A prospective cohort study of maternal and neonatal morbidity in relation to use of episiotomy at operative vaginal delivery

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Objective To evaluate the maternal and neonatal morbidity of operative vaginal delivery in relation to the use of episiotomy.

Design Prospective cohort study.

Setting Two urban maternity units in Scotland and England.

Population All nonrandomised nulliparous women delivered by forceps or vacuum during the recruitment period of a clinical trial evaluating the use of episiotomy at operative vaginal delivery.

Methods Use of episiotomy was compared to no episiotomy for all operative vaginal deliveries with sub-group analyses for forceps or vacuum deliveries.

Main outcome measures The primary outcome was anal sphincter tearing (third or fourth degree). Secondary outcomes included postpartum haemorrhage, neonatal trauma and pelvic floor symptoms up until 10 days postpartum.

Results A total of 1360 women were included in the study, of whom 294 (21.6%) did not receive an episiotomy. Vacuum delivery was associated with less use of episiotomy than forceps (56.1 versus 89.4%, OR 0.15, 95% CI 0.11–0.20). Anal sphincter tear rates were not statistically different with use of episiotomy compared with no episiotomy (9.9 versus 7.1%, adjusted OR 1.11, 95% CI 0.66–1.87). Episiotomy use was associated with higher rates of postpartum haemorrhage (28.5 versus 18.4%, adjusted OR 1.72, 95% CI 1.21–2.45), need for moderate or strong analgesia (90.5 versus 67.6%, adjusted OR 3.70, 95% CI 2.60–5.27), perineal infection (5.1 versus 1.4%, adjusted OR 4.04, 95% CI 1.44–11.37) and neonatal trauma (38.1 versus 22.0%, adjusted OR 1.65, 95% CI 1.20–2.27). Use of episiotomy did not reduce the risk of shoulder dystocia (3.5 versus 1.7%, adjusted OR 1.42, 95% CI 0.53–3.85).

Conclusions The use of episiotomy did not reduce or greatly increase anal sphincter tears and was associated with greater maternal and neonatal morbidity. This may reflect the complexity of deliveries. The role of episiotomy at operative vaginal delivery should be evaluated in a randomised controlled trial.

Keywords Anal sphincter tear, episiotomy, operative vaginal delivery, prospective cohort study.

Introduction

The operative vaginal delivery rate in the UK is currently between 12 and 15% and unlike caesarean section has remained a relatively constant component of obstetric practice.1,2 There has been considerable debate in the literature regarding the optimal conduct of these deliveries,3–6 but limited research has been carried out addressing the technical aspects of the procedures and in particular the use of episiotomy. Traditionally, episiotomy has been a routine component of operative vaginal delivery, the aim being to avoid injury to the anal sphincter and to minimise the risk of traumatic delivery for the baby. Short-term complications of perineal injury may include pain, infection and haemorrhage.7 Long-term effects include dyspareunia, incontinence of urine and incontinence of flatus or faeces.8–14 These morbidities may have a profound impact on women’s recovery, long-term health and psychological wellbeing. Neonatal injury may include bruising, lacerations, cephalhaematoma, retinal haemorrhage or brachial plexus injury.15,16 Most superficial neonatal trauma resolves within days to weeks but can generate considerable parental anxiety. Brachial plexus injury can persist with long-term neurological consequences for the child.
Randomised controlled trials (RCTs) comparing routine use of episiotomy (in all cases) with restrictive use (only if clinically indicated) during spontaneous vaginal birth suggest that there are significant benefits in adopting a restrictive policy. A restrictive approach to the use of episiotomy at operative vaginal delivery has emerged over recent years without evidence to support this change. Ideally, an intervention such as episiotomy should be evaluated in an RCT; however, an RCT is challenging, given the ethical difficulties and feasibility issues of recruitment to a study of emergency delivery in the second stage of labour. In addition, there is an element of judgement in the obstetrician’s decision whether to perform an episiotomy that may not be accurately reflected by the randomisation process. To address these concerns, we performed a prospective cohort study alongside an RCT of routine versus restrictive use of episiotomy at operative vaginal delivery. The objective of this study was to establish the maternal and neonatal morbidity following operative vaginal delivery in relation to the use of episiotomy within an entire cohort of nulliparous women delivered by forceps or vacuum extraction.

