paediatric patients Zalzal failed to find any effect of gastro-oesophageal reflux disease on the outcome of undergoing laryngotracheal reconstruction. Thus concluding that evaluation for and treatment of reflux disease had no role in this patient population.

2.2.2 Tracheo-innominate artery fistula

The first report of a tracheo-innominate artery fistula (TIF) was in 1879 when Korte described a fatal fistula in a five year old child with diptheria[135]. In a case report and clinical review from 1976 Jones et al documented a total of 127 cases from the world literature to that point[136]. The first survivor of a TIF was not reported until 1965[137]. In a series of six patients, Silen reported on the management of a young female patient who had undergone a tracheostomy for respiratory failure due to Guillain-Barre Syndrome. Five days after tracheostomy insertion she developed a TIF. This was managed with surgical excision of the necrotic portion of the innominate artery followed by over-sewing of the arterial stumps. She survived for 15 days before dying from an aspiration pneumonitis. The first long term survivor was reported by Reich in 1968 in a young female patient who again underwent resection of the necrotic arterial segment[138]. Despite multiple reports in the intervening years the mortality still remains high. A recent review[139] of the surgical management of TIF in Beijing, covering 32 years and 14 cases, reported one survivor without neurological impairment at 11 months.

Tracheo-innominate artery fistula is an uncommon and life threatening complication occurring after tracheostomy that is universally fatal without surgical intervention. The true incidence of this rare complication is difficult to assess as it is most frequently reported in small case series or isolated case reports. The incidence seems to have reduced following the widespread introduction of high volume low pressure

cuffs for tracheal and tracheostomy tubes. The overall incidence of late haemorrhage after tracheostomy has been reported at around 3%. Approximately 10% of late bleeding is thought to be related to a TIF, however, in our own series all significant late bleeding was due to TIF (0.35%[59]). Massive haemorrhage may also originate from the aortic arch, common carotid and thyroid arteries and the innominate vein[140]. Pooled data of 5530 tracheostomies recorded the incidence of delayed massive haemorrhage as 0.3%[141]. In our own series of 1000 percutaneous procedures performed using the single tapered dilator, the rate is around 0.4% (see Chapter 5). Elsewhere, reported rates are 0.1–1% after surgical and 0.3% after percutaneous tracheostomy, with peak incidence 7–14 days post procedure[142,143].

2.2.2.1 Pathophysiology

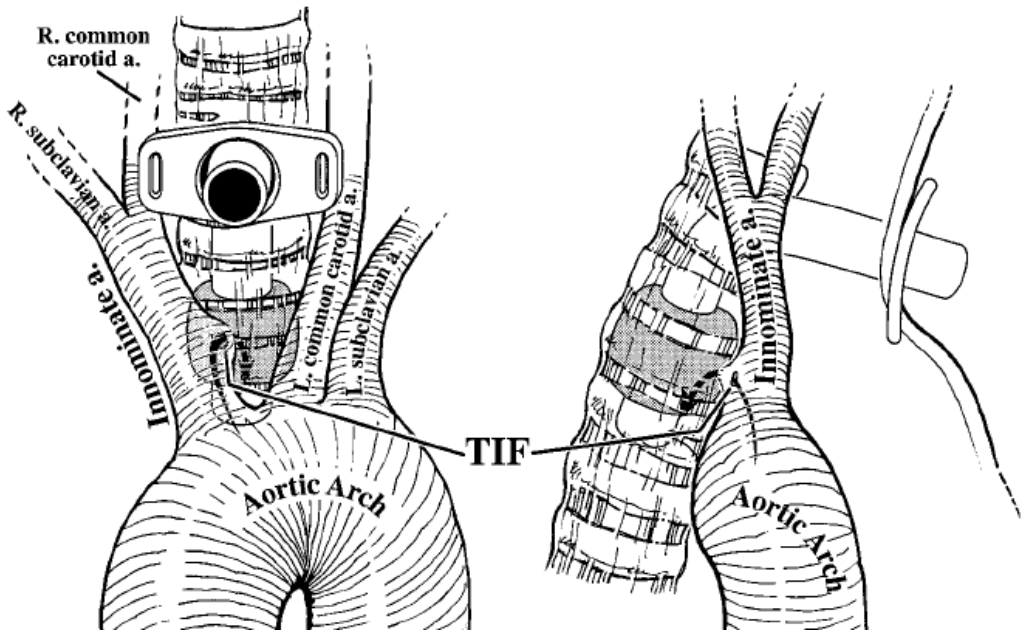
The tracheo-innominate artery is the first branch of the aortic arch (figure 2.2). It divides into the right common carotid and right subclavian artery 3–4 cm lateral to the trachea, behind the right sternoclavicular joint. In its inferior proximal portion, its relations include:

a) Anterior: left tracheo-innominate vein and thymus;
b) Posterior: trachea (6–10th ring);
c) Posterior and left: left common carotid artery;
d) Right: right tracheo-innominate vein, superior vena cava and pleura.

The tracheo-innominate artery supplies blood to the right arm and the right side of the head and neck. Its absence on the left is explained by the direct branching of the left common carotid and subclavian arteries from the aortic arch. A high lying innominate artery, particularly in the thin and young, may act as a risk factor in TIF formation following tracheostomy[63].

Pressure necrosis from high cuff pressure, mucosal trauma from a malpositioned cannula tip, low tracheal incision, excessive neck movement, radiotherapy or prolonged intubation have all been implicated in TIF formation[144]. The relationship of the tracheostomy tube to the tracheo-innominate artery can be seen in figure 2.7.

Figure 2.7. *Relationship of the cuff of the tracheostomy tube to the tracheo-innominate artery – anterior and lateral representations.*



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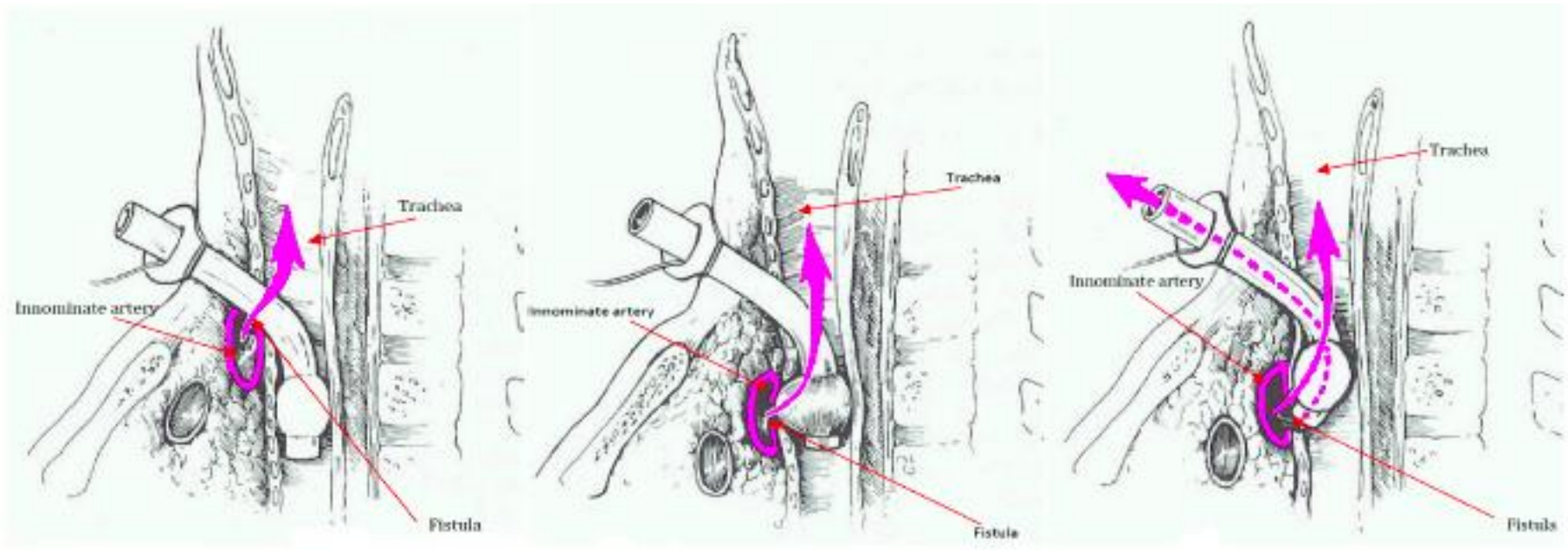
Two principal mechanisms are capable of producing sufficient pressures to generate the erosive processes that lead to fistula formation (figure 2.8):

Figure 2.8. *Mechanisms of tracheo-innominate fistula formation*

A ***B*** ***C***



- *(A): Pressure generated beneath the angulated neck of a tracheostomy tube can produce anterior tracheal wall ischaemia*
- *(B): Pressure generated by the tracheostomy tube cuff can cause anterior tracheal wall erosion*
- *(C): Pressure produced by the tip of the tracheostomy tube causes erosion through the anterior tracheal wall*

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- The first mechanism involves pressure generated beneath the angulated neck of a tracheostomy tube (figure 2.8A). This could produce ischaemia anteriorly on the tracheal mucosa and into the innominate artery.
- A fistula may also occur between the anterior tracheal wall and artery. This is secondary to the mechanical force generated by either the tracheostomy tube cuff or tube tip depending on the relative positioning of the tube within the trachea (figure 2.8B & 2.8C).

Some authors suggest that a low lying tracheostomy tube is an obvious cause of fistula formation[73]. However, even when the tracheotomy incision is placed between the second and third tracheal rings as recommended, these complications can still occur. In a post-mortem study, Oshinsky found that ten standard vertical incisions placed in the second and third rings resulted in all subsequently placed tracheostomy tubes having either cuff or tip anatomically adjacent to the innominate artery, suggesting the potential presence of this complication in all patients with tracheostomies[146].

2.2.2.2 Diagnosis

Any peri-stomal bleed or haemoptysis should lead to a full clinical investigation to ascertain the underlying cause. A differential diagnosis is based on the lag time between the tracheostomy and subsequent haemorrhage. Haemorrhage within 48 h is typically associated with local factors such as traumatic puncture of anterior jugular or inferior thyroid veins, systemic coagulopathy, erosions secondary to tracheal suction or bronchopneumonia.

Vascular erosion from a tracheostomy tube, resulting in a TIF, requires at least 48 hours to develop even in the most friable mucosa. Haemorrhage occurring 3 days to 6

weeks after tracheostomy should be thought of as a result of TIF until proven otherwise[147]. Other causes of catastrophic pulmonary haemorrhage include pulmonary artery flotation catheter induced arterial rupture, thoracic aneurysm rupture and less common vascular fistula (carotid artery, inferior thyroid). It is likely that the majority of TIF will occur in the Critical Care Unit, as 70% of all delayed haemorrhage occurs during the first 3 weeks[148]. A sentinel bleed is reported in more than 50% of patients who then develop massive delayed haemorrhage[136,149]. Haemorrhage occurring after more than 6 weeks is rarely related to TIF and more likely to be secondary to granulation tissue, tracheo-bronchitis or malignancy.

2.2.2.3 Clinical management

Adequate oxygenation is the mainstay of immediate management with simultaneous identification and termination of bleeding. In most TIF related deaths the cause of death is hypoxia due to bleeding into the airway rather than exsanguination from massive haemorrhage[144].

Management of a suspected TIF will depend upon whether there is active bleeding into the airway hindering adequate ventilation (Figure 2.9). The use of immediate bronchoscopy to confirm the extent and source of bleeding has been advocated[144]. Although bronchoscopy is unlikely to identify the fistula opening per se, it may exclude other pathology and allows direct monitoring of attempts to obtain a blood-free airway. Rigid bronchoscopy to clear the tracheobronchial tree of aspirated blood and to terminate blood flow is ideal, but this may not be possible.

If bronchoscopy confirms that the main bronchi are blood-free then immediate intervention is not required but further investigation to confirm the cause of bleeding is vital. Other causes of haemorrhage must be excluded before a sentinel bleed

associated with TIF can be confirmed. If no other cause is evident then a provisional diagnosis of TIF should be made; urgent surgical advice and consideration of stoma exploration should follow. If, in the presence of active bleeding, bronchoscopy indicates that the airway is clear of blood but there is ongoing external haemorrhage, the potential for catastrophic airway contamination is real. Overinflating the cuff provides additional airway protection and may control the bleeding temporarily. If, however, bleeding continues then pressure dressings should be applied to the stoma site. These manoeuvres temporarily control bleeding by a direct tamponade effect in more than 80% of patients[150]. As long as the airway remains free of blood, no attempt should be made to manipulate the tracheostomy tube. Immediate surgical exploration should follow.

Where bronchoscopy confirms that there is active bleeding into the airway, the major threat is respiratory compromise rather than hypovolaemia[151]. Airway protection is the primary management aim. Movement of the tracheostomy tube may precipitate disastrous airway occlusion[143]. The aims must be to gain temporary control of the bleeding, get adequate oxygenation and proceed to immediate stomal exploration and definitive treatment.

i Haemorrhage control measures

- Over-inflation of the tracheostomy cuff is first line management.
  If this measure fails to reduce bleeding in to the trachea then proceed immediately to trans-laryngeal intubation with digital compression.

- Trans-laryngeal intubation and digital compression of the innominate artery against the posterior surface of the manubrium. A cuffed oral tracheal tube is advanced so that the balloon lies distal to the tracheostomy stoma. The

tracheostomy tube should only be withdrawn to facilitate simultaneous trans-laryngeal tracheal intubation. This procedure should terminate bleeding in > 90% patients and if maintained, allows transfer to the operating theatres.

- If digital compression fails to stem bleed, slow withdrawal of the tracheal tube and cuff over-inflation should follow. Manipulating the ETT tube, and its cuff to produce tamponade is the only other manoeuvre available in this situation and attempts should persist.

If the bleeding stops, and ventilation is acceptable, then immediate surgical intervention should follow. There is no evidence to support any imaging prior to immediate surgical exploration.

ii Surgical management

It is clear from the literature that the mortality for TIF without surgery is close to 100%. There remains a degree of controversy around the optimal surgical management.

Most surgical approaches utilise a median sternotomy or upper sternotomy extended to the second right intercostal space to access the fistula.

Thereafter the controversy revolves around the two basic strategies for fistula management and concerns relating to post-operative neurological deficit.

- ***Maintenance of flow within the innominate artery***

  Direct repair of the fistula

  Graft interposition

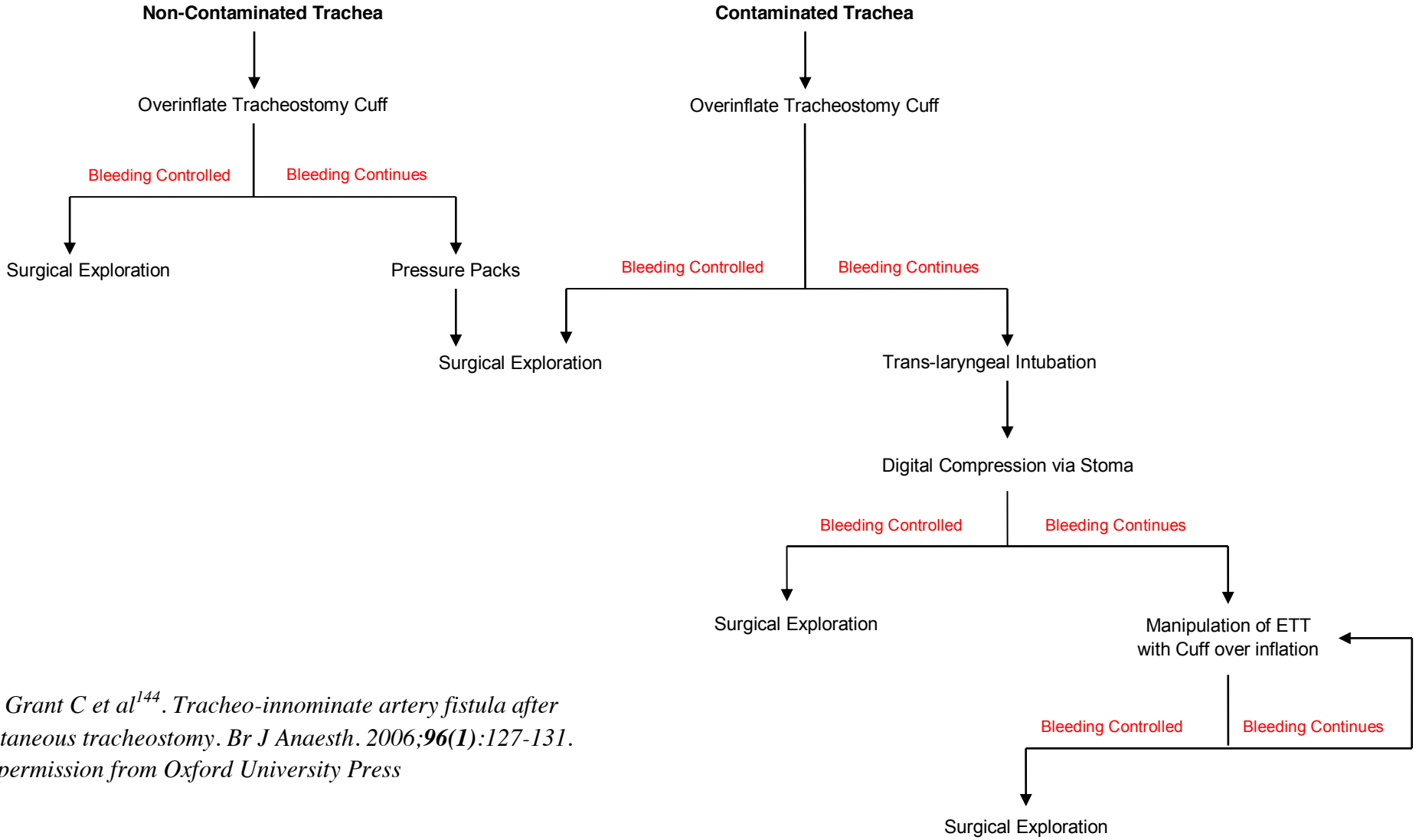
- ***Interruption of flow within the artery***

  Simple ligation of the innominate artery

Bypass grafting – aorto-axillary

The principal concern relating to maintenance of flow within the vessel is related to the risk of re-bleeding. The area surrounding the fistula is highly like to have active underlying infection and ongoing inflammation. Repair of the fistula or interposition of a foreign body to bypass the defect are therefore highly likely to fail. In a review of 37 cases published between 1975 and 1988 Yang described the outcomes of patients surviving to undergo operative intervention[152]. Fourteen patients underwent resection or ligation of the innominate artery with a re-bleeding rate of 7% and 64% long-term survival. Ten patients underwent procedures maintaining flow within the innominate artery and had a re-bleeding rate of 60% and a long-term survival of 10%. Similarly Gelman reported on the outcomes of 71 TIF survivors in 1994[151]. With maintenance of flow within the vessel re-bleeding rates were 60% versus 7% when there was disruption of flow. With maintenance of flow mortality was 86% versus 29% with disruption. Even with ligation of the innominate artery, reported neurological sequelae were minimal. Despite these data, continued reports of stent interposition[153,154], vascular grafting[155] and endovascular embolisation[156,157] continue to appear. Reported neurological sequelae are unusual with arm weakness occurring in around 4% of patients and more significant neurological deficit in less than 5% of patients[158] .

***Figure 2.9**. Algorithm for management of delayed (> 48 hours) tracheal haemorrhage.* *From: Grant*[144]



From Grant C et al[144]*. Tracheo-innominate artery fistula after percutaneous tracheostomy. Br J Anaesth. 2006;**96(1)**:127-131. With permission from Oxford University Press*

2.2.3 Tracheo-oesophageal fistula

Tracheo-oesophageal fistulae related to tracheostomy insertion may occur as both an early and late complication. Trauma to the posterior tracheal wall during tracheostomy insertion may lead to direct fistula formation although a simple posterior tracheal wall tear with entry only into the mediastinum is perhaps more likely. Such fistulae will usually be evident immediately post-operatively although diagnosis may be delayed[159,160]. Features suggestive of an immediate problem include a persistent cuff leak with the formation of subcutaneous and mediastinal emphysema as well as pneumothoraces.

Although tracheo-oesophageal fistulae (TOF) may result from several different aetiologies, including trauma and post-surgically, those originating after prolonged tracheal intubation and tracheostomy remain the commonest. TOF due to tracheostomy cuff erosion was first reported in the 1960s[161-163], with Flege being the first to postulate ischaemic necrosis, due to the cuff of the tube impairing tracheal wall capillary perfusion, as the underlying cause[162]. The reported incidence is similar to that of TIF[164] formation although the presentation maybe somewhat later with median times to diagnosis around 30 – 35 days from onset of mechanical ventilation[165,166]. Similarly to TIF and TS, with the introduction of high volume low pressure tracheostomy tube cuffs, the incidence of TOF appears to have diminished[167]. Muniappan recently reviewed cases of TOF presenting over a 35 year period extending from 1975 to 2010 and reported a falling incidence of post intubation lesions from 71 to 47%[168].

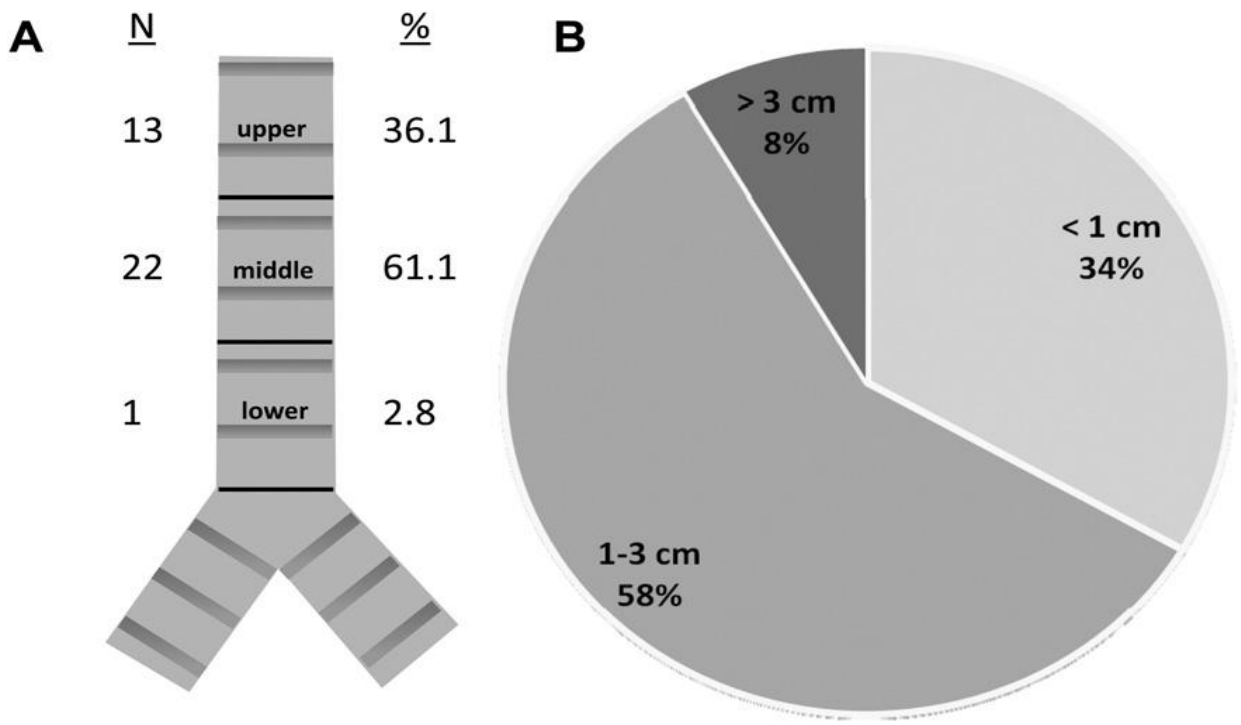
2.2.3.1 Pathophysiology of late TOF

The aetiology of late TOF is essentially the same as that described above for both TIF

and TS. Over inflation of the tracheostomy tube cuff will lead to pressure necrosis, additionally malpositioning of the tube may also lead to erosions of the posterior tracheal wall by the tip of the tracheostomy tube. After short periods of intubation, epithelial disruption, basement membrane loss, and / or an appearance of ischemic non-inflammatory necrosis can occur. More prolonged intubation results in broader, deeper ulcers, disruption of basement membranes and ischemic necrosis. Similar to the aetiology of tracheal stenosis, cuff pressures of greater than 20-30 cm of water contribute to mucosal ischemia[67,68,83]. The effects of cuff related mucosal injury may be exacerbated by repeated tracheal tube manipulations, intubations, or excessive movements of the tracheostomy tube and ventilator circuitry. Additional factors important in the aetiology may be the presence of a naso-gastric tube, advanced age, diabetes mellitus, steroid therapy, prolonged hypotension, oesophageal infections and prolonged cannulation[169]. However, pressure related necrosis may be more likely to be associated with the rigid cartilaginous anterior tracheal wall than the soft tissue of the musculo-membranous posterior wall. This may account for the more frequent descriptions of TS and TIFs[170].

As most TOF related to prolonged intubation and tracheostomy insertion are related to mucosal ischaemia produced by the cuff of the tube their site is usually in the proximal trachea. Muniappan in a report of 74 cases of TOF, of which 59% were post intubation / tracheostomy, described the site of the fistula in the upper trachea in 36%, the mid-trachea in 61% and the lower trachea in 3%[168]. Additionally, 35% of lesions were < 1cm, 58% were 1 – 3cm and 8% were in excess of 3cm (figure 2.10).

Figure 2.10 Location (**2.10 A**) and size (**2.10 B**) of tracheo-oesophageal fistulae. Fistulae are found predominantly in the proximal and mid-trachea and are usually less than 3cm in length.



Reprinted from *Muniappan A et al*. *Surgical treatment of non-malignant tracheo-oesophageal fistula: a thirty five year experience*. *Annals of Thoracic Surgery* 2013;**95(4)**:1141-1146. *Copyright (2013) with permission from Elsevier*.[168]

2.2.3.2 Diagnosis

Hallmarks of TOF include persistent choking or coughing in relation to swallowing leading to aspiration pneumonitis. An ongoing air leak around the cuff of the tracheostomy tube, gastric distention and abdominal air movement synchronous with respiration may be seen. Further signs may include subcutaneous and mediastinal emphysema and pneumothorax[171]. As the underlying pathology is similar to that responsible for both TS and TIF the timing of presentation of late TOF is likely to be several days to weeks following the tracheostomy.

Whilst the diagnosis is largely made on clinical grounds, with associated plain radiology showing evidence of mediastinal or pleural air, CT scanning will confirm the diagnosis. The fistula may be visualised directly by fibre-optic bronchoscopy although if due to erosion from the cuff it may be obscured by the tracheostomy tube itself. Definitive visualisation, prior to operative intervention, will be achieved by rigid bronchoscopy and oesophagoscopy.

2.2.3.3 Clinical management

When the diagnosis of TOF is confirmed the initial management involves avoiding further aspiration of gastric secretions into the tracheo-bronchial tree. The cuff of the tracheostomy or trans-laryngeal tube should be advanced beyond the fistula and the nasogastric tube should be removed. Gastric reflux should be reduced by the insertion of a gastrostomy tube and enteral feeding continued via jejunostomy. Antibiotic treatment of associated aspiration pneumonitis may also be required. These measures should prevent further aspiration pneumonitis and allow weaning from mechanical ventilation before more invasive therapies are contemplated.

i Conservative management

Whilst spontaneous healing of a TOF, over many months, with conservative management of gastrostomy, jejunal feeding and re-positioning of the tracheostomy tube has been reported this is far from usual[172] . Surgical treatment remains the mainstay of treatment but a number of less invasive therapies have been described in recent years. In a series of 25 patients with oesophageal leaks or fistulae Blackmon reported the use of metallic stents in their management[173]. Only four patients had TOF and in only two of whom was this due to prolonged intubation. The authors reported that in two of these four patients their fistulae sealed, whether further surgery was required or not was not reported. In another report of stenting for TOF Eleftheriadis described the management of twelve mechanically ventilated patients[166]. Whilst the authors stated that stent insertion was successful in all cases with sealing of the fistula and no migration only three of the twelve patients survived to surgery. Whether the stent placement resulted in a delay in referral for surgical intervention or, due to reduced gastric aspiration, allowed an improvement in the patients' general condition to enable consideration of surgery is unclear[168]. The use of fibrin glue to close a TOF in a mechanically ventilated patient has also been reported[174].

ii Surgical management

Repair of TOF is a major undertaking in the critically ill patient. Consequently most authors advocate waiting until the patient has been weaned from mechanical ventilation and largely recovered from the after effects of their critical illness including any critical illness related neuro-muscular weakness[164]. This will allow improvement in nutritional status and reduce the risk of further post-operative prolonged mechanical ventilation. In a recent report of 13 patients undergoing TOF

repair Foroulis described the use of a pre-sternocleidomastoid incision with interposition of a vascularised sternocleidomastoid pedicle[165]. Five of the thirteen patients were still mechanically ventilated at the time of operation, of whom three died in the post-operative period (60% mortality). In the eight patients in whom surgery was performed after weaning from mechanical ventilation there were no deaths.

The surgical approach to repair is largely dependent upon the site of the fistula and whether there is associated tracheal involvement. For those fistulae that are small (< 3cm) without tracheal involvement then a direct repair via a pre-sternocleidomastoid approach, with or without extension in to the superior mediastinum may be the most appropriate option. When there is associated tracheal disease (stenosis or tracheomalacia) a combined tracheal resection and oesophageal repair, as popularised by Grillo, is the most frequently used technique[175]. For more distal and complex lesions the use of a median sternotomy or thoracotomy may be required along with oesophageal reconstruction using gastric or colonic interposition. In addition to repairing the defect most authors recommend the interposition of vascularised pedicled muscle flaps (sternocleidomastoid, strap or pectoralis major muscles) to separate the tracheal and oesophageal anastomoses[168,176] although the need for these has recently been questioned[177]. In their series of 25 patients Marulli reported the use of a cervical approach in 56%, a combined cervical & sternotomy incision in 24% and a thoracotomy in 16% of cases[176]. In the same patients they undertook a direct fistula repair in 60% and a combined tracheo-oesophageal resection in 32%.

Although early reports for mortality after TOF repair were as high as 28%[178,179] most case series published after 2000 have reported mortalities of less than

10%[168,176,177,180]. Complication rates, however, remain high (32-56%)[168,176] with anastomotic breakdown and pulmonary infection being the most common.

2.3 Summary

The first reports of long-term complications of tracheostomy in significant numbers followed the poliomyelitis epidemics in the 1940s and 50s with the first widespread use of tracheal intubation and cuffed tracheostomy tubes for the purposes of mechanical ventilation. Whilst the absolute incidence of each complication has fallen with the introduction of high volume low-pressure cuffs, improved monitoring of cuff pressures and ventilator circuitry the underlying prevalence continues to increase as increasing numbers of patients receive these treatments.

Treatment of each complication is dependent upon the complexity of the lesion present, the symptoms produced and co-existing co-morbidities for any given patient. In a population of critically ill patients all long-term complications of tracheostomy will pose significant problems with considerable morbidity and mortality.

For TS tracheal resection provides the best chance of a lasting cure with success rates in the region of 90% for simple lesions and 80-85% for more complex ones. Endoscopic treatments are largely reserved for symptom relief pending definitive surgery or for those deemed unfit for tracheal resection.

For TIF outcomes are directly related to rapid diagnosis and surgical intervention. With techniques involving ligation or resection of the innominate artery long-term survival of 70% of patients surviving to the operating theatre is possible.

Tracheo-oesophageal fistulae require an approach to minimise ongoing gastric aspiration to facilitate weaning from mechanical ventilation and allowing

improvement in general health and nutritional status prior to attempting surgical repair. With this cautious approach mortality rates of less than 10% can be achieved[168,176,177,180], however, operating on patients who remain ventilator dependent still results in much higher death rates[165].

Whilst the incidence of TS following percutaneous tracheostomy is evident from a number of long term cohort studies[57-59] the issue of missed or sub-clinical stenoses has not been fully addressed. Non-specific symptoms are common following critical care admission and PDT, with frequent reports of voice changes, swallowing difficulties, cough and shortness of breath[181,182]. We hypothesised that, in this cohort of patients, there are a number of patients with undetected TS.

2.4 Aims

- To identify aetiological factors in initiation of tracheal stenosis with particular reference to peri-operative events
- To determine the role of early complications that may be postulated to play a part in the genesis of the late complications of tracheal stenosis, tracheo-innominate artery fistula and tracheo-oesophageal fistula
- To determine the prevalence of sub-clinical tracheal stenosis following percutaneous tracheostomy using the single tapered dilator technique.
- To determine possible aetiological factors for such sub-clinical stenoses namely tracheal ring fracture and duration of cannulation
- To determine whether sub-clinical tracheal stenosis may be presenting atypically in the post-critical care population
- To determine the utility of simple spirometry and a symptom based questionnaire in identifying sub-clinical tracheal stenosis

Chapter 3

Rationale for thesis

3.1 Systematic Review

Percutaneous dilatational tracheostomy (PDT) has become widely adopted in critical care units following Ciaglia's first description of the dilatational technique[40]. Since then multiple percutaneous techniques have been described, introduced and widely evaluated in comparison to both each other and surgical tracheostomy (ST). Whilst the short-term complications of these techniques are well described, the prevalence and impact of longer-term outcomes, particularly TS, is unclear. Previous meta-analyses have attempted to address this problem but have been confounded by the low incidence of TS and, in particular, the limited number of studies reporting long-term outcomes [51-55].

On examination of current evidence, the meta-analysis published by Delaney et al, found a significantly decreased rate of wound infection after all commonly performed percutaneous techniques compared to surgical tracheostomy[51]. Additionally, there were reductions in mortality and bleeding in patients undergoing percutaneous tracheostomy in the critical care unit as opposed to ST in the operating theatre. Higgins et al, also reported a tendency towards a reduction in overall complications for percutaneous procedures[53]. In contrast, Oliver et al, found an increased incidence of minor early complications associated with percutaneous techniques but insufficient evidence to suggest a difference in late complications of poor cosmetic results and tracheo-cutaneous fistulae[52]. Cabrini et al, found that the six percutaneous techniques analysed (Ciaglia multiple dilator method (CPDT), guide wire dilating forceps (GWDF), single tapered dilator (STD), trans-laryngeal tracheostomy (TLT), balloon dilator (BD), single step rotational dilator (SSRD)) were largely comparable with the exception of the TLT, which was associated with an increased conversion rate to ST or other percutaneous technique and more severe early complications[54]. They also

found the STD was associated with fewer complications and failures. In a later analysis the same authors reported less operative bleeding and fewer technical difficulties associated with the STD technique compared to the GWDF technique using a composite endpoint[55].

The meta-analyses described above have included only randomised controlled trials (RCTs). The only exception to this was the analysis by Oliver which also included non-randomised prospective studies[52]. The largest single study incorporated into the previous analyses comprised 346 patients[56]. It is perhaps unsurprising, therefore, that none of the previous meta-analyses have reported differences in late complication rates. The exact incidence of long term complications following tracheostomy procedures in the critically ill is difficult to quantify due to the associated mortality of critical illness, the sub-clinical nature of many tracheal stenoses and the difficulty maintaining follow up of these cohorts. From a number of prospective cohort series it would appear that sub-clinical TS is found in around 10% of survivors[79] with clinically evident lesions presenting in 0 - 0.35%[57-59].

Despite its low incidence, TS causes significant ongoing morbidity and healthcare costs associated with its management. The management of choice for TS has been segmental tracheal resection since Grillo[183] and Pearson[112] demonstrated good outcomes. However, in some patients stenoses may not be amenable to surgery. Management of such patients presents a challenge; alternative treatments include endoscopic dilatation, laser ablation, tracheal stenting and cryosurgery[107]. These interventions may temporarily alleviate the symptoms of TS but as re-stenosis is a frequent occurrence repeated procedures are often necessary. Given this associated morbidity and the cost associated with the management of TS a clearer picture of the risk associated with each tracheostomy technique performed within the critical care

setting is required.

There is little direct evidence for the association of any peri-operative complications with the aetiology of TS. In a study, pre-dating the widespread introduction of PDT, assessing the impact of prolonged tracheal intubation and tracheostomy Stauffer identified a high incidence of complications associated with ST (36% for stomal bleeding, 36% for stomal infection) and a 65 % tracheal stenosis incidence[74]. Despite a number of moderate sized case series from tertiary centres reporting of the management of tracheal stenosis none have specifically looked at the role of peri-operative events in the initiation of TS[71,75,88,184]. The only peri-operative event that has been postulated to have a role in the genesis of TS is tracheal ring fracture. Whilst a number of authors[184-186] have suggested that tracheal ring fracture may be of significance this is not necessarily borne out within large cohort studies[59]. Further studies have considered a role for infection in the initiation of TS. In an animal model of tracheal stenosis Squire inoculated the tracheas of rabbits with *Staphylococcus aureus*[66]. When compared to those without bacterial inoculation the incidence of tracheal stenosis was higher and the resultant lesions narrower. Additionally, Welkoborsky examined operative specimens removed from 18 patients undergoing surgical resection for TS and felt infection at the stenotic segment played a part in its initiation in 4 patients[69]. Despite this work and evidence to suggest a greater incidence of stomal infections for ST compared to PDT[51] there is no evidence to that the incidence of TS differs between the two techniques or that antimicrobial treatment reduces the incidence of TS.

Despite this lack of direct evidence for the association of peri-operative events with the development of TS we postulated that some complications maybe surrogate markers for a more severe tracheal injury at the time of tracheostomy and thus affect

the healing process. When considering such problems it is possible that many of the events listed in Appendix 1 may lead the operator to settle for sub-optimal tracheostomy tube positioning which may have an impact on later healing or predispose to infection. We, therefore, felt that the role such factors may play in the initiation of tracheal stenosis was worthy of further study.

Therefore, we performed a systematic review of all prospective studies that reported long-term outcomes and assessed potential predisposing factors. Our aim was to determine if longer-term complication rates, with particular reference to TS, differed between percutaneous and surgical tracheostomy techniques in the critical care setting.

3.2 Single tapered dilator percutaneous tracheostomy: An 11-year review

Despite the popularisation of the percutaneous dilatational approach by Ciaglia[40,41] and the proliferation of a number of similar techniques[42-44,47,187] the long term outcomes and survival following percutaneous tracheostomy remain unclear. A number of large cohort studies have described late complications and short term survival following PDT[57-59,188] but survival beyond 12 months has not been previously been reported.

Percutaneous dilatational tracheostomy has now largely replaced conventional surgical tracheostomy in critical care patients, with benefits in terms of cost, ease of performance, and reduced complications[51]. In 2000, the first description of a modification of the original CPDT technique described by Ciaglia[40] was reported using a single tapered dilator[44]. The STD method has now largely supplanted the sequential dilatational procedure and appears to be the single most common technique for performing a PDT in the critical care setting[45,46,189].

Several authors have published large PDT case series. Kearney, in perhaps the largest single centre evaluation to date, reported the outcome of an eight year review of the CPDT technique[188]. Diaz-Reganon reported an evaluation of both CPDT (51 patients) and GWDF (749 patients) in a single centre study[58] whilst Kost reported outcomes of both CPDT and STD techniques across multiple units in Montreal[57]. Here, we update our earlier single centre evaluation of the STD technique[59] reporting long term outcomes over an 11 year study period.

3.3 Tracheal stenosis following percutaneous tracheostomy: A MRI study

Whilst the incidence of TS following percutaneous tracheostomy is evident from a number of long term cohort studies[57-59] the issue of missed or sub-clinical stenoses has not been fully addressed. Non-specific symptoms are common following critical care admission and PDT, with frequent reports of voice changes, swallowing difficulties, cough and shortness of breath[181,182]. We hypothesised that, in this cohort of patients, there are a number of patients with undetected TS.

Earlier studies have attempted to identify the prevalence of TS following PDT using CT[181,190], MRI[80], plain linear tomography[191], spirometry with fibre-optic laryngoscopy[192], or fibre-optic laryngoscopy alone[193]. Norwood's study[181] using CT evaluation of tracheal anatomy after sequential dilatation PDT and correlation with symptoms found an incidence of TS of 31%, 20% of whom were symptomatic, but could not determine whether voice changes or respiratory problems were a result of critical illness or PDT itself. Spirometry has been variably described as straightforward but with unproven utility in detecting stenosis[194] and as unhelpful in detection of TS in patients after critical illness, with poor correlation between spirometry findings and endoscopic features[192]. The forced expiratory volume in 1 second (FEV_1) to peak expiratory flow rate (PEFR) ratio (FEV_1: PEFR) ratio was

demonstrated by Empey to be useful in distinguishing upper airway obstruction from lower airways disease but has not been widely adopted[195].

Despite the above attempts to delineate tracheal post-PDT changes there are limited data pertaining to STD PDT. Although Fikkers used MRI to evaluate long-term outcome only 14 STD patients were evaluated[80]. We therefore undertook a prospective study to radiographically evaluate tracheal changes following STD PDT in an attempt to better define the prevalence of sub-clinical TS.

3.4 Statement of Aims

Systematic review

- To identify aetiological factors in initiation of tracheal stenosis with particular reference to peri-operative events
- To determine the utility of adjunctive techniques (bronchoscopy & ultrasound scanning) in reducing complications of percutaneous tracheostomies percutaneous tracheostomy technique and hence determine the safest percutaneous technique
- To determine the incidence of common early and late complications and outcomes of PDT techniques in relation to surgical tracheostomy.
- To determine the role of early complications that may be postulated to play a part in the genesis of the late complications of tracheal stenosis, tracheo-innominate artery fistula and tracheo-oesophageal fistula
- To determine the relative indices of early and late complications in relation to percutaneous tracheostomy technique and hence determine the safest percutaneous technique

Cohort study

- To determine the role of early complications that may be postulated to play a part in the genesis of the late complications of tracheal stenosis, tracheo-innominate artery fistula and tracheo-oesophageal fistula
- To determine long term survival following percutaneous tracheostomy

MRI study

- To determine the prevalence of sub-clinical tracheal stenosis following percutaneous tracheostomy using the single tapered dilator technique.
- To determine possible aetiological factors for such sub-clinical stenoses namely tracheal ring fracture and duration of cannulation
- To determine whether sub-clinical tracheal stenosis may be presenting atypically in the post-critical care population
- To determine the utility of simple spirometry and a symptom based questionnaire in identifying sub-clinical tracheal stenosis

Chapter 4

Long-term outcome following tracheostomy in critical care: A systematic review

4.1 Search strategy

We searched Embase, PubMed-Medline and the Cochrane Central Register of Clinical Trials for prospective studies involving humans in the critical care setting that reported tracheostomy outcome data and included patients that had received at least one PDT either alone or in comparison with ST or another percutaneous technique. To reflect contemporary practice we limited the search to studies published from the year 2000 onwards. The search was restricted to full text reports of papers published in English in peer-reviewed journals. In addition, reference lists of those studies returned in the above search were scrutinised for additional relevant papers.

