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DOI:

[10.1016/j.midw.2014.08.009](https://doi.org/10.1016/j.midw.2014.08.009)

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Document Version

Peer reviewed version

Citation for published version (Harvard):

Silf, K, Woodhead, N, Kelly, J, Fryer, A, Kettle, C & Ismail, K 2015, 'Evaluation of accuracy of mediolateral episiotomy incisions using a training model', *Midwifery*, vol. 31, no. 1, pp. 197-200.
<https://doi.org/10.1016/j.midw.2014.08.009>

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PII: S0266-6138(14)00209-5
DOI: <http://dx.doi.org/10.1016/j.midw.2014.08.009>
Reference: YMIDW1573

To appear in: *Midwifery*

Received date: 7 April 2014
Revised date: 25 July 2014
Accepted date: 25 August 2014

Cite this article as: K. Silf MBBS, MMedSci, N. Woodhead MBChB, J. Kelly, A. Fryer PhD FRCPATH, C. Kettle PhD, Dip Mid, SCM, KMK. Ismail MSc, MD, PhD, FRCOG, Evaluation of accuracy of mediolateral episiotomy incisions using a training model, *Midwifery*, <http://dx.doi.org/10.1016/j.midw.2014.08.009>

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Accepted manuscript

Evaluation of accuracy of mediolateral episiotomy incisions using a training model

Introduction

Episiotomy is one of the most commonly performed surgical procedures performed on women worldwide. In many countries, particularly those classed as low or middle income; the majority of women having a vaginal birth will have a routine episiotomy (Liljestrand 2003, Graham et al. 2005) such that episiotomy rates in Latin America are approximately 90% (Althabe et al. 2002). Over the years there has been considerable debate around the practice of routine versus selective episiotomy (Carroli and Mignini 2009). Sleep and associates (1984) found no difference in pain or urinary symptoms with either restrictive or liberal episiotomy use. In the UK the use of episiotomy is selective, and if deemed necessary then a RMLE is recommended as standard practice (National Institute of Health and Care Excellence, 2007).

The UK preference for RMLE originates from evidence that the midline technique is more likely to be associated with OASIS (Klein et al. 1994) and this has been confirmed in more recent studies (Sooklim et al 2007). Furthermore, there is emerging evidence that the angle of episiotomy affects the risk of OASIS. A case controlled study from Ireland, which was designed to examine the impact of RMLE on incidence of OASIS, included 54 primiparous women who sustained an OASIS and 46 primiparous controls. This study reported that if a RMLE is indicated then the incision “should be made at as large an angle as possible” to reduce the incidence of OASIS (Eogan et al. 2006). Indeed, Eogan and colleagues reported that there was a 50% relative reduction in risk of sustaining OASIS for every 6° cut away from the midline. Similarly Kalis et al. reported an incision angle of 60 degrees made from the central axis of the perineum was associated with the same beneficial effect (Kalis et al 2011).

Internationally, there is no standardised definition or categorisation of mediolateral episiotomies (MLEs), there is however a call for standardised

terminology, which would allow for future comparison and meta-analysis. In a recent review Kalis et al. (2012) recommended that a MLE be defined as originating within 3mm of the midline in the posterior fourchette and directed laterally at an angle of at least 60 degrees from the midline towards the ischial tuberosity (Kalis et al. 2012). The National Institute of Health and Care Excellence (NICE, 2007) guideline for intrapartum care states “Where an episiotomy is performed, the recommended technique is a mediolateral episiotomy originating at the vaginal fourchette and usually directed to the right side. The angle to the vertical axis should be between 45 and 60 degrees at the time of the episiotomy”. (Figure 1)

Figure 1: Correct placement of right MLE

- A) Midline
- B) Angle of 45-60°

Several studies, using different study designs, have highlighted the issue of inaccuracies in relation to RMLE incisions amongst practitioners in the UK (Tincello et al. 2003; Andrews et al 2005). However, these studies preceded the NICE (2007) guideline and the growing trend of formalised training for perineal trauma assessment and repair. Therefore, the aim of this study was to audit the accuracy of RMLE performed by a multiprofessional cohort of clinicians in the UK against the criteria set by NICE (NICE 2007).

