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Evidence Update

Does routine episiotomy for vaginal births prevent major degree perineal tears? Summary of the evidence and its application to Sri Lanka

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Abstract

An updated Cochrane Review concluded that in addition to increasing the risk of major perineal/vaginal trauma by 30%, routine episiotomy does not play a role in lowering the risk of many other outcomes including blood loss at delivery, perineal pain, delivering a non-asphyxiated baby or urinary incontinence at six months compared to selective episiotomy.

This review evaluated 12 randomized controlled trials carried out on 6177 women from Europe, North America, South America, South Asia and South-East Asia.

Following critical evaluation of the systematic reviews conducted so far in this field along with local evidence and the aptness of this evidence to local setting, we strongly recommend changing the current practice of routine episiotomy to selective episiotomy in vaginal delivery, in accordance with the National Guidelines of Sri Lanka.

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Introduction

Episiotomy, defined as a surgical incision of the vagina and perineum carried out by a skilled birth attendant to enlarge the vaginal opening [1], is one of the most commonly performed surgical procedures throughout the world [2]. Millions of women undergo episiotomy every year with or without their informed consent.

The origin of episiotomy is difficult to determine, but one of the first to document it was a midwife, Sir Fielding Ould in 1742 [3]. The procedure is carried out mainly with the intention of minimizing third- and fourth-degree perineal tears during the delivery. Expected other outcomes include rapid surgical healing, less blood loss at delivery, less pain, delivery of a non-asphyxiated newborn, prevention of urinary incontinence and genital and urinary prolapse and dyspareunia in the long run [1]. Extensive use of this practice in the United States of America was a result of Dr. DeLee's address at the American Gynaecological Society in Chicago in 1920, based on his personal experience

rather than on evidence [4]. Numerous factors in the first four decades of the 20th century such as increased number of births taking place at hospitals, the evolution of the new specialty of obstetrics and uptake of new interventions to improve the maternal and fetal outcomes of child birth are said to have increased the widespread acceptance of this practice [3].

However, practice of routine episiotomy has been a subject of debate since early 1980s. The literature discusses the lack of evidence in favour of routine episiotomy over selective episiotomy [5]. More importantly, recent evidence demonstrates more harm in the procedure than benefit [6]. In Sri Lanka, episiotomy is used almost routinely in vaginal deliveries without anaesthesia [7], despite the national recommendation to avoid routine episiotomy during spontaneous vaginal birth [8]. Many local studies confirm widespread use of routine episiotomy in the local setting. The episiotomy rate at the Castle Street Hospital for Women was 97.8% for primiparous women and 94% for multiparous women, and at Teaching Hospital, Anuradhapura the rate was 85% for primiparous women and 29.9% for multiparous women [9].

In the light of this background, evaluation of evidence on the practice of routine episiotomy and application of this evidence to the Sri Lankan setting is timely.

International evidence on episiotomy

Many reviews on episiotomy have been published prior to the most recent one by Jiang et al in 2017 [6]. Thacker and colleagues (1983) [10]. in their interpretative review of literature describe that there is no clearly defined evidence for the efficacy of routine episiotomy and, moreover, there is evidence that postpartum pain and discomfort are accentuated after episiotomy. In 2005, Hartmann and colleagues [11] analyzed 45 primary studies in their systematic review on outcomes of routine episiotomy. Following the meta-analysis, the authors concluded that immediate maternal outcomes of routine episiotomy, including severity of perineal laceration and pain, are not better than those with restricted episiotomy.

Regarding long term outcomes, analysis proved that there were no improvements in continence of urine or stools or in pelvic floor muscle function among women who had had episiotomy compared to those who had not. Furthermore, no trial has found that any form of episiotomy, routine or selective, improves sexual functions. The first Cochrane systematic review comparing the outcomes of routine and selective episiotomy (2009) similarly concluded that routine episiotomy, is not justified by current evidence [12].