4.1.1 Study selection

Titles and abstracts of the references obtained were reviewed by three independent reviewers (G Dempsey, B Morton & C Hammell). Studies were categorised as - for inclusion, possible inclusion and exclusion. In the absence of a decision by two investigators to exclude a paper, data extraction of full text articles was undertaken by two of the three reviewers independently. Discrepancies between reviewers prompted a re-evaluation of the paper. Ongoing disagreement was resolved by the third reviewer. If the outcome data in the original article was unclear the corresponding author was contacted for clarification. Our protocol relating to study selection and data extraction is published on:

http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014008830

4.1.2 Data extraction and outcomes

A database was constructed to incorporate outcomes common to previous systematic reviews of percutaneous tracheostomy (additional parameters not presented in the main text of this chapter can be found in appendix 1). Outcomes were defined *a*

priori. The primary outcome was TS. Secondary outcomes were wound infection requiring treatment and bleeding (major and minor).

4.1.3 Internal validity and risk of bias assessment

The internal validity and risk of bias for RCTs was assessed using the Oxford Quality Scoring System (Jadad Score)[196]. The score is based on randomization (0-2 points), blinding (0-2 points), and withdrawals / dropouts (0-1 point). Studies scoring < 3 are considered to be of low quality[197]. Non-randomised cohort studies were assessed using the Newcastle-Ottawa score for cohort studies[198]. The scale assesses patient selection (0-4 stars), comparability of patient cohorts (0-2 stars) and outcomes (0-3 stars). Responses indicating high quality earn a star resulting in a maximum possible quality summary score of nine. Assessments were undertaken and confirmed by two independent reviewers. There is a lack of formal assessment tools for observational studies therefore no assessments were performed on the single arm observational studies.

4.1.4 Data analysis

For each complication, we calculated the risk difference (RD) and 95% confidence interval (CI) in each study that had compared two or more techniques. Studies that specifically reported that no events of a particular type had occurred were included in analyses as zero events. The RD was used as the measure of effect as the data were sparse in many studies and we wanted to ensure that studies with zero events in both arms contributed to meta-analyses. We used a random effects meta-analysis to pool the RD across multiple studies[199]. Analyses were performed in STATA version 9.2

(StataCorp, 2005 *Stata Statistical Software: Release 9*. College Station, TX: StataCorp LP).

As we were interested in estimating the complication risks associated with each technique we calculated the proportion of total patients with a complication and 95% CI in each study that provided data for a particular technique. Proportions were first transformed via the Freeman-Tukey double arcsine method[200] which were then pooled using random effects meta-analysis[199]. Analyses were performed in StatsDirect statistical software version 2.7.9 (StatsDirect Ltd, 2013 England).

We assessed statistical heterogeneity through visual inspection of the forest plot and interpretation of the I^2 statistic (percentage of variation across studies that is due to heterogeneity rather than chance)[201] and the Cochrane Q test. Where a sufficient number of studies were included in analyses, funnel plots were examined and Egger's test applied to assess potential bias in meta-analyses[202].

A sensitivity analysis was performed to compare results when restricted to RCTs only.

4.2 Results

4.2.1 Search results

Database search results yielded 463 studies that were subsequently assessed for eligibility (figure 4.1). One hundred and twenty four studies were subjected to full text review with 95 failing to meet inclusion criteria[47,48,56,181,184,185,190,203-290]. One study was excluded due to possible duplication of results and a lack of response to a clarifying e-mail query (figure 4.1)[216]. A total of 29 papers reporting on 5473 patients were included in the analysis (table 4.1).[57-59,80,187,188,291-313]

4.2.2 Study characteristics

Of the 29 studies included, nine (n=1023 patients) were RCTs that evaluated two or more percutaneous techniques.[80,187,292,295,297,298,303,305,310] Of the remaining 20 studies, one was a prospective cohort study comparing three techniques (ST, TLT and CPDT n=100 patients)[300] , two compared prospective PDT techniques with historical surgical control groups (n= 421; the retrospective ST patients were not included in our analysis)[294,309], three were prospective observational studies reviewing more than one technique (n=1513)[57,58,311] and 14 were single arm prospective studies (n=2416)[59,188,291,293,296,299,301,302,304,306-308,312,313]. Further details of study characteristics including risk of bias assessments can be seen in table 4.1. The mean Jadad score for RCTs was 2.4 and mean Newcastle Ottawa score for the cohort studies was 6.25.

In all studies evaluating the CPDT, the Ciaglia Percutaneous Tracheostomy Multiple Dilator set (Cook Critical Care, Bloomington, IN) was used. All studies assessing the GWDF technique used the Portex kit (SIMS Portex Ltd, Hythe, Kent, UK). For studies evaluating STD the Ciaglia Blue Rhino Percutaneous Tracheostomy Introducer set (Cook Critical Care, Bloomington, IN, USA) was used in six [57,59,187,293,295,309] and the Portex Ultraperc (Smith Medical, Hythe, Kent, UK) was used

Figure 4.1. Study selection flow chart

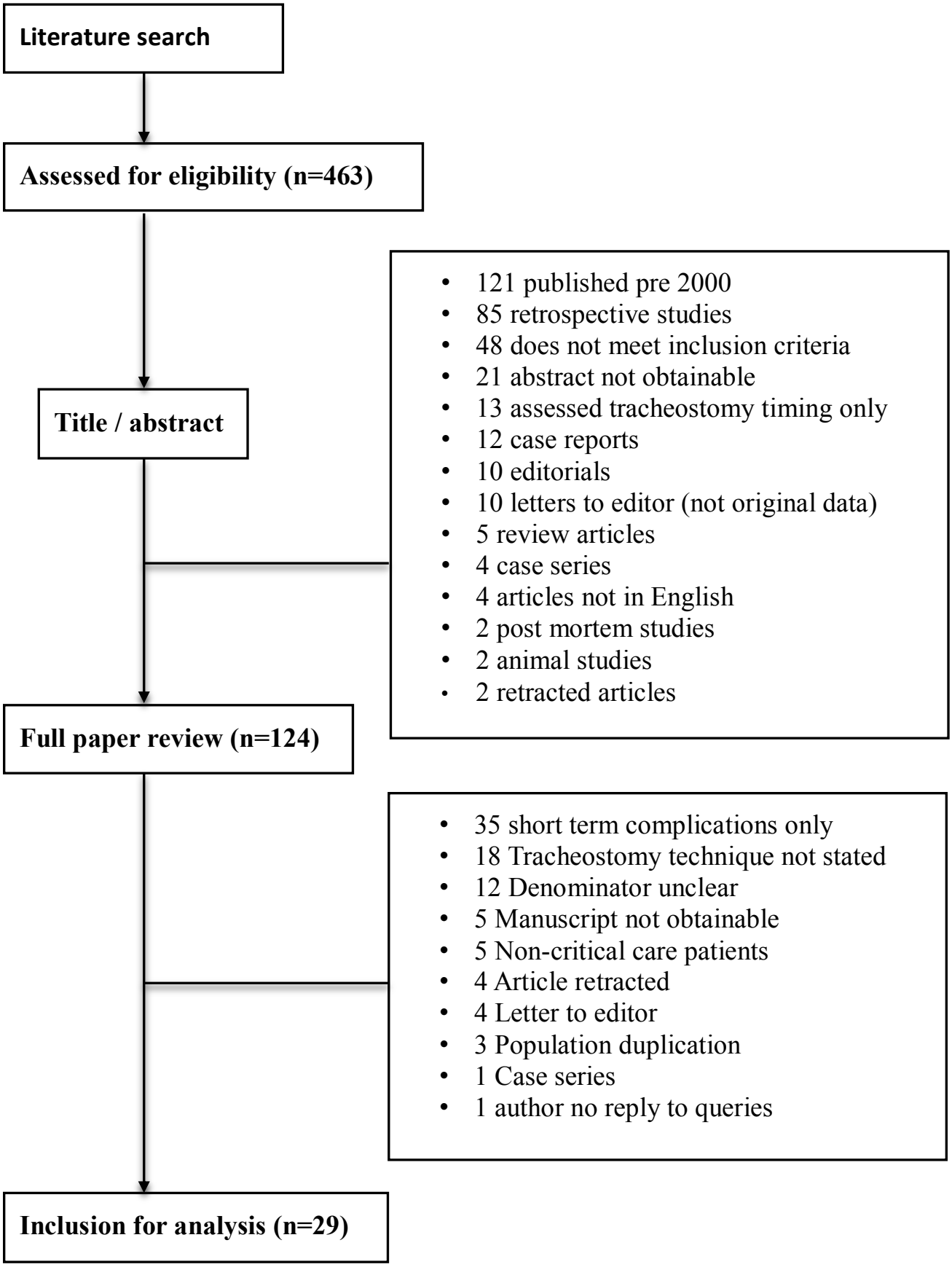


Table 4.1. Characteristics of studies included in analysis

First author (year)	Mean age	Males (%)	Study design	Techniques (patients)	Bronchoscopic control	Stated length of follow up	Risk of bias assessment[a]
Diaz-Reganon (2008)	62***	570 (71)	PO	CPDT (51), GWDF (749)	35/800 procedures	6 months	*6*
Kost (2005)	Not reported	280 (56)	PO	CPDT (191), STD (309)	Yes	3-4 months	*7*
Chen (2002)	44	14 (67)	PO	GWDF (21)	No	6 months	-
Yurtseven (2007)	61	83 (64)	RCT	CPDT (44), GWDF (41), SSRD (45)	Yes	6 months	3
Fikkers (2002)[1]	57	70 (70)	PO	STD (100)	Yes	12 months	-
Donaldson (2000)*	64	39 (72)	PO	CPDT (54)	Yes	3 months	-
Anon (2004)	63	38 (72)	RCT	STD (27), GWDF (26)	No	282 days****	2
Sviri (2003)	56	66 (62)	PO	GWDF (106)	No	30 months***	-
Lukas (2007)	65	125 (61)	RCT	GWDF (100), ST (105)	No	6 months	2
Kearney (2000)	56	519 (63)	PO	CPDT (824)	Selected cases	461 days****	-
Heikkinen (2000)	65	40 (71)	RCT	GWDF (30), ST (26)	No	18 months	2
Fikkers (2011)	62***	81 (68)	RCT	GWDF (60), STD (60)	Yes	3 months	3
Fikkers (2002)[2]	62***	99 (58)	PO	GWDF (171)	Yes	2.5 years***	-
MacCallum (2000)	63	65 (65)	PNR	ST (50), TLT (37), CPDT (13)	Only TLT group	6 months	*6*
Cianchi (2010)	61***	52 (74)	RCT	STD (35), BD (35)	Yes	LTOR	2
Dempsey (2010)	58	340 (59)	PO	STD (576)	Yes	3 months	-
Ben Nun (2005)	62	90 (58)	PO	GWDF (154)	No	6 months	-
Velmahos (2000)	42	72 (72)	PO	CPDT (100)	First 14 cases	10 months****	-
Silvester (2006)	64***	137 (69)	RCT	CPDT (100), ST (100)	80% CPDT	20 months***	3
Mittendorf (2002)	54	45 (63)	PO	CPDT (71)	No	3 months	-
Melloni (2002)	57	31 (62)	RCT	ST (25), CPDT (25)	100% CPDT	6 months	2
Gatti (2004)	71	18 (55)	PO	CPDT (33)	No	3 months	-
Escarment (2000)	52	117 (72)	PO	GWDF (162)	13% (selected cases)	3 months	-
Dollner (2002)	65	21 (55)	PO	GWDF (162)	Yes	22 months****	-
Beltrame (2008)**	65	26 (72)	PO	STD (367)	Yes	10 months****	-
Antonelli M (2005)	64	83 (60)	RCT	TLT (67), ST (72)	No	1 year	3
Polderman (2003)	54	N/A	PO	GWDF (173), ST (40)	GWDF 77%	14 months****	*6*
Stochetti (2000)	47	14 (70)	PO	TLT (20)	Yes	3 months	-
Joshi (2006)	35	18 (45)	PO	CPDT (40)	No	LTOR	-

*Also reviewed 29 ST patients retrospectively – not included in analysis

** Also reviewed 161 ST patients retrospectively – not included in analysis

[***] Reported as median

[****]Reported as mean

[1]Fikkers BG et al *Anaesthesia* 2002;**57**(11):1094-7

[2]Fikkers BG et al *Head Neck* 2002;**24**(7):625-31

[a] Risk of bias assessments – RCT - Jadad score (0-5)

The score is based on randomisation, blinding, and withdrawals / dropouts. Studies scoring < 3 are considered to be of low quality.[197.] See text for details.

Observational studies - Newcastle Ottawa Scale (0-9)

The scale assesses patient selection, comparability of patient cohorts and outcomes. Responses indicating high quality earn a star with a maximum possible score of 9. See text for details.

Single arm studies – no assessment

Note: Scores for RCTs & observational studies are not directly comparable

PO	Prospective Observational
RCT	Randomised Controlled Trial
PNR	Prospective Non-Randomised
CPDT	Ciaglia multiple dilator method
STD	Single tapered dilator
GWDF	Guide wire dilating forceps
TLT	Trans-laryngeal tracheostomy
BD	Balloon Dilator
SSRD	Single step rotational dilator
ST	Surgical tracheostomy
LTOR	Length of follow up not stated but long term outcomes reported

in one[80]. For the TLT technique two studies did not specify the equipment used[300,310] and in the third the Mallinckrodt kit (Mallinckrodt Medical, Mirandola, Italy) was used[312]. The study evaluating the BD technique[187] used the Ciaglia Blue Dolphin Percutaneous Tracheotomy Introducer Kit (Cook Critical Care Inc., Bloomington, IN, USA) whilst the PercuTwist® Set (Rüsch GmbH, Kennen, Germany) was used for the SSRD study[292]. For surgical tracheostomy two studies used a modified Bjork flap technique[297,298], one used a midline vertical incision[303], one used an H shaped incision[305] whilst in three others the technique used was not described[300,310,311].

Three studies were conducted in multiple centres[57,295,300], four were undertaken within multiple units within the same hospital[294,302,305,309] and 22 were conducted within a single critical care unit (CCU)[58,59,80,187,188,291-293,296-299,301,303,304,306-308,310-313]. Of the 26 studies conducted within a single institution 23 were in a university / teaching centre[58,59,80,187,188,291-294,296,297,299,301-305,307,308,310-313]. There were two studies respectively reporting findings from neuro[291,312] and cardiac surgical[306,308] populations, the remaining studies were of mixed populations. In 12 studies the primary operators were CCU physicians / anaesthetists[59,80,187,292,295,296,303,305,307,309,310,313], in six studies they were surgically trained[57,291,294,298,302,304], in a further nine studies there was a mixture of both surgical and CCU personnel[58,188,297,299-301,306,308,311] and two studies failed to specify the background of the operator[293,312].

4.3 Data analysis

4.3.1 Comparative analyses

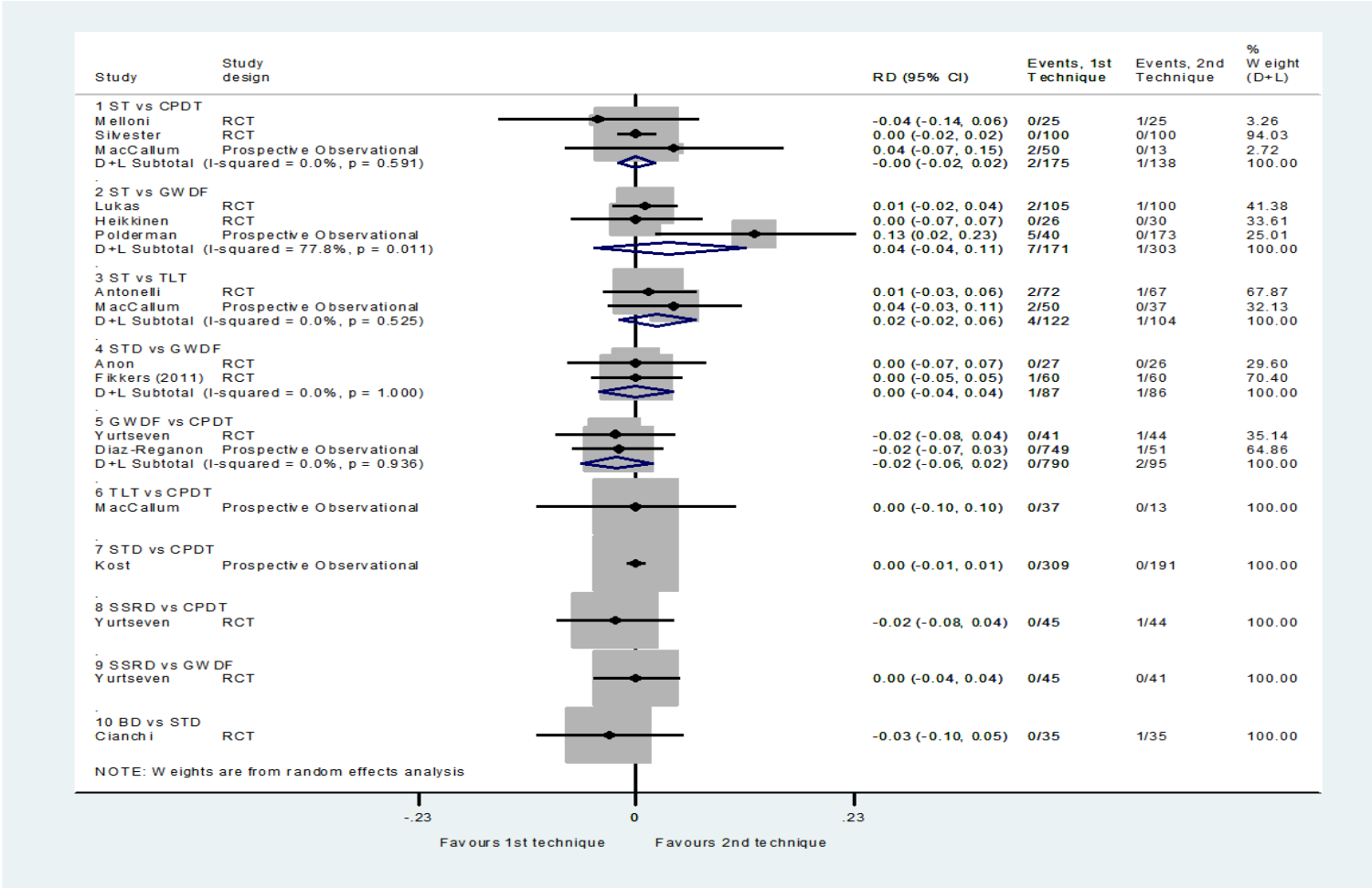
Figures 4.2 - 4.5 summarise meta-analyses of studies that provide comparative data (RCT and prospective cohort data) between individual techniques for the

complications of TS, total bleeding episodes, major bleeding and wound infections respectively. Overall there are few studies, all with small sample sizes, that provide data comparing the different techniques, particularly in relation to those described more recently (STD, SSRD, BD). We did not identify direct comparisons between STD, BD or SSRD versus ST. A statistically significant risk difference was not identified for any of the meta-analyses, apart from the comparison between ST and CPDT in relation to wound infection (figure 4.5), with a pooled RD (95% CI) of 0.12 (0.02, 0.23) in favour of CPDT. There was evidence of heterogeneity for several comparisons that could not be explored in detail due to the limited number of studies. However, heterogeneity was accounted for by using a random-effects meta-analysis. A sensitivity analysis restricting meta-analyses to only RCTs suggested that results and conclusions were similar although for the bleeding complication results were statistically significant for two comparisons when restricted to RCTs only [ST vs GWDF: -0.06 (-0.25 to 0.12) RCTs and prospective observational studies, (-0.15 (-0.23 to -0.08) RCTs only); and ST vs TLT 0.05 (-0.02 to 0.11) RCTs and prospective observational studies, (0.08 (0 to 0.16) RCTs only].

4.3.2 Single-arm studies

To supplement the comparative analyses, a crude overall summary of incidence of TS, bleeding episodes (total and major) and wound infection, pooled across all studies (single-arm studies and the relevant arm data from comparative studies) according to the random effects proportion meta-analysis, is given in Tables 4.2 - 4.5. There is a high degree of heterogeneity (measured by the I^2 statistic) between studies suggesting that the complication risk could vary according to setting or patient. Direct comparisons between the complication incidences for different techniques should not be made based on these pooled estimates due to their observational nature.

Figure 4.2. *Forest plot comparing risk of tracheal stenosis for different percutaneous tracheostomy and surgical tracheostomy techniques.*



Forest plot detailing comparisons between surgical and percutaneous tracheostomies techniques for the development of post-operative tracheal stenosis. There are no significant differences between any of the techniques compared.

Key:

ST: Surgical tracheostomy

CPDT: Ciaglia percutaneous dilatational tracheostomy

GWDF: Guide wire dilating forceps

TLT: Trans-laryngeal tracheostomy

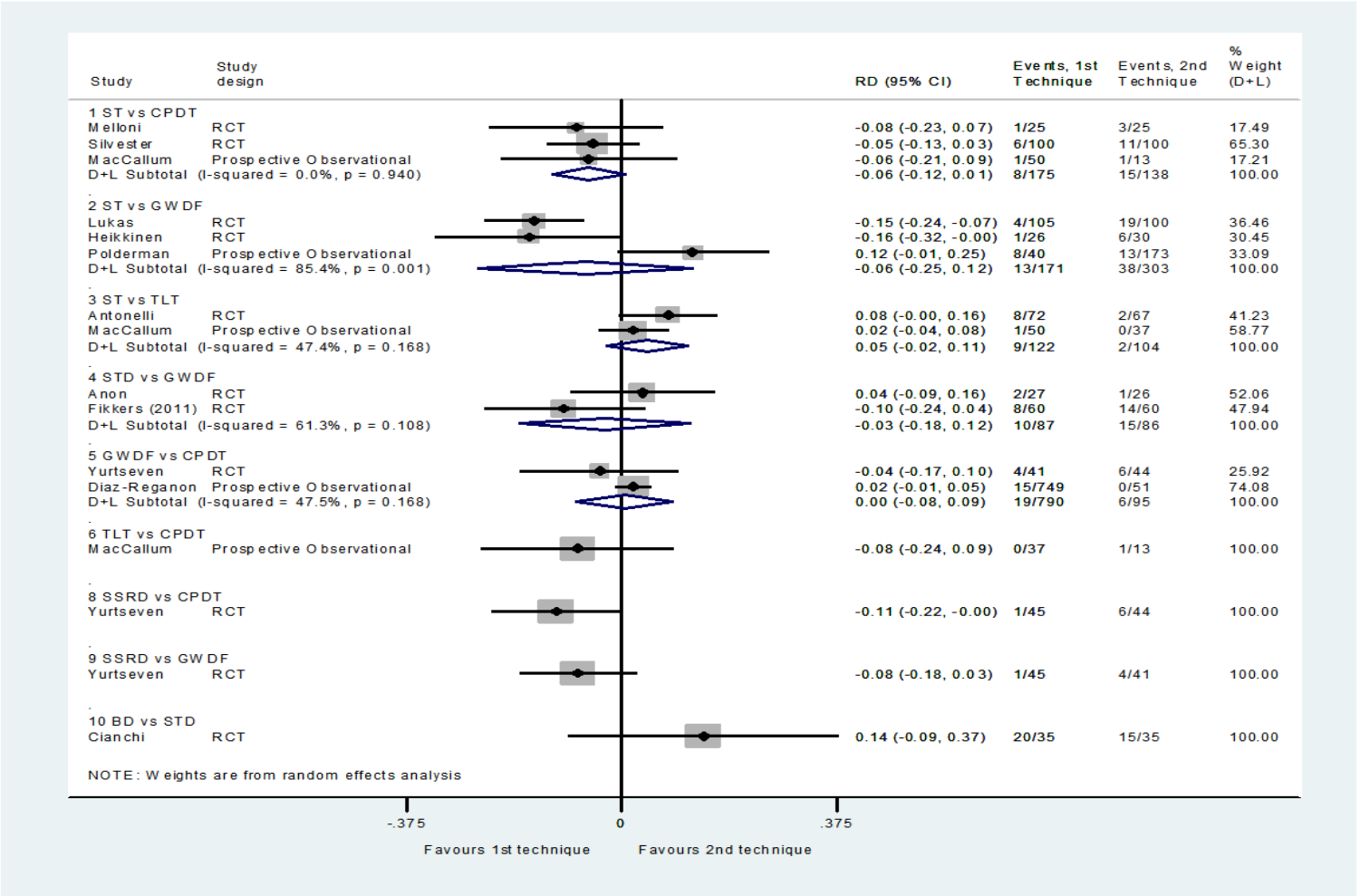
STD: Single tapered dilator

SSRD: Single step rotational dilator

BD: Balloon dilator

RCT: Randomised controlled trial

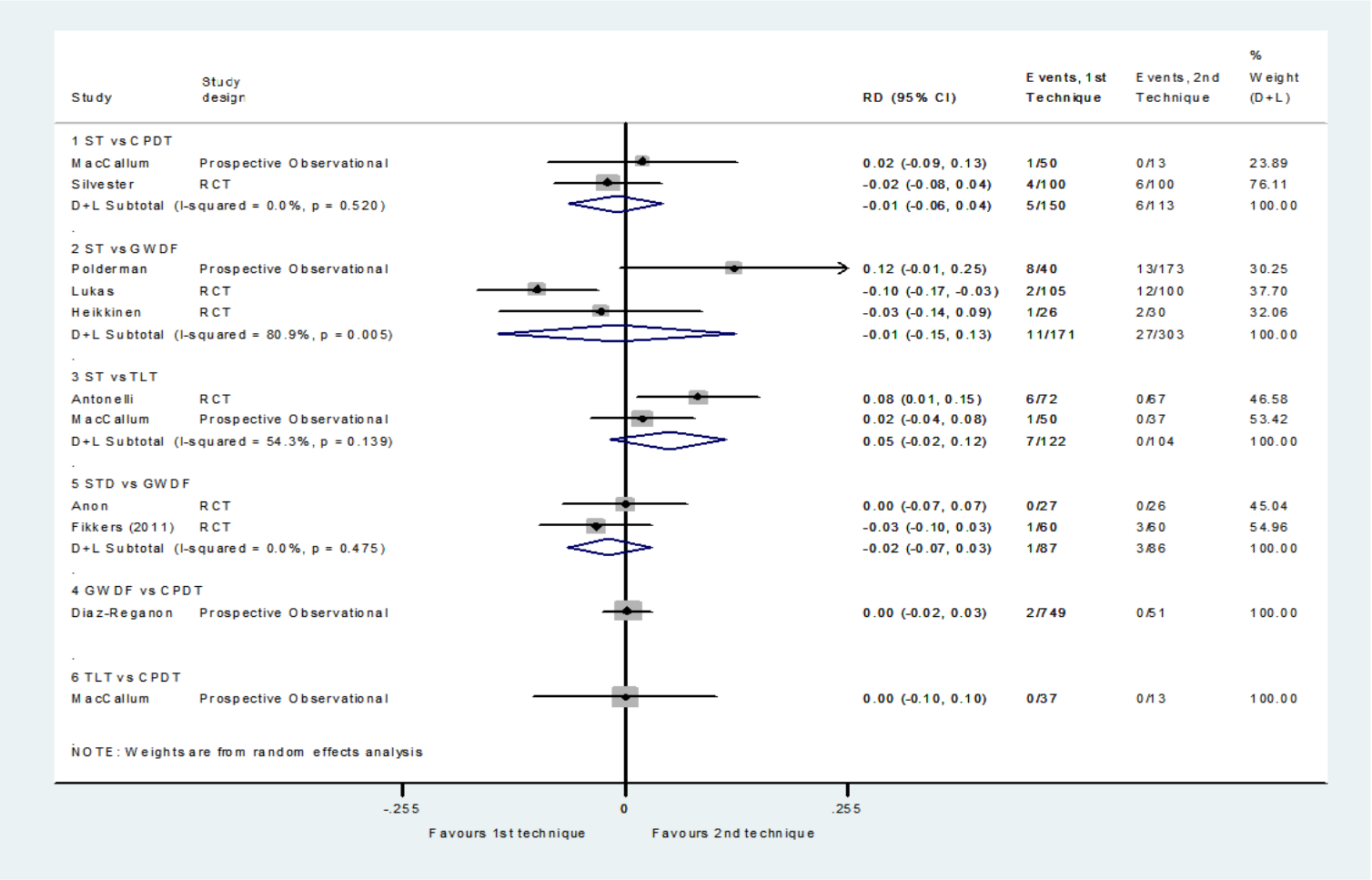
Figure 4.3. *Forest plot comparing risk of all bleeding (major and minor) episodes reported for different percutaneous tracheostomy and surgical tracheostomy techniques.*



Forest plot detailing comparisons between surgical and percutaneous tracheostomy techniques for total bleeding episodes. There are no significant differences between any of the techniques compared. When observational studies are excluded and RCTs considered in isolation the comparison for ST versus TLT become significant (favouring TLT) as does the comparison between ST and GWDF (favouring ST) although the numbers of studies and patients for each comparison are small (see page 101).

Key: as per figure 4.2

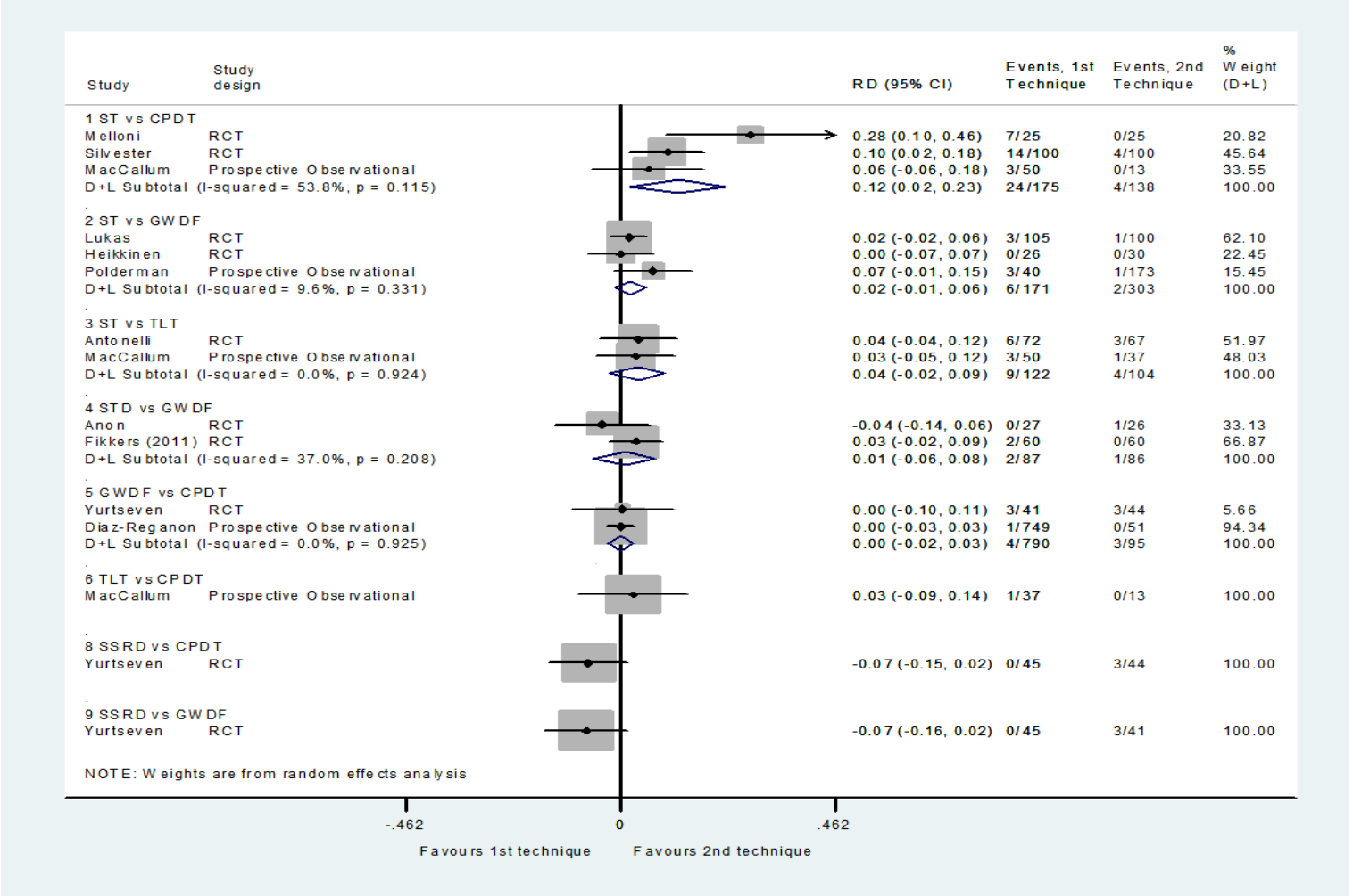
Figure 4.4. *Forest plot comparing risk of major bleeding (requiring blood transfusion or surgical intervention) episodes reported for different percutaneous tracheostomy and surgical tracheostomy techniques.*



Forest plot detailing comparisons between surgical and percutaneous tracheostomy techniques for major bleeding episodes. There are no significant differences between any of the techniques compared.

Key: as per figure 4.2

Figure 4.5. *Forest plot comparing risk of wound infection for different percutaneous and surgical tracheostomy techniques.*



Forest plot detailing comparisons between surgical and percutaneous tracheostomy techniques for post-operative stomal infections. There is a significant difference between surgical tracheostomy and the Ciaglia Percutaneous dilatational tracheostomy (favouring the percutaneous technique). Further comparisons failed to reveal additional significant differences.

Key: as per figure 4.2

Table 4.2. *Tracheal stenosis according to tracheostomy technique: Random effects proportion meta-analysis*

Tracheostomy technique	**Number of studies (patients included)**	**Number of stenoses**	**Pooled estimate (%) and 95% CI***	**I^2 % (95% CI)**
Surgical tracheostomy (ST)	7 (418)	11	2.8 (0.8 - 5.9)	57.9 (0 - 79.9)
Guide Wire Dilating Forceps (GWDF)	13 (1831)	10	0.9 (0.3 – 1.7)	50.3 (0 – 72)
Ciaglia technique (CPDT)	12 (1546)	15	1.0 (0.4 – 1.9)	33.7 (0 – 66)
Single Tapered Dilator (STD)	7 (1474)	7	0.6 (0.2 – 1.2)	22.6 (0 – 67)
Trans-laryngeal tracheostomy (TLT)	3 (124)	1	1.5 (0.1 – 4.3)	0 (0 – 73)
Single step rotational dilator (SSRD)	1 (45)	0	-	-
Balloon dilator (BD)	1 (35)	0	-	-

*Calculated from random effects model

CI: Confidence intervals

Table 4.3. *Total bleeding episodes according to tracheostomy technique: Random effects proportion meta-analysis*

Tracheostomy technique	Number of studies (patients included)	Total number of bleeding episodes	Pooled estimate (%) and 95% CI*	I^2 % (95% CI)
Surgical tracheostomy (ST)	7 (418)	29	7.3 (4 to 11.4)	52.1 (0 - 78)
Guide Wire Dilating Forceps (GWDF)	11 (1687)	100	9.2 (5 to 14.4)	88.8 (82 - 92)
Ciaglia technique (CPDT)	11 (1355)	64	6.6 (4 to 9.7)	62.9 (12 - 79)
Single Tapered Dilator (STD)	6 (1165)	80	12.1 (3.3 to 25.3)	96.3 (95 - 97)
Trans-laryngeal tracheostomy (TLT)	3 (124)	2	2 (0.3 to 5.3)	0 (0- 73)
Single step rotational dilator (SSRD)	1 (45)	1	-	NA
Balloon dilator (BD)	1 (35)	20	-	NA

** Calculated from random effects model*

Studies not reporting bleeding:

GWDF – (Dollner, Sviri)

Bleeding events not attributable to technique:

Kost (CPDT & STD)

CI: Confidence Interval

NA: Not Applicable (only one study)

Table 4.4 *Major bleeding episodes (need for surgical cautery or blood transfusion) according to tracheostomy technique: Random effects proportion meta-analysis*

Tracheostomy technique	**Number of studies (patients included)**	**Major bleeding episodes**	**Pooled estimate (%) and 95% CI (%)***	**I^2 % (95% CI)**
Surgical tracheostomy (ST)	7 (418)	17	4.7 (2.8 – 7.1)	7 (0 – 64)
Guide Wire Dilating Forceps (GWDF)	11 (1687)	36	3.4 (1.4 – 6.3)	82 (66 - 89)
Ciaglia technique (CPDT)	11 (1355)	18	1.8 (0.7 – 3.5)	55.7 (0 - 78)
Single Tapered Dilator (STD)	6 (1165)	10	1.1 (0.2 – 2.7)	65.1 (0 - 85)
Trans-laryngeal tracheostomy (TLT)	3 (124)	0	0.6 (0.01 – 2.6)	0 (0 – 73)-
Single step rotational dilator** (SSRD)	1 (45)	0	-	-
Balloon dilator** (BD)	1 (35)	0	-	-

* *Calculated from random effects model*

CI: Confidence Interval

Table 4.5. *Wound infection according to tracheostomy technique: Random effects proportion meta-analysis*

Tracheostomy technique	**Number of studies (patients included)**	**Number of tracheostomy wound infections**	**Pooled estimate (%) and 95% CI***	**I^2 % (95% CI)**
Surgical tracheostomy (ST)	7 (418)	36	8.5 (4.1 – 14.4)	71.5 (18 – 85)
Guide Wire Dilating Forceps (GWDF)	10 (1666)	16	1.5 (0.6 – 2.8)	61.5 (1.6 – 79)
Ciaglia technique (CPDT)	11 (1355)	11	1.0 (0.36 – 2.1)	32.5 (0 – 66)
Single Tapered Dilator (STD)	4 (554)	6	1.7 (0.02 – 5.9)	80.1 (17.4 – 90.6)
Trans-laryngeal tracheostomy (TLT)	3 (124)	4	3.9 (1.26 – 8)	0 (0 – 73)
Single step rotational dilator** (SSRD)	1 (45)	0		
Balloon dilator** (BD)	1 (35)	0		

** Calculated from random effects model*

CI: Confidence Interval

Studies not reporting infection:

Guide wire dilating forceps (GWDF) – 3 (Sviri, Chen & Dollner)

Single tapered dilator (STD) – 2 (Cianchi, Dempsey)

Infection episodes not attributable to technique:

Kost (Ciaglia multiple dilator method & single tapered dilator)

4.4 Discussion

We have investigated the incidence of long-term TS in patients undergoing tracheostomy in a critical care setting. Additionally, we have estimated the incidence of peri-procedural complications (bleeding and wound infection) that we have postulated may have a role in the development of TS. When considering published RCTs and comparative observational studies reporting long-term outcomes we have found ST and all percutaneous techniques (CPDT, GWDF, STD, TLT, SSRD, BD) broadly similar in terms of TS and bleeding. In keeping with earlier meta-analyses we have also found a higher incidence of wound infection when comparing ST to CPDT[51]. Despite the frequency with which percutaneous tracheostomies are performed within the critical care setting there appear to be relatively few high quality studies assessing long term outcomes between techniques.

When considering our pooled proportions meta-analysis across all studies, the TS rate reported varies from 2.8 to 0.6% for ST and STD respectively with all percutaneous techniques being broadly comparable (table 4.2). The point estimate of rate for total bleeding episodes varies from 12.1% for STD to 2% for TLT (table 4.3) but the confidence intervals around some of these estimates are wide with a substantial degree of between study heterogeneity. Major bleeding ranges from 4.7% for ST to 0.6% for TLT, whilst wound infection for ST is 9.9% and 1.1% for CPDT, again with wide 95% CIs and substantial between study heterogeneity.

By incorporating cohort studies as well as RCTs into our analysis we have adopted a different methodology to earlier meta-analyses. The majority of studies incorporated into previous analyses were RCTs of relatively small samples sizes and as such, given the low incidence, were limited in their ability to detect a difference in risk of TS. Whilst the incorporation of non-randomised studies may introduce an element of bias,

work by Golder et al has suggested this effect may be minimal[314]. In a meta-analysis of meta-analyses they found a high degree of concordance between meta-analyses of adverse events comparing data solely from RCTs with those from both RCTs and observational studies (with less discrepancy for larger studies) concluding that meta-analyses of adverse events should not, necessarily, be confined to specific study types. In a sensitivity analysis, we excluded the non-randomised studies and compared meta-analysis results to those that include both RCT and prospective observational studies. Overall, results were similar but changed from being non- significant to statistically significant for bleeding complication for two comparisons, suggesting that there may be important differences between RCTs and observational studies (see below).

Another potential limitation to accurate determination of the incidence of TS, following percutaneous tracheostomy, in the current study is the possibility that patients who are perceived to be predisposed to a difficult tracheostomy may be assigned to the ST group in non-randomised studies. In support of this concern, of the seven studies assessing ST, five were RCTs [297,298,303,305,310] reporting a TS incidence of 1.4% (4/328) and two were prospective non-randomised studies with a TS incidence of 8.4% (7/90)[300,311]. In addition, the risk difference estimates for TS from the prospective non-randomised studies were each more extreme than corresponding estimates from RCTs in those comparisons between ST and percutaneous tracheostomy. Of the non-randomised studies, the study by MacCallum (reporting 2 stenoses) provides no information on group allocation other than stating that procedures were performed consecutively[300]. In contrast, Polderman (5 stenoses) reports that 7 patients were allocated to the ST group because of perceived difficult anatomy whilst the remainder of patients were allocated randomly.[311] No information as to whether those patients with difficult anatomy were also the patients who

developed TS was provided. The choice between surgical and percutaneous tracheostomy in most situations is not a random event with most operators opting for the surgical approach when potential difficulties or safety concerns are anticipated. It is probable, therefore, that many of the surgical tracheostomies described within the studies herein would be more prone to the occurrence of complications. It is possible, therefore, that the observed differences in complication rates we have demonstrated in our analyses could be due to patient factors rather than the operative technique per se. However, as discussed above, other than a potential role for tracheal ring fracture there is little evidence for peri-operative complications causing TS.

