

Studying episiotomy: when beliefs conflict with science

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In 1984, we proposed to study the need for episiotomy in the first North American randomized controlled trial on this subject. Getting funded and published proved to be difficult since we were questioning not only established views on episiotomy but also conventional beliefs about birth. During the 10-year process from conceptualization to publishing, we were confronted with the paradigm of birth as a pathological state and episiotomy as of trivial consequence. Although many of the reviewers of our study found the topic to be of little importance and some disputed its scientific merit, others saw the study as both important and well conceived. The tension between these views and the place of episiotomy in a wider context of maternity care forms the subject of this paper.

Key words. Episiotomy; randomized controlled trial; publishing; research support; funding, capital; paradigm; beliefs; intervention; birth; physicians practice patterns. (*J Fam Pract* 1995; 41:483-488)

My views about episiotomy were formed by an experience in the early 1960s in Ethiopia, where I worked with midwives who attended births without routine episiotomy. Twenty, years later while on sabbatical at Oxford University, I collaborated with midwives who rarely employed episiotomy yet obtained apparently good results. Back in my usual setting in Montreal, our family practice maternity group employed the techniques I had learned in England. Our episiotomy rate was less than 20%, while the institutional rate was in excess of 60% overall and greater than 80% among primiparous women.

Why Study Episiotomy?

The idea of conducting a randomized controlled trial (RCT) of episiotomy developed because of our awareness of the high rates of performing the procedure throughout North America in the face of retrospective evidence that did not support this approach. The final stimulus for our research occurred with the publication of the first large, well-conducted, midwifery-based RCT in England, which showed no benefit from a policy of routinely using mediolateral episiotomy.[1] We observed that the results of this trial were easily rejected in North America, where physicians normally attend birth, and the usual technique, except where the British influence is strong, is a median episiotomy. Since previous research had shown that the mediolateral incision was more painful than the median,[2] we felt justified in studying median episiotomy, which is usually practiced by North American obstetricians and family physicians.

Pressure on the Established Paradigm

What was the paradigm we were challenging? As physicians, many of us continue to view the laboring woman with some suspicion. We view her reproductive system as complex and intrinsically untrustworthy. It needs to be managed, controlled, improved upon. Birth needs to be expedited, the fetus liberated from an unsafe environment. The place of episiotomy in this model is clear. Labor can be slightly shortened by employing episiotomy. Those who feel this procedure is important often express concern about the negative effects of birth without episiotomy. The absence of episiotomy, they are concerned about pressure on the fetal brain, and

maternal soft tissue support and subsequent pelvic floor function, including delayed morbidity, such as urinary incontinence.

Kuhn's analysis in *The Structure of Scientific Revolutions*[3] Can help us understand the historic development of episiotomy and related techniques and its place in the development of obstetrics as a distinct profession separate from both midwifery and general practice. Kuhn says it is often the elaboration of a new paradigm that transforms a group into a profession. Obstetricians in the 1920s developed the current paradigm in response to their need to define and distinguish themselves by their tools and unique skills, ie, episiotomy, forceps, cesarean section, from competitors, such as midwives and general practitioners, whom they perceived to be less skilled. At the time, childbirth was justifiably considered extraordinarily dangerous to mother and child, and the new management techniques offered hope for better outcomes. Within this context, the recommendations of DeLee[4] on both episiotomy and linked outlet forceps were well received and eagerly adopted.

Are we in the process of a paradigm shift? While some physicians remain caught in the old conceptual model, others conceive a new vision. For example, there are episiotomy studies emanating from solid academic centers that are questioning established practice.[5-8] Other aspects of "standard" practice, such as advice about activity in pregnancy, the need for universal screening for glucose intolerance, the frequency of many procedures, and characteristics of the birth environment, all should be subjected to assessment.[9] We need to critically study our role in both the problem and the solution. Such work is underway and is slowly gaining scientific acceptance. It was within a framework of questioning both old and new technologies and approaches that we began to study episiotomy.

Getting Funded

In early 1986, our Montreal-based research group, representing McGill University, the University of Montreal, and three hospitals, submitted an application to the Medical Research Council [MRC] of Canada for a classic RCT of episiotomy. Reviews were mixed.

Reviewer 1: The applicants ... discuss the justification to carry out another study when the [previous] British study[1] confirms the value of noninterference, but they fail to convince that this expensive controlled clinical trial will provide much benefit to patient management or yield important biological information.