Methods

A convenience sample comprised of two hundred midwives and trainee obstetricians. All agreed to participate either during a national midwifery conference or prior to a multi-professional perineal management and repair multi-professional training workshop in the West Midlands region.

Participants were informed of the purpose of the study and the intended use of the findings. All of the data obtained were anonymised at the point of collection.

Participants were asked to make an episiotomy incision in line with their usual practice, using a bespoke training model (The Keele & Staffs Episiotomy Repair Trainer, Limbs and Things, UK)

<http://limbsandthings.com/global/products/keele-staffs-episiotomy-repair-trainer/>).

The training model can be adapted and used to deliver 'hands on' clinical skills training for the following scenarios:

- i) How to perform an episiotomy incision
- ii) Basic surgical skills (correct use of instruments, handling perineal tissue and surgical knot tying)
- iii) Techniques for the repair of muscle and skin layers when repairing episiotomies and second-degree perineal tears.

The episiotomy-cutting component of the training model was used in the study reported here, which is designed to give a realistic representation of a stretched perineum at crowning of the baby's head (Figure 2).

Figure 2: Episiotomy incision pad of the Keele and Staffs Episiotomy repair trainer

Prior to making the incision, all 200 participants were asked to complete a questionnaire to capture baseline information on their clinical role (i.e. midwife or obstetrician), the number of years in clinical practice. Participants were asked to state if they had received any previous perineal repair training, however, we did not collect any further information about what their training involved. Each participant was allocated a unique study number, which was written on the episiotomy repair trainer removable pad and at the top of the participant questionnaire, to facilitate matching data during analysis. Participants were blind to the incisions performed previously by other clinicians and incisions were performed in absence of the study team to minimise the risk of bias.

Initial data analysis of the episiotomy incisions was performed independent of, and prior to, the analysis of the baseline questionnaires. Four parameters were considered during the analysis of the episiotomy incisions:

1. The distance of the starting point of the incision from the midline in millimeters (D)
2. The angle subtended by the incision to the perpendicular in degrees (A)
3. The length of the incision in millimeters (L) (Figure 3)
4. The nature of the incision (curved, straight or J-shaped)

Figure 3: Episiotomy incision measurement parameters

D: The distance of the starting point of the incision from the midline in millimeters.

A: The angle subtended by the incision to the perpendicular in degrees

L: The length of the incision in millimeters

These parameters were measured using a standard ruler and protractor. In the case of a curved incision, a string was laid along the line of the incision and then measured against a ruler to obtain accurate length measurements. This methodology is similar to that described by Tincello et al. (2003). To allow for a realistic degree of variability in correct incisions, we decided a priori that the overall incision was considered correct if the incision subtended an angle between 40-60 degrees to the perpendicular and started within ± 5 mm from the midline (ideally should be zero, a negative score was given if the starting point of the incision was to the left side of the midline).

The assessor taking the measurements (KS or KI) was not involved in participants' recruitment or present at the time incisions were performed. To assess inter-observer reliability, both assessors independently measured 20 randomly selected episiotomy pads, using the same methodology described above but blind to the other observer measurements. Data generated by both observers were later compared for statistical correlation using the Kappa test for inter-rater agreement.

Findings

Baseline data relating to previous training were available for 190 participants. Thirty respondents reported they had received no formal perineal repair training (15.7%), 71 had received one-to-one training (37.3%), 57 had received group training (30.0%) and 32 had received both one-to-one and group training (16.8%).

Data from the episiotomy incision pads were available for 197 participants (144 midwives [73.1%] and 53 trainee obstetricians [26.9%]). Data analysis showed that of the 197 RMLE incisions made by participants, 95 were curved (48%), 98 straight (50%), and four were J-shaped (2%). With regards to incision placement, 76.4% (n=110/144) of midwives and 52.8 % (n=28/53) of trainee obstetricians started the incision within ± 5 mm from the midline ($\chi^2_1=10.2$, $p=0.001$). However, 31.9% (n=46/144) of midwives and 41.5% (n=22/53) of trainee obstetricians made the episiotomy incision at an angle ranging from 40-60° ($\chi^2_1=1.6$, $p=0.210$).