Accepting these potential limitations, in the critical care setting, there is a trend toward increased risk of TS for surgical tracheostomy patients.

Our data confirm our view that in the critical care setting, in common with previous authors, a percutaneous procedure should be the technique of choice as it is both safe and cost effective[51].

It is somewhat surprising (and a common theme across all previous meta-analyses), given the frequency with which PDTs are now undertaken, that we have only identified 29 studies reporting upon the long term outcomes of 5473 patients over the preceding 14 years. We find it concerning that some techniques in relatively widespread use (SSRD, BD, TLT) have such sparse long-term outcome data. When specifically considering the issue of TS and the possibility of unrecognised sub-clinical TS in this patient population, very few studies have undertaken comprehensive radiological imaging to determine the underlying prevalence of stenosis. Considering that the STD technique appears to be currently the most widely used approach,[45,46,189] until recently there were only 14 patients described in the

literature who had undergone radiological imaging after STD tracheostomy to determine the underlying prevalence of both clinical and sub-clinical TS[80].

Reporting of complications across studies remains far from standardised and posed significant problems during data extraction. We had initially set out to collect data for a significant number of secondary outcomes (appendix 1). However, lack of uniform reporting made this aim much more difficult and ultimately of little value as many complications are reported infrequently with marked differences in incidences across studies. Even reporting of our primary and secondary outcomes was inconsistent, with some studies failing to quote an incidence for TS, bleeding and wound infection. One study appeared to describe an apparent incidence of TS (presence of stridor with spirometry findings in keeping with upper airway obstruction) but failed to ascribe these findings to a diagnosis of TS.[296] A lack of a consistent definition for significant versus minor bleeding lead us to analyse total bleeding episodes as well as those categorised as major. Additionally, one study reported stomal decay as an outcome, interpreted as infection for our analysis.[297] Additionally, we were unable to explore the possible relationships between bleeding and stomal infection and TS. Whilst most of the studies included in the analysis reported TS, bleeding and stomal infection rates there was little, if any, supplemental data reported for us to ascertain whether these events were associated and occurring within the same patients or not. A number of other studies that detailed complications of multiple techniques reported composite outcomes where the complication rate for a given technique was impossible to ascertain. In this circumstance we wrote to the author for clarification. In some instances this resolved the problem either completely or partially. In others, where there was no reply from the corresponding author the study was excluded from the

analysis. These limitations highlight the vital need to develop and report standardised core outcome measures to improve the synthesis of trial data.[315]

Whilst RCTs to compare long term outcomes, particularly TS, following individual PDT techniques would be desirable it is highly unlikely that they will be performed. TS has a low incidence, critical illness mortality is high and long term follow up difficult. An adequately powered study would require at least 2000 patients to detect a reduction in TS from 2.8% to 1% ($\alpha = 0.05$ $\beta = 0.8$) and this figure excludes drop out. Thus we believe our study, despite the limitations described, is currently best placed to inform clinicians in this area.

Chapter 5

Single tapered dilator percutaneous tracheostomy in the critical care unit: An eleven-year single centre review

5.1 Methods

This prospective service evaluation was carried out at Aintree University Hospital NHS Foundation Trust (AUH). The critical care unit (CCU) at AUH is a 23-bedded mixed medical and surgical unit undertaking between 80 - 100 PDTs per year. The regional referral centre for head and neck cancer, the largest such unit in the UK, is also situated at AUH. The need for PDT in any individual case was determined by the duty consultant intensivist. After the decision to proceed with a tracheostomy, all patients were fully evaluated and examined before operation. In all cases, when a tracheostomy is deemed appropriate, patients are assessed as to their suitability for a PDT. Patients undergoing ST as part of their surgical management for head and neck cancer were not included in the study.

From November 2003 to February 2015, data were prospectively collected on all PDTs performed at AUH. All PDTs were performed by critical care physicians at the bedside using the Blue Rhino® Percutaneous Tracheotomy Introducer Kit (Cook Critical Care, Bloomington, IN). All patients were over the age of 16 and each received intravenous general anaesthesia with neuromuscular block. Each procedure was undertaken with bronchoscopic guidance to ensure correct placement of the guide-wire.

Before commencement of the procedure, the patient was positioned with the head extended and the lungs were ventilated with 100% oxygen. Throughout the procedure, heart rate, arterial pressure, and oxygen saturation were monitored continuously. After digital palpation of the neck, direct laryngoscopy was performed to position the tracheal tube (TT) above the site of the proposed PDT insertion point. Local anaesthesia and vasoconstriction were achieved using 2% lidocaine with 1:100,000

epinephrine administered subcutaneously to the pre-tracheal tissues. A 1 cm horizontal skin incision was made midway between the cricoid cartilage and the sternal notch. Pre-tracheal tissues were separated by blunt dissection. Tracheal puncture was performed with the standard 15-gauge needle. After bronchoscopic confirmation of the position, the guide-wire was passed into the tracheal lumen. A 4.5 cm 14 Fr gauge dilator was passed over the guide-wire after which the STD was used to expand the tract between the skin and the tracheal lumen. The appropriate-sized tracheostomy tube was introduced into the tracheal lumen utilising a loading dilator.

Perioperative data on each patient were recorded prospectively and included age, sex, reason for admission, admission APACHE II score, and intraoperative and postoperative complications as detailed below.

A PDT was assigned as 'technically difficult' or complicated as described previously[59,316]. Routine post-procedural chest X-rays (CXRs) were performed after the first 384 PDTs. Thereafter, CXRs were limited to those PDTs considered technically difficult.

After critical care discharge, further surveillance was provided by the AUH Critical Care Outreach Service and after hospital discharge by the critical care follow-up clinic allowing identification of late complications. Long-term survival data was cross-referenced with the AUH clinical records system (System C Medway Sigma, Maidstone, UK).

5.2 Results

During the study period, 1056 CCU patients required a tracheostomy. In 1025 patients, a PDT was attempted, and in 1019 (99%), the procedure was completed successfully at the first attempt (Table 5.1). Two further patients underwent successful PDT at the second attempt. In four patients (0.4%), PDT was abandoned due to excess bleeding; three of these patients subsequently went on to have an ST. Consequently, a total of 31 (3% (n=1056) patients underwent ST. In the remaining patient, the procedure was abandoned and ST considered inappropriate due to worsening multiple organ failure. All PDTs were undertaken between the hours of 09:00 and 17:00 and 929 (91%) were performed on a weekday (figure 5.1). Number of PDTs performed by year is presented in figure 5.2. Nine hundred and fifty one (93%) procedures followed an emergency critical care admission. In 813 (79%) cases, the most senior clinician present was a consultant. For the remainder, in 190 (19%) and 22 (2%) cases, the most senior clinician present was a senior critical care trainee (clinical fellow) and a specialist anaesthetic registrar, respectively.

Figure 5.1 Tracheostomy insertion by day of the week

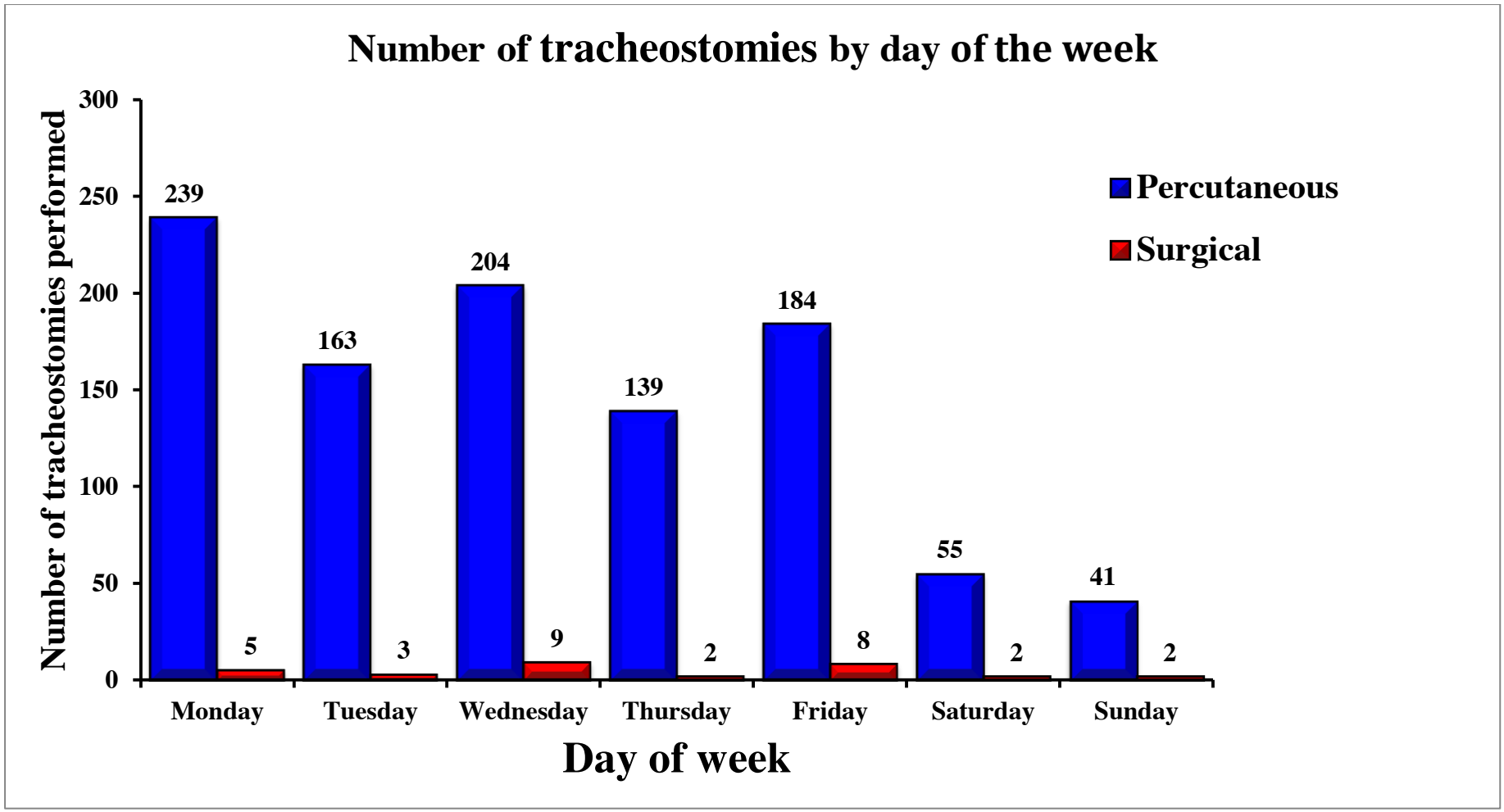
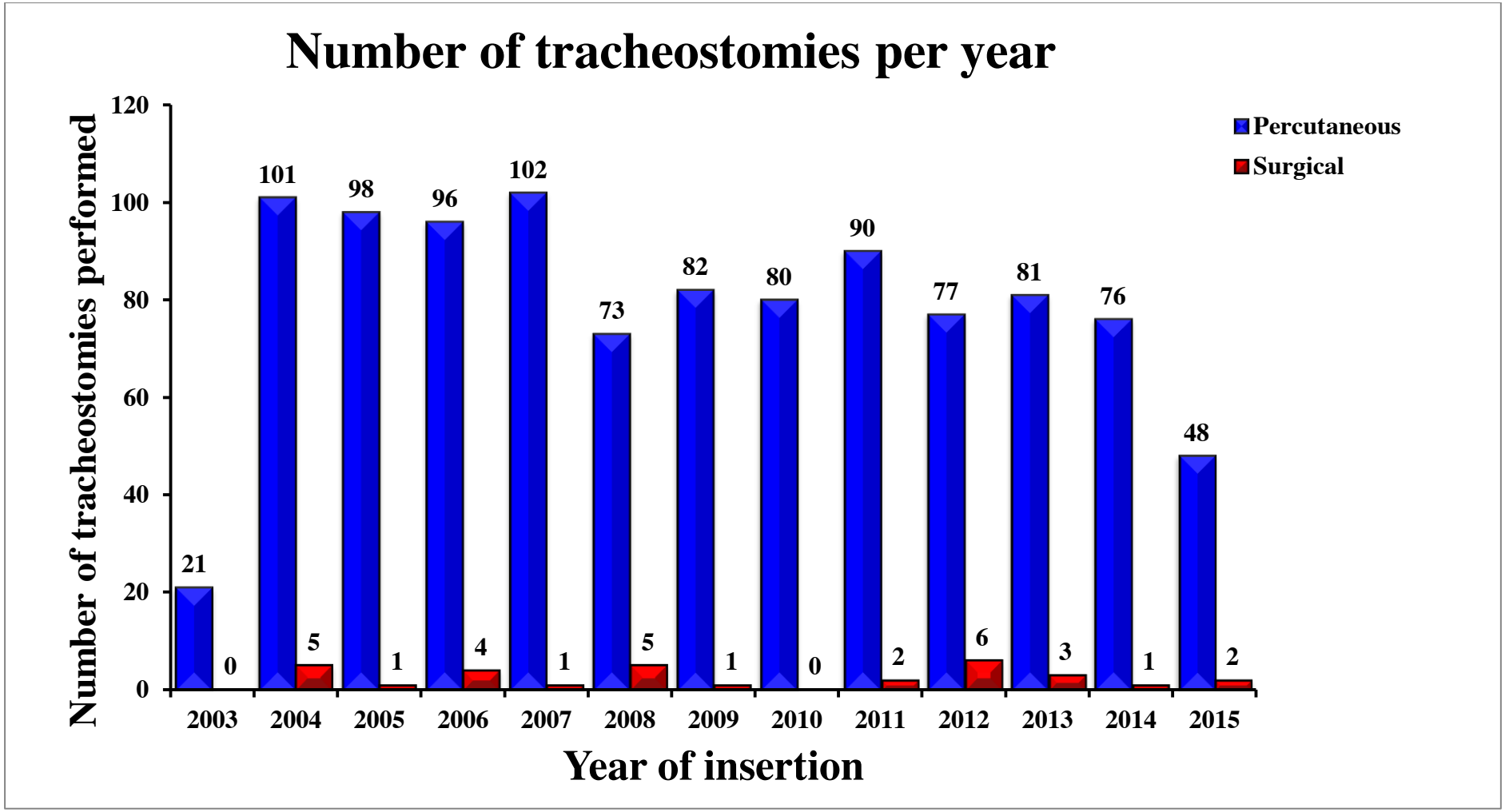


Table 5.1 Patient characteristics for those undergoing tracheostomy. ***PDT:*** *Percutaneous dilatational tracheostomy,* ***CCU:*** *Critical care unit,* ***IQR:*** *Inter quartile range,* ***sd:*** *Standard deviation*

	Type of tracheostomy	
	Percutaneous n= 1025	**Surgical n= 31**
Age in years (sd)	59 (15.8)	55 (21.2)
Male (%)	608 (59%)	17 (55%)
Mean admission APACHE II Score	18.7 (5.7)	18.4 (5.4)
Number of emergency admissions (%)	951 (93%)	28 (90%)
Median day to PDT from CCU admission (IQR)	5 (4, 7)	5 (2,9)
Median day to PDT from tracheal intubation (IQR)	4 (3, 6)	4 (2, 8)
Number of medical patients (%)	540 (53%)	12 (39%)
Number surviving to CCU discharge (%)	757 (74)	25 (81%)
Median length of CCU stay in days for non-survivors (IQR)	15 (10, 23)	11 (5,18)
Median length of CCU stay in days for survivors (IQR)	19 (14, 27)	16 (10, 29)
Number surviving to hospital discharge (%)	687 (67%)	23 (74%)
Median hospital stay in days for CCU survivors (IQR)	34 (7, 400)	34 (19, 68)
Number surviving beyond 1 year (%)	555 (54)	18 (58%)

Figure 5.2 Number of tracheostomies performed by year



Thirty-one surgical tracheostomies were performed during the study period (table 5.1). Three followed failed percutaneous procedures detailed above, four were performed in post-operative oesophagectomy patients, seven in patients who had sustained trauma to the neck including spinal injuries, eight patients had head and neck infections or tumours and the remaining nine patients had perceived difficult anatomy. All STs were completed uneventfully. The most senior operating surgeon was a consultant in 18 (58%) procedures and a specialist registrar in 13 (42%).

According to the definitions described above, technical difficulties were encountered in 230 (22%) procedures (Table 5.2). The overall complication rate was 3.5% (36/1025). Twenty-six (2.5%) procedures were deemed as having early complications. These included ten cases of significant bleeding (including four where the PDT was abandoned), four cases resulting in para-tracheal placement of the tracheostomy tube, four with significant surgical emphysema, three pneumothoraces (one tension), two with significant posterior tracheal wall injury (one of whom also had significant surgical emphysema), and two cases where the tracheostomy tube was malpositioned. In two instances tracheal ring fracture resulted in the fractured ring directly abutting the posterior tracheal wall. In both cases the tracheal ring was resected endoscopically. Eleven cases (1%) were associated with significant late complications. Of these, two patients developed tracheal granulation tissue delaying decannulation. In both cases this was excised endoscopically with no further problem. Four patients (0.4%) developed a tracheo-innominate fistula (TIF) and five patients (0.5%) developed a tracheal stenosis (TS). In only one of these procedures was the initial tracheostomy regarded as being technically difficult (oxygen desaturation and a tracheal ring fracture in a patient subsequently developing TS). The four patients who developed TIF died as a result of haemorrhage in to the airway whilst still patients on

the CCU and represent a mortality directly attributable to PDT of 0.4%.

Late complications of ST were present in three patients (9.7%). One patient developed a tracheal stenosis (3%) and was felt to be unsuitable for tracheal resection. One patient developed a stomal infection requiring antimicrobial treatment and one had a poor cosmetic result.

Table 5.2 *Adverse events during 230 technically difficult PDT procedures*

Difficulty	Number (%) n=1025
Minor posterior wall injury	12 (1)
Tracheal ring fracture	112 (11)
Multiple attempts to cannulate trachea	73 (7)
Minor bleeding	38 (4)
Oxygen desaturation	25 (2)

There were no significant differences demonstrated between grade of most senior physician present and technical difficulties / complications encountered (Table 5.3).

Table 5.3 *Early complications and technically difficult tracheostomies by grade of most senior physician present*.

Grade of most senior doctor present	Number of uncomplicated tracheostomies (%)	Number of technically difficult tracheostomies (%)	Number of major complications (%)
Consultant (813)	615 (76)	175 (22)	23 (2)
Clinical fellow (190)	138 (72)	50 (26)	2 (2)
Registrar (22)	16 (73)	5 (23)	1 (4)

Overall survival of the cohort is presented in figure 5.3 demonstrating a median survival of 3.3 years (95% CI 2.4 – 5.3). Estimated five year survival is 44% (Standard Error (SE) 0.02). Survival by age is shown in figure 5.4 demonstrating median survivals of 380 and 69 days for those 60-75 years and over 75 years respectively. Estimated five year survival by age is 61% (SE 0.02), 31% (SE 0.03) and 24% (SE 0.04) for those aged < 60, 60 – 75 and over 75 years respectively.

Survival by APACHE II score is presented in figure 5.5 with median survivals of 9.9 years, 3.5 years (95% CI 1.9 – 5.1) and 1.6 years (95% CI 0.9 – 2.2) for those with APACHE II scores of less than 15, 15 – 20 and greater than 20 respectively. Estimated five year survival according to APACHE II score was 56%, 44% and 36% respectively. There were no differences in survival by admission category (emergency / elective), diagnostic category (medical / surgical), type of tracheostomy (PDT / surgical) and gender.

Figure 5.3 *Kaplan Meier plot of overall survival (all patients undergoing tracheostomy – both percutaneous and surgical n = 1056). Median survival is 3.3 years (95% CI 2.4 – 5.3) with estimated five-year survival of 44% (Standard Error (SE) 0.02)*

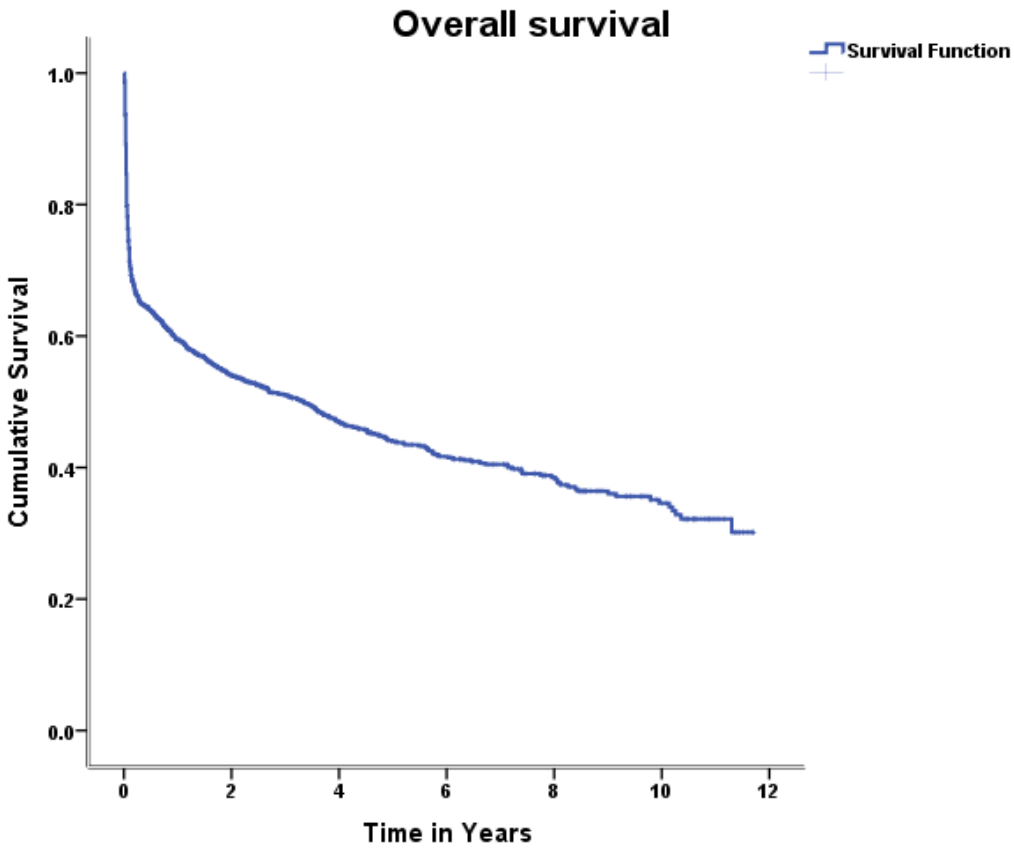
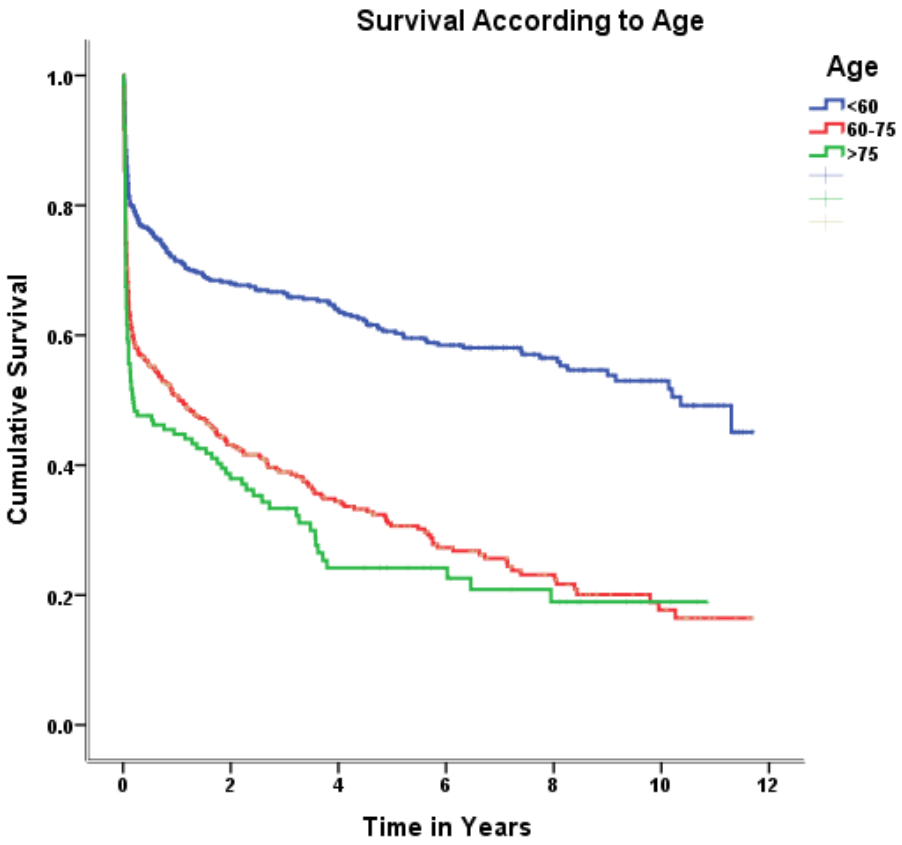


Figure 5.4 *Kaplan Meier plot of survival of patients undergoing percutaneous tracheostomy (n = 1025) by age demonstrating significantly worse survival for older age groups. Median survivals are 380 and 69 days for those 60-75 years and over 75 years respectively. Estimated five year survival by age is 61% (SE 0.02), 31% (SE 0.03) and 24% (SE 0.04) for those aged < 60, 60 – 75 and over 75 years respectively.*

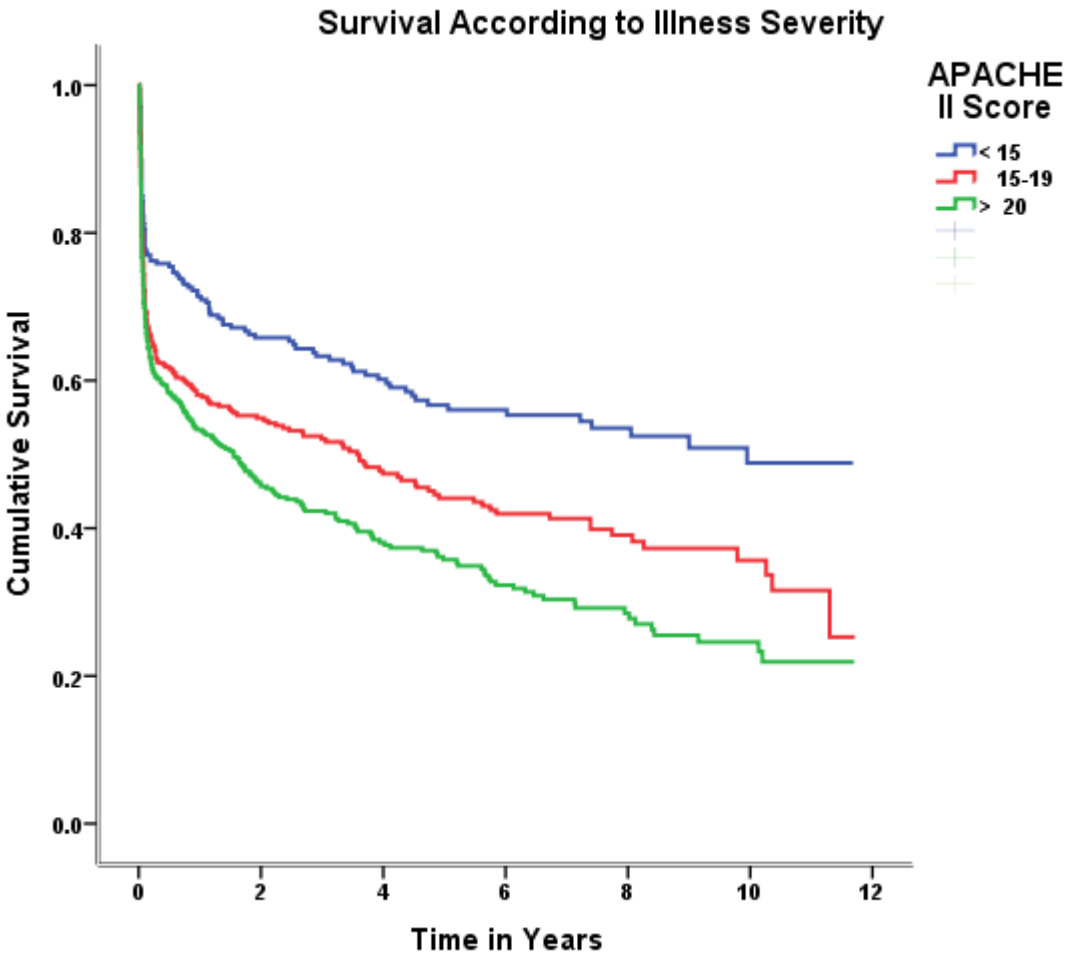


< 60 years n = 476

60 – 75 years n = 407

> 75 years n 142

Figure 5.5 *Kaplan Meier plot of survival for all percutaneous tracheostomies (n = 1025) by APACHE II Score demonstrating significantly worsening survival with increased illness severity. Median survivals are 9.9 years, 3.5 years (95% CI 1.9 – 5.1) and 1.6 years (95% CI 0.9 – 2.2) for those with APACHE II scores of less than 15, 15 – 20 and greater than 20 respectively. Estimated five year survival according to APACHE II score was 56%, 44% and 36% respectively.*



< 15 n =258

15 – 19 n = 352

≥ 20 n = 415

Six hundred and eighty seven (67%) PDT patients survived to hospital discharge. At follow up 543 had no tracheostomy related issues, seven patients had not been decannulated (for reasons other than TS), six had a sub-clinical TS picked up as part of an earlier study[79] or from incidental imaging. Five patients developed symptomatic

TS, one underwent corrective surgery, one died from rapidly progressive malignant disease and three had no surgical management. Ninety-seven patients had no documented follow up appointment. Of these 63 had been referred from outside our catchment area and 34 were AUH patients. Of the remaining 30 patients, 16 died before a follow up appointment and 13 had not reached 3 months from hospital discharge at the time of writing.

5.3 Discussion

When considering these updated results in light of our previous report the most reassuring finding is the consistency of the outcomes. The rate of technical difficulties, early and late complications have changed little. In our earlier paper we described a 26% rate of technically difficult PDTs. This has reduced slightly over time to 22% in the current paper. This would indicate a technical difficulty rate of 18% for the more recent patients (149 / 576 versus 81 / 449). Similarly, the early complication rate remains low at 2.5 percent (26 / 1025) in comparison to the previously reported three percent (16 / 576). Again, when considering the outcomes for more recent patients the rates remain almost identical at 2.2% (10 / 449). The rates for later complications have remained constant across both study periods with four tracheo-innominate fistulae (2/576, 2/449) and five tracheal stenoses (2/576, 3/449). Given the high consultant presence during the PDTs undertaken a reduction in peri-operative technical difficulties with time may point to a prolonged learning curve where continued exposure and practice may subtly diminish complications. Given the constancy of our late complications it may also indicate that peri-operative events have a relatively small role to play in long term outcomes with patient factors being the most important determinant here.

When comparing our data with previous reports the most direct comparisons come

from large, long term observational studies similar to our own. Kearney et al, in perhaps the first large observational cohort study of PDT, described their eight year experience of the original CPDT reporting an overall complication rate of 15%[188]. The intra-operative complication rate was six percent with the most frequent events being premature tracheal extubation, bleeding and para-tracheal placement of the tracheostomy tube. They also reported major peri-operative complications of tracheal laceration requiring thoracotomy (1 patient) and tracheo-oesophageal fistulae (2 patients). Their late complications consisted of a 1.6% rate of TS with no reported TIF. They reported a procedure related death rate of 0.6% largely related to early post-procedural complications. Diaz-Reganon et al reported on the outcomes of 800 predominantly guide wire dilating forceps (GWDF) PDTs (749 GWDF, 51 CPDT)[58]. They reported an overall complication rate of four percent with 2.1% intra-operative, 0.75% early post-operative and 1.1% late. The most common procedural complication was minor bleeding with one reported TS. Kost reported the outcomes of 500 procedures (191 CPDT, 309 STD) performed across a number of critical care units in Montreal[57]. The overall complication rate was 9.2% although considering the STD group alone this was 6.5% with the most common events being oxygen desaturation and bleeding. Kost also reported upon the effects of a learning curve with the CPDT technique in that complications were more common for the first 30 patients undergoing CPDT. This effect was not apparent for the STD group. No cases of TS were reported.

For the above studies the overall complication rates appear to be around 15% for CPDT, 4% for GWDF, 6.5% for STD and 3.5% for the present study. Some of this discrepancy can be accounted for on the basis of differing definitions for complications used by each paper and some from a degree of reporting bias. There

may, however, also be an inherent difference in complication rates between the techniques that has not previously been picked up in RCTs comparing the techniques. In two recent meta-analyses Cabrini and co-workers have tried to better quantify this situation[54,55]. In their earlier paper, using data from 13 RCTs, they noted that the different techniques were largely comparable with the exception of the retrograde (trans-laryngeal) tracheostomy which was associated with more severe complications[54]. The STD technique was associated with fewer failures and less minor complications leading the authors to conclude that it seemed to be the most reliable in terms of safety and success rate. A later paper by the same authors assessed five RCTs comparing GWDF to STD PDT using a composite outcome of difficult cannula insertion / difficult dilatation / failure[55]. The incidence of this composite outcome was 15.5% for GWDF versus 4.9% for STD. They also noted more frequent bleeding with GWDF (19.3 v 7.6%) with no difference in long-term outcomes. A recently completed systematic review incorporating data from RCTs and observational studies has failed to show a difference in long term outcomes of tracheostomy techniques commonly used within the critical care setting (ST, CPDT, GWDF, STD, TLT, BD, SSRD) from RCT data. However, when adding data from observational studies the pooled proportions meta-analysis seems to indicate a difference in reported TS rates from 0.6% for STD to 2.8% for ST, very similar to the rates described herein.[317]

To our knowledge, long-term outcomes and survival much beyond 12 months have not been previously reported for PDT in the CCU setting. Our data represent survival data for up to 11 years after PDT. Six hundred and eighty seven PDT patients (67%) survived to hospital discharge. The overall median survival for the cohort was 3.3 years (95% CI 2.4 – 4.3). Unsurprisingly, this is significantly impacted upon by age

with median survival reducing to 69 days (95% CI 0, 292) for those patients aged over 75 years. Similarly, illness severity significantly reduced survival with those with an APACHE II score in excess of 20 having a median survival of 1.6 years (95% CI 0.9 – 2.2). Perhaps somewhat unexpectedly, there were no outcome differences related to category of admission (elective versus emergency and medical versus surgical). To some extent this may be explained by those patients admitted to the CCU after an elective surgical admission who subsequently require a PDT have invariably had a significant complication during their stay which will adversely affect their outcome. The reason for a lack of a difference between medical and surgical patients is less clear but may be due to a degree of selection bias on the part of the attending intensivist with PDT not being undertaken on those patients felt to be more likely to have poorer outcomes.

The rate of PDT has changed over the course of our study whilst the number of admissions per year has remained relatively constant. For the earlier years of the study we were undertaking approximately 100 PDTs per year with this number falling to around 80 for more recent years (figure 5.2)[55]. The reasons for this may be several. Firstly, whilst the number of CCU admissions has remained relatively constant, the case mix appears to have changed with an increase in level II patients. This may be accounted for by the introduction of a hospital wide medical emergency team (MET) in 2009 resulting in patients being referred to the unit at an earlier stage. Secondly, during the course of the study, a number of papers have evaluated the role of tracheostomy, particularly in relation to timing of the procedure, in the CCU[22,23,24]. The most recent meta-analysis concluding that early tracheostomy produced no mortality benefit, no reduction in ventilator associated pneumonia, length of stay or sedative usage[25]. Given that each of the above studies have demonstrated a delay in

performing a tracheostomy invariably results in some patients not needing the procedure at all this work may partly explain the reduction seen here. However, the timeline does not entirely fit with the data as presented. Our tracheostomy rate fell from 2008 onwards, with most of the above publications being dated 2010 or later. Additionally, whilst our rate of PDT has fallen there has been little change in the timing of the tracheostomy from our earlier study. This is largely due to the fact that within our unit the tracheostomy is not utilised in isolation but as part of a package of care to facilitate early withdrawal of sedation, mobilisation, enhanced nutrition and weaning from mechanical ventilation.

Whilst the reported complication rates presented herein are in keeping with, if not an improvement upon, those published previously this remains a single centre evaluation with its attendant limitations. It may, however, add weight to the gathering evidence that the STD PDT is one of the safer techniques available. Our rate of early technical difficulties appears to be reducing whilst long-term outcomes remain unchanged.

Chapter 6

Tracheal stenosis following percutaneous dilatational tracheostomy using the single tapered dilator: a MRI study

6.1 Methods

This prospective cohort study was carried out at Aintree University Hospital NHS Foundation Trust.

A database of all patients receiving PDT, including associated outcome data, undertaken within the CCU at AUH has been kept since 2003. All PDTs are performed by critical care physicians at the bedside using the STD technique with bronchoscopic guidance. All patients were over the age of 18 and each received intravenous general anaesthesia with neuromuscular blockade during the procedure.

Following ethical approval (Liverpool (UK) Research Ethics Committee: Reference No 08/H1005/121) patients surviving for a minimum of three months from the insertion of PDT were identified from the database. Cross-referencing with AUH clinical records system (System C Medway Sigma, Maidstone, UK) and following contact with the patient's general practitioner, when required, confirmed whether patients were still alive. They were then contacted by telephone, informed of the nature of the study and invited to AUH to complete a simple questionnaire, undergo spirometry and MRI scanning (figure 6.1).

Following written informed consent, background data including age, sex, admission illness severity (APACHE II), duration of oro-tracheal intubation prior to PDT, complications and technical difficulties during PDT[59], duration of cannulation, length of critical care and hospital stay were collected. A PDT was considered complicated if there were one or more technical difficulties (multiple tracheal punctures (≥ 3), tracheal ring fracture, minor bleeding - > 3 soaked gauze swabs) or significant complications (pneumothorax, subcutaneous emphysema, major bleeding – need for surgical intervention or transfusion). A Health Status Screening Questionnaire

(Appendix 2) was devised and used to ascertain evidence of pre-existing respiratory disease, respiratory symptoms after critical care and current exercise tolerance. Simple spirometry was then undertaken using a micro-loop spirometer (CareFusion Health UK 232 Ltd, Basingstoke, UK) to obtain values for FEV_1, PEFR and forced vital capacity (FVC). The best of three readings obtained were used to calculate the FEV_1/PEFR ratio. This constitutes the Empey Index (EI) (EI= FEV_1/PEFR) and previous data have reported a ratio > 10 to be clinically significant[195].

MRI scanning was undertaken using a Siemens 1.5 T Avanto scanner (Siemens, Munich, Germany). A T2-weighted coronal scan using 5 mm slices was carried out, along with a T1 flash sagittal 3D volume scan with 1 mm slices. Multi-planar reformats were constructed from the volume scan in the axial and coronal planes. All sequences included the trachea from the inferior border of the cricoid cartilage to the carina. All images were reviewed by a single consultant radiologist, unaware of the clinical details of the patient pertaining to the PDT. Coronal and sagittal measurements were reported at the narrowest section of the trachea at or above the level of the tracheostomy and compared to normal tracheal dimensions above or below the abnormality. TCSA at each level was calculated using the Picture Archiving and Communications System (PACS – Carestream Vue PACS, Carestream Health, Hertfordshire, UK). A significant stenosis amounting to a reduction in the TCSA of 10% or more when compared to normal trachea above or below the abnormal segment was defined as TS for the purpose of this study in common with previous similar studies[181,191,192]. All patients with identified TS on MRI were then referred to a consultant head and neck surgeon for further evaluation. In these cases, each patient was initially investigated with fibre-optic laryngo-tracheoscopy, continuing to rigid tracheo-bronchoscopy under general anaesthesia if this was

considered necessary.

6.2 Statistical analysis

Data were analysed initially using Microsoft® (Redmond, WA, USA) Excel™ software. GraphPad (GraphPad Software Inc, La Jolla, CA, USA) was used to carry out Fisher's exact test for categorical data and Mann-Whitney U tests for continuous data. A p value of less than 0.05 was considered statistically significant.

6.3 Results

At the time of the study the database contained 745 patients who had undergone STD PDT more than three months previously. Four hundred and eighty-three of these patients survived to hospital discharge. A further 178 died within six months of hospital discharge, leaving 305 eligible for inclusion. One hundred and twenty patients were contacted by telephone. Seventy patients declined the invitation or were unable to attend for MRI scanning, including 11 who failed to present for pre-arranged appointments. The remaining 50 patients underwent MRI (Figure 6.1). Of these, 49 also attended for interview, during which a standardised questionnaire was completed (Appendix 2).