Two others disagreed:

Reviewer 2: Such a trial has not been performed in North America and has widespread clinical implications in a time of consumer challenge to established medical practice. If the more restricted use of episiotomy produces the same or less postpartum morbidity, then a rational challenge could be made to the established clinical dogma. . . . Perineal injury may have major long-term implications for individual women. But the reason why I feel that the Council should consider this proposal very seriously is that this is a problem which applies to such very large numbers of women. I strongly support the application.

Reviewer 3: The majority of women who have vaginal deliveries sustain trauma to the perineum. The pain and discomfort which this causes is thus a source of misery for hundreds of thousands of women worldwide. Furthermore, it is not uncommon for perineal problems originating at birth to persist for months and even years. For these reasons even relatively small

improvements in perineal management may have substantial implications for the longer term health of women.... There are wide variations in the use of episiotomy during normal vaginal delivery and this reflects differing opinions about the relative merits of episiotomies and vaginal tears. Some argue that liberal use of episiotomy is advantageous for both mother and baby; others believe that episiotomies cause more problems than the tears which they aim to prevent and argue that the use of episiotomy should be restricted to fetal indications only.... A proposal to compare two contrasting policies of perineal management is therefore very welcome.

In-house Assessor: This study is basically well designed and one reviewer [emphasis added] was supportive.

Despite three of four reviewers being positive, we did not receive funding from the MRC. We moved on to submit to Health and Welfare Canada. This agency was known to be more responsive to epidemiological, utilization, and policy-related research. We were given some encouragement and mixed reviews. This pattern of mixed reviews was representative of many that would follow in the publication process. Of the first two reviewers, one was favorable and one unfavorable. The third and fifth reviewers questioned the value of the study:

Reviewer 3: ...little new knowledge will be revealed from this study since previous work has demonstrated the expected differences in episiotomy rates but no differences in measured discomfort or perineal muscle tone between groups of women subjected to similar management strategies as here proposed. As a result, the study is unlikely to contribute a solution to a major health problem.

Reviewer 5: The research questions are not relevant to clinical practice and the answers will not likely provide assistance in practice.... It is not a significant health problem.... This proposal should not be funded, the request is far too high and there are far more important female health problems.

The fourth reviewer disagreed:

Reviewer 4: As clearly stated by the authors, a number of studies have cast doubt upon the traditional claims for routine episiotomy. The justification for replicating these studies has been made in a reasonable and clear fashion.... The research questions are relevant to clinical practice and the answers provided will be of assistance in the practice of obstetrics.... just as importantly, answers will be supportive of all of our attempts, whether emanating from the laity or from the profession, to humanize obstetrical care....The research will certainly contribute to the knowledge of whether or not routine episiotomy, without maternal or fetal indication, is justifiable. Whether or not the use of routine episiotomy is a major health problem depends upon your vantage point; for the woman experiencing an otherwise normal pregnancy, labour, and delivery, who takes home a normal child, the painful perineum is a real problem.

One of the in-house reviewers recommended funding; the other did not. Had it not been for the encouragement by the project officer, who clearly represented in-house forces who wanted the study carried out, we would have given up. We addressed the methodological issues of the reviewers in a revised manuscript and addressed the ideological issues of the fifth reviewer in a detailed response along lines suggested by our project officer. In doing so, we drew on commentary emanating from respected sources in the obstetrical literature:

Our response: It will be very hard to convince Reviewer 5 that this study is worth doing, but there are nevertheless certain points raised by Reviewer 5 that should be

addressed. He says that there are clearly more important health care problems than the one we propose to study. While it is generally not a good idea to debate such issues at this point in the review process, we would draw attention to an editorial in the British Journal of Obstetrics and Gynaecology[10]: "It is surprising that a surgical procedure which is performed as commonly as [episiotomy] has been the subject of so little scientifically sound research." Also " . . . the lack of interest [for this type of research] amongst both those who sponsor and those who conduct research in obstetrics almost certainly reflects an attitude that the study of such problems is not only unglamorous, but is also not really true science."

We then referred to a retrospective study[11] in which the authors describe the different attitudes toward episiotomy among the obstetricians involved in the reported study and illustrate how obstetrician attitudes and behaviors may affect outcome. To avoid this problem, the authors suggested that a "prospective study, in which patients are arbitrarily assigned to one group or the other, would circumvent this problem of personal judgment. Bias resulting from the issue of tissue laxity or elasticity would also be obviated by a prospective study."

Thus, they called for exactly the type of study we proposed to conduct.