When examining the overall correctness for both angle and placement, only 25/197 of incisions made met both criteria (12.7%) [21/144 midwives (14.6%) and 4/53 trainee obstetricians (7.5%), $\chi^2_1=1.73$, $p=0.188$]. Data on previous training was available for 24 of the 25 who correctly performed a MLE, where 79% (n=19/24) self-reported that they had received previous training. Of the 87.3% (n=172/197) clinicians who incorrectly performed MLE, data on previous exposure to training was available for 166 participants, with 86% (n=142/166) self-reporting that they had received previous perineal repair training. A 2-sided Fisher's exact test showed no significant difference between the two groups ($p=0.377$).

Using a Kappa test, the inter-rater agreement between the two observers for the measured parameters was 0.77 ($p<0.0001$) for incision placement (to ± 5 mm from midline), 0.44 ($p<0.0001$) for length of incision (to ± 2 mm) and 0.54 ($p<0.0001$) for angle of incision (to ± 2 degrees). Using the Landis and Kock scale (1977), there was substantial agreement between the two

observers in incision placement and moderate agreement in length and angle of incision measurements.

Discussion

In this study we found, amongst the sample of UK midwives and trainee obstetricians asked to perform a RMLE, there was wide variation in practice. The majority of incisions performed on the bespoke training model, designed to replicate a stretched perineum as the fetal head is crowning, did not meet the cut-offs set for this study or indeed the standard set for performing episiotomy incisions in national guidance (NICE 2007). Our results are comparable to those reported in an earlier study by Andrews et al. (2005) who examined 98 real life episiotomy incisions, performed by midwives and doctors in one maternity centre in the UK, who reported that only 13.3% of the total incisions were correct. However, they reported a higher percentage of overall correct incisions amongst obstetricians compared to midwives, whereas we found the opposite with midwives performing better than trainee obstetricians. A possible explanation for this discrepancy is that they examined actual episiotomy incisions made on women, with the majority of those made by obstetricians being at the time of an operative vaginal delivery (91.4% of incisions), which is a clinical situation that requires an experienced obstetric trainee. Moreover, it is plausible that the trainee obstetricians who participated in this study were fairly junior and had limited clinical experience compared to midwives.

It is recognised that the type of episiotomy is an important determinant of ease of repair, and of risk of extension of this episiotomy to involve other structures, particularly the anal sphincters. It is well documented that midline episiotomies carry an increased risk of causing OASIS, and one of the main reasons for performing a RMLE in UK clinical practice is that it is thought to carry a reduced risk of OASIS when compared to midline incision (Thacker and Banta, 1983). Interestingly, a study examining the effects of the angle of episiotomy on the risk of anal sphincter damage, reported that the mean episiotomy angle in 54 cases of primiparous women that had anal sphincter injury was 30°, range 18-50°, whereas the mean angle in 46 primiparous

controls who sustained episiotomy and no anal sphincter damage was 38°, range 20-55° (Eogan et al. 2006). Undoubtedly, ensuring correct placement in line with national guidelines of the type of episiotomy cut is a significant confounding factor that should be taken into account when designing or re-analysing primary studies that evaluate the effectiveness and risk factors of MLE different types of episiotomy incision. This, in turn, has potential to undermine the fundamental assertions of the risks and benefits of MLE because the majority of these procedures may not have been MLE in the first place. Therefore, to reduce subjectivity and improve accuracy in cutting MLEs the Episcissors-60® were designed and piloted in the clinical setting with initial encouraging results (Freeman et al. 2014).

Our study has highlighted a lack of association between history of self-reported perineal repair training and correctness of episiotomy performed. We believe that the most plausible explanation for this finding is that the majority of perineal trauma management training programs in the UK focus on methods and materials for perineal repair with little attention to the actual technique of 'How to cut an episiotomy?' In England, the Clinical Negligence Scheme for Trusts (CNST) handles all clinical negligence claims against member NHS bodies. In line with CNST standards NHS hospital are expected to put in place training provision in perineal assessment and repair to comply with CNST recommendations for staff members involved in the delivery of intra-partum care. However, there is lack of clear guidance as to what constitutes an optimal training programme. We believe that it is imperative to include structured instructions about parameters of correct RMLE and technique of cutting an episiotomy in any perineal assessment and repair training. This information is of significance when devising quality improvement interventions to address the identified problem.