**Methods**

Ninewells Hospital, Dundee, and St Michael’s Hospital, Bristol, are consultant-led maternity units in teaching hospitals with approximately 3500 and 4700 deliveries, respectively, in 2005 and operative vaginal delivery rates of 14.5 and 11%, respectively. These units differ in their instrument preference with clinicians in Dundee favouring forceps delivery (79.6% forceps versus 20.4% vacuum) and those in Bristol preferring vacuum extraction (51.5% vacuum versus 48.5% forceps), reflecting national variation in practice. There are labour ward protocols in each unit that provide guidance on the conduct of operative vaginal delivery, but the approach to use of episiotomy is left to the individual obstetrician or supervising obstetrician according to experience.

**Cohort**

All women delivered by operative vaginal delivery in these units were eligible for inclusion in the study if they were nulliparous (no previous delivery ≥24 weeks of gestation), with a live singleton pregnancy and cephalic presentation at term (gestation of ≥37 weeks). Participants were identified from labour ward records and the electronic maternity databases. Women were not included in the cohort study if they had been randomised within the continuing RCT. The study period in Dundee was from October 2004 to September 2006 and in Bristol from June 2005 to August 2006.

**Explanatory variables**

A dataset was completed from handwritten records and the computerised obstetric and neonatal databases. Detailed data were extracted on maternal and infant characteristics, antenatal, intrapartum and postnatal factors and the outcome measures of interest (described in detail within the accompanying trial).

**Outcome measures**

The primary outcome measure was extensive perineal tearing involving the anal sphincter (third- or fourth-degree tears). Classification of anal sphincter tears was according to the Royal College of Obstetricians and Gynaecologists (RCOG) green-top guideline. Secondary outcomes investigated included postpartum haemorrhage, shoulder dystocia, analgesia requirements, the length of postnatal hospital stay, urinary or bowel symptoms and the rate of healing complications. Neonatal outcomes included low Apgar scores, low arterial blood gases, admission to the neonatal intensive care unit (NICU) and trauma.

**Statistical analysis**

We used descriptive statistics of the maternal, neonatal, labour and delivery factors to characterise the cohort in relation to use of episiotomy. The primary analyses were in two groups comparing episiotomy versus no episiotomy for both primary and secondary outcomes. Results are presented as odds ratios and 95% CI or with chi-square test for differences in proportions and Student’s t test for differences in means. Multivariable logistic regression models were performed adjusting for important confounding factors. Factors were tested in the multivariable models based on a statistically significant difference between the two groups in the univariable analyses (P < 0.05) or if there was a biologically plausible potential for confounding. Results are reported as adjusted odds ratios with 95% CI. Subgroup analyses compared the primary and secondary outcomes according to use of vacuum or forceps for delivery. The statistical package SPSS (version 13.0; SPSS, Chicago, IL, USA) was used for analysis.

**Results**

**Participants**

A total cohort of 1360 women had an operative vaginal delivery in the second stage of labour; 1243 had not been recruited to the contemporaneous trial and 117 had been recruited but were not randomised. An episiotomy was performed on 1066 (78.4%) women and 294 (21.6%) were delivered without the use of an episiotomy. Factors associated with use of episiotomy included maternal pre-eclampsia (OR 2.23, 95% CI 1.01–4.95), increasing infant birthweight (P ≤ 0.001) and head circumference (P = 0.001), spinal anaesthesia (OR 2.35, 95% CI 1.50–3.68), prolonged total duration of labour (OR 2.39, 95% CI 1.72–3.31), prolonged second stage of labour (OR 1.82, 95% CI 1.41–2.37), meconium-stained liquor (OR 1.46, 95% CI 1.07–2.00) and fetal malposition (OR 2.38, 95% CI 1.75–3.24).
Vacuum delivery was associated with less use of episiotomy than forceps (OR 0.16, 95% CI 0.12–0.22), as was birth of a small-for-gestational-age infant (OR 0.67, 95% CI 0.47–0.96), use of pudendal anaesthesia (OR 0.62, 95% CI 0.44–0.87) and a pathological cardiotocograph recording (OR 0.62, 95% CI 0.48–0.80). These factors were identified as possible confounders to the primary and secondary outcomes and as such were tested in the multivariable models. Operator grade did not appear to significantly influence the use of episiotomy (Tables 1 and 2).

