

Are You Happy with the Epi(siotomy)?

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The potential advantages of a perineal incision for the enlargement of the vaginal orifice during labor and delivery, perineotomy, or episiotomy – the term in common use – were first discussed by Sir Fielding Ould in 1742 [1]. The “cut” did not gain popularity in the 19th century because physicians effectively discouraged the acceptance of a “new” maternity practice that was against “natural law.” However, in the 20th century, a radical shift took place in obstetricians’ belief systems. In the United States, at the beginning of the 20th century, the normal process of childbirth requiring little intervention was substituted by a perception of childbirth as a pathologic process, believed to necessitate prophylactic intervention to prevent fetal and maternal damage. Famous and influential obstetricians recommended episiotomy. In 1918, Pomeroy [2] made the accusation “that a long second stage has destroyed innumerable children...” and DeLee [3] wrote in 1920, “Perineotomy undoubtedly preserves the integrity of the pelvic floor...and forestalls...the long train of sequellae...” In England, the acceptance of “active management of labour” in the 1970s removed the philosophical barriers regarding labor as a physiologic process, favoring the superiority of obstetric intervention [4]. As a result, routine episiotomy, median or mediolateral, became an essential part of “modern” childbirth, the most common operation in obstetrics, and among the top ten of all surgical procedures.

The purported benefits of routine episiotomy were: prevention of serious damage to the pelvic floor, prevention of trauma to the fetal head and prevention of brain injury, reducing the likelihood of third and fourth degree lacerations, and an easier repair and healing of a surgical incision than a ragged spontaneous perineal tear. According to current standards, the practice of a new operation cannot be introduced universally, unless prospective randomized studies could demonstrate a clear beneficial effect of the operation accompanied by reasonable risks. However, the practice of episiotomy was introduced on a theoretical basis more than on evidence-based data.

Different practices for different reasons

Episiotomy rates vary around the world. In the early 1980s the rate in British maternity units was 14–96% in primiparas and 16–71% in multiparas [5]. In Denmark, the overall episiotomy rate in 1990 was 37% [6]. In Canada and the USA, there was a clear tendency of decreasing episiotomy rates from the 1980s to the 1990s, from 66.8% to 37.7% and from 61.1% to 39.3% [7,8]. However, in Latin America, episiotomy is still performed routinely in primiparas with a

median rate of 92.3% [9]. During 2001, in the three maternity units of Haifa, including 9,414 vaginal deliveries, the episiotomy rates varied between 29 and 37%, with an average of 32.5% (personal communication).

A recent report from Philadelphia [10] noted a decrease in episiotomy rates by 72% (from 69.9% in 1983 to 19.4% in 2000). The authors attributed this change in practice mainly to the impact of the growing body of literature against routine episiotomy. Using logistic regression models, however, among the most significant variables effecting this decrease were non-medical factors, such as insurance status or race. Having Medicaid insurance was associated with a decreased episiotomy risk, and black women consistently underwent fewer episiotomies than white women, even when controlling for age, parity, insurance status and operative delivery [10]. In another report [11], the strongest factor associated with the practice of episiotomy was the category of obstetric provider: private providers had the highest episiotomy rates (55.6%), faculty providers (33.3%) and midwives the lowest rate (21.4%). This difference could not be explained by clinical characteristics or demographic factors.

Evidently, episiotomy rates vary between countries, institutions and individuals, most likely because of differences in attitudes and training. Different types of obstetric providers may have different propensities for performing episiotomies [11–14]. However, these differences could also represent markers for perceived threat of malpractice suits or patient expectations [10]. Another reason might be providers’ convenience, since episiotomy reduces the time needed to be spent at the bedside of the parturient [15].

As a result, the impact and acceptance of new evidence-based data concerning the operation depends on the general and local medical climate, and on the interreaction between obstetric providers and consumers, which differs around the world.

Episiotomy: the evidence of no benefits

Over the years, hundreds of articles, reports and book chapters have been written on the various aspects of episiotomy. With the evolution of evidence-based medicine, a more critical examination of the operation was undertaken and critical reviews of the episiotomy literature were followed by a gradual change of scene. The first major critical review was Thacker and Banta’s review of the English literature from 1860 through 1980 [1]. They found no clearly defined evidence of any benefit of the operation and suggested serious complications associated with the procedure.

As this review found only a few good studies, it initiated further investigation.