***Figure 6.1**: Recruitment to study*

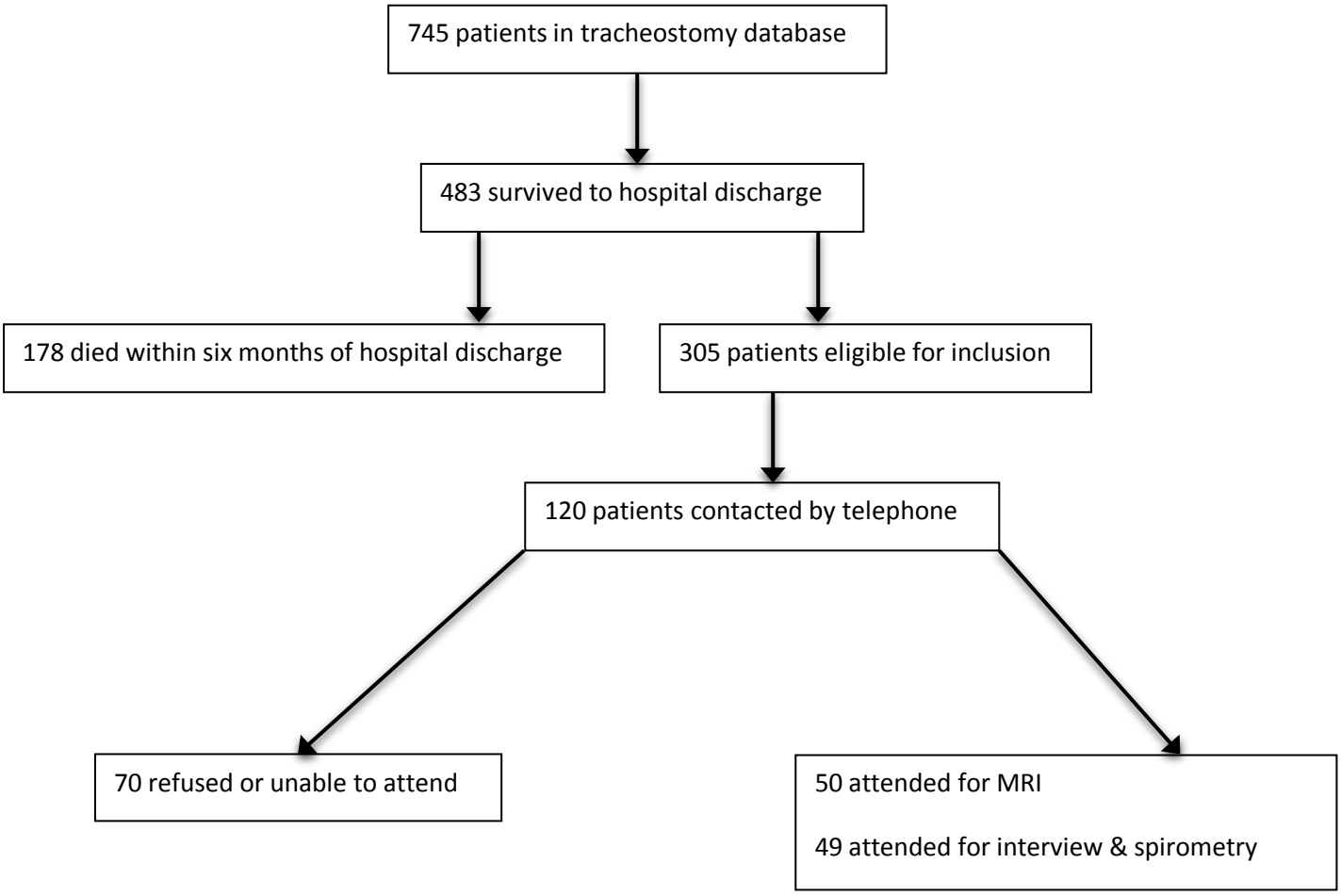


Table 6.1. *Characteristics of patients with tracheal stenosis compared to those without and patients declining the invitation to attend for MRI scanning*

	Stenosis (n = 5)	**No stenosis (n = 45)**	**Non-Attenders (n= 70)**
Age median (IQR)	51 (39-59)	58 (48-72)	58 (42-67)
Male n (%)	2 (40)	26 (58)	45 (64)
Admission APACHE II score, median (IQR)	14 (14-15)	16 (14-19)	16 (13-21)
Oro tracheal intubation prior to PDT days, median (IQR)	4 (4-5)	4 (2-5)	4 (3-5)
Duration of cannulation days, median (IQR)	15 (12-21)	9 (6-15)	15 (11-23)
Time from decannulation to MRI months, median (IQR)	22 (12-58)	24 (10-45)	—
Peri-operative complications, n (%)	4 (80)*	2 (4)*	22 (31)
Bleeding	1 (20)	0 (0)	4 (6)
Multiple tracheal punctures	2 (40)	1 (2)	9 (13)
Tracheal ring fracture	1 (20)	1 (2)	9 (13)

IQR Inter-quartile range **p=0.002 Fisher's exact test*

Of the 50 patients undergoing MRI scanning, 5 patients (10%, 95% CI 3-22%) were diagnosed with TS as per the study criteria. Patient characteristics of those with and without TS (non-TS: nTS) and non-attenders are presented in table 6.1. Median reduction in TCSA for those with TS was 30% with individual stenoses documented as 16, 24, 30, 38 and 46% respectively (table 6.2). There were no differences between the groups with respect to age, sex, illness severity and number of days of oro-tracheal intubation prior to PDT insertion and time from PDT to MRI scan. The

difference in median duration of cannulation of 15 days in the TS group and 9 days in nTS group was not statistically significant (p=0.17).

