

## *Episiotomy and severe perineal trauma*

# Of science and fiction

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### Résumé

LES ÉTUDES CLINIQUES SUR L'ÉPISIOTOMIE comme facteur de risque de traumatismes graves du périnée prolifèrent depuis 20 ans. La plupart de ces recherches se font sous forme d'études par observation longitudinale, d'études par observation transversale et d'études cas-témoin. L'étude décrite par le Dr Michel Labrecque et ses collègues dans le présent numéro (page 797) allie une conception longitudinale et transversale et l'on examine minutieusement un vaste éventail de facteurs de confusion. Labrecque et ses collaborateurs concluent qu'il y a une association solide entre l'épisiotomie médiale et des lacérations du périnée du troisième et du quatrième degrés. Même si des études contrôlées randomisées ont démontré que, pour chaque patiente, l'épisiotomie accroît le risque de déchirure grave du périnée, l'adoption d'une politique de pratique restreinte n'a pas eu pour effet de réduire l'incidence des déchirures périnéales. Comme les avantages de l'épisiotomie n'ont pas été démontrés, on ne peut justifier son utilisation répandue.

*Ignorance is preferable to error; and he is less remote from the truth who believes nothing, than he who believes what is wrong.* — Thomas Jefferson (1743–1826)

Clinical research on the practice of episiotomy has proliferated in the last 2 decades, coinciding with the shift toward evidence-based practice. Literature appraisal and the promotion of research have become integral to obstetrics training in Canada, reflecting not only the profession's desire for the truth but also the public's demand for quality assurance in health care. It is not uncommon for pregnant women to question their physicians about various aspects of their practice, including their attitudes toward episiotomy.

Our first obligation as physicians is "do no harm," but we must also ensure that the benefits of an intervention outweigh the risks. This is of concern in the use of episiotomy. Most Canadian physicians practising today were taught that the best means of preventing damage to the posterior wall during childbirth was the use of episiotomy and that episiotomy should be performed on all primiparous women. We were also taught that episiotomy prevents jagged perineal lacerations and are easier to repair than jagged tears. Episiotomy is performed by many physicians in the belief that it reduces the duration of the second stage of labour, reduces metabolic and mechanical risk to the infant, protects the bladder and prevents future perineal relaxation. In their landmark review Thacker and Banta<sup>1</sup> concluded that most research published up to 1980 was inadequate to determine whether the championed benefits of episiotomy really held true.

Since that time the traditional view of episiotomy has been challenged.<sup>2</sup> Clinical researchers have become more concerned with the possible harms of episiotomy than with its perceived benefits. Concerns about immediate and delayed perineal pain, third- and fourth-degree tears, excessive blood loss, wound infections, long-term dyspareunia, and fecal and urinary incontinence have become the focus of research. Risk factors associated with the performance of an episiotomy have also been studied. We are now at a crossroads in our evaluation of this practice. On the evidence, can we justify the liberal use of episiotomy?

Clinical studies on episiotomy and its possible association with severe perineal trauma have used various designs, each of which has inherent limitations. Longitudinal observational studies have been the most common. These usually describe



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practice trends over time and try to correlate changes in practice with changes in rates of complications. Of 6 studies of this type published since 1980<sup>3-8</sup> all except one showed no statistically significant change in rates of third- or fourth-degree perineal tears with changes in episiotomy rates. The remaining study<sup>8</sup> showed that the rate of third-degree tears increased with a switch in practice from mediolateral to median episiotomy. These studies, however, did not properly address changes in confounding factors that occurred over the observation period.

The second main type of study uses a cross-sectional observational design and typically examines how rates of episiotomy and of complications vary according to different types of care facility,<sup>6,9-11</sup> different categories of health care providers<sup>6,9-12</sup> or the practice patterns of individual physicians.<sup>13-15</sup> With a few exceptions, these studies have demonstrated no significant association between rates of episiotomy and rates of severe perineal laceration. They rarely account for major bias in such areas as patient selection and referral. Biases related to practitioners' attitudes toward such matters as the use of oxytocin or forceps, the acceptable duration of the second stage of labour, the type of episiotomy performed, fetal presentation and the management of fetal distress tend to run rampant. Although some studies have attempted to correct for bias with multiple logistic regression analyses,<sup>9,11</sup> important confounding factors still tend to be overlooked. As a result, they cannot demonstrate that any perceived association between episiotomy and severe perineal tears is in fact a causal relation.

