**Cost analysis and outcomes of endoscopic, minimal access and open pancreatic necrosectomy**

Rebecca Saunders MBChB. Department of Molecular & Clinical Cancer Medicine, University of Liverpool, UK

Faye E Hughes, BSc. Department of General & Pancreatic Surgery, Liverpool University Hospitals NHS Foundation Trust, UK

Jonathan C Evans, MRCP, FRCR. Department of Radiology, Liverpool University Hospitals NHS Foundation Trust, UK

Howard L Smart, DM FRCP. Department of Gastroenterology, Liverpool University Hospitals NHS Foundation Trust, UK

Paula Ghaneh, MD, FRCS. Department of Molecular & Clinical Cancer Medicine, University of Liverpool, UK. Department of General & Pancreatic Surgery, Liverpool University Hospitals NHS Foundation Trust, UK

Jayapal Ramesh, FRCR. Department of Gastroenterology, Liverpool University Hospitals NHS Foundation Trust, UK

Robert Sutton, DPhil, FRCS. Department of Molecular & Clinical Cancer Medicine, University of Liverpool, UK. Department of General & Pancreatic Surgery, Liverpool University Hospitals NHS Foundation Trust, UK

Christopher M Halloran, BSc, MD, FRCS, SFHEA. Department of Molecular & Clinical Cancer Medicine, University of Liverpool, UK. Department of General & Pancreatic Surgery, Liverpool University Hospitals NHS Foundation Trust, UK

*Corresponding author:*

Professor C.M Halloran, Institute of Systems, Molecular & Integrative Biology, Department of Molecular & Clinical Cancer Medicine, 2nd Floor Sherrington Building, University of Liverpool, Ashton Street, Liverpool, L69 3GE UK

Email: [halloran@liverpool.ac.uk](mailto:halloran@liverpool.ac.uk)

Tel: +44 (0)151 795 8031

Reprints will not be available from the author(s).

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*Running head*

Outcome & cost of EN, MARPN & OPN

**INTRODUCTION**

Acute Pancreatitis is a potentially fatal condition and results in approximately 100 acute admissions per year for most acute hospitals in the United Kingdom 1. Approximately 20% of patients will develop pancreatic necrosis as a complication of acute pancreatitis with infected pancreatic necrosis subsequently occurring in 30-70% of this group 2,3. The resultant mortality is between 20-30% 4-9. In most cases of infected pancreatic necrosis intervention is required 10, 11.

For the last decade minimally invasive pancreatic necrosectomy has been the gold standard of management for pancreatic necrosis requiring intervention 10, 12. More recently endoscopic transluminal drainage and necrosectomy has been developed and has been shown to be an effective alternative for appropriate patients 12, 13. Open necrosectomy is a more invasive treatment approach and overall, its use has declined as it has been confirmed to be associated with a higher incidence of morbidity and mortality 6, 14,15. Current evidence is inconclusive regarding the advantages of an endoscopic approach compared to minimally invasive surgical interventions in terms of clinical outcomes 16. The TENSION trial concluded that an endoscopic step-up approach was not superior to a surgical step-up approach 12, however a smaller trial found that an endoscopic approach reduced major complications and increased quality of life 17.

Patient level information and costing systems (PLICS) have become mandatory for acute activity in NHS hospitals from the 2018/19 financial year, moving forward from reference costs 18. Costings are derived from tracking all resources used by an individual patient during their admission and calculating the actual costs incurred. This provides several advantages over the previous reference system which was based on healthcare resource group (HRG) averages and cannot be easily linked to an individual patient 19. HRGs are groupings of clinically similar events or treatments that are judged to use comparable levels of healthcare resource 20. Patient level costing allows for more accurate comparisons between different organisations nationally and provides more accurate data for agreeing on local pricing for patient care. It is also more accessible for clinicians, allowing validation of activities and costs and a potential avenue of improving care pathways 18.

Previous cost comparisons of endoscopic necrosectomy and a step-up surgical approach have demonstrated a trend towards reduced cost for an endoscopic approach 12, 17, 21. The aim of this study was to evaluate any potential cost benefit for a particular intervention for pancreatic necrosis by performing a clinical comparison and cost-consequence analysis using individual patient costings.

