**Full Title- Neonatal and Maternal Outcomes of Successful Manual Rotation to Correct Malposition of the Fetal Head**; A Retrospective and Prospective Observational Study.

**Short Title-** Instrumental delivery with Manual rotation to Correct Fetal Malposition.

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# Abstract

**Objective**

To evaluate the neonatal and maternal outcomes associated with successful operative vaginal births assisted by manual rotation.

**Design**

Prospective and retrospective observational study.

**Setting**

Delivery suite in a tertiary referral teaching hospital in England.

**Population**

A cohort of 2,426 consecutive operative births, in the second stage of labour, complicated with malposition of the fetal head during 2006-2013.

**Methods**

Outcomes of all births successfully assisted by manual rotation followed by direct traction instruments were compared with other methods of operative birth for fetal malposition in the second stage of labour (rotational ventouse, Kielland forceps and caesarean section).

**Main outcome measures**

Associated neonatal outcomes (admission to the special care baby unit, low cord pH, low Apgar and shoulder dystocia) and maternal outcomes (massive obstetric haemorrhage (blood loss of >1500ml) and obstetric anal sphincter injury).

**Results**

Births successfully assisted with manual rotation followed by direct traction instruments, resulted in 10% (36/346) of the babies being admitted to the Special Care Baby Unit, 4.9% (17/349) shoulder dystocia, 2% (7/349) massive obstetric haemorrhage and 1.7% (6/349) obstetric anal sphincter injury, similar to other methods of rotational births.

**Conclusions**

Adverse neonatal and maternal outcomes associated with successful manual rotations followed by direct traction instruments were comparable to traditional methods of operative births. There is an urgent need to standardise the practice (guidance, training) and documentation of manual rotation followed by direct traction instrumental deliveries that will enable assessment of its efficacy and the absolute safety in achieving a vaginal birth.

245 Words

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# Introduction

Malposition of the presenting fetal head is defined as any position other than occiput anterior (eg. occipito-transverse (OT) or occipito-posterior (OP)) and is the commonest indication for caesarean section (CS) in the second stage of labour [1]. There is a severe lack of contemporary evidence from randomised trials to inform best practice for assisted operative birth when malposition complicates the second stage of labour [2,3]. The American College of Obstetrics and Gynecology advises that operative vaginal birth in the second stage of labour by experienced, proficiently trained physicians should be considered as a safe and acceptable alternative to CS whilst highlighting the need for training, and ongoing maintenance of practical skills in this context [4].

Manual rotation (MROT) where the fetal head is rotated and corrected by the operators’ hand, prior to completing the vaginal birth with direct traction forceps or non-rotational ventouse is increasingly being used in the second stage of labours complicated with fetal malposition where a prior requirement for expedited delivery exists [5]. Most regulatory authorities in the western world, either endorse the routine use or initial consideration of MROT followed by direct traction instruments in such labours prior to embarking on a traditional rotational instrumental birth or CS [4,6]. However, outcome data on morbidity and mortality associated with MROT (which includes subsequent direct traction instruments to complete birth as a single entity) in this context are scarce [7]. Some authors refer to anecdotal evidence of efficacy and safety [8], whilst others seem to rely on their personal perception that MROT is a safe procedure [9].

There are many described methods of MROT [8-10] and reports suggest that correcting malposition of the fetal head with MROT even without immediately completing the delivery with the use of a direct traction instrument may decrease the rates of both instrumental births and CS [9,11-14]. A recent Cochrane systematic review highlighted the need for further appropriately designed trials to determine the efficacy of MROT [9]. Compared with the explicit and formal guidance provided by the regulatory authorities on performing, documenting and training for other operative methods of births [2,6,8], similar guidance is not available for MROT. This, when combined with the different methods described to complete a MROT [8-10] may result in a potentially highly unregulated procedure.

Considering this paucity of evidence and the absence of guidance, our primary aim was to test the hypothesis that the successful use of MROT (a method which includes the immediate use of direct traction forceps/ventouse to complete the delivery) would be associated with comparable neonatal and maternal outcomes to all other established methods of operative births that can be employed to deliver a malpositioned fetus in the second stage of labour. The other operative methods considered included rotational ventouse (RV), Kielland forceps (KF) and primary emergency caesarean section in the second stage of labour without a trial of instrumental birth (pEMCS).