A review by Wooley in 1995 [16] summarized the English literature since 1980 and concluded that episiotomy failed to accomplish any of the traditionally believed benefits: prevention of pelvic floor relaxation and its sequelae, and protection of the newborn from intracerebral hemorrhage or intrapartum asphyxia. Despite the large number of reports on the subject, only six studies met the criteria of randomized controlled trials to be included in the Cochrane Reviews on the possible benefits of this surgical procedure on a routine basis [17]. According to this meta-analysis, restrictive episiotomy policies appear to have a number of benefits as compared to routine episiotomy policies. However, even in the included randomized studies, the definitions of interventions in the restrictive groups were subjective and wishy-washy, such as "Try to avoid an episiotomy," or "if a laceration appeared imminent" [17]. Furthermore, it was shown that even in randomized studies there was a poor compliance of physicians with the trial protocol, depending on the strength of their views on episiotomy [12].

The latest update of the Cochrane Review on the subject was conducted in May 1999 [17]. Since then, additional reviews and editorials that include more and recent data have been published in leading medical journals, all questioning the benefits versus the risks associated with the operation [15,18–21].

In places where episiotomy is not performed on a routine basis and most deliveries are attended by midwives and in a non-private set-up, such as in Israel, the decision whether to perform an episiotomy during delivery is usually not made *a priori*, according to prior risk factors or concerns for the prevention of remote postpartum effects. Rather, it is *ad hoc*, according to the professional judgment of the obstetric provider, based on fetal indications or when it is felt that there is an imminent risk for significant perineal trauma unless an episiotomy is performed, and with the best intentions to prevent tearing. In many delivery wards "tears" are still considered as "failures," an attitude that results in midwives preferring to perform an episiotomy rather than being reproached by the obstetrician called upon to repair the tear. However, even this last argument in the episiotomy debate was recently challenged. A recent review looking at preventing perineal trauma during childbirth concluded that avoiding episiotomy decreased perineal trauma, mediolateral episiotomy did not protect the anal sphincter, and median episiotomy clearly put it in greater peril [18].

Episiotomy: the evidence of more risks

In addition to the overwhelming evidence that episiotomy is rarely of any benefit, the literature also provides sound evidence that episiotomy is associated with severe maternal morbidity. Episiotomy substantially increases blood loss and the occurrence of postpartum hemorrhage, is associated with an increased rate of third and fourth-degree lacerations and causes more pain than spontaneous lacerations; there is an earlier return to sexual intercourse following spontaneous tears and no evidence was found that episiotomies are easier to repair than spontaneous lacerations but do need more suturing time and material and incur increased costs [1,6,15–19,22–27]. Furthermore, several studies

suggest that the consequence of sphincter damage is more severe if it occurs following an episiotomy, as compared to an extension of a spontaneous tear [22,28]. Moreover, the outcome of a spontaneous second-degree tear is similar to or even less harmful than a surgically induced second-degree tear, i.e., an episiotomy [25,26,28,29].

As a result of the large body of literature strongly advocating the restrictive use of episiotomy, a significant reduction in overall episiotomy rates has been observed in many places [6–8,10], followed by the publication of several retrospective cohort studies, some defined as "natural experiments" [30–32]. In these studies, similar or even better obstetric results were demonstrated following the introduction of restrictive policies in using episiotomy. As for operative vaginal deliveries, in one study it was found that a *reduction* of episiotomies in operative vaginal deliveries *decreased* the rate of fourth-degree tears, without changing the rate of third-degree tears [31]. In another study, the use of an episiotomy in vacuum extraction deliveries was associated with a tenfold *increased* risk of significant perineal trauma [33].

Obstetric providers, belief systems and episiotomy

Due to professional socialization and the belief systems working among physicians [12,34,35], the practice of routine episiotomy had and, in certain places, still has a strong hold among obstetricians. The fact is that belief systems affect "clinical judgment" probably more than do evidence-based clinical data. Graham [35], in *The Lancet*, commented cynically with regard to episiotomy: "I believe, therefore I practise," and a recent editorial in the *British Medical Journal* brought the routine practice of episiotomy as an example of the "mismatch between evidence and practice" attributed to "...barriers to changing practices" among the providers [21].