**METHODS**

*Patients*

All patients undergoing pancreatic necrosectomy at the Royal Liverpool University Hospital from 1 April 2015- 31 March 2017 were included and analysed on an intention to treat basis. Patients with admissions extending out of these times were excluded from the study. This tight time frame was chosen to accommodate whole patient episodes in which procedures were undertaken within a negotiated block contract, with a fixed budget agreed by NHS commissioners. Patients were prospectively recorded on to an electronic database.

All patients were managed in accordance with current IAP/APA guidelines 10. Intervention was delayed until 4 weeks post onset of acute necrotising pancreatitis unless the clinical condition of the patient necessitated earlier drainage or laparotomy. Every patient was discussed at the weekly benign multi-disciplinary team (MDT) meeting, attended by pancreatic surgeons, endoscopists, radiologists and specialist nurses. The overall management plan and the nature of any required intervention was agreed by the MDT. The mode of intervention was decided on a patient-by-patient basis, following review of the individual’s condition and the position of the necrosis. However, if the clinical condition changed, patients were treated accordingly to their emergent situation. Specific indications for intervention included clinical suspicion or documented infected necrosis, ongoing non-improving organ failure, ongoing gastric or biliary obstruction. APACHE II scores were calculated prior to the initial intervention performed.

*Necrosectomy techniques*

Endoscopic approach (EN)

Endoscopic transluminal drainage was the initial intervention in an endoscopic step-up approach. Under endoscopic ultrasound (EUS) guidance the optimum site for stent placement was established. Cyst puncture was performed with a 19 gauge needle and aspirated fluid was sent for culture. A lumen apposing metal stent (LAMS) with enhanced delivery system (Hot AXIOS, Boston Scientific) or biflanged metal stent (Nagi, Taewoong Medical Co.Ltd) was placed into the collection. Fluoroscopy was not routinely used for Hot AXIOS stent insertion. Necrosectomy was then performed using the ‘flush’ method of extra-cavity lavage using jet pump irrigation and suction 22. A cap was placed on the tip of the endoscope to aid suction. Instrumentation and debridement of the cavity was avoided within the cavity. A radial expansion balloon or snares were used to unblock the stent if required. The patient underwent weekly scheduled repeat necrosectomy procedures until necrosectomy was complete; these were undertaken as an outpatient if the patient was sufficiently well. Once imaging confirmed the cavity had completely collapsed, the stent was removed, preferably within 6 weeks of insertion. Multiple metal stents or anchoring plastic stents were used at the discretion of the endoscopist.

Minimal access retroperitoneal pancreatic necrosectomy

Minimal access retroperitoneal pancreatic necrosectomy (MARPN) was performed as previously described 6, 7. Initial percutaneous drainage was performed with a 12 French pigtail catheter inserted under CT guidance. In patients with central or left sided collections, the drainage catheter was inserted via the left flank between the spleen and splenic flexure. It was possible to insert catheters anteriorly or via the right flank in patients with right sided or complex collections. MARPN was performed under general anaesthetic or sedation. The pigtail drain was exchanged for a guidewire under fluoroscopic guidance and the tract dilated up to 30 Fr using serial dilators. A sheath was inserted into the tract allowing the passage of an operating nephroscope. Necrosis was removed piecemeal under direct vision with a minimal necrosectomy on the initial procedure due to immature necrosis and to prevent bleeding. Tissue samples were sent to microbiology for culture and sensitivities. A 10 or 12 Fr nasogastric tube was sutured inside a 28 Fr chest drain and inserted into the cavity allowing post-operative irrigation. Repeat MARPNs were performed every 7-10 days until necrosectomy was complete and healthy granulation tissue was visualised. A fistulogram was performed to confirm the cavity had collapsed. The chest drain was downsized to a nasogastric tube and the patient was discharged when sufficiently fit.