# Materials and Methods

Liverpool Women's Hospital (LWH) has approximately 8,500 births per annum and is a tertiary referral centre with level three neonatal intensive care facilities. The LWH labour ward is directly supervised by a senior registrar in obstetrics (with at least 6–7 years of specialist training) 24 hours a day. In addition, there is at least one junior registrar (with a minimum of 3 years of specialist training) and an early career trainee with less than 3 years of specialist training. Throughout the study period, there was 90 hours per week of direct consultant presence, whilst indirect consultant supervision (consultant contactable by telephone for advice and to attend on demand as required) was available at all other times. In addition, local guidelines mandated that all births for malposition in the second stage of labour should be directly supervised or conducted by an experienced obstetrician (senior registrar with at least 6–7 years of specialist training in obstetrics or a consultant). All senior trainees were initially directly supervised in performing operative rotational vaginal births and subsequently deemed competent by consultant staff before being permitted for independent practice or to supervise other trainees.

For the purpose of our study, MROT births were defined as births where malposition was identified in the second stage of labour and MROT was employed to correct malposition followed by the immediate use of either direct traction forceps or non-rotational ventouse to complete the vaginal birth. The deliveries were assisted by direct traction forceps or non-rotational ventouse since expedition of birth had been deemed necessary due to fetal distress or delay.

Neonatal and maternal outcome data in all successful MROT births and all other successful traditional operative methods of assisting birth for a malpositioned fetal head in the second stage (RV, KF and pEMCS) were collected during the period from the 2nd November 2006-31st of August 2013 and reported as per STROBE guidelines (15). All assisted rotational vaginal operative births and pEMCS (n=2058) were identified retrospectively from the hospital database for the 60 month period from the 2nd of November 2006 to the 31st of August 2012, and reviewed. From the 1st of September 2012 to the 31st of august 2013 we prospectively collected outcome data, using a paper based proforma, (n=368). After each delivery complicated by malposition at full dilatation, the operating surgeon completed a paper based proforma during the prospective part of the audit. These proformas were collected by the clinical team completing the study and the data (no patient identifiable data was collected or retained) was input into an EXCEL file. Data from the retrospective database or paper-based proformas were verified against the information in the computerised hospital notes system used at LWH (Meditech), the paper based hospital clinical records, the LWH risk management database, transfusion database, postnatal perineal clinic data, neonatal computerised notes database (BADGER; for all neonatal outcomes) before tabulating. When collecting demographic data, we considered the factors that may have influenced both the choice and the potential outcomes of the method employed to assist birth. For example, when the indication to assist birth is a diagnosis of potential fetal compromise, it may affect neonatal outcomes, as well as the decision making process regarding the method of birth. The operator seniority is expected to influence failure rates and outcomes; and there is prior evidence that epidural analgesia during labour increases vaginal operative birth rates [16]. A prolonged second stage of labour, has been associated with reduced umbilical cord pH values and Apgar scores [17,18]. Birth weight impacts on success rates of operative vaginal birth [19], in addition to increasing the risk for other outcome measures such as shoulder dystocia, obstetric anal sphincter injury (OASI) and massive obstetric haemorrhage.

Maternal and neonatal outcomes were chosen for their important clinical relevance, associated morbidity for the mother and baby and cost implications for the health care provider (National Health Service) and society. Admission to special care baby unit (SCBU), incidence of babies with cord pH <7.1 at birth, Apgar score <5 at 5 minutes, and the incidence of shoulder dystocia (defined as a vaginal cephalic delivery that requires additional obstetric manoeuvres to deliver the fetus after the head has delivered and gentle traction has failed [20]) were the neonatal outcomes collected. Maternal outcome variables collected were; massive obstetric haemorrhage (blood loss of >1500 ml, estimated or weighed following delivery) and OASI (3rd or 4th degree tear).

The finalised dataset of 2,426 singleton births at 36 weeks or more gestation was entered into excel spreadsheets (all patient identifiable data were excluded) and migrated into SPSS version 22 for analysis. Ethical approval was not required for these audits, (no patient identifiable data was collected) for which approval was granted by the directorate audit committee at LWH. No formal sample size was calculated as we collected data on all cases over a specified time period. Continuous variables were reported using means and standard deviations, categorical variables were reported using counts and percentages. Between group differences were initially assessed using analysis of variance and chi-squared tests. If a difference was detected between the four groups, pairwise post-hoc tests, with Bonferroni correction, were used to identify which groups were responsible for the differences.