Local evidence on episiotomy

Two randomized controlled trials (RCT) conducted in Sri Lanka comparing routine versus selective episiotomy revealed contradictory results. Kannangara (2011) [13] assessed the percentage reduction in the episiotomy rate in the interventional group compared to the control as the primary outcome, and posterior perineal trauma and anterior vaginal wall tears as secondary outcomes among 176 women in his study. The author reports

significantly higher rates of first (8.4% Vs 1.2%) and second degree (9.6% Vs 2.4%) posterior perineal tears and anterior vaginal wall tears (18.1% Vs 8.1%) in the interventional group compared to control group, despite the 28% reduction of episiotomy rate in the interventional group. However, the risk of bias in most domains assessed according to Cochrane Risk of Bias Tool [14], including allocation concealment, blinding of patient and personnel and blinding of outcome assessment are high, leading to low overall quality of evidence.

De Silva (2010) determined the percentage of primigravidae delivering without episiotomy but without any adverse effects [15]. The study revealed a significant 68.1% drop in the episiotomy rate without any fetal or maternal compromise in the intervention group compared to the control group. Furthermore, he described a significantly higher total perineal tear rate in the intervention group (70.7%) compared to the control group (36.0%).

Sub-analysis of the tears according to site and degree revealed a significantly higher anterior tear rate in the control group ($p=0.004$), posterior tear rate in the intervention group ($p<0.001$) and 1st degree tear rate in the control group ($p=0.04$). Out of the secondary outcomes assessed, only immediate postpartum pain was found to be significantly higher ($p<0.001$) in the control group, while dyspareunia after 3 months, urinary incontinence after 3 months and admissions to newborn intensive care unit failed to show significant differences between the two groups.

However, the authors of the current paper find these findings inconclusive as the outcome rates for the intervention group were calculated considering only the proportion of women who underwent episiotomy in that group. The quality of evidence from this study is moderate and the risk of bias according to Cochrane Risk of Bias Tool [14] was unclear for most of the domains assessed.

Latest evidence on episiotomy

An update of the Cochrane systemic review, which considers recent published and unpublished studies of good quality around the world, summarizes the findings of clinical trials on selective versus routine episiotomy [6]. Selected primary studies were carried out on 6177 women from 12 countries representing Europe, North America, South America, South Asia and South-East Asia. Studies that were included assessed outcomes among women above 16 years of age, between 28 weeks of gestation and full term, with a live singleton fetus, without severe medical or psychiatric conditions and with vaginal births. Study settings were hospitals in high, middle and low-income countries.

The rate of the intervention, selective episiotomy, ranged from 8% to 59% whereas the rate of the comparator, routine episiotomy, ranged from 61% to 100%.

Details of the Cochrane systematic review [6]

Types of studies	Twelve RCTs in 22 reports were included in the review. No cluster-RCTs were found.
Study settings	Seven of the 12 studies were from high income countries, including Canada, Germany, Ireland, Spain and the UK. Other five studies were from low-middle income countries, and these included Argentina, Columbia, Malaysia, Pakistan and Saudi Arabia.
Participants	Pregnant women above 16 years of age, between 28 weeks of gestation and full term, with a live singleton fetus and had given vaginal birth were recruited for the trials. Those with severe medical or psychiatric illnesses were excluded.
Interventions	All studies compared selective episiotomy versus routine. However, indication for selective episiotomy was defined differently in different studies.
Outcomes	All studies reported the primary outcome of the review, severe perineal/ vaginal trauma, defined as 3rd- or 4th-degree perineal tears with or without vaginal tears. Other outcomes included maternal and newborn outcomes including blood loss at delivery, need for perineal suturing, perineal pain, Apgar score <7 at 5 minutes, admissions to special baby care unit, perineal infections and haematoma formation, long term outcomes of dyspareunia, urinary incontinence, wound dehiscence and haematoma formation at least at 6 months. One study has assessed genital prolapse at 3 years.

Analysis of the Cochrane Review [6]

Meta-analysis of the systemic review analyzed primary study findings on severe perineal / vaginal trauma, blood loss at the delivery, newborn Apgar score <7 at 5 minutes, perineal infections, moderate or severe pain, long term dyspareunia and long-term urinary incontinence between routine and selective episiotomy.