The third type of study uses a case-control design. Typically, these studies compare a cohort of patients who experienced severe perineal laceration with a cohort of patients who had intact perineums during a specific observation period and attempt to determine whether various interventions such as an episiotomy increase the risk of perineal laceration. Multiple logistic regression is usually performed to adjust for interventions that may be interdependent (e.g., forceps delivery and episiotomy). The only study to follow a strict case-control design to determine risk factors for third-degree tears showed that the most important risk factor for perineal damage was shoulder dystocia; the next most important was forceps use, and then mediolateral episiotomy.<sup>16</sup> Like longitudinal and cross-sectional observational studies, case-control studies cannot prove causality but do help to identify strong associations.

The study design best able to correct for confounding factors is the randomized controlled trial (RCT). RCTs have the potential to demonstrate causal relations as long as groups being compared are similar in all aspects except the one under study. To achieve reliable results, RCTs must meet strict criteria: randomization must be conducted properly, crossovers between the groups should be minimized, all cases randomized must be analysed according to their allocation group, and the study should have enough

statistical power to eliminate type 1 and type 2 errors.

Only 2 RCTs of episiotomy have met these criteria. The first, conducted in Argentina,<sup>17</sup> involved 2606 women who were randomly assigned to 1 of 2 groups: "routine" or "selective" use of episiotomy. The findings showed that despite differences in episiotomy rates the 2 groups did not differ with respect to the incidence of third-degree lacerations.

The second and best-designed RCT was conducted in Canada.<sup>18</sup> In this study 703 women were randomly assigned to either a "restrictive-use" group or a "liberal-use" group for median episiotomy. Intention-to-treat analysis failed to show a difference between the 2 groups in the rate of anal-sphincter tears. Because a significant number of episiotomies were performed in the restrictive-use group, secondary analysis was performed to compare patients who received an episiotomy with those who did not, regardless of allocation. After confounding factors were controlled for, it became clear that the cohort of patients in whom median episiotomy was performed showed a significant increase in the occurrence of third- or fourth-degree tears. This trial was also remarkable in its long-term follow-up of patients for other complications. The 2 allocation groups were not found to differ in the incidence of perineal relaxation as determined by electromyographic perineometry, persistence of perineal pain at 10 days, urinary incontinence at 3 months, dyspareunia and sexual satisfaction at 3 months. Given that the benefits claimed for episiotomy — i.e., that it prevents perineal relaxation, reduces dyspareunia and improves sexual satisfaction — were not proven, the authors concluded that a policy of restrictive use should be followed. One should remember, however, that even if such a policy is followed, it may not necessarily reduce the general incidence of third- and fourth-degree tears, even though the risk for a particular patient would be reduced by the avoidance of episiotomy.

In this issue (page 797) Dr. Michel Lebreque and colleagues report an association between median episiotomy and severe perineal lacerations in primiparous women. Their study is a hybrid between a longitudinal and a cross-sectional observational design. It documents trends in a large cohort of patients in the frequency of episiotomy, forceps use, birth weight and the frequency of severe perineal lacerations in a Canadian centre from 1985 to 1993. Most important, it deals in a very comprehensive manner not only with the myriad of confounding factors identified in the literature in this field but also with the impact of the experience and beliefs of the physicians involved. Labrecque and colleagues show that the most important risk factors for severe perineal laceration were, in descending order, median episiotomy, forceps use and birth weight. Of great interest is their finding that physicians' experience and their beliefs about episiotomy and perineal lacerations did not influence the rates of third- and fourth-degree tears.



In the final analysis, the liberal use of episiotomy cannot be justified. The benefits claimed for episiotomy have not been proven. On the other hand, establishing a causal relation between episiotomy and severe perineal tears has proved to be no easy feat. We must always be alert to the confounding factors and biases that plague longitudinal, cross-sectional and case-control studies. Of all research designs, RCTs are perhaps best suited to demonstrate causality. Nevertheless, the 2 largest RCTs of episiotomy failed to show that a *policy* of restrictive use reduced rates of severe perineal laceration. On the other hand, the findings of these trials suggest that women who undergo episiotomy are at increased risk for third- and fourth-degree tears. At first glance, these 2 statements may seem contradictory. In reality the difference is quite subtle.

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