Table 6.2. *Tracheal stenosis, spirometric and questionnaire data*

	Tracheal stenosis (n=5)	No tracheal stenosis (n=45)
Tracheal measurements median Reduction in tracheal cross sectional area (%) (range)	30 (16-46)	-
Pulmonary function tests (median, IQR)		
FEV_1 (ml)	2.06 (1.69-2.52)	2.3 (1.77-2.84)
PEFR (L/min)	235 (219-249)	337 (222-427)
FVC (L)	2.42(1.89-3.27)	3.06 (2.52-3.49)
Empey index	7.96 (7.19-9.4)	6.89 (6.08-8.28)
Empey index >10, n (%)	1 (20%)	3 (7%)
Pre-CCU exercise tolerance 100m or less, n (%)	1 (20%) (n=5)	4 (10%) (n=39)
Post-CCU exercise tolerance ≤100m, n (%)	4 (80%)* (n=5)	9 (23%)* (n=39)
Voice change, n (%)	2 (40%)	16 (38%)
Shortness of breath reported, n (%)	4 (80%)	17 (40%)

````*P=0.022 Fisher's exact test*

***$FEV_1$*** *Forced expiratory volume in one second*

***PEFR*** *Peak expiratory flow rate*

***FVC*** *Forced vital capacity*

***CCU*** *Critical care unit*

Overall, six of the 50 PDTs were complicated as defined above. Four of the five patients diagnosed with TS in comparison with two of 45 without, underwent complicated STD PDT (table 6.1). When complications were considered individually, patients with TS may be more likely to have multiple attempts at tracheal puncture
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(2/5 versus 1/45) but there was no apparent difference between the groups in relation to tracheal ring fracture (1/5 versus 1/45) or minor bleeding (1/5 versus 0/45) rates.

Results from the questionnaire revealed no differences in the presence of voice changes (2/5 versus 16/45) and shortness of breath (4/5 versus 17/45) between those with TS and those without. Two patients reported the presence of inspiratory noise – neither were found to be stridulous or have TS on MRI scan. Data pertaining to exercise tolerance was provided by 44 patients (5 TS and 39 nTS). Four of the five patients with TS reported an exercise tolerance of 100 metres (m) or less, two of whom reported unlimited exercise tolerance prior to critical care admission. In contrast, 9 of 39 nTS patients (23%) reported an exercise tolerance of 100m or less.

Mean values for FEV_1, PEFR and EI are shown in table 6.2. Neither FEV_1, PEFR nor EI were predictive of TS.

The five patients found to have TS on MRI scanning were referred to a consultant head and neck surgeon for further evaluation and to assess the need for additional intervention. At initial fibreoptic laryngo-tracheoscopy three of the five were deemed to have an adequate airway and further intervention was deemed unnecessary. The remaining two underwent rigid tracheo-bronchoscopic examination under general anaesthesia and were again found to have an adequate airway. It was felt that further surgical intervention would not significantly improve the airway, in a clinically meaningful way, in any of the 5 patients with TS.

6.4 Discussion

We have found a sub-clinical TS rate of 10% in fifty patients investigated ranging from a 16 – 46% reduction in TCSA. All patients with TS had fibre-optic laryngo-tracheoscopic evaluation and two of the five had rigid tracheo-bronchoscopy. No

patient required any therapeutic intervention and all were felt to have an adequate airway and were discharged from further follow-up. The low incidence and the sub-clinical nature of the stenoses is reassuring, indicating the underlying prevalence of undiagnosed TS in patients following STD PDT is of doubtful clinical significance.

There are limited studies in the literature reporting long term follow up of PDT patients using radiological imaging (CT/MRI) with very few studying tracheal calibre in patients who have had STD PDTs even though this is now probably the most frequently used technique[45,46,189]. The 10% rate of TS described herein was less than that found in another MRI study[80]. Fikkers compared long term outcome of patients randomly allocated to either GWDF or STD PDTs. Sixty patients were assigned to each group, 31 patients underwent MRI scanning (14 patients in the STD group), with 12 (39%) showing tracheal narrowing. Whilst the absolute number of patients with tracheal narrowing demonstrated by Fikkers is larger than our own, the degree of stenosis is similar in that all cases were felt to be of limited clinical consequence.

Two further studies utilised CT assessment. Norwood[4] studied 100 patients who had undergone PDT using the sequential dilators of the original Ciaglia technique (CPDT)[40]. Forty-eight of these patients underwent CT scanning. Fifteen (31%) patients were found to have more than 10% TS on CT with 10 (21%) of these being mild (tracheal narrowing of 11-25%), 4 (8%) moderate (26-50% narrowing) and 1 (2%) severe (>50% narrowing). In Karvandian's study, 20 patients were assessed using CT and fibre-optic laryngotracheosopy after CPDT[190]. Only three of the 20 patients had cannulation times of less than three weeks (none of whom had TS) and 85% had significant sub-glottic stenosis (53% with < 50% narrowing). The study group appeared different from our own with a mean duration of cannulation of 9

weeks. Additionally, 54 of 86 patients surviving four months after discharge from hospital required permanent or long-term mechanical ventilation.

van Heurn described a TS prevalence of 26% in a study of 54 patients undergoing plain linear tomography following CPDT[191]. Law used spirometry and fibre-optic laryngo-tracheoscopy without any radiological assessment in 41 patients after CPDT[192]. Three patients were found to have tracheal narrowing of between 10-30% and one with a 40% stenosis. After a median cannulation time of 20 days, a 10% rate of TS was reported.

The 10% rate of TS we describe is at the lower end of incidences reported above (10 – 85%). Part of this difference may be accounted for by differing definitions of TS. However, the definition of TS as tracheal narrowing of >10% is common to most of the studies cited above with only Fikkers[80] and Karvandian[190] not specifically stating their definition of TS. The difference might also partly be attributed to shorter tracheal cannulation times. In each of the studies described above the duration of tracheal cannulation was longer than that described in our study (15 days in the TS group and 9 days in the nTS group). Cannulation times ranged from 18 days in Fikkers GWDF group[80] to 9 weeks in Karvandian's paper[190]. Those studies reporting a lower prevalence of TS or only minor tracheal changes appear to have shorter cannulation times[80,192]. A further consideration to take into account is the duration of tracheal intubation prior to the insertion of PDT. PDT was carried out early in our patients (median 4 days), whereas previous studies have reported durations from 7 – 18 days[80,181,191,192]. Another factor to be considered is PDT insertion technique used. Most of the studies described above have used CPDT with only Fikkers[80] evaluating GWDF and STD techniques radiologically and then in only 15 and 14 patients respectively. It is possible, given the paucity of data available, that the incidence of

post PDT TS may differ significantly between commonly used techniques. Considering the widespread use of these techniques the lack of long-term radiological outcome data would appear somewhat surprising.

The TS patients appear more likely to have undergone a complicated or technically difficult PDT compared to the nTS group (table 6.1). The most frequent difficulty encountered was the need for multiple tracheal punctures to site the cannula required for guide-wire insertion. Whilst the significance of this finding is unclear, the association between multiple tracheal punctures and later tracheal narrowing has not been made previously. It is possible that several attempts to position the cannula may ultimately lead the operator to settle for a suboptimal position for the tracheostomy tube potentially causing tracheal injury and later narrowing.

As all cases of TS detected were clinically asymptomatic, with none requiring surgical correction, it is difficult to explain the significance and relevance of the reduced exercise tolerance found in these patients (four out of five reporting significantly limited exercise tolerance, two of whom had previously been unlimited). Conventionally TS is expected to become evident clinically when the tracheal narrowing reaches 50 – 75%. However, many critical care survivors are likely to have significant impairment of cardio-respiratory and neuro-muscular function. It is possible, in the setting of such limited physiological reserve, that post critical care patients may be symptomatic at lesser degrees of tracheal narrowing than would usually be the case. Under normal circumstances for gas to flow through the trachea a pressure gradient exists to overcome the resistance of the respiratory system. Flow within the trachea is usually turbulent and in such conditions the resistance is inversely related to r^{5} [64]. Therefore, the TS patient has to generate a greater pressure gradient to overcome this added resistance. Consequently, for the post critical care

patient, the symptoms of the TS may be more in keeping with significant fatigue than those usually associated with upper airway obstruction.

The principal limitations of this study are sample size and patient selection. The study population may have self-selected to some extent, being limited to those who were fit enough to travel to hospital to take part in the study. Rates or severity of TS might be different in those patients unable to come to hospital. Conversely, those who were well enough to have returned to full-time employment may not have been contactable by telephone at home during office hours so may have been missed. We were, however, unable to demonstrate any differences in patient characteristics between those attending for scans and those unable to do so (Table 6.1). Additionally, we are unaware of the cause of death in those patients surviving their critical care stay but dying prior to an invitation to attend for scan. It is possible some of these patients may have had some degree of upper airway obstruction. Given that our institution houses the regional head & neck surgery service, and such patients would have been referred back should they develop airway obstruction, this seems less likely.

Our initial intention was to assess 60 patients following STD PDT, specifically recruiting 20 after uncomplicated procedures, 20 after PDT complicated by tracheal ring fracture and a further 20 after more than 14 days cannulation. The incidences of ring fracture and of cannulation for more than 14 days were too low for the original aim to be achievable. Consequently, we recruited fifty eligible patients from the database. Whilst we were unable to study these factors as initially intended, analysis of the limited data obtained would appear to suggest that tracheal ring fracture is not obviously implicated in TS. Data pertaining to the length of tracheal cannulation may indicate a possible relationship between prolonged cannulation and TS (nTS 9 days versus 15 days TS) but this was not statistically significant. Whilst we could not

demonstrate a statistically significant association between duration of cannulation and TS further studies with larger numbers may be able to do so. Such studies are likely to be confounded by differences in timing of PDT between institutions. The long follow-up required to detect post tracheostomy TS would be another limiting factor, as would cost – particularly if only 10% cases prove positive for TS which then may be regarded to have limited clinical significance.

Chapter 7

Discussion

In the preceding chapters we have demonstrated the safety of percutaneous tracheostomy and more specifically the STD technique in relation to ST. We have shown, from the prospective studies published reporting long term outcomes, that percutaneous techniques in common use have complication rates similar to, if not better than ST. We have also illustrated, within our own unit[59], that the complication rate of the STD technique is amongst the lowest published when compared to similar studies[57,58,188] . Additionally, concerns relating to undiagnosed sub-clinical tracheal stenosis seem to be unfounded[79].

From the limited published data we have not found a significant difference in the incidence of TS between a range of percutaneous techniques and surgical tracheostomies. When considering all published data reporting long-term outcomes, our pooled proportions meta-analysis may indicate a tendency toward a higher rate of TS for ST but this finding is likely to be prone to selection bias. Similarly, in relation to major bleeding, we have not found a difference between the techniques commonly used. Again the pooled proportions meta-analysis may indicate a tendency toward more major bleeding for ST. In relation to wound infection we have found a significant reduction associated with CPDT compared to ST in keeping with earlier work[51]. Across all percutaneous techniques for the primary and secondary outcomes studied complication rates appear to be broadly similar but confidence intervals for pooled risk differences are wide and include clinically important differences in both directions. Due to limited data reporting, we were unable to identify peri-operative events that may be of significance in the generation of TS. Neither were we able to quantify the utility of adjuvant techniques (bronchoscopy and ultrasound scanning) in reducing peri-operative complications.

Whilst the reported complication rates presented within our cohort study are in

keeping with, if not an improvement upon, those published previously[57,58,188], this remains a single centre evaluation with its attendant limitations. It may, however, add weight to the gathering evidence[55] that the STD PDT is one of the safer techniques available. Our rate of early technical difficulties appears to be reducing whilst long-term outcomes remain unchanged.

We have demonstrated a lower rate of sub-clinical stenosis in patients following STD PDT than has previously been reported[79]. Whilst we considered that some degree of functional limitation, in such patients, following critical care discharge might be in part due to an underlying prevalence of TS this would appear not to be the case. Those stenoses found were felt to be of doubtful significance with no patients requiring corrective surgery and all, ultimately, discharged from further follow up. Routine radiological imaging and spirometry following STD PDT would appear to be unwarranted in asymptomatic patients.

When considering the data generated by each of the studies in the previous chapters a number of issues arise that have not been discussed previously.

7.1 Gender Bias

In both our own prospective series (608/1025) and in all but one of the papers reviewed for the systematic review[313] there is a significant gender bias toward males. The 29 papers reviewed incorporated a total of 5473 patients, only one paper failed to report a male: female ratio[311] (Polderman: 213 patients). Therefore, of 5260 patients within these trials 3153 (60%) were males. A similar position is described within Delaney's meta-analysis[51]. Of the 17 papers reviewed all but two[235,281] consisting of 123 out of 1212 patients describe a preponderance of males. This is not a phenomenon that is exclusive to trials of tracheostomy insertion or indeed to critical

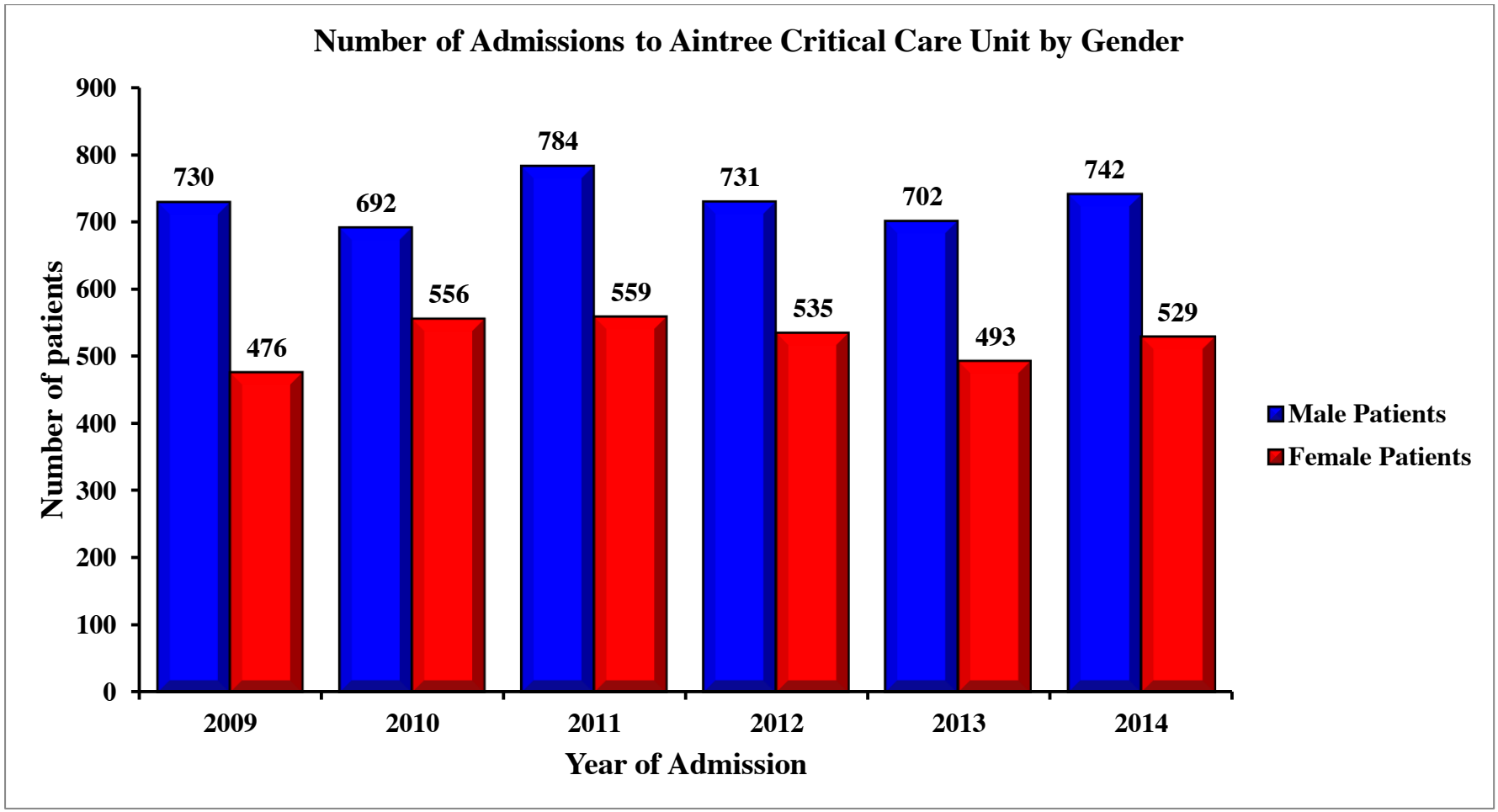
care. When reviewing a selection of landmark papers published within the New England Journal of Medicine from 1999 onwards[26,318-324] we can see a similar trend, with only one paper achieving a male : female ratio in excess of one in favour of females (table 7.1)[318] . These eight papers describe the management of 16,843 patients of whom only 6,242 (37%) are female.

Table 7.1 *A selection of landmark critical care papers published in the New England Journal of Medicine illustrating the gender bias present within such studies. All but one have a significantly higher proportion of male study entrants.*

Study	**Number of patients**	**Number of males (%)**	**Number of females (%)**
ARDSNet[26]	861	512 (59.5)	349 (40.5)
Kress[318]	128	60 (47)	68 (53)
Hebert[319]	838	524 (63)	314 (37)
Finfer[320]	6997	4197 (60)	2800 (40)
Sprung[321]	499	332 (67)	167 (33)
NICE-Sugar[322]	6104	3897 (64)	2207 (36)
Guerin[323]	466	318 (68)	148 (32)
Nielsen[324]	950	761 (80)	189 (20)

However, when we review admission data for our unit from 2009 onwards we see that a similar sex distribution to that described for our tracheostomies is maintained (figure 7.1). It would, therefore, appear that any gender bias present within the critical care department is not related to the tracheostomy procedure per se but toward the decision to admit in the first place.

Figure 7.1 *Graphical representation of gender bias for admissions to Aintree University Hospital Critical Care Unit from 2009 – 2014. The proportion of males admitted is approximately equal to the proportion undergoing tracheostomy within the study period.*



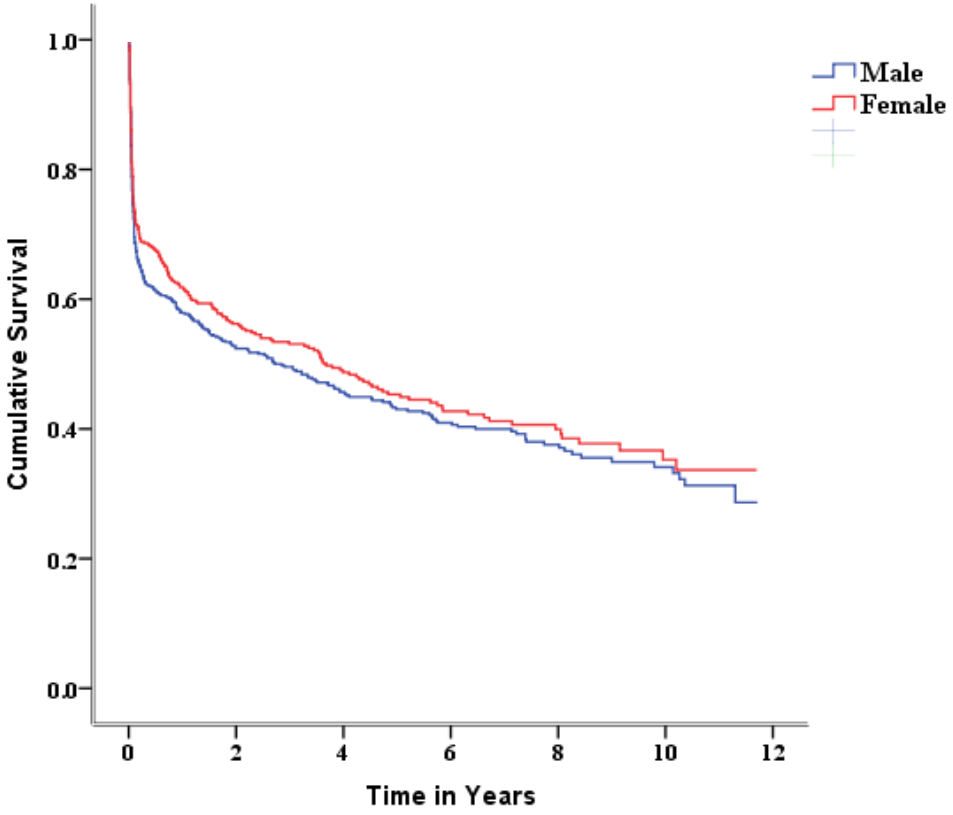
It is generally believed that access to critical care is determined by need and severity of illness with differences in admission rates between genders being accounted for by the different disease spectra between the sexes. For example, it is generally accepted that ischaemic heart disease and trauma are commoner in males. However, a number of studies have demonstrated some concerns in relation to gender bias within critical care. A Canadian study analysing over 466,000 hospital admissions found that women over 50 years of age were less likely to be admitted to a critical care unit and more likely to die than men after a critical illness[325]. In contrast, in a cohort of 26,000 patients in Austria Valentin found that whilst there was a higher illness severity in women men received an increased level of care and more invasive procedures but this did not translate in to improved outcomes[326].

A study emanating from the UK Intensive Care National Audit and Research Centre (ICNARC) examined the influence of gender on admission to critical care[327]. They examined admissions for a number of diagnostic categories for evidence of vertical and horizontal inequity. Reviewing over 46,000 admissions from 91 critical care units they were unable to find evidence of gender bias in admission or mortality in relation to cardiac arrhythmias, chronic obstructive pulmonary disease, asthma, self-poisoning and seizures. There was some evidence of vertical and horizontal inequity for females with myocardial infarction and central nervous system bleeding. There was also evidence suggestive of vertical inequity for male pneumonia and ventricular failure patients.

When considering our own data we can see that the mean admission APACHE II score for males admitted to the unit who undergo a tracheostomy is 18.3 whilst that for females is 19.3 ($p=0.005$ unpaired t test). This would indicate females admitted to our critical care unit who undergo a tracheostomy are sicker than their male

counterparts at critical care admission, possibly indicating an admission gender bias within our unit. When considering survival of these cohorts the median survival for males is 2.9 years (95% CI 1.8 – 3.9) with an estimated five-year survival of 43% (SE 0.02). For females the equivalent figures are a median survival of 3.7 years (95% CI 2.3 – 5.1) with an estimated five-year survival of 45% (SE 0.03) (figure 7.2). Therefore, whilst the illness severity for female patients is increased this is not seemingly translated in to worse survival figures as would be expected. The crude APACHE II mortality prediction for the scores described above would be 29% for males and 32% for females. Samples sizes to reliably detect such a difference should be 511 in each group (α 0.05, power 0.8).

Figure 7.2 *Kaplan Meier survival curve illustrating survival according to gender for male (n = 608) and female (n = 417) patients respectively undergoing tracheostomy in Aintree University Hospital Critical Care Unit. Despite a higher illness severity for female patients, as evidenced by their admission APACHE II Scores, there is no difference in overall survival. The median survival for males is 2.9 years (95% CI 1.8 – 3.9) with an estimated five-year survival of 43% (SE 0.02). For females the equivalent figures are a median survival of 3.7 years (95% CI 2.3 – 5.1) with an estimated five-year survival of 45% (SE 0.03).*



p=0.28

7.2 Timing of tracheostomy insertion

The median time to tracheostomy within our own series is five days from critical care admission and four days from tracheal intubation. When reviewing the literature related to tracheostomy timing insertion is broadly divided into early (< 10 days) and late (> 10 days) groups. There remains much controversy as to the optimal timing for tracheostomy insertion within a critical care population. Initial interest in early

tracheostomy was fuelled by a number of randomised controlled trials reporting improvements in ventilator associated pneumonia, ventilator free days and length of critical care stay for patients undergoing early tracheostomy[275,328,329].

An early meta-analysis by Griffiths, incorporating five trials totalling 406 patients, failed to show a mortality benefit or a reduction in ventilator associated pneumonia but did demonstrate a reduction in both duration of mechanical ventilation and critical care length of stay[330]. However, an updated review by Wang from 2011 failed to show any of the outcome benefits reported previously[331].

From 2010 – 13 a number of larger studies assessing patient outcomes related to tracheostomy timing have been published. In a study performed in 12 Italian centres Terragni randomised 419 patients to undergo tracheostomy between days 6 – 8 versus days 13- 15[332]. The primary outcome was 28-day incidence of ventilator-associated pneumonia with the study being powered to demonstrate a 35% reduction therein. Whilst there was no reduction in ventilator associated pneumonia (early 30 versus late 44 pneumonias p= 0.07) there were reductions in duration of mechanical ventilation, critical care length of stay and duration of weaning from mechanical ventilation for the early tracheostomy group. There were no differences in mortality or hospital length of stay. In a study of tracheostomy timing in the cardiac surgical setting Trouillet studied 216 patients and failed to demonstrate outcome benefits in relation to nosocomial infection, length of stay or mortality[333]. They did, however, demonstrate significantly less sedative usage, less agitation and delirium, improved oral nutrition and earlier mobilisation for the early group. The Tracman study, performed within the UK, is the only study to date with 30 day mortality as the primary outcome[334]. The targeted recruitment to achieve this aim was 1208 patients to detect a 7.5% reduction in critical care mortality. The study failed to recruit to target,

being halted at 909 patients, the principal reasons being recruitment fatigue and exhaustion of funding. There was no difference in any of the outcome measures reported above other than a reduction in sedative usage in the early tracheostomy group.

The most recent Cochrane review of tracheostomy timing has been published in 2015[335]. In a review of eight studies incorporating 1977 patients, including each of the larger studies alluded to above[332-334], the authors reported a lower risk of mortality at the longest follow up time available (28 days – two years) in the early group (Relative Risk (RR) 0.83, 95% CI 0.70 to 0.98; P = 0.03) stating that 11 patients would need to be treated with an early tracheostomy instead of a late one to prevent one death. The probability of discharge from the critical care unit was also higher at 28 days for the early tracheostomy group day (RR 1.29, 95% CI 1.08 to 1.55; P = 0.006). When reviewing the quality of the evidence available the authors concluded that for mortality it was of moderate quality and for discharge at day 28 was high quality.

7.3 Reasons for tracheostomy insertion

The reasons for tracheostomy insertion in the critical care setting are frequently subjective and complex (table 7.2). In our own unit time of insertion may differ quite markedly for different patient groups (figure 7.3). Potential outcome benefits in relation to mortality, critical care length of stay and reductions in nosocomial respiratory infections have been suggested as reasons but, as can be seen from the above, the evidence in this regard can be contradictory. Further potential reasons put forward for tracheostomy insertion include improvements in patient comfort, safety, oral nutrition and hygiene and reduced work of breathing[336]. When considering the evidence supporting these assertions it is frequently confined to uncontrolled reports, clinical opinion and theoretical analysis.

Figure 7.3 Tracheostomy insertion algorithm

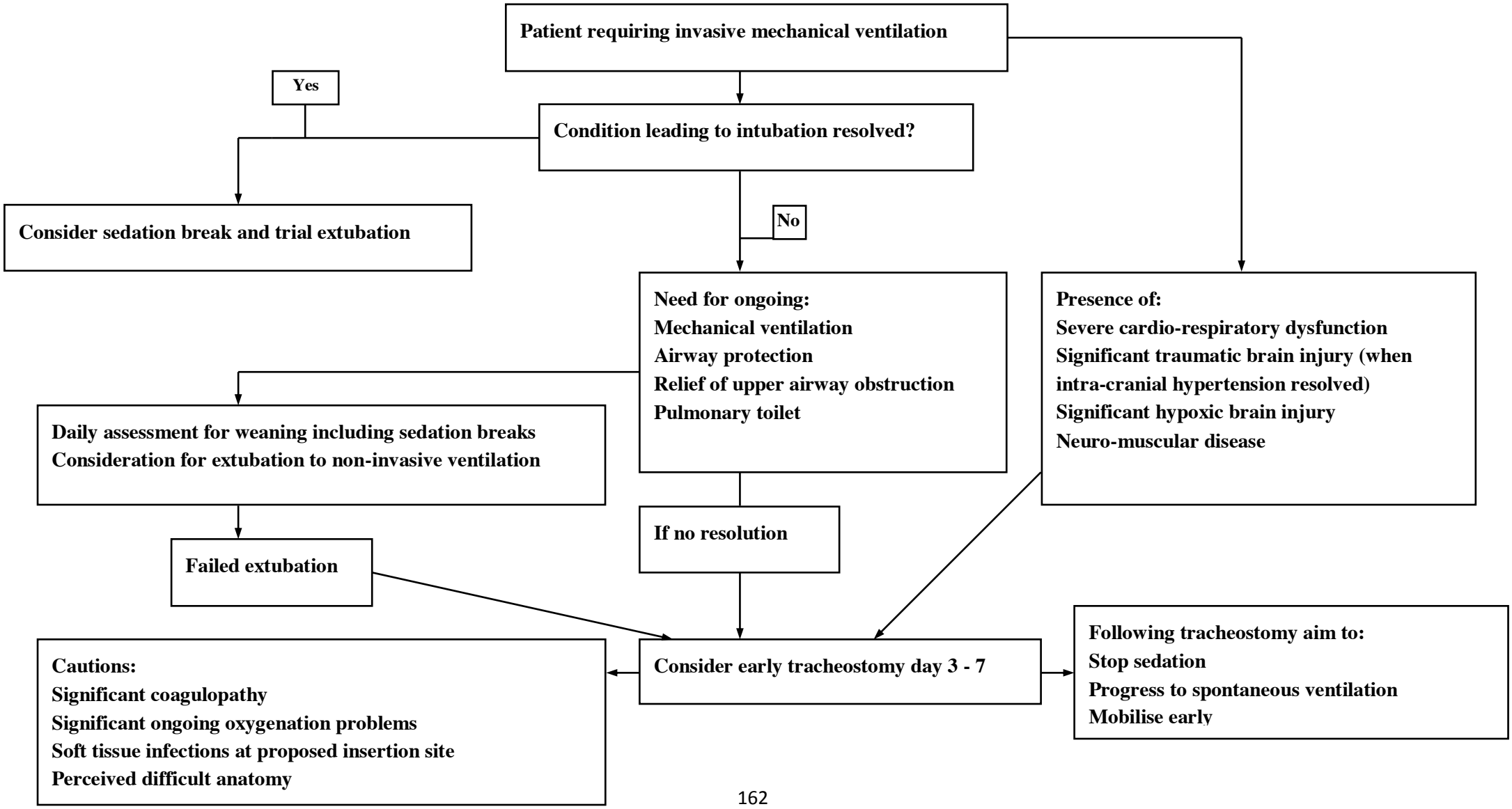


Table 7.2 *Reputed benefits of changing from a trans-laryngeal endotracheal tube to a tracheostomy tube, and level of evidence supporting such a decision, in a patient who requires prolonged intubation.*

Benefit	Type and Quality of Literature Support Showing Benefit
Improved patient comfort	Uncontrolled reports, clinical opinion
Less need for sedation	Several RCTs
Lower work of breathing	Theoretical analysis, one small study
Improved patient safety	Clinical belief but minimal data, some contradictory (see text for details)
Improved oral hygiene	Clinical observation
Oral intake more likely	Opinion only
Earlier ability to speak	Uncontrolled reports
Better long-term laryngeal function	Large uncontrolled reports
Faster weaning from mechanical ventilation	One RCT
Lower risk of ventilator-associated pneumonia	Controversial, data support for both sides
Lower mortality	One RCT supports, many do not, but a large RCT supports mortality not higher with tracheostomy
Shorter intensive care unit and hospital stay	Several meta-analyses

RCT = randomized controlled trial

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When strategies for tracheostomy insertion within the critical care setting are considered it is frequently noted that many of those patients allocated to late insertion do not necessarily undergo the procedure[334]. An argument is then proposed that the risk of the tracheostomy is difficult to justify in this patient group. This viewpoint assumes that prolonged trans-laryngeal intubation is a risk free management plan. This is quite clearly not the case, with at least one series of patients with tracheal stenosis reporting a higher rate associated with trans-laryngeal intubation alone as opposed to tracheostomy following trans-laryngeal intubation[88]. Additional risk factors associated with prolonged trans-laryngeal intubation include vocal cord

oedema, mucosal erosions, laryngeal scarring and stenosis and recurrent laryngeal nerve damage. These changes may be seen within several days with the likelihood of recovery directly related to the duration of intubation[336].

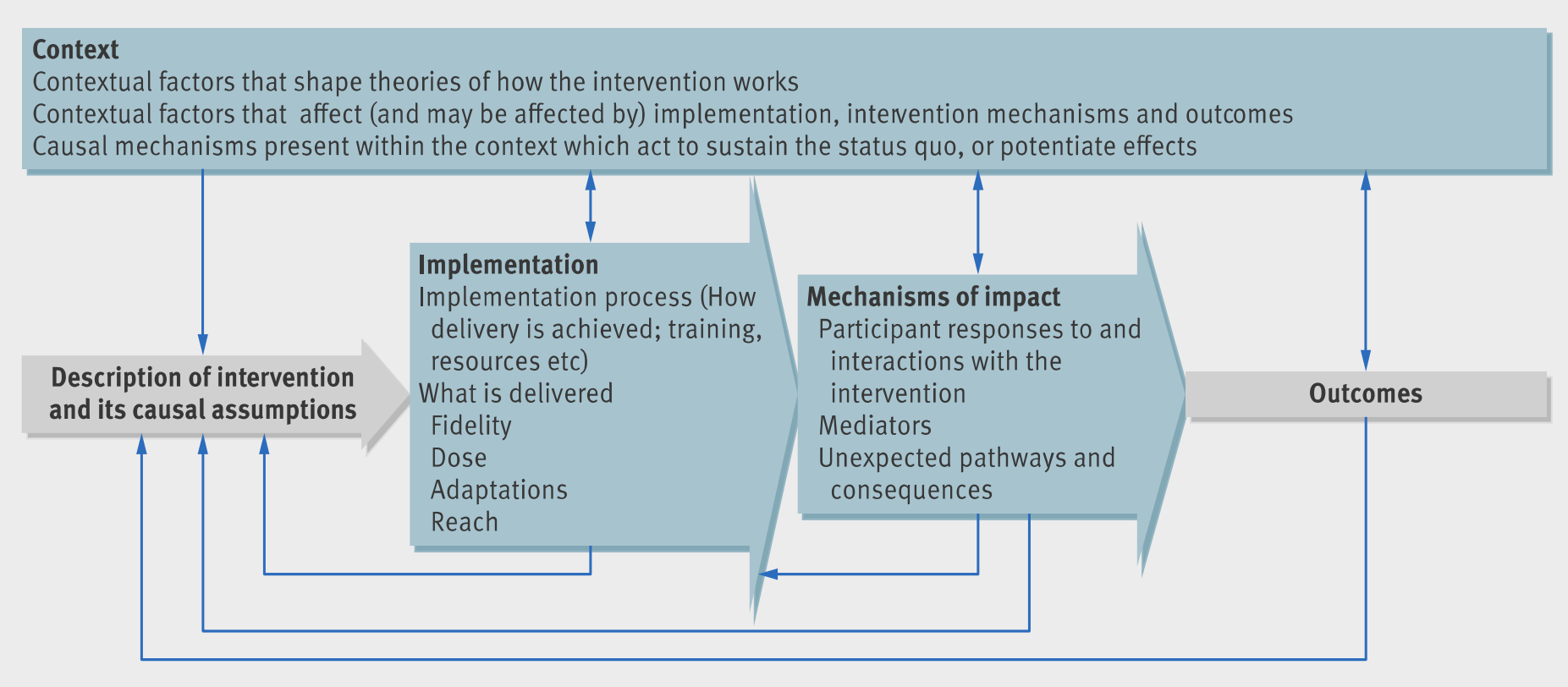
7.3.1 Complex intervention

On initial reflection the decision to insert a tracheostomy may be viewed as a simple intervention with a number of limited and predictable consequences. However, when we begin to consider our ability to transfer our findings and experience to other settings and centres we need to take in to account several factors surrounding the decision to perform a tracheostomy, the package of care delivered after its insertion along with staff, patient and family attitudes (see section 7.9). Complex interventions have previously been defined as those that comprise multiple interacting components [337]. In this context, therefore, it is clear that inserting a tracheostomy in to a critical care patient is part of a highly complex intervention package rather than a simple isolated procedure. Traditionally randomised controlled trials have been regarded as the gold standard for establishing the effectiveness of an intervention but they may not provide information pertaining to how the intervention will be delivered outside of the clinical trial setting or if the suspected outcomes will be delivered[338].

The key steps in evaluating a complex intervention are illustrated in figure 7.4.

When considering our intervention of tracheostomy insertion with a view to replicating our findings beyond Aintree University Hospital there are several barriers that would currently prevent this process.

Figure 7.4 *Key functions of process evaluation and relations among them for complex interventions. Implementation, mechanisms of impact and context are felt to be the key components of a process evaluation*



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7.3.1.1 Defining the intervention

Whilst it is a simple task to identify all critical care patients in whom a tracheostomy has been inserted it is more difficult to quantify the change in care that results from it. Within our unit the intervention is not simply tracheostomy insertion but the package of care delivered thereafter. Although it is easy to observe this change, as yet, we have not documented the process. This would require, as a minimum, assessments addressing sedative usage, time spent out of bed and mobilising, changes in ventilator management and additional time spent by allied health professionals with the patient. Additionally, patient factors further complicate our ability to define the intervention with some patients receiving a tracheostomy earlier (severe end organ dysfunction) whilst in others this may be delayed (figure 7.3).

7.3.1.2 Implementation

The first barrier to acceptance of a process of early tracheostomy and its associated package of care within other centres may lie in its acceptance. There is limited data showing a mortality benefit in relation to early tracheostomy insertion with most recent large randomised controlled trials failing to demonstrate a difference in outcome[332-334]. The most recent systematic review does, however, seem to indicate both a mortality benefit and a reduction in critical care length of stay[335].

Further process evaluation to assess how the intervention would be delivered would be required. This would need to include elements of resource allocation, assessment of training needs (both for those undertaking the tracheostomy and for those delivering care after insertion), staff and organisational communication issues, measurement of delivery as well as adapting the intervention to different settings[338].

7.3.1.3 Impact and outcomes

Any potential positive benefits related to the package of care delivered around early tracheostomy insertion may be difficult to identify given the negative outcomes associated with previous studies[332-334]. If this were to be the case this may be related to poor initial study design with a failure to fully define the intervention or poor implementation[339]. Surrogate endpoints designed to assess patient non-mortality related outcomes are likely to be required and may include duration of mechanical ventilation, length of critical care and hospital stay, incidence of delirium, assessments of neuromuscular function and psychological well-being. Further assessments of patient and family acceptance would also be required (see section 7.9). It is also possible that the positive effects of tracheostomy insertion may be seen even when the intervention package is not fully delivered. Whilst there may be no mortality benefit for early tracheostomy insertion the cessation of sedation may provide unexpected benefits that are more difficult to measure. From our own data 26% of patients undergoing tracheostomy do not survive to critical care discharge (table 5.1). It is possible, that in such patients, after sedation has been stopped an enhanced ability to communicate with family and friends may contribute to a more favourable end of life experience.

7.4 Aetiological factors associated with tracheal stenosis

In both our prospective cohort and within the systematic review we have attempted to identify factors present at tracheostomy insertion that may be associated with the aetiology of tracheal stenosis. To this end we have largely been unsuccessful. Within our own series, the reason for this was largely due to the low incidence of tracheal stenosis preventing meaningful interpretation of our data. Of the five stenoses observed one patient had a peri-operative tracheal ring fracture and oxygen

desaturation, another had marked laryngeal mucosal injury from trans-laryngeal intubation at tracheostomy insertion. The remaining three patients had uneventful tracheostomy insertions.

The only peri-operative event described within the literature and postulated to be associated with the development of tracheal stenosis is tracheal ring fracture at tracheostomy insertion[184-186]. Within our own series we reported a rate of tracheal ring fracture of 11% and a TS rate of 0.5%. Only one of those patients was noted to have a tracheal ring fracture at tracheostomy insertion. Additionally, a number of authors have noted differing rates of tracheal ring fracture with the various percutaneous techniques with reported rates being higher with the STD technique[54]. However, the pooled proportions meta-analysis from our systematic review suggested, that of the percutaneous techniques, the rate of TS for the STD was lowest – seemingly indicating a lack of correlation between ring fracture and TS. A further consideration to factor in is that tracheal ring fracture is almost certainly underreported following PDT and is largely dependent upon the bronchoscopist actively seeking this complication. This assertion is supported by work from cadaveric studies[340]. Walz undertook a clinico-pathological study of tracheal specimens following PDT from critical care patients who had died from causes unrelated to their tracheostomy. In twelve out of forty two specimens there was an inter-cartilaginous rupture of the tracheal wall associated with a tracheal ring fracture and in 10 of 42 there was a cartilage defect at the stomal site. Each of these specimens revealed denuded cartilage with necrotic lesions that were related to duration of cannulation.

From the data presented it would seem the most important aetiological factors associated with the genesis of TS are stomal and cuff related ischaemic damage, duration of cannulation and inherent patient factors.

7.5 Critical care survival

The survival data presented within Chapter 5 demonstrates significantly worsening outcomes with both increased illness severity and advancing age. This is in keeping with previously published data[341] and our own, as yet, unpublished observations (see below).

7.5.1 Survival to hospital discharge

We have studied a cohort of 505 elderly patients over the age of 80 years undergoing non-elective admissions to our critical care unit from January 2010 to December 2014. We have found the predominant predictors of survival to hospital discharge on univariate analysis are related to category of admission (medical versus surgical) and acute physiological derangement (APACHE II score, SOFA score & modified SOFA score) (table 7.3). Survival to hospital discharge appears to be unrelated to indices of chronic health and co-morbidities (Functional co-morbidity score, chronic health evaluation of APACHE II score).

Table 7.3 *Univariate analysis of factors predicting survival to hospital discharge of elderly patients admitted to Aintree University Hospital Critical Care Unit (n= 458). The most significant predictors are all related to the degree of acute physiological derangement present at critical care admission.*

	Odds ratio	95% CI	P
Gender	1.04	(0.73, 1.51)	0.801
Age	0.99	(0.94, 1.05)	0.760
Type of admission (Med / Surg)	1.67	(1.15, 2.43)	**0.007**
APACHE II Score	0..9	(0.87, 0.93)	**<0.001**
SOFA Score			
1-3	0.52	(0.31, 0.86)	**0.011**
≥ 4	0.31	(0.19, 0.50)	**<0.001**
AMSS			
2-4	0.58	(0.35, 0.96)	**0.033**
≥5	0.20	(0.12, 0.33)	**<0.001**
Functional Co-morbidity Score			
1	0.66	(0.39, 1.10)	0.112
2	0.86	(0.50, 1.46)	0.569
≥3	0.81	(0.45, 1.47)	0.487
Cardio-respiratory-FCS			
1	0.69	(0.47, 1.03)	0.071
≥2	0.75	0.41, 1.36)	0.338

APACHE II*: Acute Physiology Age & Chronic Health Evaluation*

SOFA*: Sequential Organ failure Assessment score*

AMSS*: Aintree Modified SOFA Score*

FCS *– Functional co-morbidity score*

The functional co-morbidity score assesses a range of 13 co-morbid states. For the presence of each co-morbid state the patient scores 1 if there is no co-morbidity the patient scores 0. The total score is that generated across all 13 disease states.

When considering multivariable analyses we find the only independent predictors of survival to hospital discharge is the modified SOFA score (table 7.4 & figure 7.3).

Table 7.4 *Multivariable analysis of factors predicting survival to hospital discharge of elderly patients admitted Aintree University Hospital Critical Care Unit (n= 458). The only significant association with survival to hospital discharge is the modified SOFA Score*

	Odds ratio	95% CI	P
APACHE II	0.67	(0.4, 1.13)	0.135
AMSS			
2-4	0.31	(0.17, 0.55)	**<0.001**
≥5	0.93	(0.89, 0.97)	**<0.001**

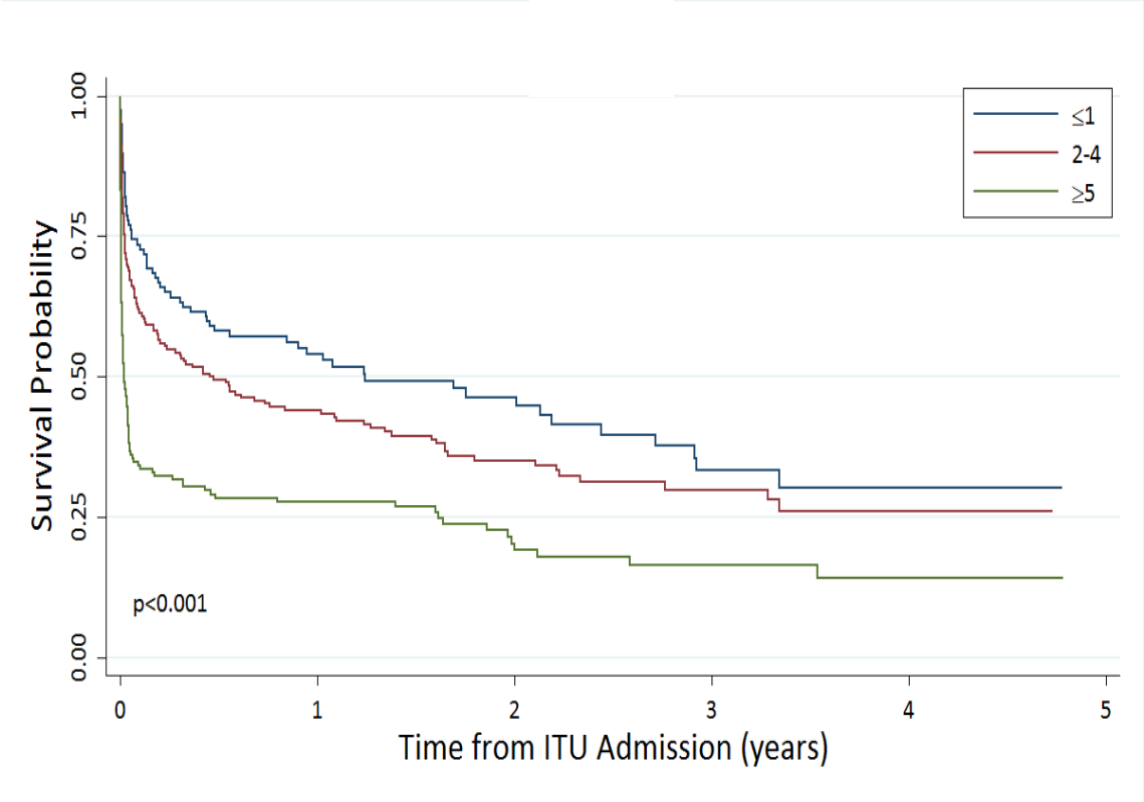
APACHE II: *Acute Physiology Age & Chronic Health Evaluation*

SOFA score *– Sequential Organ Failure Assessment*

AMSS *– Aintree Modified SOFA Score*

The modified SOFA score is amended to include scores for worsening pH and serum lactate measurements.

Figure 7.5 *Survival amongst elderly emergency admissions to Aintree University Hospital Critical Care Unit (n = 458) according to the ranked modified SOFA score shows worsening survival with increasing score (increasing physiological derangement). Score ≤ 1 n=117 (26%), score 2 - 4 n =186 (41%), score ≥ 5 n= 155 (34%).*



7.5.2 Survival to one year from critical care admission

In the same cohort of elderly non-elective critical care patients when considering univariate analyses the predominant factors predicting survival to one year remain the degree of acute physiological derangement present at admission (higher APACHE, SOFA and modified SOFA scores predicting worse outcomes) (table 7.5). However, when subjected to multi-variable analyses the independent predictors of 12-month survival are age, APACHE II score and a cardio-respiratory functional co-morbidity score of ≥2 (table 7.6 and figure 7.4). With each year increase in age one-year survival decreases by 8% and each unit increase in the APACHE II score reduces one-year survival by 6%. Median survival for those patients with Modified SOFA scores ≥5 are 7 days (95% CI 3 – 11) and for a cardio-respiratory functional co-morbidity score ≥2 are 43 days (95% CI 0 – 110)

Table 7.5 *Univariate analysis of factors predicting one-year survival for elderly patients admitted to Aintree University Hospital Critical Care Unit (n = 458). Even at twelve months after critical care admission the most significant predictors of long-term outcome continue to be those related to the degree of acute physiological derangement at critical care admission.*

	Odds ratio	95% CI	P
Gender	0.95	(0.64, 1.39)	0.786
Age	0.95	(0.89, 1.01)	0.100
Type of admission (med/surg)	1.34	(0.91, 1.97)	0.141
FCS			
1	0.94	(0.55, 1.60)	0.817
2	0.98	(0.56, 1.71)	0.939
≥3	0.93	(0.50, 1.72)	0.814
Apache:	0.92	(0.89, 0.96)	**<0.001**
SOFA Score:			
1-3	0.80	(0.49, 1.31)	0.374
≥4	0.60	(0.38, 0.97)	**0.037**
AMSS:			
2-4	0.88	(0.55, 1.40)	0.583
≥5	0.44	(0.26, 0.73)	**0.002**
CR-FCS:			
1	0.74	(0.49, 1.11)	0.147
≥2	0.51	(0.26, 1.01)	0.054

APACHE*: Acute Physiology Age & Chronic Health Evaluation*

SOFA*: Sequential Organ failure Assessment score*

AMSS*: Aintree Modified SOFA Score*

CR-FCS*: Cardio-respiratory functional co-morbidity score*

Table 7.6 *Multivariable analysis of factors predicting one-year survival for elderly patients admitted to Aintree University Hospital Critical Care Unit (n = 458). Only when we subject our data to multi-variable analysis does an element of chronic health appear to be significant.*

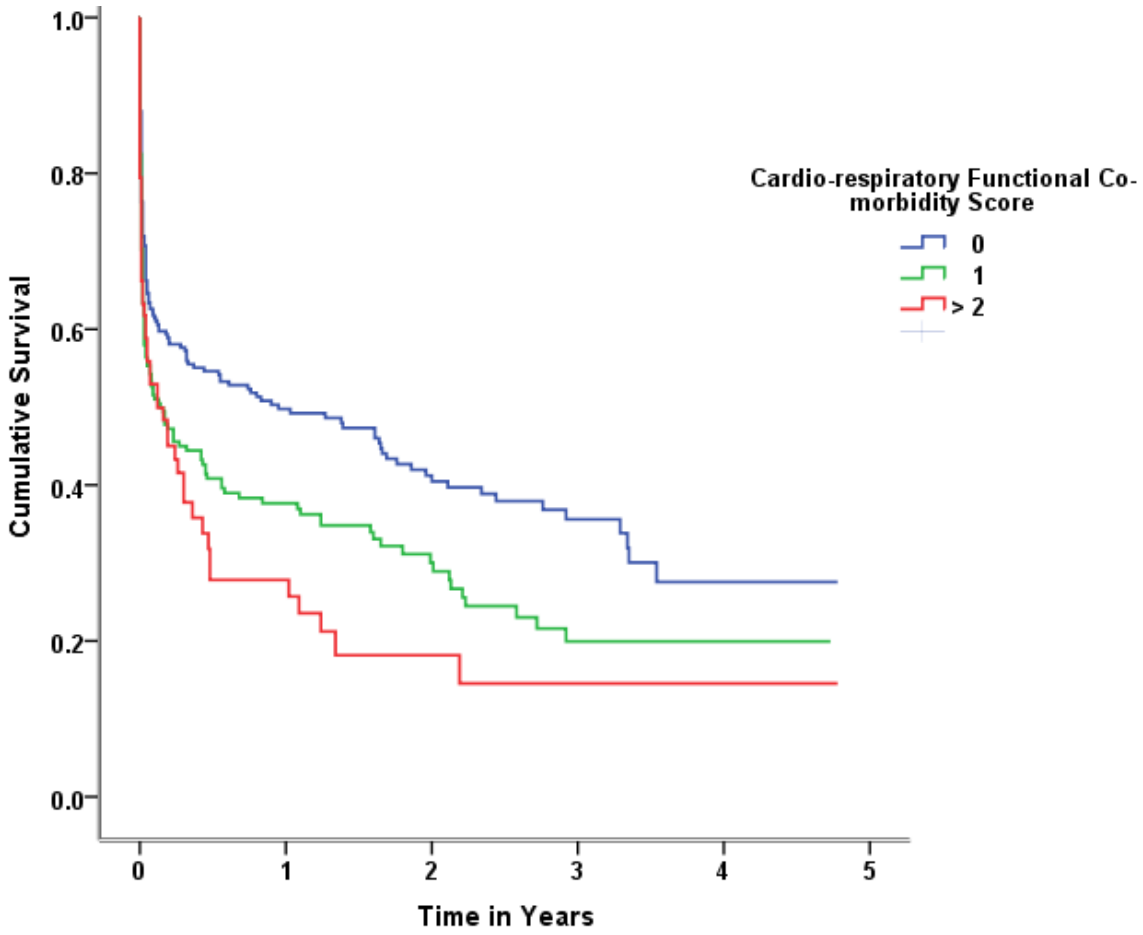
	Odds ratio	95% CI	P
Age	0.92	(0.87, 0.99)	**0.017**
Apache	0.94	(0.90, 0.97)	**0.001**
AMSS:			
2-4	0.97	(0.59, 1.60)	0.90
≥5	0.59	(0.33, 1.06)	0.08
CR-FCS			
1	0.79	(0.51, 1.22)	0.282
≥2	0.47	(0.23, 0.95)	**0.036**

APACHE*: Acute Physiology Age & Chronic Health Evaluation*

AMSS*: Aintree Modified Sequential Organ failure Assessment (SOFA) Score*

CR-FCS*: Cardio-respiratory functional co-morbidity score*

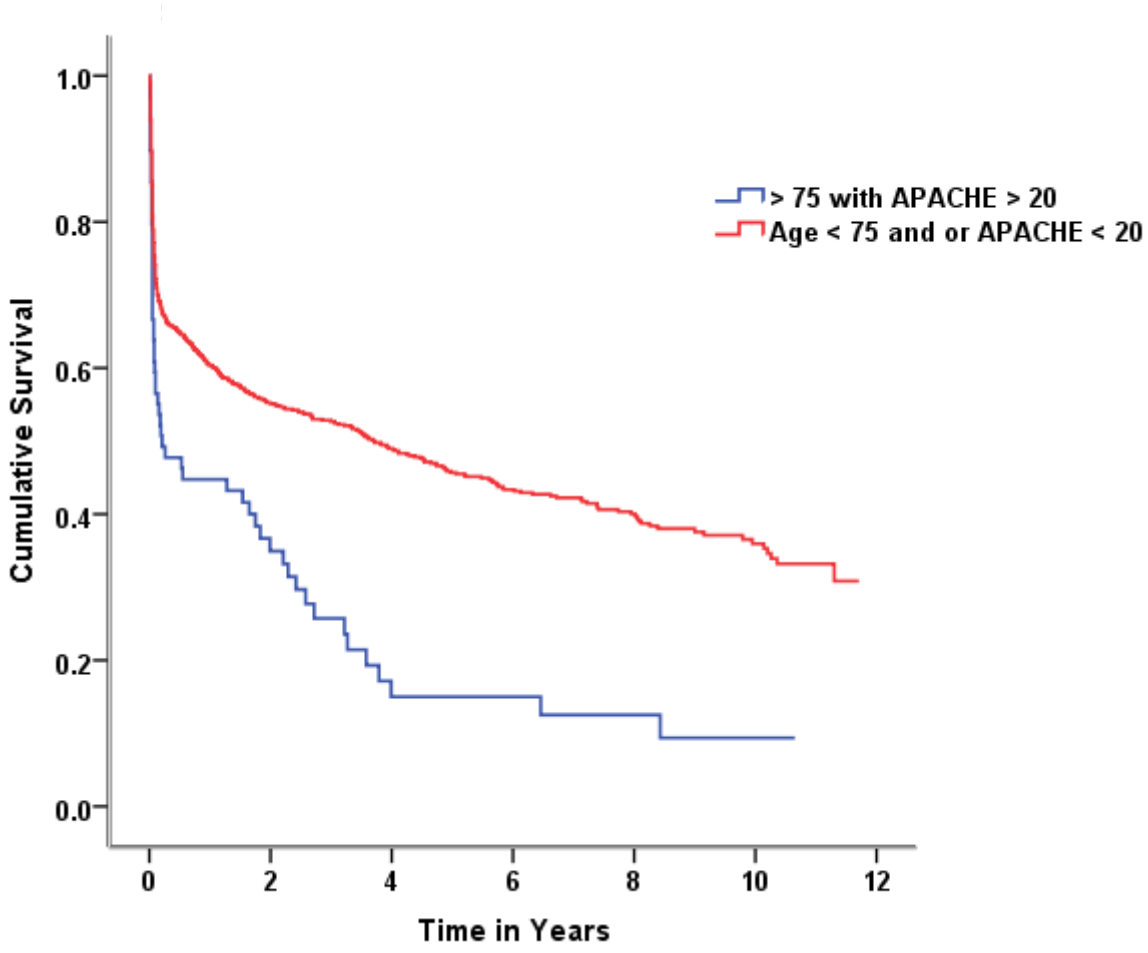
Figure 7.6 *Survival of a cohort of elderly non-elective patients admitted to Aintree University Hospital Critical Care Unit (n = 458) according to their functional co-morbidity score. Score 0 n =232 (51%), Score 1 n =173(38%), Score ≥ 2 n =53 (12%).*



When we attempt to make a more direct comparison between our tracheostomy data and our elderly survival data the similarities remain. For those over 80 years of age with an APACHE II score in excess of 20 the median survival is eight days. When we look solely at those tracheostomy patients over 75 years of age with an APACHE Score of ≥ 20 the median survival is 76 days compared to 3.7 years for those < 75 and / or with an APACHE II Score < 20 (figure 7.5). Whilst this survival is better than the elderly population alone it remains a very poor prognostic group. The discrepancy

between the two groups is probably accounted for by the fact that the elderly cohort is slightly older and an unselected group of patients reviewed from the date of admission. For the tracheostomy group, patients must survive a median of five days prior to tracheostomy insertion. Therefore, those patients with the worst prognoses will not undergo the procedure.

Figure 7.7 *Survival of patients undergoing percutaneous tracheostomy (n = 1025) comparing those over 75 years with and APACHE II Score ≥ 20 (n = 69) to the remainder of patients (n = 956).*



7.6 Critical care length of stay

Whilst the durations of critical care and hospital length of stays are somewhat less than previously published tracheostomy studies[58,80] it is probable that this is related to timing issues surrounding tracheostomy insertion. Most if not all of our tracheostomies are inserted prior to day ten of mechanical ventilation (median 5 days to PDT from critical care admission). Despite this apparently favourable comparison there is little doubt we would be able to reduce this length of stay with a more intense multi-disciplinary team involvement in patient assessment and rehabilitation[342]. To this end increased physical and occupational therapy services may improve functional

well-being, speech and language therapy input may improve swallowing (and thus reduce episodes of aspiration pneumonitis), nutrition and communication, psychological therapy may improve mental well-being and reduce the incidence of post-traumatic stress disorder. After critical care discharge the maintenance of the above services with enhanced input from the critical care outreach team may further reduce length of stay and allow earlier identification of patient deterioration. Despite this well recognised need for enhanced observation and rehabilitation amongst the critical care patient population easily achieved interventions are not frequently undertaken. In a recent study performed across 12 critical care units in Australia and New Zealand incorporating 192 patients 52% of patients were found to have critical care associated weakness which was associated with an increased risk of death following critical care discharge[343]. Despite this 84% of patients did not receive any attempts at early mobilisation (defined as any active exercise where the patient could assist the activity using their own muscle strength).

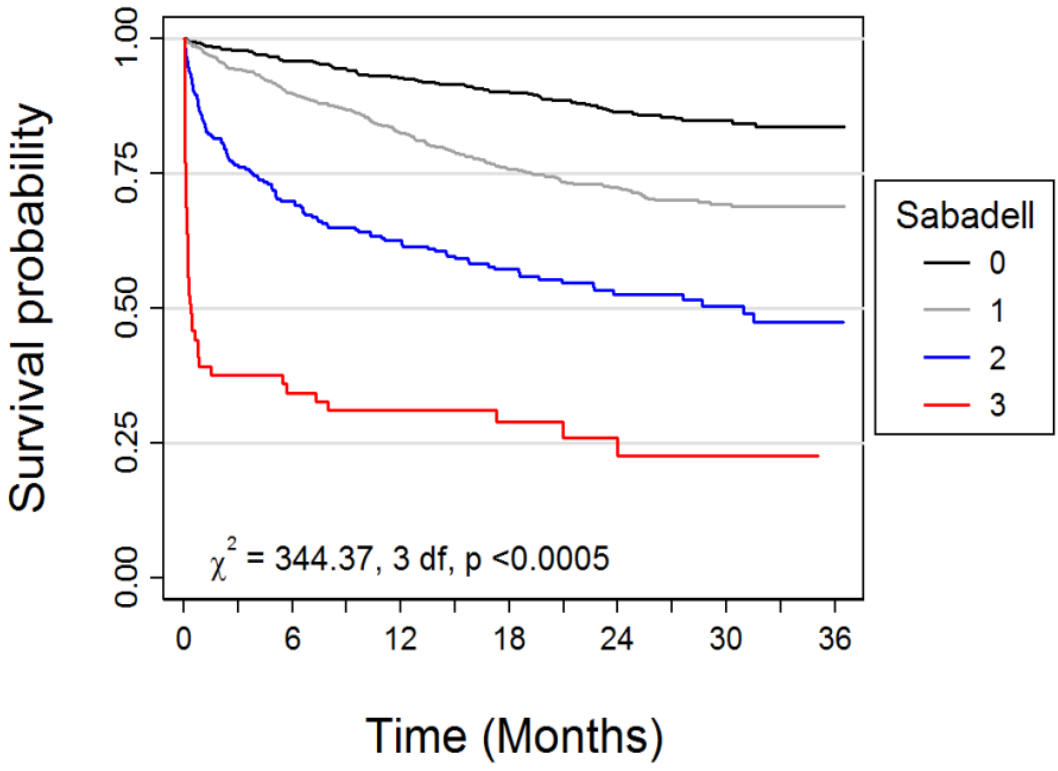
There remains, however, a degree of uncertainty relating to the implementation and timing of critical care rehabilitation programmes. In part this is due to a lack of funding for resource intense interventions where the outcome is not immediately demonstrable and in part from a lack of experience in delivering such interventions. The evidence is further clouded by the differing levels of physiotherapy support currently provided as the norm across units in North America, Europe and Australasia with much higher levels provided in Europe and Australasia [342]. A number of studies have demonstrated the benefits of early initiation of a rehabilitation programme[182,342,344,345] but this has not been universal[346]. The benefit of rehabilitation programmes instituted following critical care discharge have been more disappointing

with several trials failing to achieve a positive outcome[347-349] perhaps indicating that intervention at this point is too late.

7.6.1 Future work

Our own intention in relation to improving outcomes for patients discharged from our unit was to attempt a targeted intervention based on our use of the Sabadell Score. We have shown that the in hospital mortality of patients discharged from our unit who are assigned a Sabadell 2 score is 16% (figure 7.6). We postulated that by targeting an intense rehabilitation programme, involving increased senior medical, physiotherapy and critical care outreach nursing input, toward a group of patients at high risk of in-hospital mortality we may be able to improve on earlier studies where the intervention has been delivered to all patients discharged. We have, so far, been unable to secure funding for this project.

Figure 7.8 *Survival from the point of critical care discharge according to the Sabadell Score – data from Aintree University Hospital 2011 -2013 (n = 1916). The Sabadell score is a subjective scoring system applied at critical care discharge based on the patient's expected long-term prognosis. Sabadell 0 patients (n = 652 (34%)) would be expected to have a good long-term prognosis and survive beyond 12 months. Sabadell 1 patients (n = 954 (50%)) would be expected to have a good short-term prognosis but with survival beyond 12 months less clear. Sabadell 2 patients (n = 249 (13%)) would be expected to have a poor short-term prognosis but survival to hospital discharge would be expected. Sabadell 3 patients (n = 61 (3%)) would be expected to die within the same hospital admission.*



7.7 Percutaneous tracheostomy use outside the critical care unit

7.7.1 Emergent airway access