Our trial was funded at the proposed level and ran for 2 years. Then came the task of getting it published. This management trial analyzed by "intention to treat" showed that there was little difference in multiple outcomes based on a policy that restricted episiotomy to specified fetal and maternal indications vs the routine way that it is commonly employed. This was true for short-term and 3-month perineal pain, perineal trauma pattern, and sexual and pelvic floor functioning at 3 months postpartum, but overall, multiparous women in the episiotomy-restricted arm of the study required less surgical repair.

Getting Published

Paper No. 1: Does Episiotomy Prevent Perineal Trauma and Pelvic Floor Relaxation?

We first submitted our paper to The New England journal of Medicine (NEJM), which never sent it out for review and responded " . . . we thought it would be more suitable for publication in a specialty journal."

We then submitted to The Journal of the American Medical Association (JAMA). There were four reviews. The first was overwhelmingly positive. The second was negative based on statistical concerns that we felt were adequately addressed in the paper. The third was positive and was primarily devoted to suggestions for improving the style and presentation. The fourth reviewer was overwhelmingly negative, questioning the value of the study as a legitimate area of research: "The authors ... seem to have a bias against episiotomy ... there is a statement that there has been no 'North American clinical trial' [emphasis added] of the question of episiotomy use. The authors obviously overlooked Dr Harold Gainey's publications in the early 40s and 50s."

As researchers, we were concerned about many of the comments of this reviewer, but in particular about his reference to the author Gainey,[12,13] who is often cited by those attached to routine episiotomy and whose work was not a clinical trial. Gainey was a meticulous observer who studied 1000 women in the 1930s at a teaching clinic where neither episiotomy nor outlet forceps were employed. He then compared 1000 women attended in the 1940s and 1950s in a private clinic where he personally supervised the routine use of both procedures, and concluded that episiotomy was better than no episiotomy. Gainey's two populations were separated in time and place and were uncontrolled for social, obstetrical, or

demographic factors as well as the skill of the operator, and in the second report, timing of observations, which ranged from 2 months to 164 months, was not standardized. In a telephone conversation with the associate editor at JAMA, I explained the problem with the Gainey reference. This editor told me that the reviewer was one of JAMA's principal obstetrical consultants. Moreover, the editor added, JAMA was not interested in a study "by intention to treat" but would consider one based on those who "received or did not receive episiotomy." My arguments about "intention to treat" being the only acceptable methodology for a management trial were not persuasive.

Profoundly discouraged, we sent our study on to Online Journal of Current Clinical Trials, where it was quickly reviewed and published.[14] They were delighted with it and used it to launch the first issue of this new electronic journal. While we would have preferred having the article printed in a conventional general readership journal, we were pleased with the media response to the published article. The day after publication, our study was reported on page 2 of The New York Times, the front page of USA Today, prominently in dozens of US and Canadian newspapers, and, eventually, in the popular press, eg, Family Circle magazine, Reader's Digest, Parents Magazine, Redbook, Macleans, and Runner's World.

Publication resulted in a debate with Dr Wallace Shute in, of all places, the Toronto Globe and Mail, Canada's leading newspaper. Shute, an outspoken proponent of routine episiotomy, addressed the consequences of not performing episiotomy in a personal letter to me:

What is the result? A permanently enlarged vagina, a damaged urethro-vesical angle, partial or total avulsion of the sub-urethral fascia and a vulva which never returns to normal dimension again. The grave final consequence? Lack of marital interest in a very high percentage of patients, often too shy to confess it--a legacy for the rest of their lives with resultant marital discord and its social sequelae; such damage to the submucosal fascia, anteriorly and posteriorly that, in 20 or 30 years, that injudicious obstetrics leads inexorably to reparative surgery which may or may not prove effective. The midwife who prides herself on never having a visible perineal tear, leaves her signature of anatomical ignorance on her patient forever. The family physician [sic] who performs a half-hearted incision when he too obviously must, and when damage to bladder and rectum has already occurred, also leaves his indelible imprint, until his colleague, the gynaecologist, comes to the patient's rescue 20 years later--what perfect cooperation!

I cite Shute's opinion because he represents one extreme in the beliefs of a number of practitioners. He is situated in the DeLee tradition,[4] and his opinions can be used to predict the study acceptance problems that we would learn to expect, at least from some traditional quarters.

Paper No. 2: Physician Beliefs About Episiotomy and Perineal Management: Consequences for Primips Under Their Care. Further Results from the McGill/Universite de Montreal Episiotomy Trial.