Open pancreatic necrosectomy (OPN)

At laparotomy the necrotic area was exposed by transection of the gastro-colic and duodeno-colic ligaments or through the space of Riolan adjacent to the ligament of Treitz, allowing blunt dissection then debridement of necrotic tissue. At least 2 wide bore drains were placed into the cavity through separate incisions and the cavity managed by closed continuous local lavage 6, 23. Abdominal packing and second look laparotomies were not routinely performed.

For all techniques additional percutaneous drains were inserted in to flank or loculated collections when indicated.

*Statistical analysis*

Descriptive statistics were performed on patient characteristics and outcome measures. A Chi-square test or a Kruskall Wallis test was performed to test for statistical significance at the 5% level. Univariate logistic regression and multivariate logistic regression modelling including all factors with P <0.1 in univariate analysis were also performed.

*Outcomes*

Length of stay including any admission in the referring centre was calculated. Procedure related adverse events included bleeding requiring intervention, visceral perforation, problematic fistulae and stent related events. Adverse events were separated into clinical adverse events: hospital acquired pneumonia, persistent sepsis, pulmonary embolism, cardiac events, and venous thrombosis and procedural adverse events: bleeding, perforation, fistulae, stent migration and stent malfunction. Additional percutaneous drainage was defined as a radiological guided drain placed into an extra-pancreatic collection.

*Economic analysis*

Individual patient costs were provided by the hospital finance department for 2015-2016 and 2016-17 financial years using patient-level information and costing systems (PLICS). Individual patient costs for all diagnostic tests, treatment, inpatient stay, critical care stay and outpatients were available from the Trust finance department. Endoscopy records were also interrogated to provide an accurate cost of any stents or disposable equipment used, as this is not currently represented in the PLICS data.

The drugs/treatment category included drugs, high cost drugs, pharmacy costs, and transfusion services. Staff costs consisted of both medical staff and allied health professionals including physiotherapists, dieticians, occupational therapists and specialist nurses. The Clinical Negligence Scheme for Trusts (CNST) contributions were not included in the analysis.

A cost consequence analysis (CCA) was performed due to the difficulties in establishing one discrete outcome for the procedure required for cost-effectiveness analysis. A CCA is a practical method by which cost and outcome data can be structured to enable decision makers to improve the decision-making process.

We performed a statistical analysis of the comparative costs of EN versus MARPN versus OPN, and a subsequent cost comparison analysis of EN vs MARPN. Multiple studies have demonstrated that a minimal access approach is to be preferred over an open approach 6, 13, 24, unless there are extenuating factors necessitating an open approach, therefore a separate analysis to compare these two interventions was performed to help inform our practice. Such extenuating circumstances include rapid clinical deterioration, sepsis, requiring organ support or suspected additional intra-abdominal pathology such as visceral perforation or pancreatitis associated visceral infarction.

**RESULTS**

*Clinical outcomes*

In total, 86 patients were included the analysis: 38 patients underwent EN, 35 underwent MARPN and 13 underwent OPN. Patient demographic information is shown in Table 1. There were no differences in sex, age, aetiology, number of tertiary referrals, time to intervention, or modified CT severity score between the 3 groups. There was, however, a significant difference in the maximum width of collections (113mm vs 147mm vs 106mm for EN, MARPN and OPN respectively, p<0.001) and in the location of necrosis. 32 (91.4%) of 35 patients undergoing MARPN had necrosis in the body or tail whereas 34 (89.5%) of 38 patients undergoing EN had necrosis in the head or body. Patients undergoing OPN and MARPN had higher APACHE II scores (6 vs 9 vs 9, p=0.017) and higher CRP levels than those patients treated by EN (107 vs 204 vs 278, p=0.012).