Despite several of the early developments in relation to percutaneous tracheostomy being suggested as suitable interventions for gaining emergent airway access[37,38] current guidelines preclude its use,[350] frequently suggesting it as a contraindication[351]. Despite this, however, there are a number of reports of the successful use of PDT in

the emergency setting.[352-356] It seems likely, that those expert in the insertion of a PDT would be able to achieve emergent airway access within the time frame consistent with a satisfactory neurological outcome. It also seems likely that such individuals would be much more comfortable gaining airway access in this setting via a PDT rather than using those techniques set out within difficult airway guidelines.

7.7.2 Future work

We would like to further investigate the hypothesis that PDT insertion in the emergency airway setting is contra-indicated. We would postulate that for those expert in its insertion it may be a credible alternative to crico-thyroidotomy. We would assess this using a bench test of timed airway access using either an airway mannequin or pig larynx. We would assess two groups of individuals trained in airway management but with one group also being expert in PDT insertion (intensivist group). We will assess time to securing the airway via surgical means according to the Difficult Airway Society surgical crico-thyroidotomy approach and also via a standard STD PDT approach. We could potentially expect a rapid securing of the airway with the STD PDT in the intensivist group but assessment of the speed of airway access in the non-expert group would also be an interesting addition to the literature.

7.8 Percutaneous versus surgical tracheostomy in the elective setting

Despite our unit housing the largest Head and Neck unit within the UK we have limited experience in the use of PDT in the setting of elective head and neck cancer surgery. We have used PDT in a small number of such patients but this was abandoned for reasons other than those related to PDT insertion. Use of PDT within an elective head and neck cancer population have formed part of some studies

assessing PDT outcomes[357] but the majority of patients within this study were critically ill. There are no reports detailing the use of PDT solely within a head and neck cancer population. In addition to the low morbidity we have described herein there are other benefits that may be realised in the head and neck oncology patient. It has been clearly shown, both within our own meta-analysis and others, that the incidence of stomal infection is reduced with PDT. Siting of the PDT in a surgical patient allows the tracheostomy wound to be clearly separated from any neck wound. This, in association with the reduced rate of stomal sepsis, may lead to a reduction in post-operative neck wound infection in elective cancer patients if routine PDT use were considered. Significant safety related concerns would, however, remain should the tracheostomy become displaced in the early post-operative period. The use of PDT within our unit stopped following a case of accidental decannulation (non-PDT patient) on the first post-operative night in a patient undergoing tumour resection and free tissue transfer. In this patient it proved impossible to rapidly re-secure the airway leading to a hypoxic brain injury. Our current practice, therefore, is to use Bjork flap surgical tracheostomies in these patients. Despite these concerns, within the critical care unit (where these patients are routinely nursed), we have not had a significant problem with accidental decannulation for either surgical or percutaneous tracheostomies.

7.8.1 Future work

Whilst we have no current plans to explore the role and efficacy of percutaneous tracheostomy in the elective surgical setting this would be a relatively simple undertaking. A small randomised pilot study may help to evaluate a potential place for PDT in this setting. We would assess not only the safety concerns relating to inadvertent post-operative decannulation that have previously been raised within our

unit but also its effect on post-operative infection and the impact on the patient experience. Given the general dislike of tracheostomies amongst the surgical population further work may explore the role of smaller tracheostomy tubes, uncuffed tubes and guidelines toward earlier decannulation for these patients.

Widespread adoption of percutaneous tracheostomy within the elective surgical setting would, however generate its own concerns. Currently head and neck surgeons in training gain experience required for securing the emergency surgical airway in the elective setting. If percutaneous tracheostomy were to be widely adopted in favour of surgical this could potentially raise significant training issues and a deskilling of the surgical team.

7.9 Perceptions of tracheostomy in critical illness survivors

As can be seen above (table 7.2) the reasons for tracheostomy insertion within critical care are frequently subjective with sometimes questionable evidence to support the decision making process. It is often assumed by critical care staff that tracheostomy insertion leads to a more settled and comfortable patient. This is in stark contrast to the experience of our head and neck unit where the presence of the tracheostomy is often the most complained about aspect of surgical head and neck cancer care (personal communication). The assumption that patients are more comfortable has, however, been relatively untested. In a review of qualitative studies of patient experiences related to weaning from mechanical ventilation Cook described uncertainty, stress, discomfort and a lack of control of surroundings and events as common themes[358]. Whilst not all of the patients assessed within this analysis will have had tracheostomies inserted it is easily appreciated that many of these symptoms could be ascribed to such patients. In a small qualitative study of eight patients (not exclusively critical care patients) Sherlock undertook a semi-structured interview to

identify common factors relating to their tracheostomy experience[359]. All but two of the patients included had been decannulated at the time of interview. They divided their interviews and responses into four themes namely; physical sensations, understanding, information and feelings after tracheostomy removal. They found that whilst most patients understood the reason for the tracheostomy and understood the reasons for its presence there were less positive experiences reported in relation to the physical presence of the tube, eating and drinking, tracheal suctioning and communication. Additionally, three of the six patients who had been decannulated reported panic attacks following removal of the tube despite happily anticipating this event. Whilst Sherlock's study offers some insights in to the experiences of tracheostomised patients it does not exclusively study critical care patients. Additionally, only patients capable of participating in 45-minute interview with a recordable voice were included and all had previously undergone at least one tracheostomy change. The evolving contemporaneous experiences of these patients as they progress through their critical care stay are yet to be documented although some insight in to this has been provided by Flinterud[360]. In a study of eleven patients from a university hospital in Norway they documented similar emotions to those described by Sherlock namely frustration, panic and anger, powerlessness, despair and loss of control. However, they also noted a time related improvement associated with development of coping strategies to enable easier communication.

7.9.1 Future work

It is our intention to explore the patient experience in relation to tracheostomy insertion in more detail over the coming months and years. We initially envisage a study conducted solely within the critical care unit undertaken with patients who have their tracheostomy in situ at the time of interview. We would also like to capture the

experience of the small group of patients who tolerate oro-tracheal intubation without sedation prior to either extubation or tracheostomy and compare their experiences with those of patients with tracheostomies. We would then intend to follow up all surviving patients to compare their memories and experiences following decannulation or extubation. Additionally, we would like to compare the experiences of these patients with those of their carers and families. To this end, we would hope to either confirm or refute much of the subjective reasoning behind tracheostomy insertion in the critically ill.

7.10 Conclusion

From the limited published data we have not found a significant difference in the incidence of TS between a range of percutaneous techniques and surgical tracheostomies. When considering all published data reporting long-term outcomes, our pooled proportions meta-analysis may indicate a tendency toward a higher rate of TS for ST but this finding is likely to be prone to selection bias. Similarly, in relation to major bleeding, we have not found a difference between the techniques commonly used. Again the pooled proportions meta-analysis may indicate a tendency toward more major bleeding for ST. In relation to wound infection we have found a reduction associated with CPDT compared to ST in keeping with earlier work[51]. Across all percutaneous techniques for the primary and secondary outcomes studied complication rates appear to be broadly similar but confidence intervals for pooled risk differences are wide and include clinically important differences in both directions.

Whilst the reported complication rates presented within our cohort study are in keeping with, if not an improvement upon, those published previously, this remains a

single centre evaluation with its attendant limitations. It may, however, add weight to the gathering evidence that the STD PDT is one of the safer techniques available. Our rate of early technical difficulties appears to be reducing whilst long-term outcomes remain unchanged.

We have demonstrated a lower rate of sub-clinical stenosis in patients following STD PDT than has previously been reported. Whilst we considered that some degree of functional limitation, in such patients, following critical care discharge might be in part due to an underlying prevalence of TS this would appear not to be the case. Those stenoses found were felt to be of doubtful clinical significance with no patients requiring corrective surgery and all, ultimately, discharged from further follow up. Routine radiological imaging and spirometry following STD PDT would appear to be unwarranted in asymptomatic patients. The principal limitation of this study is related to the small sample size being significantly underpowered for the stated intent. This was in a large part due to the funding limitations placed upon us. We were able to undertake the study due to grant monies received from the Intensive Care Society UK but this only allowed us to perform 50 MRI scans. It is doubtful, however, given the unremarkable nature of the findings of this study whether further scanning would have yielded significantly different results. Additionally, given the limited numbers of patients who experienced post-operative complications (particularly tracheal ring fracture) and prolonged cannulation we would have needed to both capture almost all patients in both categories and significantly extend the study period to provide a more meaningful analysis.

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Appendices

Appendix 1.

Additional data extracted from systematic review papers

Mean APACHE II / Mean SOFA scores
Location of procedure
Operator experience
Mean duration trans-laryngeal intubation (days)
Mean duration of tracheostomy
Duration sedation post tracheostomy
Mean ventilator dependent days
Mean critical care unit length of stay
Mean Hospital length of stay
Mortality (1 month procedure)
Average duration of procedure (minutes)
Number of episodes hypoxia (S_aO_2 < 91%)
Number of cardiac arrhythmia
Incidence of hypotension (systolic blood pressure <90mmHg)
Number of tracheal cuff punctures
Number of paratracheal insertions
Number of tube displacements or loss of airway
Number of pneumothorax
Number of pneumomediastinum
Number of subcutaneous emphysema
Episodes of atelectasis
Incidence of aspiration
Number of oesophageal injuries
Number of posterior tracheal wall injury
Number of peri-operative mortalities
Number of peri-operative cardiac arrest
Number of pneumonias
Frequency of delayed wound healing (> three weeks)
Number of tracheo-innominate artery fistula
Incidence of failure to decannulate
Number of reintubations
Difficulty in recannulation
Hypercapnia
Increased airway pressure
Stomal enlargement
Tracheal dilatation
Dysphagia
Respiratory problems
Bronchoscopic damage
Poor visualisation of tracheal structures
Late tracheal wall injury / haematoma / swelling
Chyle leak (requiring intercostal drainage)
Laryngeal perichondritis

Appendix 2

Assessment of tracheal stenosis following percutaneous tracheostomy

Outpatient appointment date: __/___/__

Patient sticker

Date of critical care admission: __/___/__
Date first intubated: __/___/__

No. extubations pre-tracheostomy: _____
Date of percutaneous tracheostomy: __/___/__
Date of decannulation: __/___/__

(Dates of re-cannulation, if applicable:)

Complications of tracheostomy: _____

Pre-existing respiratory disease

Smoking history: _____ pack years Still smoking Y/N
Established COPD: Y/N
Other respiratory disease:_____
Pre-ITU spirometry: FEV_1_____l FVC_____l
Pre-ITU Exercise tolerance on flat:_____m Limiting factor:

Current symptoms

Change in voice Y/N
Short of breath Y/N Exertion/ rest
Stridor Y/N Exertion/ rest
Exercise tolerance on flat: ____m Limiting factor:
Other:
(difficulty expectorating? difficulty swallowing? problematic scar?)

Examination

Scar Not visible/ Acceptable/ Disfiguring/ Tethering
Short of breath Y/N Exertion/rest
Stridor Y/N Exertion/ rest

Spirometry

Measured values					**Calculated values**	
	1.	2.	3.	Best		
FIF50						
FEF50					FEF50/ FIF50	
FEV_1					FEV1/PEFR	
PEFR						
FVC					FEV_1/FVC	

NB. Any one of: FIF50 <100 l/min, FEF50/FIF50 ≥1, FEV1/PEFR > 10l/ml per min

Appendix 3

Publications associated with this work

1. Kumar VM, Grant CA, Hughes MW, Clarke E, Hill E, Jones TM, **Dempsey GA**. Role of routine chest radiography after percutaneous dilatational tracheostomy. *British Journal of Anaesthesia* 2008;**100** (5): 663–6
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2. Grant CA, **Dempsey G**, Harrison J, Jones T. Tracheo-innominate artery fistula after percutaneous tracheostomy: three case reports and a clinical review. *British Journal of Anaesthesia* 2006; **96** (1): 127–31
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3. **Dempsey GA**, Grant CA, Jones TM. Percutaneous tracheostomy: a 6 year prospective evaluation of the single tapered dilator technique. *British Journal of Anaesthesia* 2010;**105** (6): 782–8
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4. Young E, Pugh R, Hanlon R, O'Callaghan E, Wright C, Jeanrenaud P, Jones TM, **Dempsey GA**. Tracheal stenosis following percutaneous dilatational tracheostomy using the single tapered dilator: an MRI study. *Anaesthesia & Intensive Care* 2014; 42(6):745-751
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5. **Dempsey GA**, Morton B, Hammell C, Williams LT, Tudur-Smith C, Jones TM. Long-term outcome following tracheostomy in critical care: A systematic review. *Critical Care Medicine in press.*
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Role of routine chest radiography after percutaneous dilatational tracheostomy

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Background. The role of routine chest radiography (CXR) after percutaneous dilatational tracheostomy (PDT) has been questioned.

Methods. We performed a prospective observational study, on a mixed medical/surgical critical care unit in a university teaching hospital. We studied all patients undergoing PDT as part of their critical care management from November 1, 2003 until July 31, 2007. All PDTs were performed under bronchoscopic guidance. After PDT, we reviewed the immediate post-procedural films to assess the utility of routine postoperative CXR. For the purposes of CXR review, we considered a procedure to be either uncomplicated or technically difficult. Clinically relevant CXR findings were new barotrauma (pneumothorax, pneumomediastinum) or a significant change in consolidation from the pre-procedure film.

Results. A total of 384 patients underwent PDT during the study period. Of these, 345 had immediate post-procedural CXRs available for review. There were 252 PDTs (73%) documented as uncomplicated. There were 93 (27%) technically difficult procedures, with 107 adverse events recorded. In 82 (24%) procedures, these difficulties were described as minor procedural complications [multiple attempts at needle insertion ($\geq$3), minor bleeding or tracheal ring fracture]. Significant complications (mal-placement in the anterior mediastinum and major bleeding) were documented in 12 (3.5%) patients. New abnormalities were noted on 8 (2.3%) immediate post-procedural CXRs. In only one patient was there a new CXR change in an uncomplicated PDT.

Conclusions. Immediate CXR after uncomplicated PDT performed under bronchoscopic guidance rarely reveals unexpected radiological abnormalities. The role of CXR after PDT appears to be restricted to those patients undergoing technically difficult and complicated procedures. A change in practice to this effect will lead to reductions in both medical costs and exposure of staff and patients to ionizing radiation.

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Percutaneous dilatational tracheostomy (PDT) has become a commonly performed procedure in the intensive care unit (ICU) in those patients subjected to prolonged mechanical ventilation.[1] It has largely replaced the conventional surgical tracheostomy in critical care patients, with benefits in terms of cost, ease of performance, and reduced complications.[2] Significant complications associated with PDT, including haemorrhage,[3] pneumothorax,[4] and paratracheal placement,[5] have ranged in various series from 3 to 18%.[6 7] Several authors have claimed that bronchoscopic guidance during PDT provides a higher degree of safety and decreases the incidence and severity of complications.[8 9] The role of the post-procedural chest X-ray (CXR) has been investigated by other authors. Their work concluded that there is little or no role for routine CXR after PDT.[10–13 15] However, because of the small sample sizes used, these conclusions have been criticized.[14]

Post-procedural CXR has been a standard practice in our institution since the introduction of PDT more than

14 years ago. It has been our impression that this investigation rarely impacts upon patient management. The aim of this study was, therefore, to determine whether routine CXR after insertion of a PDT resulted in the detection of unexpected clinically significant complications. We also sought to address criticisms of previous work by investigating a larger patient population in a prospective manner.

Methods

This prospective study was undertaken at University Hospital Aintree (UHA) Critical Care Unit, a 19 bedded mixed medical/surgical unit performing 110–120 tracheostomies per annum, 97% of which are PDTs. As no additional interventions were performed, this was considered to be under the remit of audit and hence consent was deemed unnecessary.

All patients undergoing PDT from November 2003 to July 2007 were studied. All procedures were performed at the bedside under bronchoscopic control using a Ciaglia Blue Rhino® Percutaneous Tracheostomy Introducer Set (Cook Medical). The CXR examined was the immediate post-procedural film. Clinically relevant CXR findings were considered to be new barotrauma (pneumothorax and pneumomediastinum) and a significant change in consolidation from the most recent pre-procedure film. Other data recorded included age, sex, time to insertion of tracheostomy from ICU admission, and seniority of a supervising doctor.

In defining a complicated procedure, for the purposes of CXR review, we felt that it was important to include PDTs that were technically challenging in addition to the more traditional classifications of a complicated procedure. Our institution's tracheostomy proforma requires all procedural related events to be documented by the operator. This allows for recording of technical difficulties and documentation of clinically insignificant events and periprocedural events with clinical sequelae. A PDT was considered technically difficult if there was one or more of the following during the procedure: oxygen desaturation (major if $\leq$90%, minor if $\geq$2% desaturation from baseline), multiple attempts ($\geq$3) at tracheal cannulation, bleeding (major if $\geq$3 swabs, minor if $<$3 swabs), tracheostomy tube misplacement, surgical emphysema, cardiovascular instability, supra-stomal tracheal ring fracture, and posterior tracheal wall injury (major if mucosal tear, minor if single puncture).

Each PDT was, therefore, considered to be either technically difficult or uncomplicated for the purposes of CXR analysis.

Results

During the study period, 384 patients underwent a PDT as part of their critical care management. There were 345 (90%) immediate post-procedural films available for review. As our institution has recently moved to a digital radiology system, this accounts for some films being unavailable.

The characteristics for the 345 PDT patients are shown in Table 1. The most senior physician present during the PDT was a consultant in 223 (67%) procedures, an advanced level critical care trainee in 94 (28%) procedures and a registrar in 16 (5%) procedures.

There were 107 adverse events recorded during 93 (27%) technically difficult PDTs. The majority of these were minor procedural complications (Table 2). Significant procedural complications occurred during 12 (3.5%) PDTs, these consisted of significant ($>$3 soaked swabs) bleeding (3), mal-positioning of the tracheostomy tube (4), severe surgical emphysema (4), and significant posterior tracheal wall injury (1). There were a total of eight significant new abnormalities on immediate post-procedural CXRs. Of these abnormalities, one occurred in the uncomplicated group and seven occurred in the technically difficult group. The new CXR abnormality in the uncomplicated group was subcutaneous emphysema; however, this was overlooked by the critical care clinicians. In this patient, a tension pneumothorax developed within 24 h of the PDT. The seven CXR abnormalities in the complicated group consisted of two pneumothoraces, one pneumomediastinum (after tracheostomy tube misplacement), and four episodes of significant surgical emphysema. There were no instances of a significant change in consolidation between the pre- and post-procedural films.

Discussion

The overall complication rate of 27% post-PDT under bronchoscopic guidance in our institution would initially appear disproportionately high. However, we feel that this can be explained by our broadening the definition of a 'complicated' procedure to include technical difficulties in addition to conventional complications. Our liberal interpretation of a complicated PDT was, we felt, necessary as technical difficulties, which do not necessarily result in clinical sequelae, are not included in the traditional description of what comprises a complication but could feasibly result in CXR changes. The true value of the post-procedural CXR cannot be appreciated if it is used indiscriminately.

The data we present suggest that by targeting these technically difficult procedures, which actually means a CXR

Table 1 Patient characteristics. Data are given as mean (SD) or median [IQR]

Age (yr)	59 (15.3)
Admission APACHE II score	19 (5.3)
Male, *n*	196
Medical, *n*	160
Day to PDT	5 [4]

Table 2 Technical difficulties

Technical difficulty	Number
Multiple tracheal punctures (≥3)	34
Tracheal ring fracture	34
Posterior tracheal wall injury	9 (1 major)
Oxygen desaturation	4
Bleeding	18 (3 major)
Tracheostomy tube misplacement	4
Surgical emphysema	4

for 27% of PDTs, we direct the radiological investigation more effectively. So, when making recommendations in the past regarding the value of post-procedural CXR, it could be argued that poor yields were, in part, as a result of the widespread use of this investigation. Our rate of traditionally defined significant complications was actually 3.5% and is in keeping with the low rates reported by others.[16]

In this study there were two pneumothoraces detected on the immediate post-procedural CXR, giving an incidence after PDT of 0.6%. Despite the use of bronchoscopic control, the tracheostomy tube was misplaced during four PDTs, resulting in significant subcutaneous emphysema. On three occasions, the tube was placed in the anterior neck/mediastinum, resulting in a CXR finding of pneumomediastinum in one patient, and on one occasion the tube was inserted through the crico-thyroid membrane. In the three cases of extra-tracheal placement, tracheal tube sizes were such that effective ventilation of the lungs was inadequate with a bronchoscope *in situ*. The bronchoscope was, therefore, used to confirm correct placement of the guide wire within the trachea. Thereafter, the bronchoscope was removed to allow continued ventilation. It was subsequently re-inserted to confirm or refute intra-tracheal tube placement.

Given the low incidence of complications during PDT, it is likely that routine use of CXRs post operatively will have a low detection rate of new CXR findings. It is therefore unsurprising that the overall detection rate for new CXR findings after operation was 2.3% (8/345). We have shown that in the 252 uncomplicated PDTs there was one unexpected CXR finding on the immediate post-procedural film which ultimately resulted in a tension pneumothorax. Therefore, in seven of the eight cases the new CXR changes were found in the technically difficult group (two pneumothoraces, one pneumomediastinum and four cases of subcutaneous emphysema). In the cases of those patients with subcutaneous emphysema, this was immediately diagnosed clinically. In no patient was there an underlying pneumothorax, despite there being new CXR changes, and so clinical management remained unaltered.

Our study differs from earlier work in that it is both prospective and significantly larger than earlier published studies. In introducing the concept of a technically difficult PDT, it is immediately apparent that more CXRs will be performed than if one were restricting post-procedural CXRs to traditionally defined complicated PDTs. Indeed, previous authors have suggested that there is no role for routine CXR after PDT.[10 17] From the data presented here; however, we would suggest that there is a role following a technically difficult PDT, which in the current series would amount to performing a post-procedural CXR in 27% patients. The paper by Datta and colleagues[10] was criticized for recommending that post-procedural CXR was not necessary after a retrospective assessment of only 60 patients. Haddad and colleagues[17] studied 239 patients but used a conventional definition of a 'complication' and hence may account for their only new finding of atelectasis in 10% of patients. In our 252 patients undergoing uncomplicated PDT, the detection rate for new abnormalities on CXR was 0.4%. In the 93 patients undergoing a technically difficult PDT, the detection rate for new CXR abnormalities was 7.5%. Given that the majority of these abnormalities were related to the presence of subcutaneous air, which was clinically evident in all cases before CXR, the yield of unexpected new abnormalities on CXR in this group was still low.

Since we have found only one new abnormality in the 73% patients who underwent an uncomplicated PDT on the immediate post-procedural CXR, there would appear to be little utility in this investigation in this group of patients. However, the failure to recognize this subcutaneous air subsequently led to the development of a tension pneumothorax. Had this subcutaneous air been recognized on the immediate CXR, it is still likely that there would have been no change in the initial post-PDT clinical management other than a greater degree of vigilance in the postoperative period. Therefore, we would still argue that there is no role for routine CXR in the setting of uncomplicated PDT. However, it could equally be argued that given the subsequent gravity of this complication post-procedural CXRs are still warranted in this group of patients.

If one accepts the argument that post-procedural CXRs are unnecessary after a truly uncomplicated PDT, then this will lead to modest cost savings and a reduction in the exposure of staff and patients to ionizing radiation (a single CXR equates to 0.1 mSv or 10 days of background radiation) within the critical care unit. In our institution, the distance of the tip of the tracheostomy tube from the carina is routinely measured with the bronchoscope and so we do not require radiographic confirmation of this measurement.

We feel, therefore, that the rate of new CXR findings of 7.5% in the technically difficult group is high enough to justify continued routine utilization of post-procedural CXRs in this group. Only in truly uncomplicated PDTs, with a new abnormality rate on post-procedural CXR of 0.4%, there is, arguably, no role for routine post-procedural CXR.

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Case Report

Tracheo-innominate artery fistula after percutaneous tracheostomy: three case reports and a clinical review

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Tracheo-innominate artery fistula (TIF) is an uncommon yet life threatening complication after a tracheostomy. Rates of 0.1–1% after surgical tracheostomy have been reported, with a peak incidence at 7–14 days post procedure. It is usually fatal unless treatment is instituted immediately. Initial case reports of TIF resulted from surgically performed tracheostomies. We present three fatalities attributable to TIF, confirmed by histopathology, after percutaneous dilatational tracheostomy (PDT). The use of PDT has resulted in tracheostomies being performed by specialists from different backgrounds and the incidence of this complication may be increasing. Pressure necrosis from high cuff pressure, mucosal trauma from malpositioned cannula tip, low tracheal incision, radiotherapy and prolonged intubation are all implicated in TIF formation. Massive haemorrhage occurring 3 days to 6 weeks after tracheostomy is a result of TIF until proven otherwise. We present a simple algorithm for management of this situation. The manoeuvres outlined will control bleeding in more than 80% of patients by a direct tamponade effect. Surgical stasis is obtained by debriding the innominate artery proximally, then transecting and closing the lumen. Neurological sequelae are few. Post-mortem diagnosis of TIF may be difficult, but specific pathology request should be made to assess innominate artery abnormalities.

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Percutaneous dilatational tracheostomy (PDT) has become a standard technique in critical care medicine. As a result of its widespread use, it continues to attract controversy and debate. The UK Intensive Care Society recently launched the TracMan trial which concluded in its preface that PDT is 'a common procedure but with limited evidence base to support its use.' We present three fatalities resulting from tracheo-innominate artery fistulae (TIF) after PDT.

Although possible to perform under local anaesthesia, the majority of PDTs are performed under general anaesthesia with neuromuscular block on Critical Care Units by non-surgically trained operators. Complications of PDT are traditionally divided into early and late. The majority of publications centre on early complications including bleeding, pneumothorax, technical failure and perioperative hypoxia.[1] The major reported late complications include tracheo-oesophageal fistula, tracheomalacia and tracheal stenosis.[2]

TIF is an uncommon yet life threatening complication that can occur after a tracheostomy. Reported incidence is 0.1–1% after surgical tracheostomy, with peak incidence 7–14 days post procedure.[3 4] It is usually fatal unless treatment is instituted immediately.[5 6] We present a case-series of tracheo-innominate arterial fistulae after PDT with histopathological confirmation.

Case 1

A 43-yr-old female with a community-acquired pneumonia presented to the Critical Care Unit requiring invasive ventilatory support. Subsequent management included an uneventful PDT 11 days from her critical care admission.

Two subsequent uneventful tracheostomy tube exchanges were performed during the admission. Thirty-two days after this procedure, a small haemorrhage developed from the tracheostomy site. This was self-limiting and bronchoscopic investigation did not identify a bleeding site within the respiratory tract. Similarly, no signs of inflammation or infection were present in the tracheostomy wound. However, within 3 h of this initial bleed, massive oral and tracheal haemorrhage occurred. Bleeding did not initially appear pulsatile but the volume of blood prevented effective oxygenation. The trachea was intubated translaryngeally, allowing removal of the tracheostomy tube, inspection of the stoma and digital compression of the suspected bleeding site. Failure to terminate the bleeding and persistent suboptimal ventilation resulted in a fatal cardiac arrest.

Case 2

A 57-year-old male was admitted to the Critical Care Unit following a road traffic accident. His injuries consisted of a fractured pelvis, which required external fixation, and an extensive retroperitoneal haemorrhage. Inability to withdraw mechanical ventilation and an associated pneumonia led to an uneventful PDT on Day 11. Twelve days after the PDT, his respiratory function had improved sufficiently to allow consideration of decannulation. However, prior to this, sudden haemorrhage developed via the tracheostomy tube. Adequate ventilation failed because of the amount of blood in the major airways. Tracheal intubation was achieved via the translaryngeal route. It was not possible to identify a bleeding point and a double lumen endobronchial tube and bilateral intercostal drains were inserted. Unsuccessful attempts, using fibreoptic bronchoscopy, to suction the aspirated blood from the tracheobronchial tree followed. It proved impossible to re-establish effective ventilation, resulting in a fatal hypoxic cardiac arrest.

Case 3

A 69-yr-old female was admitted to the Critical Care Unit after an elective oesophagogastrectomy for oesophageal carcinoma. Her initial postoperative course was uncomplicated until Day 5 when she developed bronchopneumonia. On Day 8, inspiratory stridor and acute respiratory failure led to emergency tracheal intubation and mechanical ventilation. A PDT followed on the same day. Her subsequent management was unremarkable and artificial ventilation was discontinued by Day 10. She was discharged to the ward with a tracheostomy tube *in situ*. On Day 17, she developed massive haemorrhage into the airway resulting in desaturation and cardiac arrest. Despite translaryngeal intubation and prolonged attempts to clear the airway, resuscitation was not possible.

Each procedure was bronchoscopically guided and performed in the presence of an intensive care consultant. Ciaglia Blue Rhino® (Cook, Letchworth, UK) tracheostomy set was used and a size 8.0 mm Crystal Clear® (Rusch, Lurgan, UK) tracheostomy tube was used in each case. Each PDT was considered to have been between tracheal rings I and IV. All cuff pressures were monitored regularly, as is our standard practice.

The occurrence of these three cases within 18 months of each other aroused clinical suspicion of a potential link in underlying pathology. After direction from the clinicians involved, the subsequent post-mortem examinations looked specifically at both the tracheostomy site and the tracheo-innominate trunk.

As a result of their small size, post-mortem diagnosis of TIF can be difficult. For all three patients, sections from the tracheo-innominate artery at the level of the tracheostomy site revealed a small focus of active chronic inflammation extending through the full thickness of the arterial wall into the luminal surface. Histological evidence of necrosis was identified extending through the adjacent wall of the trachea with consequent focal disruption of the tracheal wall. The histopathological confirmation of a TIF was reported on the subsequent death certificates.

Tracheo-innominate fistula

The true incidence of this rare complication is difficult to assess. After surgical tracheostomy, the incidence has been estimated to be 0.1–1%.[4] Pooled data of 5530 tracheostomies recorded the incidence of delayed massive haemorrhage as 0.3%.[7] Initial case reports of TIF resulted from surgically performed tracheostomies. However, the incidence may have declined because of advances in tracheostomy tube technology and the introduction of PDT. The increased popularity of PDT has resulted in tracheostomies being performed by an increasing number of specialists from different backgrounds. It is conceivable that the rate of such a rare complication is perceived by different clinical groups, to be lower than it actually is. Consequently we suggest that TIF, although rare, should be borne in mind by all those involved in tracheostomy management. In our institution more than 1000 PDT have been performed since 1994, giving a crude incidence of 0.3%.

Pathophysiology

Knowledge of the anatomy of the innominate (brachiocephalic) artery (Fig. 1) and its relationship to a tracheostomy tube is essential in understanding the pathophysiology of TIF. The tracheo-innominate artery (or trunk) is the first branch of the aortic arch. It divides into the right common carotid and right subclavian artery, 3–4 cm lateral to the trachea, behind the right sternoclavicular joint. In its inferior proximal portion, its relations include:

- anterior: left tracheo-innominate vein and thymus;
- posterior: trachea (~6–10th ring);
- posterior and left: left common carotid artery;
- right: right tracheo-innominate vein, superior vena cava and pleura.

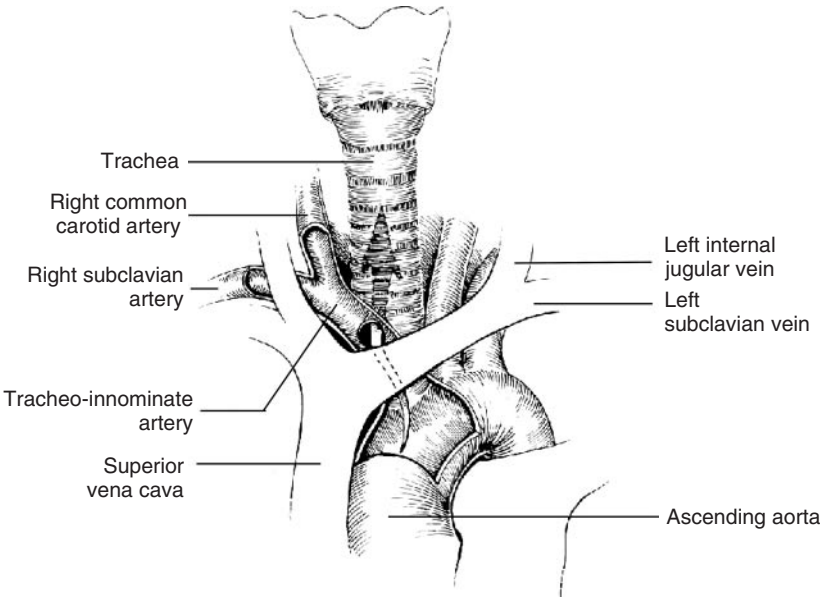

Fig 1 Tracheo-innominate artery fistula. *Source:* Amended from Wolfe: *Complications of Thoracic Surgery: Recognition and Management.* Figure 27-3 © 1992 Mosby, with permission from Elsevier.

The tracheo-innominate artery supplies blood to the right arm and the right side of the head and neck. Its absence on the left is explained by the direct branching of the left common carotid and subclavian arteries from the aortic arch. A high lying innominate artery, particularly in the thin and young, may act as a risk factor in fistula formation.

Aetiology

Pressure necrosis from high cuff pressure, mucosal trauma from malpositioned cannula tip, low tracheal incision, excessive neck movement, radiotherapy or prolonged intubation have all been implicated in TIF formation. Utilization of a high-volume low-pressure cuff may reduce subsequent fistula formation.

Two main mechanisms are capable of producing sufficient pressures to generate the erosive processes that lead to fistula formation:

- A fistula may occur between the anterior tracheal wall and artery. This is secondary to the mechanical force generated by either the tracheostomy tube cuff or tube tip depending on the relative positioning of the tube within the trachea.
- The second mechanism involves pressure generated beneath the angulated neck of a tracheostomy tube. This could produce ischaemia anteriorly on the tracheal mucosa and into the innominate artery.

Several authors suggest that a low lying tracheostomy tube is an obvious cause of fistula formation.[8] However, even when the tracheotomy incision is placed between the second and third tracheal rings, as recommended, these complications can still occur. In a post-mortem study, Oshinsky and colleagues[9] found that 10 standard vertical incisions placed in the second and third rings resulted in all subsequently placed tracheostomy tubes having either cuff or tip anatomically adjacent to the innominate artery, suggesting the potential presence of this complication in all patients with tracheostomies.

Diagnosis

Any peri-stomal bleed or haemoptysis should lead to a full clinical investigation to ascertain the underlying cause. A differential diagnosis for attending clinicians is based on the lag time between the tracheostomy and subsequent haemorrhage.

Haemorrhage within 48 h is typically associated with local factors such as traumatic puncture of anterior jugular or inferior thyroid veins, systemic coagulopathy, erosions secondary to tracheal suction or bronchopneumonia. Usually, the haemodynamic stability of the patient allows easy identification of the problem and corrective action to be taken with minimal morbidity.[10] Vascular erosion from a tracheostomy tube, resulting in a TIF, requires at least 48 h to develop even in the most friable mucosa.

Haemorrhage occurring 3 days to 6 weeks after tracheostomy should be thought of as a result of TIF until proven otherwise.[11] Other causes of catastrophic pulmonary haemorrhage include pulmonary artery flotation catheter induced arterial rupture, thoracic aneurysm rupture and less common vascular fistula (carotid artery, inferior thyroid). It is likely that the majority will occur in the Critical Care Unit, as 70% of all delayed haemorrhages occur during the first 3 weeks.[12] A sentinel bleed is reported in more than 50% of patients who then develop massive delayed haemorrhage.[6 8 13]

Haemorrhage occurring after more than 6 weeks is rarely related to TIF and more likely to be secondary to granulation tissue, tracheobronchitis or malignancy.

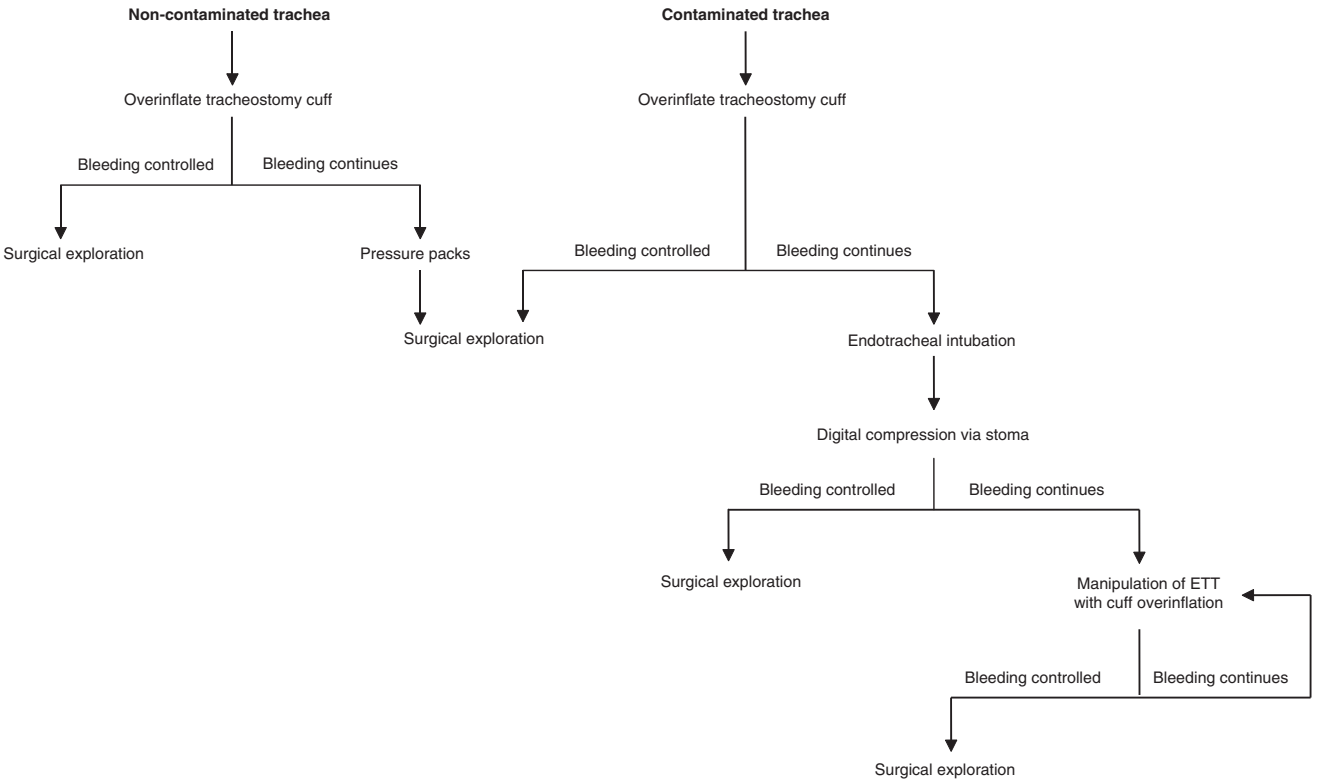

Fig 2 Clinical management of TIF.

Clinical management

Adequate oxygenation is the mainstay of immediate management with simultaneous identification and termination of bleeding. The basic principles of resuscitation, together with the management of early (within 3 days) bleeding, will not be considered here.

Management of a suspected TIF will depend upon whether there is active bleeding into the airway hindering adequate ventilation (Fig. 2).

We advocate the use of immediate bronchoscopy to confirm the extent and source of bleeding. Although bronchoscopy is unlikely to identify the fistula opening *per se*, it may exclude other pathology and allows direct monitoring of attempts to obtain a blood-free airway. Rigid bronchoscopy to clear the tracheobronchial tree of aspirated blood and to terminate blood flow is ideal, but this may not be possible.

Around 50% of TIF present with a self-terminating, sentinel bleed. If bronchoscopy confirms that the main bronchi are blood-free then immediate intervention is not required but further investigation to confirm the cause of bleeding is vital. Other causes of haemorrhage must be excluded before a sentinel bleed associated with TIF can be confirmed. If no other cause is evident then a provisional diagnosis of TIF should be made; urgent surgical advice and consideration of stoma exploration should follow.

If, in the presence of active bleeding, bronchoscopy indicates that the airway is clear of blood but there is ongoing external haemorrhage, the potential for catastrophic airway contamination is real. Overinflating the cuff provides additional airway protection and may control the bleeding temporarily. If, however, bleeding continues then pressure dressings should be applied to the stoma site. These manoeuvres temporarily control bleeding by a direct tamponade effect in more than 80% of patients.[5] As long as the airway remains free of blood; no attempt should be made to manipulate the tracheostomy tube. Immediate surgical exploration should follow.

Where bronchoscopy confirms that there is active bleeding into the airway, from the major threat is respiratory compromise rather than hypovolaemia.[14 15] Airway protection is the primary management aim. Movement of the tracheostomy tube may precipitate disastrous airway occlusion.[4] The aims must be to gain temporary control of the bleeding, get adequate oxygenation and proceed to immediate stomal exploration and definitive treatment.

(i) Overinflating the tracheostomy cuff is first line management. If this measure fails to reduce internal tracheal bleeding then proceed immediately to translaryngeal intubation with digital compression.[7 16] A cuffed oral tracheal tube should be advanced so that the balloon lies distal to the tracheostomy stoma (bronchoscopy should confirm ETT tip just proximal to the carina). The tracheostomy tube should only be withdrawn to facilitate simultaneous translaryngeal tracheal intubation. Digital compression consists of inserting the finger into the pretracheal space to tamponade the innominate

artery against the posterior surface of the manubrium.[11 12] This procedure should terminate bleeding in >90% patients and if maintained, allows transfer to the operating theatres.[6 17]

(ii) If digital compression fails to stem bleed, slow withdrawal of the tracheal tube and cuff over-inflation should follow. Manipulating the ETT tube, and its cuff to produce tamponade is the only other manoeuvre available in this situation and attempts should persist.

If the bleeding stops temporarily, and ventilation is acceptable, then immediate surgical intervention should follow.

Management of TIF is a surgical emergency. Mortality is ~100% without operative intervention. The paucity of evidence to support any imaging leads us to recommend the immediate surgical exploration. The index of clinical suspicion precludes delaying surgical intervention and any imaging, we feel, should only be undertaken within the theatre suite in conjunction with surgical management.

