

**What are the maternal and newborn outcomes associated with
episiotomy during spontaneous vaginal delivery?**

Evidence Summary No. 13

**Developed as part of the OHRI-Champlain LHIN
Knowledge to Action research program
For BORN Ontario**

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What are the maternal and newborn outcomes associated with episiotomy during spontaneous vaginal birth?

The objective of this report is to summarize evidence around the risks and benefits to mothers and newborns subsequent to practice of episiotomy during spontaneous vaginal birth. Its intention is to support a quality improvement initiative that seeks to reduce rates of episiotomy among women who having a spontaneous vaginal birth in Ontario.

Key Messages

- Episiotomy represents a unique obstetrical practice in that it became a part of accoucheurs' repertoire of interventions based on its theoretical value rather than any demonstrated worth, and has remained a conventional practice (more or less) despite strong empirical evidence disfavoring its use.
- Two systematic reviews based on thousands of women evaluated in multiple RCTs have unequivocally determined the practice of restrictive episiotomy during vaginal birth to be better than routine episiotomy with respect to numerous maternal outcomes.
- There is insufficient evidence to support the practice of episiotomy for improving neonatal outcomes.
- When episiotomy is 'indicated', there is insufficient evidence to know the relative value of midline vs. mediolateral types of incisions.
- Future work is urgently required to systematically determine which remaining indications for episiotomy are in fact supported by improved maternal and/or neonatal outcomes.

Who is this summary for?

This summary was undertaken for BORN Ontario and is intended for use by local Ontario health systems stakeholders, policy-makers and decision-makers within Ontario

Information about this evidence summary

This report covers a broad collection of literature and evidence sources **with a search emphasis on systematic reviews.**

As such, evidence summarized from systematic reviews is highlighted in blue boxes, like this one. Systematic reviews are generally favoured over other study designs, because they incorporate evidence from multiple primary studies, instead of reporting evidence from just one study.



This summary includes:

- **Key findings** from a broad collection of recent literature and evidence sources.



This summary does not include:

- **Recommendations;**
- **Additional information** not presented in the literature;
- **Detailed descriptions of the interventions** presented in the studies.

Many sections conclude with a **“Bottom line”** subsection that provides a statement summarizing the studies or aims to provide some context. These statements are not meant to address all of the evidence in existence on the subject, rather, only that which is featured in this document.

All papers summarized in this document are available by request to kkonnyu@ohri.ca.

I. Background

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Episiotomy is an obstetric practice employed during childbirth in which the vaginal opening is enlarged by a surgical cut to the perineum with scissors or scalpel (Carroli and Mignini 2009). Historically, episiotomy has been performed prophylactically to prevent severe vaginal tears and to facilitate an easier/faster birth of the baby (Carroli and Mignini 2009, ACOG 2006). Other suggested maternal benefits include the preservation of muscle relaxation of the pelvic floor leading to improved sexual function, reduced risk of faecal and/or urinary incontinence, and improved surgical healing (i.e., subsequent to a clean surgical incision and repair, rather than a potential 3rd or 4th degree laceration). For the neonate, it is suggested that a faster birth may be protective against the risks of a prolonged second stage of labour (>120mins), which may lead to fetal asphyxia, cranial trauma, cerebral haemorrhage and mental retardation (Carroli and Mignini 2009). Alternatively however, hypothesized adverse risks may include extensions of the episiotomy to 3rd or 4th degree tears, unsatisfactory anatomic results (e.g. skin tags, vaginal prolapse, recto-vaginal fistula), increased blood loss and haematoma, pain and edema of the episiotomy region, infection, sexual dysfunction, anal sphincter dysfunction, and dyspareunia (Carroli and Mignini 2009, ACOG 2006).

What is interesting about episiotomy is how the procedure became routine despite limited to no data supporting its effectiveness. Although it has been cited in the literature for more than 300 years, the practice was not widely employed until the mid-20th century when there was an increased focus to have women give birth in the hospital and greater medical involvement in the birthing process (Carroli and Mignini 2009, ACOG 2006). Although knowledge surrounding the benefits and harms of episiotomy has grown substantially since then, rates of episiotomy remain highly variable (e.g. 9.7% in Sweden vs. 100% in Taiwan) (Carroli and Mignini 2009). In Ontario, the rate of episiotomy ranges from 7% to 31% (**Figure 1**; Dunn et al. 2011). Given such wide practice variations, it has been suggested that the primary drivers of episiotomy use relate more to regional and individual circumstances (local professional norms, experiences in training, and individual provider preference) than specific variation in the physiology of vaginal birth (Viswanathan et al. 2005).