There are a number of limitations to our study. Firstly, the number of participants recruited is based on a convenience sample of clinicians during a pre-specified time period. However, the fact that our participants were recruited from a multi-professional sample of clinicians working at different

maternity units makes these findings generalisable, at least to UK practice. Secondly, the majority of participants involved were recruited at perineal repair workshops and a national midwifery conference. It could be argued that this may have introduced an element of selection bias to those members of staff keen to update their skill or alternatively aware to their personal needs in training in episiotomy incision and correct angle placement. In contrast, there is also the possibility that participants were attending the training workshops because they identified a weakness in their clinical practice and the need to improve their knowledge of perineal care in labour. Nevertheless, our findings were comparable to those reported by other authors in the UK (Tincello et al. 2003; Andrews et al. 2005). Finally, it is possible that participants found the training model unrealistic and therefore the samples collected were not representative of their normal practice, however our results are comparable with studies that have assessed real life episiotomies (Andrews et al., 2005). One of the main strengths to this work is that the practitioners involved in this study were not affiliated to a single unit, the use of a training model enabled accurate measurement of episiotomy parameters at the time of incision and that we were able to explore the association between accuracy of episiotomy and prior exposure to perineal repair training.

In conclusion, there is a high degree of variability in right MLE incisions that are performed by practicing clinicians, midwives and trainee obstetricians. The majority of these incisions do not fulfill the standard criteria for a MLE in spite of access to training. Therefore, it is essential to incorporate information about parameters of a correct MLE and clear instruction on how to perform the episiotomy in any perineal assessment and repair training programme.

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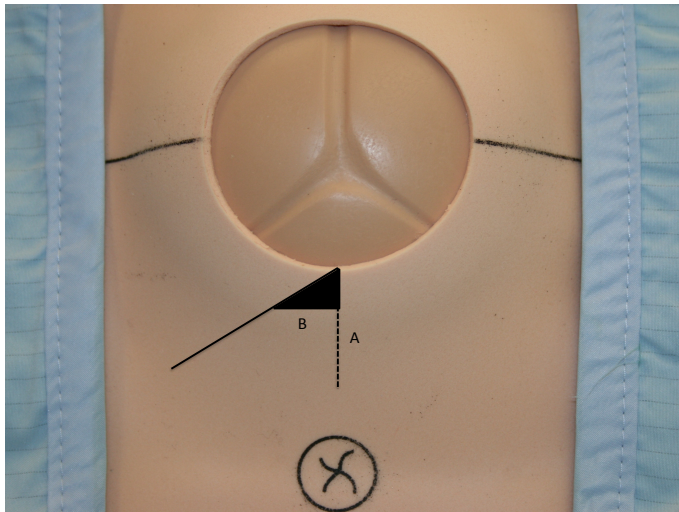
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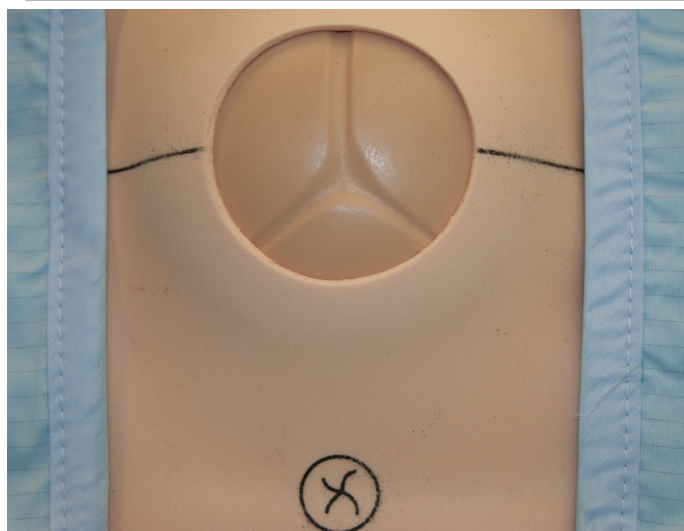
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Accepted manuscript

Highlights

- We audit the accuracy of right mediolateral episiotomy incisions performed on a training model
- Only a minority of clinicians performed a correct mediolateral episiotomy with correct angle and placement
- There was no correlation between previous training and accuracy of incision
- Practitioners should receive practical training on technique of *performing* a correct mediolateral episiotomy





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