A standard median sternotomy approach is appropriate for access. It has been suggested that in specialist units, two separate incisions involving a right anterior thoracotomy and neck approach may be advantageous in terms of prevention of mediastinitis and sternal dehiscence.[13] Successful surgical interventions have included the use of saphenous vein and innominate vein grafts, sternocleidomastoid patches or pedicled pericardial grafts.[17] However, the mainstay of surgical treatment is to terminate flow within the innominate artery by debriding the innominate artery proximally until healthy tissue is obtained, then transecting and closing the lumen. There is no convincing evidence to suggest that this leads to significant neurological or vascular compromise.[18 19] Arterial reconstruction should no longer be considered, as arterial tie-off presents significantly better mortality and morbidity results.

In a patient presenting with fresh haemorrhage beyond 72 h after tracheostomy, the overriding concern should be of an underlying TIF. The simple algorithm that we have presented may be a useful guide. Our understanding of the long-term sequelae of the PDT is poor. We recommend that any death that results from, or is associated with massive haemorrhage from the respiratory tract in a patient who has received a PDT should have a post-mortem looking specifically at innominate artery pathology.

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CRITICAL CARE

Percutaneous tracheostomy: a 6 yr prospective evaluation of the single tapered dilator technique

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Key points

- A large single-centre service evaluation of percutaneous dilatational tracheostomies (PDTs) in a critical care unit over a 6 yr period.
- PDT was attempted in 576 patients and successfully completed in 572 patients.
- Early complication rate was 3%, late complications 0.7%, and directly attributable mortality 0.35%.
- The paper provides the largest single-centre evaluation of PDT and its safety/risk profile.

Background. The single tapered dilator (STD) percutaneous dilatational tracheostomy (PDT) technique now appears to be the single most common method of performing a tracheostomy in the critical care unit (CCU).

Methods. A single-centre, prospective evaluation of all PDTs performed in an adult mixed surgical and medical CCU between November 2003 and October 2009 was done. All procedures were undertaken by critical care physicians. A proforma recorded intraoperative complications and technical difficulties encountered during the procedure; all patients were followed up for a minimum of 3 months for delayed complications.

Results. A tracheostomy was performed on 589 patients during the study period. PDT was attempted in 576 patients and successfully completed in 572. PDT was abandoned in four patients due to bleeding, with three of these subsequently undergoing surgical tracheostomy (ST). ST was performed in 17 patients. Intraoperative technical difficulties were encountered in 149 (26%) cases. Sixteen (3%) procedures were deemed as having early complications. A further four (0.7%) cases had significant late complications including two tracheo-innominate fistulae (TIF). Both TIF patients died as a result of their complications giving a mortality directly attributable to PDT of 0.35%. There were no differences with respect to the occurrence of complications according to grade of operator.

Conclusions. PDT performed by the STD technique is a relatively safe procedure with more than 96% of procedures performed without any early or late complications. Using this technique, more than 97% of tracheostomies undertaken during the study period were performed percutaneously. Further audit at a national level is warranted to fully evaluate long-term complications after PDT.

Keywords: complications; dilatational; percutaneous; *tracheostomy*

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Percutaneous tracheostomy was first performed in 1955[1] after Seldinger's earlier description of a needle placement over a guidewire for arterial cannulation.[2] After Ciaglia's initial report of the dilatational technique in 1985,[3] percutaneous dilatational tracheostomy (PDT) has become a commonly performed procedure in the critical care unit (CCU). It has largely replaced conventional surgical tracheostomy (ST) in critical care patients, with benefits in terms of cost, ease of performance, and reduced complications.[4 5] In 2000, the first description of a modification of the technique was published (Blue Rhino® PercutaneousTracheotomy Introducer Kit; Cook Critical Care), whereby the series of dilators was replaced with a single, sharply tapered, dilator with a hydrophilic coating, permitting complete dilatation in one step.[6] The single tapered dilator (STD) method has largely supplanted the sequential dilatational procedure and now appears to be the single most common technique for performing a PDT.[7–9]

Several authors have published PDT case series using a variety of approaches. A number of papers have reported on complications of the STD technique;[10 11] further studies have compared it with other PDT techniques[12–14] or reported on its use across multiple centres.[15] To our knowledge, we report the largest single-centre series solely utilizing the STD method.

Methods

This prospective service evaluation was carried out at Aintree University Hospital (AUH). The CCU at AUH is a 19-bedded mixed medical and surgical unit undertaking ~100 PDTs per

year. The regional referral centre for head and neck cancer, the largest such unit in the UK, is also situated at AUH.

The need for PDT in any individual case was determined by the duty consultant intensivist. After the decision to proceed with a tracheostomy, all patients were fully evaluated and examined before operation. In all cases, when a tracheostomy is deemed appropriate, patients are assessed as to their suitability for a PDT. Patients undergoing ST as part of their surgical management for head and neck cancer were not included in the study.

From November 2003 to October 2009, data were prospectively collected on all PDTs performed at AUH. All PDTs were performed by critical care physicians at the bedside. All patients were over the age of 18 and each received i.v. general anaesthesia with neuromuscular block. Each procedure was undertaken with bronchoscopic guidance to ensure correct placement of the guidewire.

Before commencement of the procedure, the patient was positioned with the head extended and the lungs were ventilated with 100% oxygen. Throughout the procedure, heart rate, arterial pressure, and oxygen saturation were monitored continuously. After digital palpation of the neck, direct laryngoscopy was performed to position the tracheal tube (TT) above the site of the proposed PDT insertion point. Local anaesthesia and vasoconstriction were achieved using 2% lidocaine with 1:100 000 epinephrine administered s.c. to the pre-tracheal tissues. A 1 cm horizontal skin incision was made midway between the cricoid cartilage and the sternal notch. Pre-tracheal tissues were separated by blunt dissection. Tracheal puncture was performed with the standard 15 gauge needle and, after bronchoscopic confirmation of the position, the guidewire was passed into the tracheal lumen. A 4.5 cm 14 Fr gauge dilator was passed over the guidewire after which the STD was used to expand the tract between the skin and the tracheal lumen. The appropriate-sized tracheostomy tube was introduced into the tracheal lumen utilizing a loading dilator.

Perioperative data on each patient were recorded prospectively and included age, sex, reason for admission, admission APACHE II score, and intraoperative and postoperative complications as detailed below.

A PDT was considered 'technically difficult' if one or more of the listed events occurred during the procedure:[16]

(i) oxygen desaturation (<88%);
(ii) multiple attempts at tracheal cannulation (>3);
(iii) bleeding (>3 soaked swabs);
(iv) tracheal ring fracture evident on bronchoscopic examination;
(v) posterior tracheal wall injury.

A PDT was considered to be 'complicated' if there was one or more of the following:

(i) bleeding requiring surgical intervention;
(ii) presence of surgical emphysema;
(iii) malpositioning of tracheostomy tube;
(iv) pneumothorax.

Table 1 Patient characteristic data of patients undergoing PDT (n=576). Data are mean (SD), mean (range), or numbers (percentage)

Age (yr)	58 (18–86)
Male (%)	340 (59)
Admission APACHE II score	19 (5.6)
Emergency admissions (%)	521 (91)
Days to PDT insertion from day of admission	5 (1–21)
Days to PDT insertion from initial tracheal intubation	4 (1–14)
Surgical patients (%)	288 (50)
Number surviving to ICU discharge (%)	395 (69)
Mean length of ICU stay non-survivors in days	18 (3–68)
Mean length of ICU stay survivors in days	20 (4–92)
Mean length of hospital stay survivors in days	42 (7–382)
Number surviving to hospital discharge (%)	360 (63)

Table 2 Rationale for opting for an ST rather than PDT (n=17). *Admission diagnoses for four patients with 'Reason not specified' for ST were pneumonia (three) and exacerbation of chronic obstructive pulmonary disease (one)

Reason for surgical tracheostomy	Number
PDT abandoned due to bleeding	3
Cervical spine fracture	3
Aberrant cervical innominate artery	2
Oesophagogastrectomy with cervical anastomosis	2
Soft tissue trauma to neck	1
Supraglottitis	1
Previous surgical tracheostomy with deep wound sinus	1
Reason not specified*	4

Routine post-procedural chest X-rays (CXRs) were performed after the first 384 PDTs. Thereafter, CXRs were limited to those PDTs considered technically difficult as defined above.[16]

After critical care discharge, further surveillance was provided by the AUH Critical Care Outreach Service and after hospital discharge by the critical care follow-up clinic allowing identification of late complications.

Results

During the study period, 590 CCU patients required a tracheostomy. In 576 patients, a PDT was attempted, and in 572 (97%), the procedure was completed successfully (Table 1). In four patients, PDT was abandoned due to excess bleeding; three of these patients subsequently went on to have an ST. Consequently, a total of 17 (3%) patients underwent ST (Table 2). In the remaining patient, the procedure was abandoned and ST considered inappropriate due to worsening multiple organ failure. All PDTs were undertaken between the hours of 09:00 and 17:00 and 522 (91%)

Table 3 Adverse events encountered during 149 technically difficult PDTs. Note more than one technical difficulty occurred during some procedures, therefore the sum of technical difficulties exceeds 149

Difficulty	Number (% of all PDTs performed, $n=576$)
Minor posterior wall injury	9 (1.6)
Tracheal ring fracture visible at bronchoscopy	56 (9.7)
Multiple attempts ($\geq$3) to cannulate the trachea	57 (10)
Minor bleeding (3–5 small soaked swabs)	25 (4.3)
Oxygen desaturation to $\leq$88%	17 (2.9)

Table 4 Technical difficulties by grade of operator; operator, person performing PDT, that is, not supervising or being supervised. $P>0.05$ Kruskal–Wallis

Grade of operator (number of PDTs performed by grade as a sole operator)	Technically difficult PDTs (% of number performed by relevant grade)
Consultant (149)	33 (22)
Fellow (151)	44 (29)
Registrar (120)	31 (26)

were performed on a weekday. Five hundred and twenty-one (91%) procedures followed an emergency critical care admission. In 406 (71%) cases, the most senior clinician present was a consultant. For the remainder, in 146 (26%) and 20 (3%) cases, the most senior clinician present was a senior critical care trainee (clinical fellow) and a specialist anaesthetic registrar, respectively.

According to the definitions described above, technical difficulties were encountered in 149 (26%) procedures (Table 3). Sixteen (3%) procedures were deemed as having early complications. These included six cases of significant bleeding (including four where the PDT was abandoned), four cases resulting in para-tracheal placement of the tracheostomy tube, three with significant surgical emphysema, one with a tension pneumothorax, one with significant posterior tracheal wall injury, and one case where the tracheostomy tube was sited in the cricothyroid membrane. Four cases (0.7%) were associated with significant late complications. Of these, two patients developed a tracheo-innominate fistula (TIF) and two patients developed a tracheal stenosis. In only one of these procedures was the initial tracheostomy regarded as being technically difficult (oxygen desaturation and a tracheal ring fracture in a patient subsequently developing tracheal stenosis). The two patients who developed TIF died as a result of massive haemorrhage whilst still patients on the CCU and represent a mortality directly attributable to PDT of 0.35%.

Table 5 Technical difficulties encountered by most senior physician present during PDT. $P>0.05$ Kruskal–Wallis

Grade of most senior physician present (number of PDTs)	Technically difficult PDTs (% of number performed by relevant grade)
Consultant (406)	107 (26)
Fellow (146)	38 (26)
Registrar (20)	4 (20)

There were no significant differences demonstrated between grade of operator and technical difficulties encountered when unsupervised procedures were excluded (Table 4). Similarly, seniority of supervising clinician had no bearing on outcome (Table 5).

Three hundred and sixty patients survived to hospital discharge. Thereafter, 25 patients died before their 3 month follow-up appointment, 36 patients were referred to AUH from outside our catchment area, eight patients were transferred to long-term care facilities for ongoing neuro-rehabilitation, and one patient remains an inpatient at AUH. Of the remaining 290 patients, 202 were seen in the critical care follow-up clinic, 59 have been seen in AUH in non-critical care clinics, four have had subsequent inpatient stays for conditions unrelated to their original critical care admission, and 25 had no evidence of follow-up.

Discussion

To our knowledge, this study is the largest single-centre evaluation of the STD technique to date. Earlier reports of STD PDT involve smaller numbers,[10] compared STD with other techniques,[12–14] were conducted in multiple centres,[15] or did not exclusively use the STD technique.[11 15] The practice within our unit, for the critically ill patient requiring a tracheostomy, is to almost exclusively perform PDT (97%). Despite this high rate of PDT, only four (0.7%) procedures were abandoned with three proceeding to ST. It is unclear from previous surveys of PDT practice as to what the ratio between ST and PDT is across UK CCUs. Although Krishnan and colleagues[7] reported the results of a postal survey that stated that 173 (97%) of UK ICUs primarily performed percutaneous tracheostomy and only rarely, resorting to open ST, the ratio of PDT:ST was not reported. The authors also stated that clinicians would opt to perform an ST in the settings of a difficult airway, morbid obesity, and earlier failed PDT. In a later, similar study, Veenith and colleagues[8] reported that 43% of UK units would perform a PDT of >95% of the time. It is, therefore, possible that a PDT rate of 97% is likely to be among the highest rates encountered within the UK. It is likely that this rate is influenced by the presence of the regional head and neck unit on site. Although the head and neck unit undoubtedly provides a level of support should a PDT become complicated this input is rarely required. We would not automatically resort to ST in the settings of a difficult airway and morbid

obesity as described above. Indeed, where there is doubt over whether to perform an ST or a PDT, the decision as to which to proceed with would usually be a two-consultant decision. Additionally, as a group of intensivists, much of our practice involves head and neck patients which inevitably leads to an awareness that factors which are known to contribute to a difficult PDT are also likely to cause significant difficulties for the surgical operator.

Despite our collective willingness to take on more complex procedures, this does not appear to have resulted in an increase in complications. During an earlier study, assessing the use of routine chest radiography after PDT, we described the concept of a technically difficult but not necessarily complicated tracheostomy.[16] We felt that the incidence of post-procedural CXR changes was more likely if a procedure was technically difficult than if it were entirely straightforward. Consequently, we have utilized the same classification for the present study. The incidence of technical difficulties on initial examination of our data seems high at 26%. However, when we consider conventionally described complications, such as pneumothorax, significant bleeding, surgical emphysema, para-tracheal placement, and posterior tracheal wall injury, this figure reduces to 3% for early complications and to 0.7% for significant late complications. This is comparable with the published literature in both rate and type of reported complications.[10 11 15] Fikkers and colleagues[10] reported a major complication rate of 6% due to bleeding, pneumothorax, and dilatation of a false tract. More recently, they have quoted rates of 1.4% for s.c. emphysema and 0.8% for pneumothorax.[17] Our rates for the corresponding complications were 0.5% (3 of 572) and 0.2% (1 of 572), respectively. Similarly, Kost[15] reported a complication rate of 6.5% with the STD technique, the most significant being oxygen desaturation and bleeding. There were, however, no reports of either pneumothorax or pneumomediastinum which she attributed to the use of fibreoptic bronchoscopy. Although the use of fibreoptic bronchoscopy was used for all procedures in the current study, we have found that para-tracheal placement of the tracheostomy tube and barotrauma still occurred. In the absence of posterior tracheal wall injury, the most likely cause of the reported surgical emphysema is the use of a tracheostomy tube that is too short allowing air to escape into the s.c. tissues around the stoma. For each occurrence of malpositioning (excluding the case where the tube was passed through the cricothyroid membrane), a 7.0 mm TT was *in situ*. Although this allowed the passage of the bronchoscope to visualize the catheter and guidewire entering the trachea, effective mechanical ventilation with the bronchoscope in position was not possible. In each of these cases, therefore, the bronchoscope was removed after confirmation of wire placement and re-introduced to confirm tracheostomy tube placement whereupon the error was detected. We feel that this reiterates the importance of continuous bronchoscopic guidance throughout the procedure and if the TT is of insufficient calibre to allow ongoing mechanical ventilation during the procedure, the TT must either be changed before commencing the PDT or a paediatric bronchoscope must be available.

The comparison of our data with the existing literature becomes more difficult when considering minor complications, or technical difficulties, as many such problems are not reported in comparable studies. Of the larger published series,[10 11 15] the reported rate of minor bleeding varies from 1.6%[11] to 14%[10] compared with our rate of 4.3% (25 of 576). It is possible that the bleeding rate may be affected by an operating technique. In our series, after skin incision, our practice was to divide the pre-tracheal tissues by blunt dissection in a manner similar to that described by Kost[15] and as recommended by the manufacturers of the Blue Rhino® STD (www.cookmedical.com/cc/home.do). Some operators, however, prefer to proceed to the dilatational phase of the PDT immediately after skin incision. In the report by Fikkers and colleagues,[10] 48 patients underwent STD PDT without blunt dissection of the pre-tracheal tissues, whereas 52 had pre-tracheal dissection. There was no difference in the bleeding rate between the two groups. There was, however, a significant increase in the difficulty of dilatation (requiring unusual force) when pre-tracheal dissection was not performed.

Minor posterior tracheal wall injury was only reported by Kost[15] (0.6%) and Fikkers and colleagues[10] (2%) in comparison with our rate of 1.6%. Oxygen desaturation during PDT was only reported by Kost[15] with a rate of 2.8% (14 of 500) almost identical to our own of 2.9% (17 of 576). None of these authors[10 11 15] has reported rates of the tracheal ring fracture or number of attempts to cannulate the trachea. Other authors have, however, reported rates of the tracheal ring fracture in association with STD PDT with incidences varying from 5.3% to 36%[18–20] in comparison with our rate of 9.7%. Such a wide variation in the reporting of tracheal ring fracture rate is almost certainly related to how closely this complication is sought by the bronchoscopist during the PDT. Some authors have suggested that the incidence of the tracheal ring fracture is higher with STD PDT when compared with the Ciaglia technique.[19 20] However, it is likely that all clinical reporting of tracheal ring fractures represents an underestimate of the actual incidence. In a cadaveric study of 42 patients who had had a PDT by the Ciaglia method, Walz and Schmidt found 12 patients with tracheal ring fractures and 10 specimens where a cartilaginous defect was demonstrated at the tracheal stoma.[21] The significance of the tracheal ring fracture after PDT with respect to long-term complications remains unclear. In the paper by Higgins and colleagues,[18] 16 patients with tracheal ring fractures (four after STD PDT) were followed up until a mean time of almost 9 months after PDT. None of these patients developed a tracheal stenosis which led the authors to conclude that the tracheal ring fracture was not associated with subsequent development of tracheal stenosis. Given the small number of patients in the study, the likely under-reporting of tracheal ring fractures, and the rarity of tracheal stenosis after PDT, this seems to be an over-interpretation of the data. In the present study, one of the

two patients subsequently developing tracheal stenosis had a clinically evident ring fracture at the time of PDT (see below).

Long-term follow-up of this patient cohort may initially appear poor with only 202 patients out of a potential 360 attending the critical care follow-up clinic. Of these 360 patients, 25 died before follow-up could be arranged, 36 were transferred to AUH from other hospitals and were subsequently referred back to the referring hospital for ongoing care after discharge from the CCU, eight were transferred to neuro-rehabilitation facilities, and one patient remains as an inpatient at AUH. The actual number of patients, therefore, who we could realistically expect to follow up was 290. We have therefore managed to see almost 70% of these patients in our follow-up clinic with a further 63 (22%) patients being seen within the hospital in some other capacity after CCU discharge. In only 25 of these patients was there no evidence of follow-up. The problem facing critical care follow-up clinics with non-attendance is well recognized. In a review of seven studies of CCU follow-up clinics, Williams and Leslie found that among hospital survivors who had not been on a CCU, 67% attended clinic within 8 weeks, this figure decreased to 30% for patients discharged alive after a CCU stay.[22] Non-attendance rates for critically ill follow-up patients varied from 10% to 30%. Placed in this context, achieving a post-discharge review rate of close to 70% is unusual. Additionally, one of the authors (T.M.J.) has a tertiary referral subspecialist interest in the management of tracheal stenosis. We are therefore confident that if any of the 36 patients repatriated to their base hospitals, within the locality, had subsequently developed a clinically relevant tracheal stenosis, they would have been referred back to AUH for further management.

Reports relating to late complications after PDT in large case series are again difficult to interpret due to the infrequency of most of these complications and the fact that many studies report predominantly early complications.[15] In the present series, there were four significant long-term sequelae—two TIF and two tracheal stenoses.

Our incidence for clinically evident tracheal stenosis: 0.35% (0.6% for those surviving to hospital discharge) is comparable with earlier series of both PDT[10 11] and ST.[23] The first case of tracheal stenosis was in a 41-yr-old male requiring admission to the CCU after an episode of near drowning. He underwent a PDT with no reported technical difficulties or complications. The tracheostomy remained *in situ* for 8 days. The second case was a 32-yr-old male admitted after a closed head injury. During his PDT, a tracheal ring fracture was noted at bronchoscopy; the procedure was otherwise complicated by a minor oxygen desaturation. His trachea remained cannulated for a total of 55 days. His critical care stay was complicated by a severe hospital acquired pneumonia and acute respiratory distress syndrome. It is likely that in the latter case, the factor of note is the prolonged duration of cannulation. As noted by Koitschev and colleagues,[24] the incidence of tracheal stenosis after PDT may be higher after prolonged cannulation. In comparison, during the study period, we have had one case of tracheal stenosis associated with translaryngeal tracheal intubation in our unit.

Similarly, the incidence of TIF was also 0.35%. Again, in keeping with the published literature, where the rate is reported to be between 0.1% and 1%.[25] Each of these patients underwent essentially uneventful PDTs and was cannulated for 10 and 12 days, respectively, before the occurrence of their TIF.[26] Since both patients with TIF subsequently died of their complications, unlike earlier papers, we are able to report a death rate of 0.35% directly attributable to the PDT itself.

There remains a paucity of information pertaining to the occurrence of uncommon but significant long-term complications after PDT. The incidence of these complications may, at least in part, depend upon the clinical setting and duration of tracheal cannulation.[24] It is possible, in the scenario of closed head injury (given the differences in incidence of tracheal stenosis between PDT and ST) described by Koitschev and colleagues,[24] where prolonged cannulation will be required, that ST may be the most appropriate means of securing the airway. Given this dearth of information relating to longer term outcome after PDT, a more extensive audit of the role of PDT in critical care, to the standards set out by the Royal College of Anaesthetists,[27] is now justified at a national level.

Our low incidence of reported complications may also, in part, be due to the routine PDT practice within the unit. A majority of the current consultant body regularly anaesthetize for major head and neck surgery with its attendant problems of difficult airway management. All procedures are performed with a minimum of two experienced clinicians, one to manage the airway (including TT manipulations and bronchoscopy) and the other to perform the procedure. All procedures are carried out between the hours of 09:00 and 17:00, with in excess of 90% also occurring between Monday and Friday.

The timing of PDT in the current study is, compared with previous work,[10 11 15] somewhat early with a mean time to PDT of 5 and 4 days from CCU admission and tracheal intubation, respectively. Our practice of early PDT may, however, not be too different to UK practice with Krishnan and colleagues[7] reporting that 50% of units perform a tracheostomy within the first week after admission and Veenith and colleagues[8] reporting that 21% of units will perform the procedure within 5 days.

Optimal timing of PDT in the critically ill remains a subject of debate and considerable controversy within the literature with the indications and timing frequently based on personal preference.[28] Indeed, even the definition of early/late tracheostomy is difficult to reach consensus on.[29] There would be little doubt, however, that the vast majority, if not all, of PDTs described herein would fit in to the early category. Scales has recently reported the findings of a retrospective analysis of almost 11 000 patients over a 12-yr-period, using the Ontario health database, comparing the mortality of early ($\leq$10 days) *vs* late ($>$10 days) tracheostomy in

critical care.[30] They reported modest reductions in 90 day and 1 yr mortality associated with early tracheostomy, along with faster weaning times and more ventilator free days. Another study in critically ill medical patients showed that early PDT was associated with reductions in duration of mechanical ventilation, CCU stay, morbidity, and mortality.[31] More recently, a meta-analysis has challenged the positive beneficial effects of early PDT on the risk of developing pneumonia and mortality but did show a reduction in the duration of mechanical ventilation and length of CCU stay.[32] It has always been our belief that the risks of early PDT were outweighed by the benefits accrued resulting from significant reductions or cessation of sedative drugs leading to the advantages described above and improved resource utilization.[33] The TracMan study in the UK reported no effects of early tracheostomy (days 1–4) compared with late tracheostomy (after day 10) on 30 day mortality.

In conclusion, we have performed the largest single-centre evaluation of the STD PDT technique to date. It would appear to be a relatively easy and safe technique when performed at the bedside. The complication rates described herein are similar to earlier reports of both PDT and ST. When taking into account the fact that the STD PDT was considered for all patients undergoing tracheostomy in our unit, with no absolute contraindications and with only four procedures being abandoned, the low complication rate is all the more remarkable. However, further large-scale audit on a national level is justified to fully evaluate the long-term outcomes after PDT.

Conflict of interest

None declared.

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Tracheal stenosis following percutaneous dilatational tracheostomy using the single tapered dilator: an MRI study

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SUMMARY

Despite widespread adoption of percutaneous dilatational tracheostomy within the critical care setting, there is still uncertainty regarding long-term complications, particularly in relation to missed or subclinical tracheal stenosis. In this study, all patients underwent tracheostomy using a single tapered dilator ≥ three months prior to enrolment and were evaluated using magnetic resonance imaging, spirometry and questionnaire. Tracheal area was recorded and deemed to be stenotic if a reduction of ≥10% was found. Fifty patients underwent magnetic resonance imaging and 49 attended for interview. Five patients were diagnosed with tracheal stenosis—none were symptomatic. Six of the 50 tracheostomies were technically difficult. Spirometry was not predictive of stenosis. A post critical care exercise tolerance of less than 100 metres was found in four tracheal stenosis patients. The prevalence of subclinical tracheal stenosis following percutaneous tracheostomy is low, with limited clinical significance. No patients required corrective surgery for tracheal stenosis. Routine airway follow-up in asymptomatic patients appears to be unwarranted.

Key Words: tracheostomy, percutaneous, dilatational, complications, critical care

Despite widespread adoption of the single tapered dilator (STD) technique for percutaneous dilatational tracheostomy (PDT) in critical care, there is uncertainty about longer-term complications, such as tracheal stenosis (TS). Whilst the incidence of TS is evident from a number of long-term cohort studies[1–3], the issue of missed or subclinical stenoses has not been fully addressed. Non-specific symptoms are common following critical care admission and PDT, with frequent reports of voice changes, swallowing difficulties, cough and shortness of breath[4,5]. We hypothesised that in this cohort of patients, there were a number of patients with undetected TS.

Earlier studies have attempted to identify the prevalence of TS following PDT using computed tomography (CT)[4,6], magnetic resonance imaging (MRI)[7], plain linear tomography[8], spirometry with fibreoptic laryngoscopy[9]; or fibreoptic laryngoscopy alone[10]. Norwood's study[4] using CT evaluation of tracheal anatomy after sequential dilatation PDT and correlation with symptoms found an incidence of TS of 31%, 20% of whom were symptomatic, but could not determine whether voice changes or respiratory problems were a result of critical illness or PDT itself. Spirometry has been variably described as straightforward but with unproven utility in detecting stenosis[11] and, as unhelpful in detection of TS in patients after critical illness, with poor correlation between spirometry findings and endoscopic features[9]. The forced expiratory volume in one second to peak expiratory flow rate ratio (FEV_1:PEFR) was demonstrated by Empey to be useful in distinguishing upper airway obstruction from lower airway disease but has not been widely adopted[12].

Despite the above attempts to delineate tracheal post-PDT changes, there are limited data pertaining to STD PDT. Although Fikkers et al used MRI to evaluate long-term outcome, only 14 STD patients were evaluated[7]. We believe the present study is the largest to exclusively radiographically evaluate tracheal changes following STD PDT in an attempt to better define the prevalence of subclinical TS.

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MATERIALS AND METHODS

This prospective cohort study was carried out at Aintree University Hospital NHS Foundation Trust (AUH). The critical care unit at AUH is a 23-bed, mixed medical and surgical unit undertaking approximately 80 to 100 PDTs per year. The regional referral centre for head and neck cancer, the largest such unit in the United Kingdom, is also situated at AUH.

A database of all patients receiving PDT, including associated outcome data, undertaken within the critical care unit at AUH has been kept since 2003. All PDTs are performed by critical care physicians at the bedside using the STD technique with bronchoscopic guidance. All patients were over the age of 18 and each received intravenous general anaesthesia with neuromuscular blockade during the procedure.

Following ethical approval (Liverpool [UK] Research Ethics Committee: Reference No. 08/H1005/121), patients surviving for a minimum of three months from the insertion of PDT were identified from the database. Cross-referencing with the AUH clinical records system (System C Medway Sigma, Maidstone, UK) and information provided from contact with the patient's general practitioner, when required, confirmed whether patients were still alive. They were then contacted by telephone, informed of the nature of the study and invited to AUH to complete a simple questionnaire and undergo spirometry and MRI scanning (Figure 1).

Following written informed consent, background data including age, sex, admission illness severity (Acute Physiology and Chronic Health Evaluation [APACHE] II), duration of orotracheal intubation prior to PDT, complications and technical difficulties during PDT[3], duration of cannulation and length of critical care and hospital stay were collected. A PDT was considered complicated if there were one or more technical difficulties (multiple tracheal punctures [≥ three], tracheal ring fracture, minor bleeding [> three soaked gauze swabs]) or significant complications (pneumothorax, subcutaneous emphysema, major bleeding [need for surgical intervention or transfusion]). A Health Status Screening Questionnaire (Appendix 1) was devised and used to ascertain evidence of pre-existing respiratory disease, respiratory symptoms after critical care and current exercise tolerance. Simple spirometry was then undertaken using a micro-loop spirometer (CareFusion Health UK 232 Ltd, Basingstoke, United Kingdom) to obtain values for forced expiratory volume in 1 second (FEV_1), peak expiratory flow rate (PEFR) and forced vital capacity. The best of three readings obtained were used to calculate the FEV_1:PEFR ratio. This constitutes the Empey Index

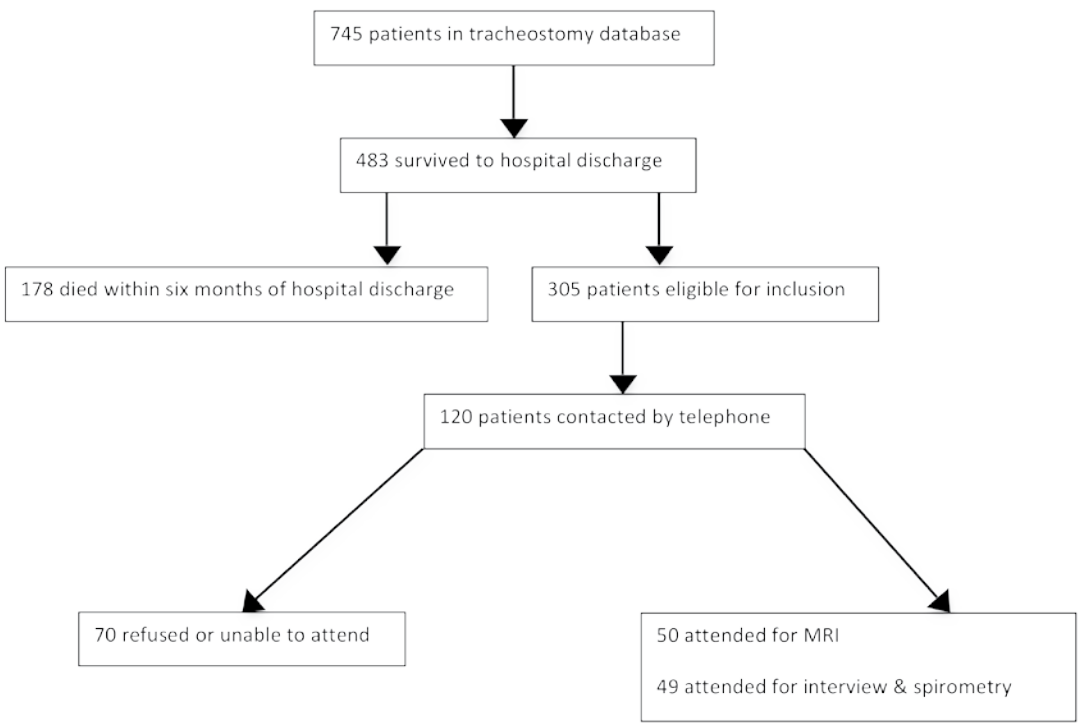

FIGURE 1: Recruitment to study. MRI=magnetic resonance imaging.

(EI) (EI=FEV_1:PEFR) and previous data have reported a ratio > ten to be clinically significant[12].

MRI scanning was undertaken using a Siemens MAGNETOM 1.5 T Avanto scanner (Providian Medical Equipment LLC, Willowick, OH, USA). A T2-weighted coronal scan using 5 mm slices was carried out, along with a T1 flash sagittal 3D volume scan with 1 mm slices. Multiplanar reformats were constructed from the volume scan in the axial and coronal planes. All sequences included the trachea from the inferior border of the cricoid cartilage to the carina. All images were reviewed by a single consultant radiologist, unaware of the clinical details of the patient pertaining to the PDT. Coronal and sagittal measurements were reported at the narrowest section of the trachea at or above the level of the tracheostomy and compared to normal tracheal dimensions above or below the abnormality. Tracheal cross-sectional area (TCSA) at each level was calculated using the Picture Archiving and Communications System (PACS) (CARESTREAM Vue PACS, Carestream Health Inc., Rochester, NY, USA). A significant stenosis amounting to a reduction in the TCSA of 10% or more when compared to normal trachea above or below the abnormal segment was defined as TS for the purpose of this study in common with previous, similar studies[4,8,9]. All patients with identified TS on MRI were then referred to a consultant head and neck surgeon for further evaluation. In these cases, each patient was initially investigated with fibreoptic laryngotracheoscopy, continuing to rigid tracheobronchoscopy under general anaesthesia if this was considered necessary.

Statistical analysis

Data were analysed initially using Microsoft® Excel software (Redmond, WA, USA). GraphPad (GraphPad Software Inc., La Jolla, CA, USA) was used to carry out Fisher's exact test for categorical data and Mann–Whitney U tests for continuous data. A *P*-value of <0.05 was considered statistically significant.

RESULTS

At the time of the study, the database contained 745 patients who had undergone STD PDT more than three months previously. Four hundred and eighty-three of these patients survived to hospital discharge. A further 178 died within six months of hospital discharge, leaving 305 eligible for inclusion. One hundred and twenty patients were contacted by telephone. Seventy patients declined the invitation or were unable to attend for MRI scanning, including 11 who failed to present for pre-arranged appointments. The remaining 50 patients underwent MRI (Figure 1). Of these, 49 also attended for interview, during which a standardised questionnaire was completed (Appendix 1).

Of the 50 patients who underwent MRI scanning, five patients (10%, 95% CI 3% to 22%) were diagnosed with TS as per the study criteria. Patient characteristics of those with and without TS (TS: nTS) and non-attenders are presented in Table 1. Median reduction in TCSA for those with TS was 30% with individual stenoses documented as 16%, 24%, 30%, 38% and 46% respectively (Table 2). There were no differences between the groups with respect to age, sex, illness severity, number of days of orotracheal intubation prior to PDT insertion or time from PDT to MRI scan. The difference in median duration of cannulation of 15 days in the TS group and nine days in nonTS group was not statistically significant

Table 1
Characteristics of patients with TS compared to those without and patients declining the invitation to attend for MRI scanning

	Stenosis (n=5)	No stenosis (n=45)	Non-attenders (n=70)
Age, median (IQR), years	51 (39–59)	58 (48–72)	58 (42–67)
Male, n (%)	2 (40)	26 (58)	45 (64)
Admission APACHE II score, median (IQR)	14 (14–15)	16 (14–19)	16 (13–21)
Orotracheal intubation prior to PDT, days, median (IQR)	4 (4–5)	4 (2–5)	4 (3–5)
Duration of cannulation, days, median (IQR)	15 (12–21)	9 (6–15)	15 (11–23)
Time from decannulation to MRI, months, median (IQR)	22 (12–58)	24 (10–45)	—
Perioperative complications, n (%)	4 (80)*	2 (4)*	22 (31)
Bleeding	1 (20)	0 (0)	4 (6)
Multiple tracheal punctures	2 (40)	1 (2)	9 (13)
Tracheal ring fracture	1 (20)	1 (2)	9 (13)

*P=0.002 Fisher's exact test. TS=tracheal stenosis, MRI=magnetic resonance imaging, IQR=interquartile range, APACHE=Acute Physiology and Chronic Health Evaluation, PDT=percutaneous dilational tracheostomy.

(P=0.17).

Overall, six of the 50 PDTs were complicated as defined above. Four of the five patients diagnosed with TS in comparison with two of 45 without, underwent complicated STD PDT (Table 1). When complications were considered individually, patients with TS may be more likely to have had multiple attempts at tracheal puncture (2/5 versus 1/45) but there was no apparent difference between the groups in relation to tracheal ring fracture (1/5 versus 1/45) or minor bleeding (1/5 versus 0/45) rates.

Results from the questionnaire revealed no differences in the presence of voice changes (2/5 versus 16/45) and shortness of breath (4/5 versus 17/45) between those with TS and those without. Two patients reported the presence of inspiratory noise – neither were found to be stridulous or have TS on MRI scaning. Data pertaining to exercise tolerance was provided by 44 patients (5 TS and 39 nTS). Four of the five patients with TS reported an exercise tolerance of 100 m or less, two of whom reported unlimited exercise tolerance prior to critical care admission. In contrast, nine of the 39 nTS patients (23%) reported an exercise tolerance of 100 m or less.

Table 2
TS, spirometric and questionnaire data

	Tracheal stenosis (n=5)	No tracheal stenosis (n=45)
Tracheal measurements median		
Reduction in tracheal cross sectional area (%) (range)	30 (16–46)	—
Pulmonary function tests (median, IQR)		
FEV_1, l	2.06 (1.69–2.52)	2.3 (1.77–2.84)
PEFR, l/minute	235 (219–249)	337 (222–427)
FVC, l	2.42(1.89–3.27)	3.06 (2.52–3.49)
Empey index	7.96 (7.19–9.4)	6.89 (6.08–8.28)
Empey index >10, n (%)	1 (20%)	3 (7%)
Pre-ICU exercise tolerance 100 m or less, n (%)	1 (20%) (n=5)	4 (10%) (n=39)
Post-ICU exercise tolerance 100 m or less, n (%)	4 (80%)* (n=5)	9 (23%)* (n=39)
Voice change, n (%)	2 (40%)	16 (38%)
Shortness of breath reported, n (%)	4 (80%)	17 (40%)

*P=0.022 Fisher's exact test. TS=tracheal stenosis, IQR=interquartile range, FEV_1=forced expiratory volume in 1 second, PEFR=peak expiratory flow rate, FVC=forced vital capacity, ICU=intensive care unit.

Mean values for FEV_1, PEFR and EI are shown in Table 1. Neither FEV_1, PEFR nor EI were predictive of TS.

The five patients found to have TS on MRI scanning were referred to a consultant head and neck surgeon for further evaluation and to assess the need for additional intervention. At initial fibreoptic laryngotracheoscopy three of the five were deemed to have an adequate airway and further intervention was deemed unnecessary. The remaining two underwent rigid tracheobronchoscopic examination under general anaesthesia and were again found to have an adequate airway. It was felt that further surgical intervention would not significantly improve the airway, in a clinically meaningful way, in any of the five patients with TS.

DISCUSSION

We have found a TS rate of 10% in fifty patients investigated, ranging from a 16% to 46% reduction in TCSA. All patients with TS had fibreoptic laryngotracheoscopic evaluation and two of the five had rigid tracheobronchoscopy. No patient required any therapeutic intervention and all were felt to have an adequate airway and were discharged from further follow-up. The low incidence and the subclinical nature of the stenoses is reassuring, indicating the underlying prevalence of undiagnosed TS in patients following STD PDT is of doubtful clinical significance.

There are limited studies in the literature reporting long-term follow-up of PDT patients using radiological imaging (CT/MRI), with very few studying tracheal calibre in patients who have had STD PDTs, even though this is now probably the most frequently used technique[13–15]. The 10% rate of TS described herein was less than that found in another MRI study[7]. Fikkers et al compared long-term outcome of patients randomly allocated to either guide-wire dilating forceps or STD PDTs. Sixty patients were assigned to each group, 31 patients underwent MRI scanning (14 patients in the STD group), with 12 (39%) showing tracheal narrowing. Whilst the absolute number of patients with tracheal narrowing demonstrated by Fikkers et al is larger than our own, the degree of stenosis is similar in that all cases were felt to be of limited clinical consequence.

Two further studies utilised CT assessment. Norwood et al[4] studied 100 patients who had undergone PDT using the sequential dilators of the original Ciaglia technique (CPDT)[16]. Forty-eight of these patients underwent CT scanning. Fifteen (31%) patients were found to have more than 10% TS on CT

with ten (21%) of these being mild (tracheal narrowing of 11% to 25%), four (8%) moderate (26% to 50% narrowing) and one (2%) severe (>50% narrowing). In Karvandian et al's study, 20 patients were assessed using CT and fibreoptic laryngotracheoscopy after CPDT[6]. Only three of the 20 patients had cannulation times of less than three weeks (none of whom had TS) and 85% had significant subglottic stenosis (53% with <50% narrowing). The study group appeared different from our own, with a mean duration of cannulation of nine weeks. Additionally, 54 of 86 patients surviving four months after discharge from hospital required permanent or long-term mechanical ventilation.

van Heurn et al described a TS prevalence of 26% in a study of 54 patients undergoing plain linear tomography following CPDT[8]. Law et al used spirometry and fibreoptic laryngotracheoscopy without any radiological assessment in 41 patients after CPDT[9]. Three patients were found to have tracheal narrowing of between 10% and 30% and one with a 40% stenosis. After a median cannulation time of 20 days, a 10% rate of TS was reported.