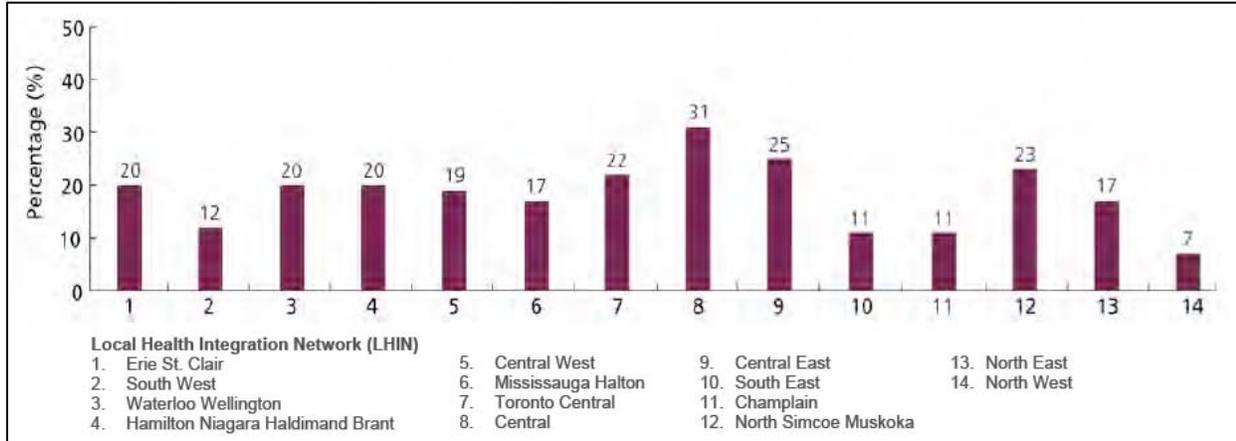
It is important to accurately assess the true utility of this practice in order to inform quality obstetric care. Thus, the objective of this review was to conduct a rapid summary of the evidence related to the benefits and harms of episiotomy during spontaneous vaginal birth in women at term gestational age. Its intention is to support efforts that seek to reduce levels of episiotomy to an appropriate level in Ontario.

Levels of evidence:

Each piece of evidence presented in this summary is assigned a level (adapted from Cochrane MSK group, 2010):

- **Platinum:** Systematic reviews and meta-analyses
- **Gold:** Randomized controlled trials (RCTs)
- **Silver:** Observational studies (non-randomized trials, case-control, time-series, cohort studies, case series)
- **Bronze:** Expert committee guidelines, reports or opinions and/or clinical experience of respected authorities (e.g. commentary, editorial)
- Level of evidence cannot be determined

Figure 1. Age-standardized episiotomy rate (percentage of hospital deliveries) among women who had full-term, singleton, vertex, vaginal delivery, by LHIN, in Ontario, 2007.



Source: Dunn et al. 2011 (Data source: Better Outcomes and Registry Network (BORN) Ontario's Niday Perinatal Database)

II. Evidence

7/11 A 2009 Cochrane systematic review sought to “determine the possible benefits and risk of the use of restrictive episiotomy versus routine episiotomy” during vaginal delivery (Carroli and Mignini 2009). In addition to this primary comparison, it compared restrictive vs. routine use of mediolateral episiotomy, restrictive vs. routine use of midline episiotomy, and use of mediolateral vs. midline episiotomy. Eight RCTs were included (n=5,541) (references of included studies listed in ‘References of interest’ below). Collectively across these studies, episiotomy was performed on ¾ of women assigned to the routine arm and ¼ of women assigned to the restrictive arm. Overall the restrictive use of episiotomy resulted in a reduced negative impact on women, including less severe perineal trauma, less suturing, and fewer healing complications. The only outcome which appeared to be improved with routine episiotomy was anterior perineal trauma. There were no differences with respect to outcomes of severe vaginal/perineal trauma, dyspareunia, urinary incontinence, or several pain measures between routine and restrictive groups. When routine vs. restrictive mediolateral midline comparisons were made, they were found to have similar outcomes to the main routine vs. restrictive comparison. Unfortunately there was insufficient evidence however to determine the relative benefit of mediolateral vs. midline episiotomy itself. A cost

effectiveness analysis from one included RCT found the practice of restrictive episiotomy to be more effective and less costly than a policy of routine episiotomy. The review did not report any neonatal outcomes. Based on these findings, the authors conclude “there is clear evidence to recommend a restrictive use of episiotomy”.