# Results

There were 56,001 babies born at the LWH from the 2nd Nov 2006 until the 31st Aug 2013, of these, 42,079 were vaginal births, 34,414 were normal spontaneous vaginal births, not requiring assistance (61.5%) and 7,665 vaginal births required operative assistance (13.7%). 6122 births were by planned elective caesarean sections (10.9%); 7800 births were by emergency caesarean section (13.9%), 790 of those were performed at full dilatation (1.4%); out of which 263 were performed for the primary indication of delay in second stage of labour due to fetal malposition without a trial of instrumental birth (pEMCS). There were 2,426 consecutive full term singleton cephalic births between the 2nd of Nov 2006 and the 31st of Aug 2013 with malposition of the fetal head during the 2nd stage of labour leading to a successful rotational delivery or pEMCS. Our final dataset included 349 successful MROT (0.62%) 171 successful RV (0.31%), 1,643 successful KF (2.93%) and 263 pEMCS (0.47%) (Figure 1).

**Figure 1. A Flowchart demonstrating how our final data set was captured.**

The maternal age, induction of labour and seniority of doctor did not differ among the patient groups (Table 1).

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**Table 1. Demographics**

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| **Variable** | **MROT****(n=349)** | **RV****(n=171)** | **KF** **(n=1643)** | **pEMCS (n=263)** | **Significance** |
| Age (yrs)1 mean (st. dev) | 29.25 (5.73) | 29.35 (5.97) | 29.25 (5.78) | 30.29 (5.96) | P=0.06 |
| BMI1 mean(st.dev) | 24.89 (4.79) | 24.48 (5.18) | 25.26 (4.89) | 26.83 (6.27) | P<0.001 |
| Multiparity2 N(%) | 56(16.0) | 49(28.8) | 289 (17.6) | 49(18.6) | P=0.002 |
| Induction2 N(%) | 115 (33.0) | 59 (34.5) | 573 (34.9) | 92 (35.0) | P=0.92 |
| Epidural2 N (%) | 169/348(48.6) | 89/171(49.7) | 833/1642(50.7) | 59/263(22.4) | P<0.001 |
| Duration 1st stage1\*Mean (st. dev) | 530.87 (306.48) | 442.62(269.73) | 556.71 (322.64) | 574.45 (291.34) | P<0.001 |
| Duration 2nd stage1\*Mean (st. dev) | 160.70 (141.29) | 119.51(77.33) | 194.27(77.33) | 213.84(83.91) | P=0.001 |
| Fetal compromise as indication2 N(%) | 101 (28.9) | 88 (51.5) | 264 (16.1) | 33 (12.5) | P<0.001 |
| Operator ST6 or above2 N(%) | 203/346(58.7) | 99/171(58.2) | 1049/1639(63.5) | 157/259(60.6) | P=0.23 |
| Birth Weight1Mean (st. dev) | 3419.05 (545.24) | 3394.71 (508.22) | 3542.54 (499.94) | 3682.62 (559.50) | P<0.001 |

1 ANOVA 2 Chi-squared test

\*Data incomplete (343 and 345 MROT, 168 and 170 RV, 1638 and 1626 KF, 185 and 185 pEMCS).

However, there were statistically significant differences between the study groups in the following variables; BMI, multi-parity, rate of epidural, duration of first and second stage of labour, evidence of coexisting fetal compromise as a secondary indication for birth and birth weight.

Considering neonatal outcomes, admission to the SCBU after MROT was not significantly different from that of other modes of birth (Table 2). Similar to the rates observed with KF births (9.9%, 163 out of 1,643), MROT was associated with a 10.3% (36/349) rate of admission to the SCBU. The babies born by pEMCS carried the highest rate of admission to the SCBU at 12.5% (33 out of 263 births) whilst RV use was associated with a much lower admission rate of 6.4% (11 of 171 births).

**Table 2 –Neonatal and maternal outcomes**

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| **Variable** | **MROT****(n=349)** | **RV****(n=171)** | **KF (n=1643)** | **pEMCS (n=263)** | **Significance** |
| Neonatal admission N(%)1 | 36/349(10.3) | 11/171(6.4) | 163/1643(9.9) | 33/263(12.5) | P=0.23 |
| Shoulder Dystocia N(%)1 | 17/349(4.9) | 6/171(3.5) | 95/1643(5.8) | NA  | P=0.24 |
| Apgar<5 at 5 mins N(%)1 | 1/348(0.3) | 0/170(0) | 6/1640(0.4) | 3/263(1.1) |  |
| ApH <7.1 N(%)1 | 14/296 (4.7) | 9/135(6.7) | 89/1401(6.4) | 13/235(5.5) | P=0.72 |
| EBL >1.5L N(%)1 | 7/349(2.0) | 4/171(2.3) | 38/1642(2.3) | 13/263(4.9) | P=0.08 |
| Sphincter injury N(%)1 | 6/349(1.7) | 1/171(0.6) | 48/1642(2.9) | NA | P=0.10 |