The 10% rate of TS we describe is at the lower end of incidences reported above (10% to 85%). Part of this difference may be accounted for by differing definitions of tracheal stenosis. However, the definition of TS as tracheal narrowing of >10% is common to most of the studies cited above, with only Fikkers et al[7] and Karvandian et al[6] not specifically stating their definition of TS. The difference might also partly be attributed to shorter tracheal cannulation times. In each of the studies described above, the duration of tracheal cannulation was longer than that described in our study (15 days in the TS group and nine days in the nonTS group). Cannulation times ranged from 18 days in Fikkers et al's guide-wire dilating forceps group[7] to nine weeks in Karvandian et al's paper[6]. Those studies reporting a lower prevalence of TS or only minor tracheal changes appear to have shorter cannulation times[7,9]. A further consideration to take into account is the duration of tracheal intubation prior to the insertion of PDT. PDT was carried out early in our patients (median four days), whereas previous studies have reported durations from 7 to 18 days[4,7–9]. Another factor to be considered is the PDT insertion technique used. Most of the studies described above have used CPDT with only Fikkers et al[7] evaluating guide-wire dilating forceps and STD techniques radiologically, and then in only 15 and 14 patients respectively. It is possible, given the paucity of data available, that the incidence of post PDT TS may differ significantly between commonly used techniques. Considering the widespread use of these techniques, the lack of long-term radiological outcome data would appear somewhat surprising.

The TS patients appear more likely to have undergone a complicated or technically difficult PDT compared to the nonTS group (Table 1). The most frequent difficulty encountered was the need for multiple tracheal punctures to the site required by the cannula for guided-wire insertion. Whilst the significance of this finding is unclear, the association between multiple tracheal punctures and later tracheal narrowing has not been made previously. It is possible that several attempts to position the cannula may ultimately lead the operator to settle for a suboptimal position for the tracheostomy tube, potentially causing tracheal injury and later narrowing.

As all cases of TS detected were clinically asymptomatic, with none requiring surgical correction, it is difficult to explain the significance and relevance of the reduced exercise tolerance found in these patients (four out of five reporting significantly limited exercise tolerance, two of whom had previously been unlimited). Conventionally, TS is expected to become evident clinically when the tracheal narrowing reaches 50% to 75%. However, many critical care survivors are likely to have significant impairment of cardiorespiratory and neuromuscular function. It is possible, in the setting of such limited physiological reserve, that post critical care patients may be symptomatic at lesser degrees of tracheal narrowing than would usually be the case. Under normal circumstances, for gas to flow through the trachea a pressure gradient exists to overcome the resistance of the respiratory system. Flow within the trachea is usually turbulent and in such conditions the resistance is inversely related to r^{5}[5,17]. Therefore, the TS patient has to generate a greater pressure gradient to overcome this added resistance. Consequently, for the post critical care patient, the symptoms of the TS may be more in keeping with significant fatigue than those usually associated with upper airway obstruction.

The principal limitations of the current study are sample size, as discussed above, and patient selection in that the study population may have self-selected to some extent, being limited to those who were fit enough to travel to hospital to take part in the study. Rates or severity of TS might be greater in those patients unable to come to hospital. Conversely, those who were well enough to have returned to full-time employment may not have been contactable by telephone at home during office hours so may have been missed. We were, however, unable to demonstrate any differences in patient characteristics

between those attending for scans and those unable to do so (Table 1). Additionally, we are unaware of the cause of death in those patients surviving their critical care stay but dying prior to an invitation to attend for scan. It is possible some of these patients may have had some degree of upper airway obstruction. Given that our institution houses the regional head and neck service, and such patients would have been referred back should they develop airway obstruction, this seems less likely.

Our initial intention was to assess 60 patients following STD PDT, specifically recruiting 20 after uncomplicated procedures, 20 after PDT complicated by tracheal ring fracture and a further 20 after more than 14 days cannulation. The incidences of ring fracture and of cannulation for more than 14 days were too low for the original aim to be achievable. Consequently, we recruited 50 eligible patients from the database. Whilst we were unable to study these factors as initially intended, analysis of the limited data obtained would appear to suggest that tracheal ring fracture is not obviously implicated in TS. Data pertaining to the length of tracheal cannulation may indicate a possible relationship between prolonged cannulation and TS (nTS nine days versus 15 days TS) but this was not statistically significant. Whilst we could not demonstrate a statistically significant association between duration of cannulation and TS, further studies with larger numbers may be able to do so. Such studies are likely to be confounded by differences in timing of PDT between institutions. The long follow-up required to detect post tracheostomy tracheal stenosis would be another limiting factor, as would cost—particularly if only 10% of cases prove positive for TS which then may be regarded to have limited clinical significance.

We have demonstrated a lower rate of subclinical stenosis in patients following STD PDT than has previously been reported. Whilst we considered that functional limitation in such patients following critical care discharge may be in part due to an underlying prevalence of TS, this would appear not to be the case. Those stenoses found were felt to be of doubtful significance with no patients requiring corrective surgery, and all ultimately discharged from further follow-up. Routine radiological imaging and spirometry following STD PDT would appear to be unwarranted in asymptomatic patients.

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APPENDIX 1: ASSESSMENT OF TRACHEAL STENOSIS FOLLOWING PERCUTANEOUS TRACHEOSTOMY

Patient sticker	Outpatient appointment date: __/___/__
	Date of critical care admission: __/___/__
	Date first intubated: __/___/__
	No. extubations pre-tracheostomy: _____
	Date of percutaneous tracheostomy: __/___/__
	Date of decannulation: __/___/__

Dates of re-cannulation (if applicable):

_____

Complications of tracheostomy: _____ ____

Pre-existing respiratory disease

Smoking history: _____ pack years Still smoking: Y/N

Established COPD: Y/N

Other respiratory disease:

_____

Pre-ITU spirometry: FEV_1_____l FVC_____l

Pre-ITU Exercise tolerance on flat:_____m Limiting factor:

Current symptoms

Change in voice : Y/N

Short of breath: Y/N Exertion/rest

Stridor Y/N Exertion/rest

Exercise tolerance on flat: _____m Limiting factor:

Other (difficulty expectorating? difficulty swallowing? problematic scar?):

Examination

Scar: Not visible/Acceptable/Disfiguring/Tethering

Short of breath: Y/N Exertion/rest

Stridor: Y/N Exertion/rest

Spirometry

Measured values					**Calculated values**	
	1.	2.	3.	Best		
FIF50						
FEF50					FEF50/ FIF50	
FEV_1					FEV1/PEFR	
PEFR						
FVC					FEV_1/FVC	

NB. Any one of: FIF50 <100 l/minute, FEF50/FIF50 ≥1, FEV1/PEFR >10l/ml per minute.

Long-Term Outcome Following Tracheostomy in Critical Care: A Systematic Review

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Objectives: The prevalence and impact of longer-term outcomes following percutaneous tracheostomy, particularly tracheal stenosis, are unclear. Previous meta-analyses addressing this problem have been confounded by the low prevalence of tracheal stenosis and a limited number of studies.

Design: Embase, PubMed-Medline, and the Cochrane Central Register of Clinical Trials were searched to identify all prospective studies of tracheostomy insertion in the critically ill. To reflect contemporary practice, the search was limited to studies published from 2000 onward. We scrutinized the bibliographies of returned studies for additional articles. Meta-analyses were undertaken to estimate the pooled risk difference of tracheal stenosis, bleeding, and wound infection comparing different techniques.

Measurements and Main Results: We identified a total of 463 studies, 29 (5,473 patients) of which met the inclusion criteria. Nine were randomized controlled trials, six were nonrandomized comparative studies, and 14 were single-arm cohort studies. Risk of wound infection was greater for the surgical tracheostomy than for the Ciaglia multiple dilator technique, pooled risk difference 0.12 (95% CI, 0.02–0.23). We did not identify significant risk differences in other meta-analyses. Pooling across all studies according to the random-effects proportion meta-analysis suggests a higher prevalence of tracheal stenosis, wound infection, and major bleeding for surgical tracheostomies.

Conclusions: Considering comparative data, there was no significant difference in the prevalence of tracheal stenosis or major bleeding between percutaneous and surgical tracheostomy. In relation to wound infection, we have found a reduction associated with the original Ciaglia technique when compared with that with the surgical tracheostomy. Considering all published data reporting long-term outcomes pooled proportion meta-analysis indicates a trend toward a higher rate of tracheal stenosis and an increased risk of major bleeding and wound infection for surgical tracheostomies. This finding may be biased as a result of targeted patient selection, and further, high-quality long-term comparative data are needed to confirm these findings. (*Crit Care Med* 2015; XX:00–00)

Key Words: complications: tracheal stenosis, infection, bleeding; critical care: systematic review; tracheostomy: surgical, percutaneous

Percutaneous dilatational tracheostomy (PDT) has become widely adopted in critical care units (CCUs) since Ciaglia first described the dilatational technique (1). Since then multiple percutaneous techniques have been described, introduced, and widely evaluated in comparison with both each other and surgical tracheostomy (ST). Although the short-term complications of these techniques are well described, the prevalence and impact of longer-term outcomes, particularly tracheal stenosis (TS), are unclear. Previous meta-analyses have attempted to address this problem but have been confounded by the low prevalence of TS and, in particular, the limited number of studies reporting long-term outcomes (2–6).

On examination of current evidence, a meta-analysis published by Delaney et al (2) found a significantly decreased rate of wound infection after all commonly performed percutaneous techniques when compared with ST. In addition, there were reductions in mortality and bleeding in patients undergoing percutaneous tracheostomy in the CCU as opposed to ST in the operating theatre. Higgins and Punthakee (3) also reported a tendency toward a reduction in overall complications for percutaneous procedures. In contrast, Oliver et al (4) found an increased prevalence of minor early complications

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associated with percutaneous techniques but insufficient evidence to suggest a difference in late complications of poor cosmetic results and tracheocutaneous fistulae. Cabrini et al (5) found that the six percutaneous techniques analyzed (Ciaglia multiple dilator method [CPDT], guide wire dilating forceps [GWDF], single tapered dilator [STD], translaryngeal tracheostomy [TLT], balloon dilator [BD], single step rotational dilator [SSRD]) were largely comparable with the exception of the TLT, which was associated with an increased conversion rate to ST or other percutaneous technique and more severe early complications. They also found that the STD was associated with fewer complications and failures. In a later analysis, the same authors reported less operative bleeding and fewer technical difficulties associated with the STD technique than those associated with the GWDF technique (6).

The meta-analyses described above included only randomized controlled trials (RCTs). The only exception was the analysis by Oliver et al (4), which also included nonrandomized prospective studies. The largest single study incorporated into the previous analyses comprised 346 patients (7). It is perhaps unsurprising, therefore, that none of the previous meta-analyses have reported differences in TS rates. The exact prevalence of TS following tracheostomy procedures in the critically ill is difficult to quantify due to the associated mortality of critical illness, the subclinical nature of many stenoses and the difficulty maintaining follow-up of these cohorts. From a number of prospective cohort series, it would appear that subclinical disease is found in around 10% of survivors (8) with clinically evident lesions presenting in 0–0.35% (9–11).

Despite its low prevalence, TS causes significant ongoing morbidity and healthcare costs associated with its management. The management of choice for TS has been segmental tracheal resection since Grillo (12) and Pearson et al (13) demonstrated good outcomes. However, in some patients, stenoses may not be amenable to surgery. Management of such patients presents a challenge; alternative treatments include endoscopic dilatation, laser ablation, tracheal stenting, and cryosurgery (14). These interventions may temporarily alleviate the symptoms of TS but as restenosis is a frequent occurrence repeated procedures are often necessary. Given this associated morbidity and the cost associated with the management of TS, a clearer picture of the risk associated with each tracheostomy technique performed within the critical care setting is required.

There is little direct evidence for the association of any perioperative complications with the etiology of TS. In a study, predating the widespread introduction of PDT, assessing the impact of prolonged tracheal intubation and tracheostomy, Stauffer et al (15) identified a high prevalence of complications associated with ST (36% for stomal bleeding, 36% for stomal infection) and a 65% TS prevalence. Despite a number of moderate-sized case series from tertiary centers reporting of the management of TS, none have specifically looked at the role of perioperative events in the initiation of TS (16–19). The only perioperative event that has been postulated to have a role in the genesis of TS is tracheal ring fracture. Although a number of authors (19–21) have suggested that tracheal ring fracture may be of significance, this is not necessarily borne out within large cohort studies (9). Further studies have considered a role for infection in the initiation of TS. In an animal model of TS, Squire et al (22) inoculated the tracheas of rabbits with *Staphylococcus aureus*. When compared with those without bacterial inoculation, the prevalence of TS was higher and the resultant lesions narrower. In addition, Welkoborsky et al (23) examined operative specimens removed from 18 patients undergoing surgical resection for TS and felt infection at the stenotic segment played a part in its initiation in four patients. Despite this work and evidence to suggest a greater prevalence of stomal infections for ST than for PDT (2), there is no evidence that the prevalence of TS differs between the two techniques or that antimicrobial treatment reduces the prevalence of TS.

Despite this lack of direct evidence for the association of perioperative events with the development of TS, we postulated that some complications maybe surrogate markers for a more severe tracheal injury at the time of tracheostomy and thus affect the healing process. When considering such problems, it is possible that many of the events listed in **Appendix 1** may lead the operator to settle for suboptimal tracheostomy tube positioning, which may have an impact on later healing or predispose to infection. We, therefore, felt that the role such factors may play in the initiation of TS was worthy of further study.

Therefore, we performed a systematic review of all prospective studies that reported long-term outcomes and assessed potential predisposing factors. Our aim was to determine whether longer-term complication rates, with particular reference to TS, differed between percutaneous and ST techniques in the critical care setting.

METHODS

Search Strategy

We searched Embase, PubMed-Medline, and the Cochrane Central Register of Clinical Trials for prospective studies involving humans in the critical care setting that reported tracheostomy outcome data and included patients who had received at least one PDT either alone or in comparison with ST or another percutaneous technique. To reflect contemporary practice, we limited the search to studies published from the year 2000 onward. The search was restricted to full-text reports of articles published in English in peer-reviewed journals. In addition, reference lists of those studies returned in the above search were scrutinized for additional relevant articles.

Study Selection

Titles and abstracts of the references obtained were reviewed by three independent reviewers (G.A.D., B.M., C.H.). Studies were categorized as for inclusion, possible inclusion and exclusion. In the absence of a decision by two investigators to exclude an article, data extraction of full-text articles was undertaken by two of the three reviewers independently. Discrepancies between reviewers prompted a re-evaluation of the article.

Ongoing disagreement was resolved by the third reviewer. If the outcome data in the original article were unclear, the corresponding author was contacted for clarification. Our protocol relating to study selection and data extraction is published on http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014008830

Data Extraction and Outcomes

A database was constructed to incorporate outcomes common to previous systematic reviews of percutaneous tracheostomy (additional parameters not presented in the main text of this article can be found in Appendix 1). Outcomes were defined a priori. The primary outcome was TS. Secondary outcomes were wound infection requiring treatment and bleeding (major and minor). Additional data were extracted but not included within the main text of this article due to space restrictions (Appendix 1).

Internal Validity and Risk of Bias Assessment

The internal validity and risk of bias for RCTs was assessed using the Oxford Quality Scoring System (Jadad Score) (24). The score is based on randomization (0–2 points), blinding (0–2 points), and withdrawals/dropouts (0–1 point). Studies scoring less than 3 are considered to be of low quality (25). Nonrandomized cohort studies were assessed using the Newcastle-Ottawa Scale score for cohort studies (26). The scale assesses patient selection (0–4 stars), comparability of patient cohorts (0–2 stars), and outcomes (0–3 stars). Responses indicating high quality earn a star resulting in a maximum possible quality summary score of 9. Assessments were undertaken and confirmed by two independent reviewers. There is a lack of formal assessment tools for observational studies; therefore, no assessments were performed on the single-arm observational studies.

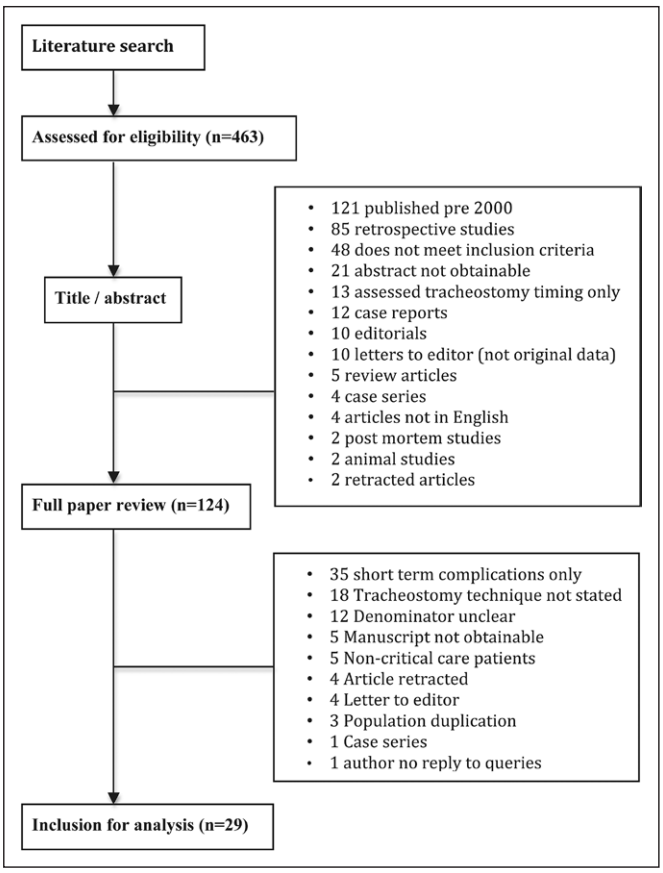

Figure 1. Study selection flow chart.

Data Analysis

For each complication, we calculated the risk difference (RD) and 95% CI in each study that had compared two or more techniques. Studies that specifically reported that no events of a particular type had occurred were included in analyses as zero events. The RD was used as the measure of effect as the data were sparse in many studies, and we wanted to ensure that studies with zero events in both arms contributed to meta-analyses. We used a random-effects meta-analysis to pool the RD across multiple studies (27). Analyses were performed in STATA version 9.2 (Stata Statistical Software 2005: Release 9; Stata LP, College Station, TX).

As we were interested in estimating the complication risks associated with each technique, we calculated the proportion of total patients with a complication and 95% CI in each study that provided data for a particular technique. Proportions were first transformed via the Freeman-Tukey double arcsine method (28), which were then pooled using random-effects meta-analysis (27). Analyses were performed in StatsDirect statistical software version 2.7.9 (2013; StatsDirect, Altrincham, Cheshire, England).

We assessed statistical heterogeneity through visual inspection of the forest plot and interpretation of the I^2 statistic (percentage of variation across studies that is due to heterogeneity rather than chance) (29) and the Cochrane Q test. Where a sufficient number of studies were included in analyses, funnel plots were examined and Egger test applied to assess potential bias in meta-analyses (30). A sensitivity analysis was performed to compare results when restricted to RCTs only.

RESULTS

Search Results

Database search results yielded 463 studies that were subsequently assessed for eligibility (**Fig. 1**). One hundred and twenty-four studies were subjected to full-text review with 94 failing to meet inclusion criteria. One study was excluded due to possible duplication of results and a lack of response to a clarifying e-mail query (Fig. 1). A total of 29 articles reporting on 5,473 patients were included in the analysis (**Table 1**) (9–11, 31–56).

Study Characteristics

Of the 29 studies included, nine (n = 1,023 patients) were RCTs that evaluated two or more percutaneous techniques (32, 35, 37, 39, 40, 43, 46, 48, 53). Of the remaining 20 studies, one was a prospective cohort study comparing three techniques (ST, TLT, and CPDT; n = 100 patients) (42), two

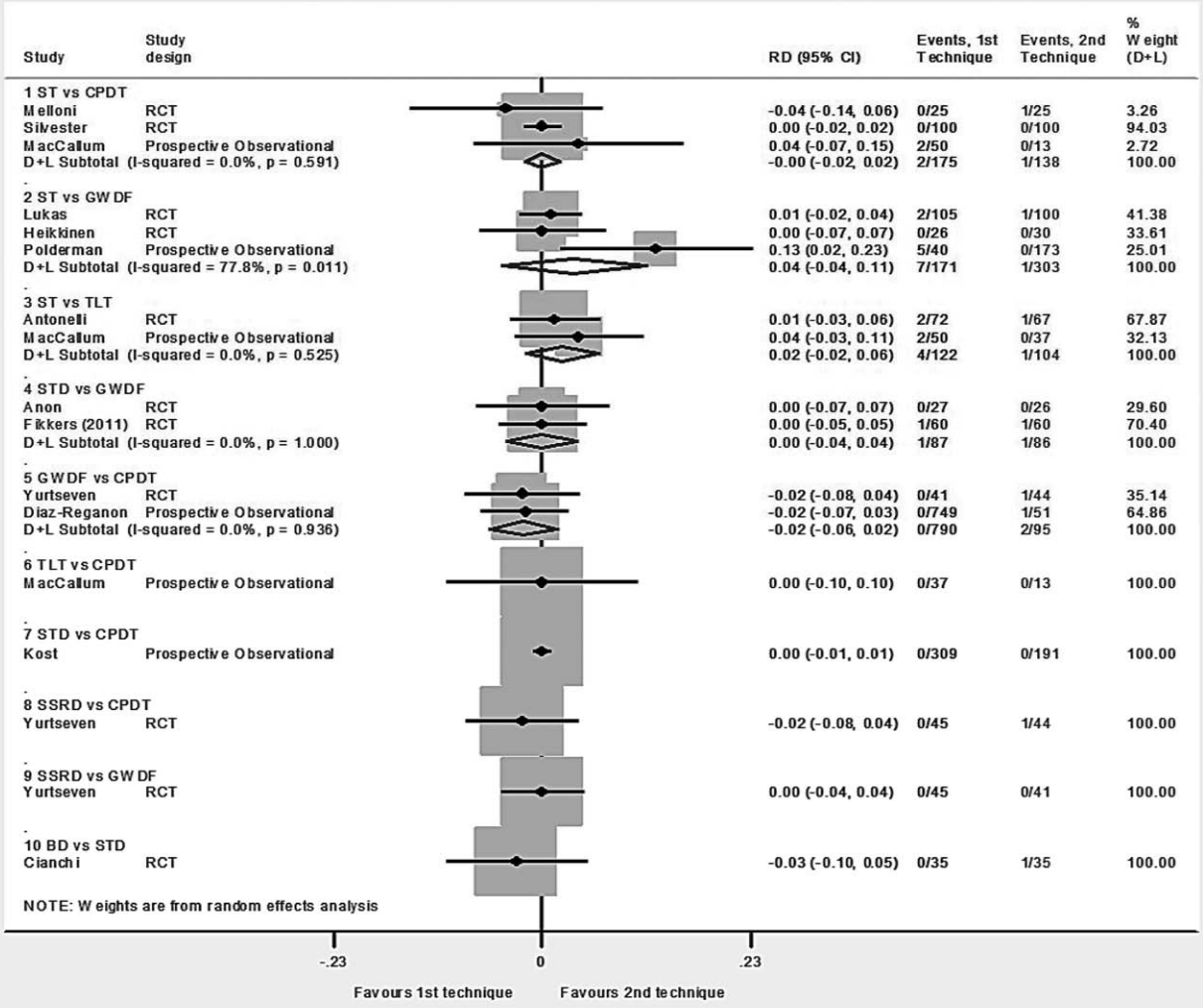

Figure 2. Forest plot comparing risk of tracheal stenosis for different percutaneous tracheostomy and surgical tracheostomy (ST) techniques. RD = risk difference, CPDT = Ciaglia multiple dilator method, RCT = randomized controlled trial, GWDF = guide wire dilating forceps, TLT = translaryngeal tracheostomy, STD = single tapered dilator, SSRD = single step rotational dilator, BD = balloon dilator, D+L = DerSimonian & Laird (27).

compared prospective PDT techniques with historical surgical control groups (n = 421; the retrospective ST patients were not included in our analysis) (34, 52), three were prospective observational studies reviewing more than one technique (n = 1,513) (10, 11, 54), and 14 were single-arm prospective studies (n = 2,416) (9, 31, 33, 36, 38, 41, 44, 45, 47, 49–51, 55, 56). Further details of study characteristics including risk of bias assessments can be seen in Table 1. The mean Jadad score for RCTs was 2.4, and mean Newcastle Ottawa score for the cohort studies was 6.25.

In all studies evaluating the CPDT, the Ciaglia Percutaneous Tracheostomy Multiple Dilator set (Cook Critical Care, Bloomington, IN) was used. All studies assessing the GWDF technique used the Portex kit (SIMS Portex, Hythe, Kent, United Kingdom). For studies evaluating STD, the Ciaglia Blue Rhino Percutaneous Tracheostomy Introducer set (Cook Critical Care) was used in six (9, 11, 33, 35, 43, 52), and the Portex Ultraperc (Smith Medical, Hythe, Kent, United Kingdom) was used in one (40). For the TLT technique, two studies did not specify the equipment used (42, 53) and in the third the Mallinckrodt kit (Mallinckrodt Medical, Mirandola, Italy) was used (55). The study evaluating the BD technique (43) used the Ciaglia Blue Dolphin Percutaneous Tracheotomy Introducer Kit (Cook Critical Care), whereas the PercuTwist Set (Rüsch GmbH, Kennen, Germany) was used for the SSRD study (32). For ST, two studies used a modified Bjork flap technique (37, 39): one used a midline vertical incision (46), one used an H shaped incision (48); whereas in three others, the technique used was not described (42, 53, 54).

Three studies were conducted in multiple centers (11, 35, 42), four were undertaken within multiple units within the same hospital (34, 45, 48, 52) and 22 were conducted within a single CCU (9, 10, 31–33, 36–41, 43, 44, 46, 47, 49–51, 53–56). Of the 26 studies conducted within a single institution, 23 were in a university/teaching center (9, 10, 31–34, 36–38, 40, 41, 43–48,

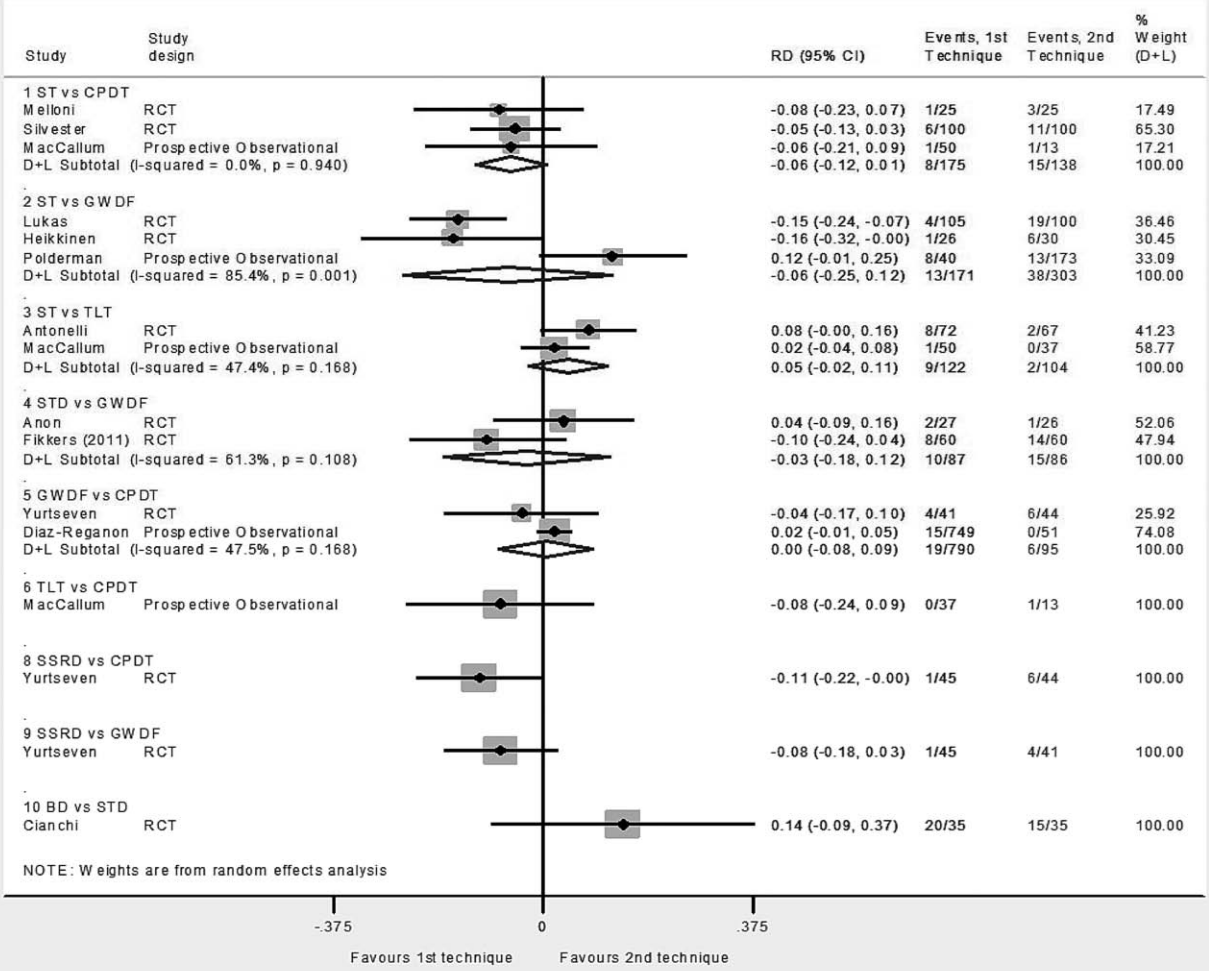

Figure 3. Forest plot comparing risk of all bleeding (major and minor) episodes reported for different percutaneous tracheostomy and surgical tracheostomy (ST) techniques. RD = risk difference, CPDT = Ciaglia multiple dilator method, RCT = randomized controlled trial, GWDF = guide wire dilating forceps, TLT = translaryngeal tracheostomy, STD = single tapered dilator, SSRD = single step rotational dilator, BD = balloon dilator, D+L = DerSimonian & Laird (27).

50, 51, 53–56). There were two studies, respectively, reporting findings from neuro (31, 55) and cardiac surgical (49, 51) populations; the remaining studies were of mixed populations. In 12 studies, the primary operators were CCU physicians/anaesthetists (9, 32, 35, 36, 40, 43, 46, 48, 50, 52, 53, 56); in six studies, they were surgically trained (11, 31, 34, 39, 45, 47); in a further nine studies, there was a mixture of both surgical and CCU personnel (10, 37, 38, 41, 42, 44, 49, 51, 54); and two studies failed to specify the background of the operator (33, 55).

Data Analysis

Comparative Analyses. **Figures 2**, **3**, **4**, and **5** summarize meta-analyses of studies that provide comparative data (RCT and prospective cohort data) between individual techniques for the complications of TS, total bleeding episodes, major bleeding, and wound infections, respectively. Overall, there are few studies, all with small sample sizes, that provide data comparing the different techniques, particularly in relation to those described more recently (STD, SSRD, and BD). We did not identify direct comparisons between STD, BD, or SSRD versus ST. A statistically significant RD was not identified for any of the meta-analyses, apart from the comparison between ST and CPDT in relation to wound infection (**Fig. 5**), with a pooled RD (95% CI) of 0.12 (0.02–0.23) in favor of CPDT. There was evidence of heterogeneity for several comparisons, which could not be explored in detail due to the limited number of studies. However, heterogeneity was accounted for by using a random-effects meta-analysis. A sensitivity analysis restricting meta-analyses to only RCTs suggested that results and conclusions were similar, although for the bleeding complication, results were statistically significant for two comparisons when restricted to RCTs only (ST vs GWDF: RCTs and prospective observational studies, –0.06 [–0.25 to 0.12]; RCTs only, –0.15 [–0.23 to –0.08] and ST vs TLT: RCTs and prospective observational studies, 0.05 (–0.02 to 0.11); RCTs only, 0.08 [0 to 0.16]).

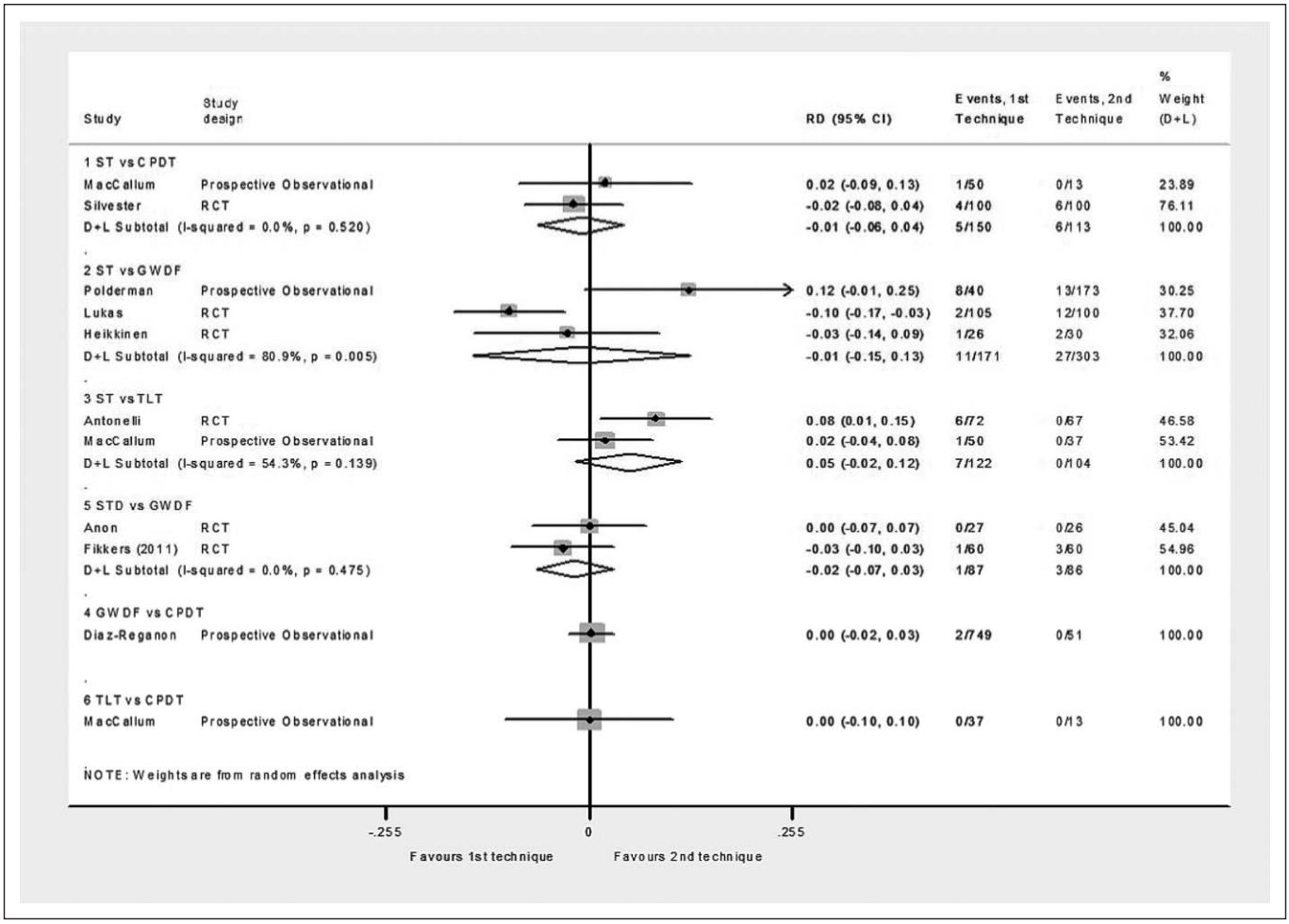

Figure 4. Forest plot comparing risk of major bleeding (requiring blood transfusion or surgical intervention) episodes reported for different percutaneous tracheostomy and surgical tracheostomy [ST] techniques). RD = risk difference, CPDT = Ciaglia multiple dilator method, RCT = randomized controlled trial, GWDF = guide wire dilating forceps, TLT = translaryngeal tracheostomy, STD = single tapered dilator, SSRD = single step rotational dilator, BD = balloon dilator, D+L = DerSimonian & Laird (27).

Single-Arm Studies. To supplement the comparative analyses, a crude overall summary of prevalence of TS, bleeding episodes (total and major) and wound infection, pooled across all studies (single-arm studies and the relevant arm data from comparative studies) according to the random-effects proportion meta-analysis, is given in **Tables 2–5**. There is a high degree of heterogeneity (measured by the I^2 statistic) between studies suggesting that the complication risk could vary according to setting or patient. Direct comparisons between the complication prevalence for different techniques should not be made based on these pooled estimates due to their observational nature.

DISCUSSION

We have investigated the prevalence of long-term TS in patients undergoing tracheostomy in a critical care setting. In addition, we have estimated prevalence of periprocedural complications (bleeding and wound infection) that we have postulated may have a role in the development of TS. When considering published RCTs and comparative observational studies reporting long-term outcomes, we have found ST and all percutaneous techniques (CPDT, GWDF, STD, TLT, SSRD, and BD) broadly similar in terms of TS and bleeding. In keeping with earlier meta-analyses, we have also found a higher prevalence of wound infection when comparing ST with CPDT. Despite the frequency with which percutaneous tracheostomies are performed within the critical care setting, there appear to be relatively few high-quality studies assessing long-term outcomes between techniques.

When considering the pooled proportion meta-analysis across all studies, the TS rate reported varies from 2.8% to 0.6% for ST and STD, respectively, with all percutaneous techniques being broadly comparable (Table 2). The point estimate of rate for total bleeding episodes varies from 12.1% for STD to 2% for TLT (Table 3), but the CIs around some of these estimates are wide with a substantial degree of between-study heterogeneity. Major bleeding ranges from 4.7% for ST to 0.6% for TLT, whereas wound infection for ST is 9.9% and 1.1% for CPDT, again with wide 95% CIs and substantial between-study heterogeneity.

By incorporating cohort studies and RCTs into our analysis, we have adopted a different methodology to earlier

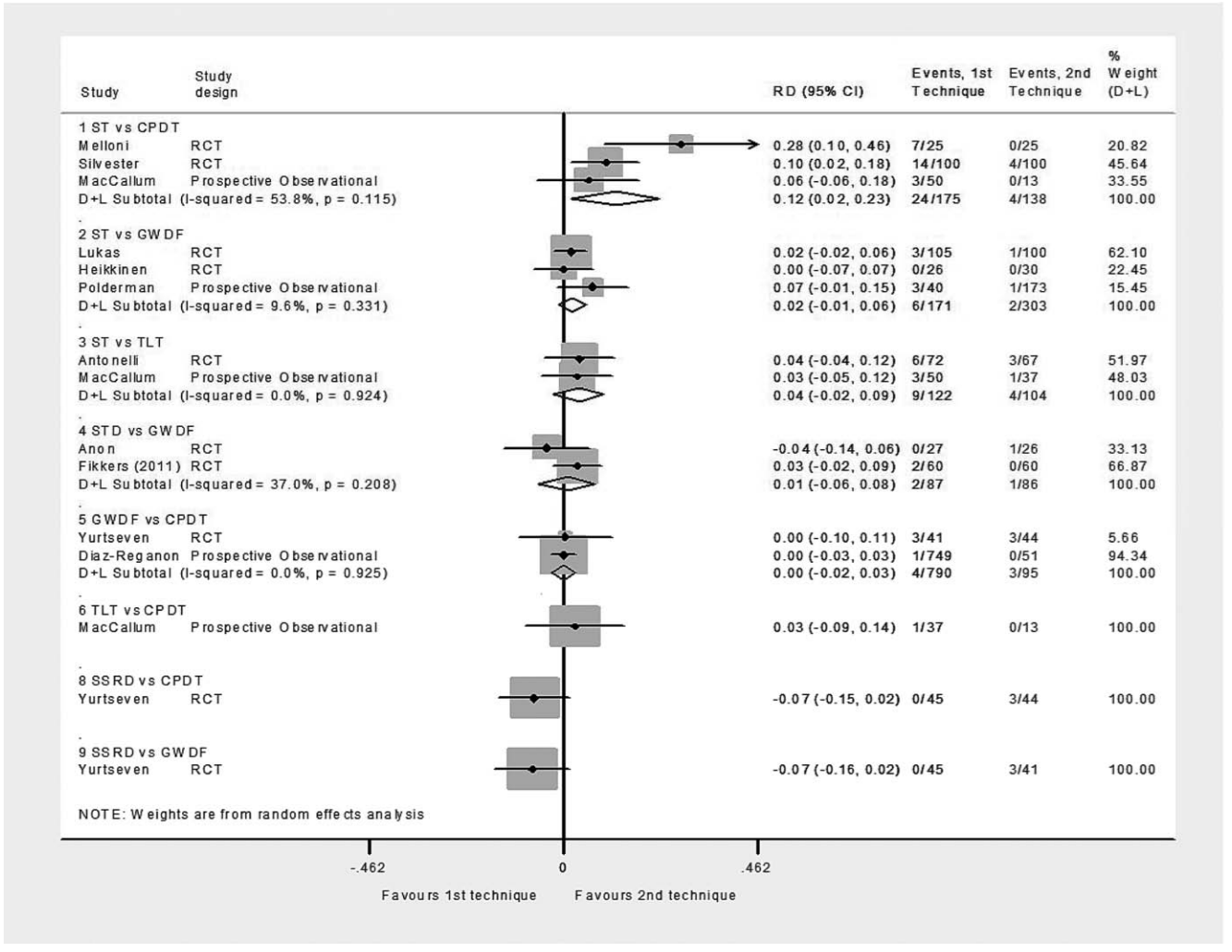

Figure 5. Forest plot comparing risk of wound infection for different percutaneous tracheostomy and surgical tracheostomy (ST) techniques. RD = risk difference, CPDT = Ciaglia multiple dilator method, RCT = randomized controlled trial, GWDF = guide wire dilating forceps, TLT = translaryngeal tracheostomy, STD = single tapered dilator, SSRD = single step rotational dilator, BD = balloon dilator, D+L = DerSimonian & Laird (27).

meta-analyses. The majority of studies incorporated into previous analyses were RCTs of relatively small samples sizes and as such, given the low prevalence, were limited in their ability to detect a difference in risk of TS. Although the incorporation of nonrandomized studies may introduce an element of bias, work by Golder et al (57) has suggested that this effect may be minimal. In a meta-analysis of meta-analyses, they found a high degree of concordance between meta-analyses of adverse events comparing data solely from RCTs with those from both RCTs and observational studies (with less discrepancy for larger studies), concluding that meta-analyses of adverse events should not, necessarily, be confined to a specific study types. In a sensitivity analysis, we excluded the nonrandomized studies and compared meta-analysis results with those that include both RCT and prospective observational studies. Overall, results were similar but changed from being nonsignificant to statistically significant for bleeding complication for two comparisons, suggesting that there may be important differences between RCTs and observational studies (see below).

Another potential limitation to accurate determination of the prevalence of TS, following percutaneous tracheostomy, in the current study, is the possibility that patients who are perceived to be predisposed to a difficult tracheostomy may be assigned to the ST group in nonrandomized studies. In support of this concern, of the seven studies assessing ST, five were RCTs (37, 39, 46, 48, 53) reporting a TS prevalence of 1.4% (4/328) and two were prospective nonrandomized studies with a TS prevalence of 8.4% (7/90) (42, 54). In addition, the RD estimates for TS from the prospective nonrandomized studies were each more extreme than corresponding estimates from RCTs in those comparisons between ST and percutaneous tracheostomy. Of the nonrandomized studies, the study by MacCallum et al (42) (reporting two stenoses) provides no information on group allocation other than stating that procedures were performed consecutively. In contrast, Polderman et al (54) (five stenoses) reports that seven patients were allocated to the ST group because of perceived difficult anatomy, whereas the remainder of patients were allocated randomly. No

TABLE 1. Characteristics of Studies Included in Analysis

References	Mean Age (yr)	Men (%)	Study Design	Techniques (Patients)	Bronchoscopic Control	Stated Length of Follow-Up	Risk of Bias Assessment[a]
Díaz-Regañón et al (10)	62[b]	570 (71)	PO	CPDT (51), GWDF (749)	35/800 procedures	6 mo	6
Kost (11)	Not reported	280 (56)	PO	CPDT (191), STD (309)	Yes	3–4 mo	7
Chen et al (31)	44	14 (67)	PO	GWDF (21)	No	6 mo	–
Yurtseven et al (32)	61	83 (64)	RCT	CPDT (44), GWDF (41), SSRD (45)	Yes	6 mo	3
Fikkers et al (33)	57	70 (70)	PO	STD (100)	Yes	12 mo	–
Donaldson et al (34)[c]	64	39 (72)	PO	CPDT (54)	Yes	3 mo	–
Añón et al (35)	63	38 (72)	RCT	STD (27), GWDF (26)	No	282 d[d]	2
Sviri et al (36)	56	66 (62)	PO	GWDF (106)	No	30 mo[b]	–
Lukas et al (37)	65	125 (61)	RCT	GWDF (100), ST (105)	No	6 mo	2
Kearney et al (38)	56	519 (63)	PO	CPDT (824)	Selected cases	461 d[d]	–
Heikkinen et al (39)	65	40 (71)	RCT	GWDF (30), ST (26)	No	18 mo	2
Fikkers et al (40)	62[b]	81 (68)	RCT	GWDF (60), STD (60)	Yes	3 mo	3
Fikkers et al (41)	62[b]	99 (58)	PO	GWDF (171)	Yes	2.5 yr[b]	–
MacCallum et al (42)	63	65 (65)	PNR	ST (50), TLT (37), CPDT (13)	Only TLT group	6 mo	*6*
Cianchi et al (43)	61[b]	52 (74)	RCT	STD (35), BD (35)	Yes	LTOR	2
Dempsey et al (9)	58	340 (59)	PO	STD (576)	Yes	3 mo	–
Ben Nun et al (44)	62	90 (58)	PO	GWDF (154)	No	6 mo	–
Velmahos et al (45)	42	72 (72)	PO	CPDT (100)	First 14 cases	10 mo[d]	–
Silvester et al (46)	64[b]	137 (69)	RCT	CPDT (100), ST (100)	80% CPDT	20 mo[b]	3
Mittendorf et al (47)	54	45 (63)	PO	CPDT (71)	No	3 mo	–
Melloni et al (48)	57	31 (62)	RCT	ST (25), CPDT (25)	100% CPDT	6 mo	2
Gatti et al (49)	71	18 (55)	PO	CPDT (33)	No	3 mo	–
Escarment et al (50)	52	117 (72)	PO	GWDF (162)	13% (selected cases)	3 mo	–
Dollner et al (20, 51)	65	21 (55)	PO	GWDF (162)	Yes	22 mo[d]	–
Beltrame et al (52)[c]	65	26 (72)	PO	STD (367)	Yes	10 mo[d]	–
Antonelli et al (53)	64	83 (60)	RCT	TLT (67), ST (72)	No	1 yr	3
Polderman et al (54)	54	N/A	PO	GWDF (173), ST (40)	GWDF 77%	14 mo[d]	*6*
Stocchetti et al (55)	47	14 (70)	PO	TLT (20)	Yes	3 mo	–
Joshi et al (56)	35	18 (45)	PO	CPDT (40)	No	LTOR	–

PO = prospective observational, CPDT = Ciaglia multiple dilator method, GWDF = guide wire dilating forceps, STD = single tapered dilator, RCT = randomized controlled trial, SSRD = single step rotational dilator, ST = surgical tracheostomy, PNR = prospective nonrandomized, TLT = translaryngeal tracheostomy, BD = balloon dilator, LTOR, length of follow-up not stated but long-term outcomes reported.

aRisk of bias assessments: RCT, Jadad score (0–5).

[b]Reported as median.

[c]Also reviewed surgical tracheostomy patients retrospectively: not included in analysis.

[d]Reported as mean.

The score is based on randomization, blinding, and withdrawals/dropouts. Studies scoring < 3 are considered to be of low quality (25) (see text for details). Observational studies: Newcastle Ottawa Scale (0–9). The scale assesses patient selection, comparability of patient cohorts, and outcomes. Responses indicating high quality earn a star with a maximum possible score of 9 (see text for details). Single-arm studies: no assessment. Scores for RCTs and observational studies are not directly comparable.

TABLE 2. Tracheal Stenosis According to Tracheostomy Technique: Random-Effects Proportion Meta-Analysis

Tracheostomy Technique	No. of Studies (Patients Included)	No. of Stenoses	Pooled Estimate (%) (95% CI[a])	I^2% (95% CI)
Surgical tracheostomy	7 (418)	11	2.8 (0.8–5.9)	57.9 (0–80)
Guide wire dilating forceps	13 (1,831)	10	0.9 (0.3–1.7)	50.3 (0–72)
Ciaglia technique	12 (1,546)	15	1.0 (0.4–1.9)	33.7 (0–66)
Single tapered dilator	7 (1,474)	7	0.6 (0.2–1.2)	22.6 (0–67)
Translaryngeal tracheostomy	3 (124)	1	1.5 (0.1–4.3)	0 (0–73)
Single step rotational dilator	1 (45)	0	–	–
Balloon dilator	1 (35)	0	–	–

[a]Calculated from random-effects model.

information as to whether those patients with difficult anatomy were also the patients who developed TS was provided. The choice between surgical and percutaneous tracheostomy in most situations is not a random event with most operators opting for the surgical approach when potential difficulties or safety concerns are anticipated. It is probable, therefore, that many of the surgical tracheostomies described within the studies herein would be more prone to the occurrence of complications. It is possible, therefore, that the observed differences in complication rates we have demonstrated in our analyses could be due to patient factors rather than the operative technique per se. However, as discussed above, other than a potential role for tracheal ring fracture, there is little evidence for perioperative complications causing TS.

Accepting these potential limitations, we contend that in the critical care setting, there is a trend toward increased risk of TS for ST patients.

Our data confirm our view that in the critical care setting, in common with previous authors, a percutaneous procedure should be the technique of choice (2) as it is both safe and cost effective.

It is somewhat surprising (and a common theme across all previous meta-analyses), given the frequency with which PDTs are now undertaken, that we have only identified 29 studies reporting upon the long-term outcomes of 5,473 patients over the preceding 14 years. We find it concerning that some techniques in relatively widespread use (SSRD, BD, and TLT) have such sparse long-term outcome data. When specifically considering the issue of TS and the possibility of unrecognized subclinical TS in this patient population, very few studies have undertaken comprehensive radiological imaging to determine the underlying prevalence of stenosis. Considering that the STD technique appears to be currently the most widely used approach (58–60), until recently, there were only 14 patients described in the literature who had undergone radiological imaging after STD tracheostomy to determine the underlying prevalence of both clinical and subclinical TS (40). This has, in part, been addressed by a recent study from the UK (8).

Reporting of complications across studies remains far from standardized and posed significant problems during data extraction. We had initially set out to collect data for a significant number of secondary outcomes (Appendix 1).

TABLE 3. Total Bleeding Episodes According to Tracheostomy Technique: Random-Effects Proportion Meta-Analysis

Tracheostomy Technique	No. of Studies (Patients Included)	Total No. of Bleeding Episodes	Pooled Estimate (%) (95% CI[a])	I^2% (95% CI)
Surgical tracheostomy	7 (418)	29	7.3 (4–11.4)	52.1 (0–78)
Guide wire dilating forceps	11 (1,687)	100	9.2 (5–14.4)	88.8 (82–92)
Ciaglia technique	11 (1,355)	64	6.6 (4–9.7)	62.9 (12–79)
Single tapered dilator	6 (1,165)	80	12.1 (3.3–25.3)	96.3 (95–97)
Translaryngeal tracheostomy	3 (124)	2	2 (0.3–5.3)	0 (0–73)
Single step rotational dilator	1 (45)	1	–	NA
Balloon dilator	1 (35)	20	–	NA

NA = not applicable (only one study).

[a]Calculated from random-effects model.

Studies not reporting bleeding: guide wire dilating forceps (Dollner et al [20, 51] and Sviri et al [36]); bleeding events not attributable to technique: Kost (11) (Ciaglia multiple dilator method and single tapered dilator).

TABLE 4. Major Bleeding Episodes (Need for Surgical Cautery or Blood Transfusion) According to Tracheostomy Technique: Random-Effects Proportion Meta-Analysis

Tracheostomy Technique	No. of Studies (Patients Included)	Major Bleeding Episodes	Pooled Estimate (%) (95% CI[a])	I^2% (95% CI)
Surgical tracheostomy	7 (418)	17	4.7 (2.8–7.1)	7 (0–64)
Guide wire dilating forceps	11 (1,687)	36	3.4 (1.4–6.3)	82 (66–89)
Ciaglia technique	11 (1,355)	18	1.8 (0.7–3.5)	55.7 (0–78)
Single tapered dilator	6 (1,165)	10	1.1 (0.2–2.7)	65.1 (0–85)
Translaryngeal tracheostomy	3 (124)	0	0.6 (0.01–2.6)	0 (0–73)-
Single step rotational dilator	1 (45)	0	–	–
Balloon dilator	1 (35)	0	–	–

[a]Calculated from random-effects model.

However, lack of uniform reporting made this aim much more difficult and ultimately of little value as many complications are reported infrequently with marked differences in prevalences across studies. Even reporting of our primary and secondary outcomes was inconsistent with some studies failing to quote a prevalence for TS, bleeding, and wound infection. One study appeared to describe an apparent prevalence of TS (presence of stridor with spirometry findings in keeping with upper airway obstruction) but failed to ascribe these findings to a diagnosis of TS (36). A lack of a consistent definition for significant versus minor bleeding lead us to analyze total bleeding episodes and those categorized as major. In addition, one study reported stomal decay as an outcome, interpreted as infection for our analysis (37). In addition, we were unable to explore the possible relationships between bleeding and stomal infection and TS. Although most of the studies included in the analysis reported TS, bleeding, and stomal infection rates, there were little, if any, supplemental data reported for us to ascertain whether these events were associated and occurring within the same patients or not. A number of other studies that detailed complications of multiple techniques reported composite outcomes where the complication rate for a given technique was impossible to ascertain. In this circumstance, we wrote to the author for clarification. In some instances, this resolved the problem either completely or partially. In others, where there was no reply from the corresponding author, the study was excluded from the analysis. These limitations highlight the vital need to develop and report core standardized outcome measures to improve synthesis of trial data (61).

It is highly unlikely that an RCT will be performed to determine the prevalence of long-term outcome measures such as TS in the future. TS has a low prevalence, critical illness mortality is high, and long-term follow-up is difficult. An adequately powered study would require at least 2,000 patients to detect a reduction in TS from 2.8% to 1% ($\alpha = 0.05$; $\beta = 0.8$), and this figure excludes dropout. Thus, we believe our study, despite the limitations described, is currently best placed to inform clinicians in this area, but further good quality comparative studies reporting complication rates are now needed.

From the limited published data, we have not found a significant difference in the prevalence of TS between a range of percutaneous techniques and surgical tracheostomies. When considering all published data reporting long-term

TABLE 5. Wound Infection According to Tracheostomy Technique: Random-Effects Proportion Meta-Analysis

Tracheostomy Technique	No. of Studies (Patients Included)	No. of Tracheostomy Wound Infections	Pooled Estimate (%) (95% CI[a])	I^2% (95% CI)
Surgical tracheostomy	7 (418)	36	8.5 (4.1–14.4)	71.5 (18–85)
Guide wire dilating forceps	10 (1,666)	16	1.5 (0.6–2.8)	61.5 (1.6–79)
Ciaglia technique	11 (1,355)	11	1.0 (0.36–2.1)	32.5 (0–66)
Single tapered dilator	4 (554)	6	1.7 (0.02–5.9)	80.1 (17.4–90.6)
Translaryngeal tracheostomy	3 (124)	4	3.9 (1.26–8)	0 (0–73)
Single step rotational dilator	1 (45)	0		
Balloon dilator	1 (35)	0		

[a]Calculated from random-effects model.

Studies not reporting infection: guide wire dilating forceps (Sviri et al [36], Chen et al [31], and Dollner et al [20, 51]) and single tapered dilator (Cianchi et al [43] and Dempsey et al [9]). Infection episodes not attributable to technique: Kost (11) (Ciaglia multiple dilator method and single tapered dilator).

outcomes, our pooled proportion meta-analysis may indicate a tendency toward a higher rate of TS for ST, but this is likely to be prone to selection bias. Similarly, in relation to major bleeding, we have not found a difference between the techniques commonly used. Again the pooled proportions meta-analysis may indicate a tendency toward more major bleeding for ST. In relation to wound infection, we have found a reduction (RD, –6% [95% CI, –12% to 1%]) associated with CPDT when compared with ST in keeping with earlier work. Across all percutaneous techniques for the primary and secondary outcomes studied, complication rates appear to be broadly similar, but CIs for pooled RDs are wide and include clinically important differences in both directions.

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Appendix 1: Additional Data Extracted From Articles

Mean Acute Physiology and Chronic Health Evaluation II/ mean Sequential Organ Failure Assessment scores
Location of procedure
Operator experience
Mean duration translaryngeal intubation (d)
Mean duration of tracheostomy
Duration sedation post tracheostomy
Mean ventilator dependent days
Mean critical care unit length of stay
Mean hospital length of stay
Mortality (1-mo procedure)
Average duration of procedure (min)
Number of episodes hypoxia ($Sa_{O_2} < 91\%$)
Number of cardiac arrhythmia
Incidence of hypotension (systolic blood pressure < 90 mm Hg)
Number of tracheal cuff punctures
Number of paratracheal insertions
Number of tube displacements or loss of airway
Number of pnuemothoraces
Number of pneumomediastinum
Number of subcutaneous emphysema
Episodes of atelectasis
Incidence of aspiration
Number of esophageal injuries
Number of posterior tracheal wall injury
Number of perioperative mortalities
Number of perioperative cardiac arrest
Number of pneumonias
Frequency of delayed wound healing (> 3 wk)
Number of tracheoinnominate artery fistula
Incidence of failure to decannulate
Number of reintubations
Difficulty in recannulation
Hypercapnia
Increased airway pressure
Stomal enlargement
Tracheal dilatation
Dysphagia
Respiratory problems
Bronchoscopic damage
Poor visualization of tracheal structures
Late tracheal wall injury/hematoma/swelling
Chyle leak (requiring intercostal drainage)
Laryngeal pericondritis