7/11 A 2005 systematic review by Viswanathan and colleagues (Viswanathan et al. 2005), prepared for the Agency for Healthcare Research and Quality in the United States, assessed the evidence on five Key Questions (KQs) related to the routine use of episiotomy during vaginal birth. Relevant questions to this summary included: 1) Does the practice of liberal or routine episiotomy, compared to more selective use of episiotomy, influence maternal postpartum outcomes?; 2) Does episiotomy incision type (i.e., midline or mediolateral), influence maternal postpartum outcomes?; 4) Does episiotomy have a long-term influence on urinary incontinence, fecal incontinence, or pelvic floor defects?; 5) Does episiotomy, incision type, or both, influence future sexual function? Only evidence from RCTs was used to answer KQs 1 and 2, while evidence from both RCTs and nonrandomized prospective cohorts was used to answer KQs 4 and 5. A total of 45 studies were included.

KQ 1: Routine vs. restrictive episiotomy

Based on findings from 7 RCTs (references 8-14, listed below in 'References of interest'), the reviewers found improved outcomes among women assigned to the restrictive use groups, including less severe posterior perineal trauma, less need for suturing, higher probability of having an intact perineum, and a higher likelihood of resuming intercourse earlier. There was no difference found with respect to wound healing complications. The authors conclude that this fair to poor evidence "provide consistent findings that clearly support limited use of episiotomy". They elaborate that "routine episiotomy achieves no short-term goals that it has been hypothesized to achieve" and in fact is more harmful because "it creates a surgical incision of greater extent than many women might have experienced had episiotomy not been performed".

KQ 2: Midline vs. mediolateral episiotomy

Based on findings from 1 RCT (reference 15, listed below in 'References of interest') the reviewers found women receiving a midline episiotomy began sexual intercourse earlier and had a better cosmetic appearance of the scar, but were more likely to have anal sphincter injuries as compared with women who received a mediolateral incision. There were no differences with respect to outcomes of pain or satisfaction with sexual intercourse. Based on "considerable methodological flaws", the authors emphasized caution in interpreting the findings of this single study.

KQ 4: Long-term maternal consequences

Based on findings from 2 RCTs, 11 prospective studies, and 1 cohort study (references 8, 11, 29, 38-48 listed below in 'References of interest') the reviewers found fair to poor evidence which "does not support use of episiotomy for the purpose of preventing pelvic floor defects, urinary incontinence, or incontinence of stool or flatus". Of note, the reviewers suggest caution in interpreting these findings because they were commonly based on non-validated intermediate outcomes rather than direct outcomes, and had limited follow-up to detect long-term disease occurrence.

KQ 5: Impact of episiotomy or incision type on sexual function

Based on findings from 4 RCTs and 5 prospective cohort studies (references 8, 11, 15, 38, 42, 49-52 listed below in 'References of interest') the reviewers determined that episiotomy does not appear to be associated with impaired sexual function.

In sum, the reviewers concluded that their "systematic review finds no health benefits from episiotomy", and asked the important question "if episiotomy were restricted to indicated uses... which, if any, of the prevailing indications for episiotomy are supported by an adequate research base?" To address this question they proposed a 2-stage research platform including systematic assessment of outcomes of episiotomy for presumed indications, followed by the collection and assessment of missing outcomes. Ultimately however, they argued that further evidence is still required in order to fully know what circumstances should be considered indications for episiotomy.

Bottom line:

This section summarized evidence from 2 systematic reviews of moderate quality. Both concluded, unequivocally, that restrictive use of episiotomy is more beneficial (with respect to maternal outcomes) than a policy of routine use. Unfortunately, neither review addressed neonatal outcomes, however it is not clear if this limitation was due to the lack of assessment of these outcomes in primary studies.

III. Guidelines

ACOG (US)

★ In 2006, the American College of Obstetricians and Gynecologists published their clinical practice guideline on episiotomy (No.71) (ACOG 2006). With respect to indications for episiotomy, the guideline's 'recommendations' are somewhat vague. The guideline restates the suggested reasons for which episiotomy is commonly indicated – that is, "where expediting delivery in the second stage of labour is warranted or where the likelihood of spontaneous laceration seems high". Although it lists the clinical circumstances

which would meet this criteria (e.g., nonreassuring fetal heart rate pattern, operative vaginal delivery, shoulder dystocia, and cases where the perineal body is thought to be unusually short), it acknowledges that “the data supporting these claims are largely descriptive or anecdotal”, and indeed “several trials suggest the lack of evidence support use of episiotomy in these circumstances”.