 1 Chi-squared

Only a very small number of babies in our dataset were born with Apgar scores less than 5 at 5 minutes across all of the groups, and no statistical differences were noted. For example, only one baby had an Apgar recorded of less than 5 at 5 minutes (0.3%) in the MROT group. This figure compared favourably with babies born in the KF group (0.4%, 6 of 1640) and in our cohort there were no babies born with an Apgar score of less than 5 at 5 minutes in the RV group. Compared to the rotational vaginal operative births, 3 out of 263 (1.1%) of the pEMCS births were associated with babies having a low Apgar score at 5 minutes.

The rate of umbilical arterial cord pH <7.1, was also comparable in all groups and MROT had the lowest rates at 4.7%, (14 of 296 babies), 5.5%, (13 of 235 babies) in the pEMCS group; 6.4% (89 of 1401 babies) in the KF group; and RV births were associated with 6.7% (9 of 135 babies) low umbilical arterial pH.

The rate of shoulder dystocia following MROT was similar to the rates associated with either RV or KF. The overall rate of shoulder dystocia with MROT was 4.9% (17 of 349), whilst it was 3.5% (6 of 171) with RV, and conversely KF births were associated with a slightly higher rate of 5.8% (95 of 1643).

Out of the 349 births assisted with MROT, 7 mothers (2%) had a massive obstetric haemorrhage (Table 2). This compares with the rates observed in both RV and KF groups, which in our cohort also carried a similar risk of massive obstetric haemorrhage, at 2.3%. Conversely, the 263 women who underwent pEMCS had an approximately doubled rate of massive obstetric haemorrhage at 4.9% yet this did not reach a statistical significance.

In our patient cohort, 55 out of all 2,162 women who experienced a successful vaginal operative birth had an OASI with an overall rate of 2.5%. The incidence of OASI specific to the MROT group was 1.7% (6 of 349), higher than that associated with RV of 0.6% (1 of 171 births) and although not statistically different, lower than that of the KF group at 2.9% (48 of 1642).

# Discussion

## Main findings

Our data suggests that successful use of MROT is associated with comparable neonatal and maternal complication rates to all other established methods of rotational operative births suitable for a malpositioned fetal head. There were no statistically different neonatal or maternal outcomes between all four modes of birth, confirming that all methods are equally acceptable to be utilised in clinical practise.

Considering most demographic features studied, MROT offered an intermediate alternative to both RV and KF; in that, comparing with RV, MROT was the choice in nulliparous women with slightly longer labours (1st and 2nd stage), whilst, RV was preferred when there was evidence of fetal compromise. The opposite was true for the comparison between MROT and KF. Finally, when compared with the pEMCS group, MROT was the method of choice for women with epidurals and a higher rate of fetal compromise but pEMCS appears to be preferentially used when a woman had a higher BMI, a longer second stage or a larger baby. Furthermore, factors that are well known to be associated with an increased risk of caesarean section in general such as higher BMI, birth weight and age were also associated with 2nd stage pEMCS group compared with the operative deliveries.

If MROT is to be utilised as a formal method of rotational vaginal birth, it must be comparable in neonatal and maternal safety parameters with all other available modes of operative births. When we considered subtle trends in safety data, similar to the demographic features, MROT occupied an equidistant position between RV and KF, in shoulder dystocia and OASI, where higher rates were seen with KF. MROT however was associated with slightly higher numbers of neonatal admissions to SCBU but had similar rates of massive obstetric haemorrhage compared with both KF and RV. Agreeing with previous publications [21,22] pEMCS carried the highest risk of massive obstetric haemorrhage and rates of neonatal SCBU admission. Therefore, although these trends are not statistically significant, we have not observed convincing data to conclude the perceived superiority of MROT use for neonatal or maternal safety against other methods of rotational births. Taken together our data suggest fetal and maternal outcomes associated with successful MROT were comparable with all other methods of rotational operative births at best (when successful), when malposition complicates the second stage of labour.

## Strengths and limitations

This is the largest reported series of consecutive operative rotational vaginal births successfully assisted by MROT to be reported from a single, busy, modern, tertiary referral hospital. Although our study was primarily designed to describe the outcomes of births assisted by MROT, our case series of rotational operative vaginal births is also the largest consecutive series ever published to include all available methods when malposition complicates the second stage of labour. Despite the above, this study was not powered to examine extremely rare cases of outcomes such as neonatal death.