Primary and secondary analyses

Maternal
An intact perineum was achieved in 44 of the 294 (15%) deliveries performed without an episiotomy (Table 3). Lacerations varied from minor abrasions to extensive perineal tears in both groups. Third- and fourth-degree tears occurred in 9.9% of women with the use of episiotomy compared with 7.1% of women with no episiotomy (OR 1.44, 95% CI 0.88–2.34). The association was attenuated after taking account of antenatal and intrapartum factors that differed between the two groups (adjusted OR 1.11, 95% CI 0.66–1.87). Episiotomy use was associated with an increased risk of primary postpartum haemorrhage (adjusted OR 1.72, 95% CI 1.21–2.45), prolonged use of a urinary catheter (adjusted OR 1.87, 95% CI 1.01–3.46), use of moderate or strong analgesia (adjusted OR 3.70, 95% CI 2.60–5.27, and 3.35, 95% CI 2.49–4.51, for inpatient and outpatient, respectively), prolonged postnatal stay (adjusted OR 1.47, 95% CI 1.01–2.14), perineal infection (adjusted OR 4.04, 95% CI 1.44–11.37) and antibiotic use up to the 10th postnatal day (adjusted OR 1.47, 95% CI 1.05–2.06). The risk of shoulder dystocia was not reduced by use of episiotomy (adjusted OR 1.42, 95% CI 0.53–3.85). Rates of adverse urinary and bowel symptoms were similar with or without episiotomy use.

Neonatal
Use of episiotomy was associated with higher rates of overall neonatal trauma (adjusted OR 1.65, 95% CI 1.20–2.27), but the association was no longer statistically significant when bruising and skin abrasions were excluded (adjusted OR 1.44, 95% CI 0.71–2.94) (Table 3). Episiotomy use did not influence the condition of the baby at birth (low Apgar scores and fetal acidosis) or admission to the NICU.

Subgroup analyses
Vacuum delivery was performed in 456 (33.5%) cases and forceps delivery in 904 (66.5%) (Table 4). Episiotomy was performed in 256 (56.1%) vacuum deliveries and 810 (89.4%) forceps deliveries. An intact perineum was achieved in 34 of 200 (17%) vacuum deliveries performed without an episiotomy compared with 10 of 94 (10.6%) forceps deliveries. Episiotomy was not significantly protective of tears involving the anal sphincter at either vacuum delivery (adjusted OR 0.77, 95% CI 0.33–1.82) or forceps delivery (adjusted OR 1.12, 95% CI 0.56–2.22). The rate of anal sphincter tearing at forceps delivery was approximately twice the rate at vacuum extraction. The risk of primary postpartum haemorrhage remained higher for vacuum delivery completed with an episiotomy (adjusted OR 1.86, 95% CI 1.12–3.10) but not for forceps delivery (adjusted OR 1.04, 95% CI 0.65–1.66). Rates of urinary symptoms were similar

Table 1. Maternal and neonatal characteristics in relation to use of episiotomy at operative vaginal delivery