Table 1: Patient demographics

Post-operative outcomes are shown in Table 2. The median (IQR) total length of stay was significantly different: 52 (29, 74) days for EN patients, 74 (55, 102) days for MARPN and 63 (53, 79) days for OPN (p=0.007). The post-operative length of stay was lower in the EN group compared to MARPN and OPN (19 vs 41 vs 42 days, p<0.001). In-patient mortality was 4 (10.5%) for EN, 8 (22.9%) for MARPN and 2 (15.4%) for OPN (p=0.379). Overall adverse events occurred in 26 (68.4%) patients undergoing EN, 24 (68.6%) for MARPN and 6 (46.2%) for OPN. Procedural related adverse events were higher in the EN group (p=0.002), whereas clinical adverse events were higher in the MARPN group (p=0.046). Confirmed infected necrosis was significantly higher for MARPN and OPN (32 (91.4%) and 11 (84.6%) vs 14 (36.8%) for the EN group), p<0.001, but only 14 patients undergoing EN had samples sent for culture, all of whom had positive cultures. The common organisms found on culture were *Escherichia coli*, *Enteroccocus* species, *Klebsiella* species and *Candida albicans*. There was no difference in difference in microbiota cultured between groups. There was no significant difference in the number of patients requiring additional percutaneous drainage (p=0.115). The median (IQR) number of necrosectomies were 4 (2, 5) for EN, 2 (1, 3) for MARPN and 1 for OPN (p<0.001).

Table 2: Postoperative descriptive statistics

Table 3 shows specific complications occurring in individual groups. There was no significant difference in complications between the interventions. The incidence of persistent pancreatic fistulae was lower after EN compared to MARPN or OPN, however this did not reach statistical significance (p=0.104). In the endoscopic group, stent related problems occurred in 16 (42.1%) patients.

Table 3: Adverse events

Univariate logistic regression analysis (see Supplementary Table 1) was performed for mortality. This demonstrated that the factors associated with increased mortality in the whole cohort of patients were age (OR 1.042, 95% CI 1.001- 1.086) transfer from another centre (OR 9.419, 95% CI 1.176-75.441), APACHEII score (OR 1.13, 95% CI 1.048-1.230), pre-operative ICU stay (OR 6.896, 95% CI 2.121-22.419) and percutaneous drainage (OR 4.386, 95% CI 1.400-13.736). Multivariate logistic regression models (see Supplementary Table 2) were performed for the outcome of adverse events. They were not performed for mortality due to the small number of events. Patients with pancreatitis secondary to alcohol (OR 0.191, 95% CI 0.046-0.799) were less likely to suffer adverse events than those with an aetiology of gallstones. A longer length ICU stay was also associated with increased adverse events (OR 1.112, 95% CI 1.008- 1.227).

Supplementary Table 1: Univariate logistic model with the outcome as mortality

Supplementary Table 2: Multivariate logistic regression model with outcome as adverse event

*Economic outcomes*

Individual patient costs were calculated using PLICS are summarised in Table 4 and Figure 1. The mean overall cost per patient was £30,981 for patients treated by EN, £52,357 for MARPN and £60,077 for OPN (p=0.006). Similarly, the ward and intensive care costs were £9,430 and £14,033; £9,890 (p=0.089) and £5,317; £16,648 and £24,722 for EN, MARPN and OPN respectively (p=.001).

Table 4: Summary table of the average cost (£) per patient for EN, OPN & MARPN

Figure 1: Graph showing average cost (£) per patient for EN, OPN & MARPN

Table 5 and Figure 2 show a cost comparison of EN and MARPN which demonstrates a significantly lower average total cost for EN (£30,981) when compared to MARPN (£52,537) (p=0.004). The cost of ward care (£9430 vs £14,033, p=0.035) and medication (£1,852 vs £3,910, p=0.006) were also significantly lower for patients undergoing EN. The operating room costs in the MARPN group were comparable with endoscopy costs for patients managed by EN (£4,420 and £4,135).