Table 1: Results generated for the main outcomes by the systematic review [6]

Outcome	Risk in control group	Risk in intervention group	RR (95% CI)
Severe perineal/ vaginal trauma	3.6:100	2.5:100	0.70 (0.52-0.94)
Blood loss at delivery	278ml	251ml	No events
Babies with newborn Apgar score <7 at 5mins	0:100	0:100	No events
Perineal infection	2:100	2:100	0.90 (0.45-1.82)
Moderate or severe pain	45.1:100	32:100	0.71 (0.48-1.05)
Long term dyspareunia (≥6 months)	12.9:100	14.8:100	1.14 (0.84-1.53)
Long term urinary incontinence	32.2:100	31:100	0.98 (0.67-1.44)

From the meta-analysis, it is evident that,

- 30% higher risk of severe perineal/ vaginal trauma, defined as 3rd- or 4th-degree perineal tears with or without vaginal trauma, in women where an unassisted vaginal birth was expected.
- No effect on reducing the risk of other outcomes assessed in primary studies.

Application of evidence to national policy and guidelines in Sri Lanka

Practicing evidence-based medicine plays a vital role in achieving desirable health outcomes effectively and efficiently. One key challenge faced by policy makers and researchers in doing so is to determine whether research evidence about the impact of an option is applicable to their setting. Assessment of aptness of the current available best evidence on episiotomy practice to the local setting is described in Table 2.

Table 2: Assessment of the aptness of the evidence to Sri Lanka

Applicability
Evaluation according to the AMSTAR criteria confirmed the review to be of good quality. Even though most study settings included in the review are high income countries, they are comparable to Sri Lanka regarding the institutional delivery rates. However, like the two local studies discussed above, the quality of evidence for the main outcome was low according to the GRADE evaluation and the Risk of Bias was unclear for most of the primary studies.
Impact
National level rates are not available to assess the impact of the main outcome of interest, severe perineal trauma, defined as 3rd- or 4th-degree trauma, in Sri Lanka. However, isolated institutional studies report incidence rates of 3rd-degree perineal tears in the range of 0.4% to 0.71% [9]. A multi-country study describes a rate of 0.63% [16] for 3rd- and 4th-degree tears in Sri Lanka. Two local RCTs discuss 3.6% [13] and 0.0% [15] major degree tear rates for the control group and 4.8% [13] and 1.5% [15] rates for the interventional groups respectively. Thus, the impact of the changed practice of episiotomy will be low according to available data, but whether the reported rates are representative of Sri Lanka is questionable.
Feasibility
Since the current practice is routine episiotomy in most institutions [7,9], there is no added cost in implementing the intervention. Rather, it is an omission of a procedure already in place. However, if the practice is changed to selective episiotomy, the health staff will need to be trained on “hands on” and “hands poised” procedures to assist vaginal births.
Acceptability
Resistance from staff against omitting an ongoing procedure is predictable, as global evidence suggests that “de-innovation” or giving up on-going practices is harder for clinicians than adopting new intervention [17]. On the contrary, the health system will embrace the change as it will save expense on materials and the time spent by health staff on suturing. Acceptability of the intervention from the patient’s perspective is always difficult to predict in the local context, where patients’ preference regarding clinical practice is often neglected.

Conclusion on applicability of the evidence to Sri Lankan setting

Applicability and feasibility of evidence stand in favour of changing the practice to selective episiotomy in Sri Lanka. Even though the burden of 3rd- and 4th-degree perineal tears is minimal in Sri Lanka, the available data are not national level data. The health system is most likely to benefit by taking up the evidence.

Recommendations based on current best evidence

The authors agree with the national guidelines on performing selective episiotomy during vaginal delivery and strongly recommend changing the existing practice of routine episiotomy to selective episiotomy in accordance with the national guidelines. Conducting high quality clinical trials to assess short term and long-term outcomes important to Sri Lanka is highly recommended to fulfill the noteworthy information gap at national level.

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