<table>
<thead>
<tr>
<th></th>
<th>Episiotomy (n = 1066)</th>
<th>No episiotomy (n = 294)</th>
<th>OR (95% CI) difference in means** (95% CI), P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age &gt;35 years, n (%)</td>
<td>87 (8.2)</td>
<td>22 (7.5)</td>
<td>1.10 (0.67–1.78)</td>
</tr>
<tr>
<td>Body mass index &gt;30, n (%)***</td>
<td>107 (10.4)</td>
<td>20 (6.9)</td>
<td>1.49 (0.91–2.42)</td>
</tr>
<tr>
<td>Pre-eclampsia, n (%)</td>
<td>55 (5.2)</td>
<td>7 (2.4)</td>
<td>2.23 (1.01–4.95)*</td>
</tr>
<tr>
<td>Suspected intrauterine growth restriction, n (%)****</td>
<td>23 (2.2)</td>
<td>11 (3.7)</td>
<td>0.57 (0.27–1.18)</td>
</tr>
<tr>
<td>Induction of labour, n (%)</td>
<td>353 (33.1)</td>
<td>94 (32.0)</td>
<td>1.06 (0.80–1.39)</td>
</tr>
<tr>
<td>Small for gestational age, n (%)*****</td>
<td>132 (13.0)</td>
<td>52 (18.2)</td>
<td>0.67 (0.47–0.96)*</td>
</tr>
<tr>
<td>Gender male, n (%)</td>
<td>575 (54.6)</td>
<td>154 (52.7)</td>
<td>1.08 (0.83–1.40)</td>
</tr>
<tr>
<td>Gestational age (weeks + days), mean (SD, days) (range)</td>
<td>40.2 (8) (37–43)</td>
<td>40.2 (9) (37–42)</td>
<td>P = 0.13</td>
</tr>
<tr>
<td>Birthweight (g), mean (SD) (range)</td>
<td>3481 (447) (1870–5180)</td>
<td>3375 (481) (1960–4830)</td>
<td>106 (47–164), P &lt; 0.001</td>
</tr>
<tr>
<td>Head circumference (cm), mean (SD) (range)</td>
<td>35.0 (1.2) (30.5–39.9)</td>
<td>34.7 (1.3) (30.5–38.0)</td>
<td>0.3 (0.1–0.4), P = 0.001</td>
</tr>
</tbody>
</table>

*P < 0.05.
**Difference between means, Student’s t test.
***BMI measured as booking weight/height (kg/m²). Numbers and denominators refer to women where height and booking weight were recorded.
****Abdominal circumference <10th percentile on ultrasound scan.
*****Small-for-gestational-age baby based on calculated birthweight <10th percentile.
within groups, but episiotomy was associated with a lower rate of faecal incontinence in the forceps group (OR 0.22, 95% CI 0.07–0.76). There were no specific differences in neonatal morbidity in relation to use of episiotomy and choice of instrument for operative vaginal delivery (Table 4).

**Discussion**

**Summary of main findings**

We found that the use of episiotomy at operative vaginal delivery was associated with an increased risk of postpartum haemorrhage and perineal infection and a greater use of moderate or strong analgesia up to the 10th postnatal day without any clear reduction in the risk of anal sphincter tearing, shoulder dystocia or neonatal trauma. Overall rates of adverse urinary and bowel symptoms were similar with or without use of episiotomy, although longer term follow up is required. Although the numbers were small, faecal incontinence was less likely in forceps deliveries completed with episiotomy compared with no episiotomy and warrants further evaluation.

**Strengths and limitations of the study**

The population consisted of a complete geographical cohort of nulliparous women undergoing operative vaginal delivery, reflecting obstetric practice in consultant-led units throughout the UK. Clinicians of all grades of experience performed the deliveries with consultant support available 24 hours a day in accordance with RCOG guidelines. The clinical outcomes were reported by the attending clinician, and there may have been underreporting or overreporting, although this potential bias is unlikely to relate specifically to the use of episiotomy.

It is recognised that the angle of episiotomy may influence the risk of anal sphincter tears, and while the policy in each unit was to perform a right mediolateral episiotomy, it was not feasible to evaluate the angle of incision in each case. The technique of episiotomy would be in keeping with standard practice in the UK. The challenge with an observational study lies in the potential for confounding. We have attempted to control for this by performing multivariable logistic regression analyses adjusting for relevant factors; however, there may still be residual confounding, and the results should be interpreted accordingly.

**Comparison with existing literature**

The increased risk of third- and fourth-degree tears in association with operative vaginal delivery is well described, although there is conflicting evidence on the role of episiotomy in preventing anal sphincter damage. There are reports of no effect on sphincter damage with use of episiotomy, of a strongly protective effect and of an increased risk of...
third-degree tears but reduced risk of fourth-degree tears. Despite compelling evidence to support a restrictive approach to use of episiotomy for spontaneous vaginal births, there is little evidence to inform obstetricians use of episiotomy at operative vaginal delivery. There are no existing RCTs and few high-quality cohort studies. A US study of 323 operative vaginal deliveries suggested that in forceps delivery, neither the type of forceps nor episiotomy influenced the risk of significant perineal trauma, but when vacuum delivery was performed, episiotomy was associated with a higher risk of significant perineal trauma. Our findings were consistent for forceps delivery but differed for vacuum delivery. However, this study reflected use of midline episiotomy and very high rates of anal sphincter tears. The authors of the Dutch study concluded that their findings supported routine use of episiotomy at operative vaginal delivery. The conflicting findings of this prospective cohort study and the large Dutch retrospective study suggest that further research is required.