Since in our unit, all obstetricians practising MROT were proficient in the use of at least one other (some all) methods of rotational operative births, our data highlight the specific demographic features that may lead clinicians to favour the choice of MROT over other methods of vaginal operative births.

The main drawback of our study is the retrospective nature of data collection employed during the first part of the study. In our unit, routine documentation of successful MROTs was similar to other operative rotational vaginal births (therefore we consider that almost all successful attempts with MROT were documented), yet failed attempts were not consistently documented. Consequently, reliable data retrieval was only possible on unsuccessful MROT during the prospective study. A similar practise of inconsistent documentation is expected to prevail in other units; therefore, our data underscores the urgent need to standardise documentation for this high risk obstetrics practise. Furthermore, the inconsistent documentation of unsuccessful MROT may also be a major obstacle in assessing the “true” effectiveness and safety of any other operative vaginal birth. We would add a caveat, that the outcomes we report for successful MROTs may be different in births that are unsuccessfully assisted by MROT.

Our study examined MROT as a single entity, defined as the rotation of the fetal head to correct malposition by hand and the immediate subsequent application of direct traction forceps/ventouse to complete birth. Our study did not intend to examine the different outcomes associated with the non-rotational, direct traction instruments used after the MROT. There are many previous publications describing the outcomes associated with non-rotational direct traction forceps vs. ventouse and future well powered studies can examine the influence of post MROT traction instruments on the clinical outcomes.

A further deficiency of this study is the lack of information on the subjective but important information on the station of fetal head, presence of caput, strength of uterine contractions and findings of the abdominal examination. This information should be collected in future prospective multicentre cohort studies to assess the best method of birth for malposition.

## Interpretation

Our data show that the use of MROT is associated with a low incidence of complications for both the infant and the woman and compares favourably with other techniques. However, these complications need to be carefully considered when another consecutive rotational operative vaginal delivery method is attempted in instances when MROT is unsuccessful [6]. Our large dataset provide information on outcomes associated with the general use of the method, however these observations will still be subjected to selection bias and the influence of skills of highly selected individuals. Our findings are observed within a specific setting where all operative techniques were either performed or directly/indirectly supervised by a group of UK consultants, most whole time obstetricians providing ongoing support and training for trainees. The low rate of sphincter damage we observe in our dataset compared with previous reports may be another consequence of this degree of senior supervision [2].

## Conclusion – practical and research recommendations

We present here the largest series of consecutive operative rotational vaginal births successfully assisted by MROT, suggesting that successful use of MROT is associated with comparable neonatal and maternal complication rates to all other established methods of operative births suitable for a malpositioned fetal head.

MROT is increasingly being employed for assisting births throughout the world, yet there is a lack of published data on safety and efficacy. Our data highlights that MROT has a role in the management of malposition at full dilatation, with comparable outcomes to traditional methods such as RV and KF. It also provides the initial evidence to encourage obstetricians and the regulating authorities to formally recognise MROT, as a high risk, practical obstetrics procedure similar to the other methods of traditional rotational operative deliveries, and formulate the fundamentally essential, yet presently non-existing guidance (including documentation), training and governance process for MROT which in parallel with other traditional methods requires the highest level of skill in acute obstetric practise. Clinicians and units that encourage the use of MROT have a responsibility to collect morbidity data which allows women and clinicians to make informed choices.

Formal documentation of MROT is necessary to assess the true efficacy of all rotational delivery methods, and more importantly to assess the complication rates associated with unsuccessful attempts of using all methods. We propose that standardised documentation (Fig 2) will not only facilitate collating data from various studies as well as reducing bias in any future prospective trials.

**Figure 2. A Sample Standard Operative Rotation Vaginal Delivery Documentation Template.** Proposed documentation proforma to record essential data that can be used in all operative methods to expedite delivery in second stage labours complicated with fetal malposition.

We conclude that our study highlights the urgent need to standardise the practice and documentation of operative births when malposition of the fetal head complicates the second stage of labour. A national, regulated prospective data collection of the outcomes of high-risk obstetric interventions including rotational births and EMCS in the second stage of labour is necessary and overdue. A reliable and standard system of reporting the efficacy and safety outcomes of these high risk births will ensure the maintenance of high standards hence quality assurance, service improvement, a benchmark for the production of formal training programmes and guidelines, assist greater public transparency and accountability in obstetric practise through a public reporting system similar to other surgical outcomes. We believe these essential changes will ensure babies and mothers receive the most appropriate and highest level of care when labour is complicated by malposition.

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