- With respect to restrictive vs. routine use of episiotomy the guideline states a restrictive policy to be preferable.
- With respect to mediolateral vs. median (i.e. midline) episiotomy, the guideline states that the data is insufficient to determine the superiority of one approach over the other, and in fact, many outcomes have been shown to be no different.
- With respect to fetal indications for episiotomy, the guideline raises concerns over insufficient evidence. It indicates that while episiotomy is proposed to result in numerous fetal benefits (e.g., cranial protection, reduced perinatal asphyxia, less fetal distress, better Apgar scores, less fetal acidosis, and reduced complications from shoulder dystocia), there is little data to support any of these claims. Even the claim of shortening the second stage of labour, the guideline argues, “has not been conclusively shown”.

Ultimately the guideline defers to clinical judgment stating that “current data and clinical opinion suggest that there are insufficient objective evidence-based criteria to recommend episiotomy, and especially routine use of episiotomy and that clinical judgment remains the best guide for use of this procedure”.

NICE (United Kingdom)

★ In 2007, the National Collaborating Centre for Women’s and Children’s Health (commissioned by the National Institute for Health and Clinical Excellence) published the 1st edition of their clinical guideline covering intrapartum care of healthy women and their babies during childbirth (National Collaborating Centre for Women’s and Children’s Health 2007). Specific to the use of episiotomy, the report offers the following recommendations:

- “A routine episiotomy should not be carried out during spontaneous vaginal birth.”
- “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° at the time of the episiotomy.”
- “An episiotomy should be performed if there is a clinical need such as instrumental birth or suspected fetal compromise.”
- “Episiotomy should not be offered routinely at vaginal birth following previous 3rd or 4th degree trauma.”

IV. Benchmarks

While rates of episiotomy vary widely across practice settings, several benchmarks to strive for have been suggested by the literature. A joint publication by Childbirth Connection, the Reforming States Group and the Milbank Memorial Fund on evidence-based maternity care suggest a benchmark episiotomy rate of 2% or less based on rates reported in large American studies (Sakala and Corry 2008). Alternatively, the Agency for Healthcare Research and Quality suggest a rate of episiotomy for spontaneous vaginal births should be <15% (Viswanathan et al. 2005).

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Methods

Detailed search strategies were developed by an experienced Information Specialist (specific search terms available upon request). Searching was limited to the following databases:

- Biomed Central;
- Cochrane Database of Systematic Reviews (CDSR);
- Database of Abstracts of Reviews of Effects (DARE)
- National Health Service Economic Evaluation Databases (NHS EED)

Search concepts included Medical Subject Headings (MeSH) and non-thesaurus terms (i.e. text words). A 'grey literature' search was also conducted for potentially relevant studies by reviewing the web sites of relevant organizations (available upon request). Guidelines based on literature review were included. To be included, all citations had to have been published in English and be available in full text electronically.

Screening and extraction was conducted by one reviewer, and thus may have introduced a marginal amount of error. Given the publication of relevant systematic reviews, no RCTs were considered for summary in this report. Risk of bias was only evaluated for the systematic reviews in this report, using the AMSTAR instrument.

Risk of Bias Assessment of Systematic Reviews

AMSTAR is an 11-item measurement tool created to assess the methodological quality of systematic reviews. Each question is scored according to 1 of 4 options (yes, no, cannot answer, not applicable) and the number of 'yes' answers tallied. A higher score indicates increased methodological quality.

The 11 assessment criteria are as follows:

1. Was an "a priori" design provided?
2. Was there duplicate study selection and data extraction?
3. Was a comprehensive literature search performed?
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?
5. Was a list of studies (included and excluded) provided?
6. Were the characteristics of the included studies provided?
7. Was the scientific quality of the included studies assessed and documented?
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
9. Were the methods used to combine the findings of studies appropriate?
10. Was the likelihood of publication bias assessed?
11. Was the conflict of interest stated?

The AMSTAR score (from 0 to 11) for each systematic review in this evidence summary is reported in the box that appears at the beginning of each finding.

Additional Information

This summary was produced by:

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Conflict of Interest

None declared

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