**Implications for practice**

A recent postal survey in the UK and Ireland explored the views held by obstetricians regarding the relationship between episiotomy use and anal sphincter tears. Two-thirds of obstetricians (66%) held the view that episiotomy use decreases the likelihood of anal sphincter tears at forceps delivery with a more balanced view for vacuum deliveries (45% decreases risk and 42% no difference). These views were reflected in our study with an episiotomy rate of 89.4% for forceps deliveries and 56.1% for vacuum extraction. However, episiotomy was used in both settings, it seems difficult to reconcile the divergent findings. It is important to note that the overall rate of anal sphincter tears appears to be far lower in the Dutch setting than in the UK, and there may well be differences in the approach to use of episiotomy or alternatively issues of incomplete ascertainment or reporting of anal sphincter tears. The authors of the Dutch study concluded that their findings supported routine use of episiotomy at operative vaginal delivery. The conflicting findings of this prospective cohort study and the large Dutch retrospective study suggest that further research is required.

Table 3. Maternal and neonatal outcomes in relation to use of episiotomy at operative vaginal delivery

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Episiotomy (n = 1066)</th>
<th>No episiotomy (n = 294)</th>
<th>Unadjusted OR (95% CI)</th>
<th>Adjusted OR** (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact perineum, n (%)</td>
<td>0 (0)</td>
<td>44 (15.0)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Third-/Fourth-degree tear, n (%)</td>
<td>106 (9.9)</td>
<td>21 (7.1)</td>
<td>1.44 (0.88–2.34)</td>
<td>1.11 (0.66–1.87)</td>
</tr>
<tr>
<td>Shoulder dystocia, n (%)</td>
<td>37 (3.5)</td>
<td>5 (1.7)</td>
<td>2.08 (0.81–5.33)</td>
<td>1.42 (0.53–3.85)</td>
</tr>
<tr>
<td>Primary postpartum haemorrhage, n (%)</td>
<td>303 (28.5)</td>
<td>54 (18.4)</td>
<td>1.76 (1.28–2.44)*</td>
<td>1.72 (1.21–2.45)*</td>
</tr>
<tr>
<td>Urinary catheter &gt; 24 hours, n (%)</td>
<td>137 (12.9)</td>
<td>13 (4.4)</td>
<td>3.19 (1.78–5.72)*</td>
<td>1.87 (1.01–3.46)*</td>
</tr>
<tr>
<td>Urinary retention, n (%)</td>
<td>10 (0.9)</td>
<td>4 (1.4)</td>
<td>0.69 (0.21–2.21)</td>
<td>0.42 (0.12–1.49)</td>
</tr>
<tr>
<td>Urinary incontinence, n (%)</td>
<td>40 (3.8)</td>
<td>10 (3.4)</td>
<td>1.11 (0.55–2.24)</td>
<td>0.85 (0.41–1.77)</td>
</tr>
<tr>
<td>Faecal incontinence, n (%)</td>
<td>10 (0.9)</td>
<td>4 (1.4)</td>
<td>0.69 (0.21–2.21)</td>
<td>0.44 (0.13–1.51)</td>
</tr>
<tr>
<td>Inpatient moderate/strong analgesia use, n (%)</td>
<td>945 (90.5)</td>
<td>196 (67.6)</td>
<td>4.58 (3.32–6.31)*</td>
<td>3.70 (2.60–5.27)*</td>
</tr>
<tr>
<td>Postnatal admission &gt;3 days, n (%)</td>
<td>230 (21.6)</td>
<td>42 (14.3)</td>
<td>1.66 (1.16–2.37)*</td>
<td>1.47 (1.01–2.14)*</td>
</tr>
<tr>
<td>Outpatient moderate/strong analgesia use, n (%)***</td>
<td>680 (66.3)</td>
<td>92 (32.1)</td>