Because of the belief systems operating among physicians, even in randomized studies there was poor compliance of physicians with the trial protocol, depending on the strength of views that they held about episiotomy [12,18]. The idea that clinicians who are very experienced with the use of episiotomy would avoid complications, such as extensions, was also challenged. It was found that in the absence of episiotomy, rates of perineal integrity were highest among clinicians who usually had the lowest rate of episiotomy use, whereas when an episiotomy was done, rates of third and fourth-degree extensions were highest among clinicians who used episiotomy most frequently [34].

All this might explain why, despite the conclusions of the reviews, editorials [15–19,21] and recent reports [23–27,30–33] – all suggesting a restrictive use of episiotomy – the task of converting "believing obstetricians" may be problematic. A recent editorial in the *British Medical Journal* made an additional accusation, namely "... providers' lack of updated medical evidence..." [21].

Episiotomy and ethics

In the light of their conclusions, many authors of the episiotomy literature attempted to quote aphorisms applied directly to the issue of the wide practice of episiotomy, despite evidence suggesting against its routine use:

- There are in fact two things, science and opinion; the former begets knowledge, the latter ignorance. (Hippocrates) [1].
- Nothing is so firmly believed as that which we least know (Michel de Montaigne) [1].
- If a study of the history of medicine reveals anything, it reveals that clinical judgment without the check of scientific controls is a highly fallible compass (Arthur Schafer) [1].
- The complete protection of the perineum has undoubtedly remained a weak spot in our art (Ritgen) [15].
- "..... would keep the knife away" [21].

According to conclusive evidence in the current literature it seems that routine episiotomy is totally contrary to physicians' basic ethical principles: a) the non-maleficence principle, *Primum non nocere*, b) the beneficence principle, *Secundum bene facere*, and c) the risk-benefit principle, *Saltem plus boni quam mali efficere conare* (at least try to do more good than harm) [16]. Many authorities quoted even from the Holy Book (Daniel, 5:27), concluding that by any standards episiotomy has "...been weighed in the balances and found wanting" [16,24,36]. In a letter in the *BMJ*, it was prophesied that the day would come in the near future when practitioners will have to defend the complications incurred as a result of episiotomy, and that episiotomy "may join barbaric procedures as blood letting" [36].

Episiotomy: what next?

Episiotomy was introduced into medical practice without adequate evidence of its effectiveness. At present, there are enough convincing data to persuade obstetric providers to abandon practices that are based on beliefs more than on facts, and to try to further restrict their use of episiotomy. We now also have the ethical justification and responsibility to perform satisfactory studies on the subject, albeit with a delay of several decades. These studies, aimed at elucidating the real beneficial or detrimental role of episiotomy, should be prospective randomized studies that include well-defined group of patients (e.g., primiparous, singleton, vertex presentation, non-macrosomic infants). In the restrictive group, the *only* indication to perform an episiotomy should be a clear need for an expeditious delivery of the fetus for fetal or maternal indications, such as fetal distress. Imminent spontaneous tears should be left to their natural course instead of an intentional surgical cut. Pleas for such randomized controlled studies were made previously [18,19], but these have not yet been published! One of the obstacles preventing the performance of such studies is that episiotomy is still perceived among many obstetric providers and opinion leaders, trial lawyers and the public as the standard of care. Absurdly, obstetric providers are willing to obtain informed consent from patients who prefer a spontaneous tear instead of an episiotomy, while the operation is performed in most places without the need for a formal informed consent. Such an approach is anything but a true exercise of free will, based on incomplete or inaccurate information at best [21].

To change common practices that are based on beliefs in a society is a complex task. Convincing research data are not sufficient for this purpose and a cultural change is also necessary.

The available evidence-based data have to be translated into practice among opinion leaders [15]. Direct information and education of the public using the written and electronic lay media might be an additional approach [37].

At the present time, given the risks associated with the procedure, episiotomy should be considered a major operation. Women need to get appropriate information and to give their informed consent to an eventual episiotomy as well as to many other possible procedures during delivery (e.g., continuous fetal monitoring, instrumental delivery). Such an informed consent, including that in favor or against an episiotomy, may be obtained during a pre-delivery session with the outline of an individualized "delivery plan," or at least at the time of admission to the delivery ward, if it is still feasible. Discussing delivery plans with patients may promote more critical thought about various intrapartum procedures among obstetric providers as well as consumers. This might also be a good starting point toward changing attitudes about the operation.

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