Table 5: Cost comparison for EN vs MARPN (£)

Figure 2: Comparison of average costs for EN vs MARPN (£)

**DISCUSSION**

This study has investigated the actual cost alongside clinical outcomes for different approaches for the management of pancreatic necrosis in a real-world setting. All patients undergoing endoscopic, minimal access or open pancreatic necrosectomy at a tertiary centre over two financial years, within a block UK NHS financial contract period, were included in the analysis. The results give an accurate representation of current costs for treating this complex cohort of patients with long and resource heavy inpatient stays. The most important finding is that patients undergoing EN had outcomes equivalent to those undergoing MARPN or OPN, with reduced inpatient stays and reduced treatment costs. Despite the less severe disease profile of patients undergoing EN, however, the average cost of EN was £30,981, whereas the NHS National Tariff for pancreatic necrosectomy for the 2019/20 financial year was only £21,212, substantially less than it costs a centre to treat the majority of these patients 25, 26. Those responsible for commissioning and allocating resources for health services should ensure that these essential costs are met.

The average cost for managing a patient with MARPN was over £20,000 more expensive than for EN. The increased cost is largely due to the significantly longer length of stay of the MARPN patients on both a surgical ward and ICU. The increased length of stay for MARPN of approximately three weeks is likely to be related to many factors, including being performed in a sicker cohort of patients and the need to prolong hospital stay until drain irrigation has been discontinued and drain downsized. Contrastingly, our protocol for EN is an initial transgastric drainage, followed by flush necrosectomy at 7 days; clinically well and suitable patients can then be discharged, without the need for irrigation, with EN performed on a weekly outpatient basis until the necrotic collection has resolved. It is reassuring that there was no increase in readmission following EN, suggesting that the protocol is safe. The finding of a reduced length of stay for endoscopic necrosectomy is consistent with previously published studies 12, 17.

OPN was associated with higher costs than the less invasive approaches, as OPN was associated with higher ICU costs and longer ICU stays. Previously published studies have found increased morbidity with OPN compared to minimal access techniques 6, 7, 13, 24, 27. Bakker et al observed a trend towards increased ITU stays for OPN but this did not reach statistical significance; they also reported an increased inflammatory response following open surgical necrosectomy compared to EN 13. This may be partly responsible for the increased ITU stay and costs found for OPN. However, the OPN cohort in our analysis may have been more physiologically unstable initially, as we report higher CRP values and APACHEII scores for the OPN compared to the EN patients.

This study is an observational analysis with intervention decided by the MDT rather than by randomisation. We started performing EN shortly before the time frame included in this study, so the learning curve period for the technique is included in these data. As clinicians became more experienced with the technique, it was performed on a wider range of patients, including those on ICU and those with less favourable collections. The pre-operative patient characteristics show that MARPN and OPN were performed in patients with higher APACHEII scores, higher CRP and associated with more ICU admissions then EN, limiting direct comparisons. Any patient who deteriorated was reassessed and the plan of intervention adjusted accordingly. Patients waiting for EN (who required a specialist endoscopist) or patients waiting for MARPN (who required an interventional radiology guidewire/drain placement as part of the procedure), in whom appropriate infra-structure was not immediately available and in whom it was felt life was in danger, underwent surgical intervention. Judgements of best care are commonplace in tertiary units, dealing with inter-regional transfers at high volume.

The site of the pancreatic necrosis has implications for the approach chosen; for EN the collection has to be accessible via the transgastric or transduodenal route, whereas collections in the tail may be inaccessible. For MARPN, collections have to be approached via the flanks, although central or right sided collections may also be accessible percutaneously in some patients.

Treatment algorithms have not been widely used for pancreatic necrosis, given the heterogeneity of the disease and variations in local expertise. One group is continuing to develop an algorithm to define the role of surgical approaches by time from onset of pancreatitis and haemodynamic status 28. We feel the optimal way to approach pancreatic necrosis is to use a treatment algorithm taking into account the location of the necrosis and physiological condition of the patient to determine the management approach. This includes percutaneous drains, endoscopic, minimal access, complex minimal access including single port necrosectomy 29, open necrosectomy or a combination of the above. Our work is ongoing.

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**Figure & Table legends**

Table 1: Patient demographics

Table 2: Postoperative descriptive statistics

Table 3: Adverse events

HAP, hospital acquired pneumonia; PE, pulmonary embolus; PV, portal vein; SMV, superior mesenteric vein.

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Supplementary Table 1: Univariate logistic model with the outcome as mortality

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