<td>4.18 (3.16–5.53)*</td>
<td>3.35 (2.49–4.51)*</td>
</tr>
<tr>
<td>Perineal infection, n (%)****</td>
<td>54 (5.1)</td>
<td>4 (1.4)</td>
<td>3.87 (1.39–10.77)*</td>
<td>4.04 (1.44–11.37)*</td>
</tr>
<tr>
<td>Any antibiotic use, n (%)****</td>
<td>301 (28.2)</td>
<td>58 (19.7)</td>
<td>1.60 (1.17–2.20)*</td>
<td>1.47 (1.05–2.06)*</td>
</tr>
<tr>
<td>Neonatal resuscitation, n (%)*****</td>
<td>107 (10.1)</td>
<td>34 (11.7)</td>
<td>0.85 (0.57–1.28)</td>
<td>0.72 (0.48–1.08)</td>
</tr>
<tr>
<td>Apgar score at 1 minute ≤ 3, n (%)</td>
<td>22 (2.1)</td>
<td>9 (3.1)</td>
<td>0.67 (0.30–1.46)</td>
<td>0.46 (0.20–1.06)</td>
</tr>
<tr>
<td>Apgar score at 5 minutes &lt; 7, n (%)</td>
<td>11 (1.0)</td>
<td>2 (0.7)</td>
<td>1.52 (0.34–6.90)</td>
<td>1.38 (0.29–6.60)</td>
</tr>
<tr>
<td>pH umbilical artery &lt; 7.10, n (%)</td>
<td>64 (8.2)</td>
<td>16 (6.9)</td>
<td>1.20 (0.68–2.12)</td>
<td>1.11 (0.61–2.02)</td>
</tr>
<tr>
<td>Base excess artery &lt; −12.0 mmol/L, n (%)</td>
<td>40 (5.3)</td>
<td>8 (3.7)</td>
<td>1.49 (0.69–3.23)</td>
<td>1.23 (0.87–1.74)</td>
</tr>
<tr>
<td>Neonatal trauma, n (%)******</td>
<td>403 (38.1)</td>
<td>64 (22.0)</td>
<td>2.17 (1.61–2.96)*</td>
<td>1.65 (1.20–2.27)*</td>
</tr>
<tr>
<td>Significant trauma, n (%)*******</td>
<td>56 (5.3)</td>
<td>10 (3.4)</td>
<td>1.57 (0.79–3.12)</td>
<td>1.44 (0.71–2.94)</td>
</tr>
<tr>
<td>Admission to NICU, n (%)</td>
<td>88 (8.3)</td>
<td>22 (7.6)</td>
<td>1.11 (0.68–1.81)</td>
<td>1.07 (0.62–1.86)</td>
</tr>
</tbody>
</table>

*P < 0.05.
**Adjusted for birthweight, head circumference, long second stage of labour, fetal distress, spinal anaesthesia and fetal malposition.
***Up to the 10th postnatal day.
****Excludes oropharyngeal suction and facial oxygen.
*****Includes bruising, skin abrasions, facial nerve palsy, Erb’s palsy, fractures, retinal haemorrhage and cephalhaematoma.
******Neonatal trauma excluding bruising and skin abrasions.
given the limitations of observational studies and the conflicting findings in different clinical settings, the most definitive method of assessing the role of episiotomy in preventing or causing anal sphincter tears at operative vaginal delivery remains the RCT. A large well-designed randomised trial of a routine approach to use of mediolateral episiotomy compared with a restrictive approach would complete the evidence base for obstetricians, allowing them to offer women the least traumatic approach when conducting an operative vaginal delivery.

Disclosure of interests
Nothing to declare.

Contribution to authorship
D.J.M. (guarantor) had the original idea for the study and, with M.M. and B.S., carried out the design. D.J.M., M.M. and B.S. obtained funding. M.M., R.B., K.G., L.H. and M.V.d.V. were responsible for data collection. M.M. and D.J.M. carried out the analysis. M.M. and D.J.M. drafted the manuscript that was revised by all authors.

Details of ethics approval
Approved by Edinburgh Multicentre Research Ethics Committee.

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