In 1992, we submitted an abstract and paper to the North American Primary Care Research Group (NAPCRG), principally a forum for family practice research. It was a further analysis of the main trial, based on the behavior of three categories of physicians within the trial. It showed that in caring for obstetrically comparable women, physicians with high episiotomy rates within the trial had a different set of behaviors regarding a range of procedures. They were more interventionist overall and saw fetal distress where those limiting episiotomy did not. Third- and fourth-degree tears were concentrated in the practices of those who were wedded to

episiotomy. The usual dichotomized reviews illustrate that tension over this type of study is not confined to one specialty.

One NAPCRG reviewer was very positive and made a few helpful comments. The second reviewer was angry and denounced the paper as a "biased" study, citing as evidence our use of the term "high cutters" to describe those who used episiotomy at the rate of 90% or more and our description of third- and fourth-degree tears as "severe perineal trauma." The paper was presented and well received.

Paper No. 3: Relation of Episiotomy to Perineal Trauma and Morbidity, Sexual Dysfunction, and Pelvic Floor Relaxation.

This paper demonstrated that the best perineal pain, sexual, and pelvic floor outcomes were found among women who had an intact perineum or spontaneous tears, while less desirable outcomes at 3 months postpartum, such as more perineal pain, pelvic floor relaxation, and sexual dysfunction, were found among women who had received episiotomy, especially among those who had an extended episiotomy. After adjusting for reasons why episiotomy might have been needed, third- and fourth-degree tears were causally related to median episiotomy (odds ratio >20).

Wanting to reach a general audience, we submitted this paper to NEJM and then to JAMA, each of which returned the manuscript in record time without external review. We then submitted it virtually unchanged to the American Journal of Obstetrics and Gynecology, which, after detailed reviews, sent us a form refusal letter. As usual, the reviews were mixed. We had some concerns about the process of review and wrote the editor a detailed response. We expressed concern that the reviewers who were critical seemed to be so on the basis of not understanding either the paper or the methodology, principally because they had not read the supplied copies of the article from the Online Journal of Current Clinical Trials,[14] which detailed the trial methodology. We said we did not believe the manuscript had been given a fair hearing and requested that it be reconsidered.

Surprisingly, the editor contacted me by telephone, having made the decision to submit the paper for another review process. He planned to include my written critique in the package sent to the reviewers. This editor said he was interested in the debate and wanted to expose his readership to the controversy. He also generously acknowledged that the previous process may have been imperfect. The final article can be found in the September 1994 issue of the American Journal of Obstetrics and Gynecology.[15]

Paper No. 4: Physician Beliefs and Behavior Within a Randomized Controlled Trial of Episiotomy: Consequences for Women Under Their Care.

In this paper we analyzed perineal outcomes on the basis of physician beliefs and linked those beliefs to a style of practice. Those who believed strongly in routine episiotomy not only employed episiotomy at high rates but employed many other procedures and approaches more often as well. Undaunted by our previous experiences, we submitted the manuscript to JAMA, which rapidly returned it without external review. We then sent it to NEJM, where it was sent out for external review and, unusually, was kept for several months, then returned with a form rejection letter. Again, it appeared that the reviewers either never read or never received the supplied original paper.[14]

Finally, having to accept that NEJM and JAMA would not be publishing this material, we submitted the physician beliefs paper to the Canadian Medical Association Journal, where it received a thorough and thoughtful review that led to changes in analysis and presentation. The editors were interested in the concepts and devoted

considerable energy to helping us improve the product. The revised manuscript has been published[16]and was the subject of two positive editorials.[17,18]

Conclusions

The process of getting our research funded and published was a long struggle but not without positive moments. Based on our experience with several publications, we have little to complain about, but at many points in the process, it would have been easy to become discouraged and abandon the research and its dissemination. Those who struggle with paradigm change must be prepared for a long fight. It is well known and appropriate that editors scrutinize papers that contest existing realities more intensely, but it is important not to take this part of the process personally. If there is a moral, I suppose it is not to give up. The system has flaws: reviewers are human, fallible, sometimes biased, silly, or frivolous, and, rarely, ignorant. While the system does not always work, it is possible to work the system, although doing so with minimum damage requires thick skin and tenacity. I am thankful that there are editors who are willing to take chances and are interested in exposing their readership to unpopular and controversial ideas. Rarely, as in our case, some editors are even willing to reconsider apparently rejected articles. While they have a process to follow, editors want to produce an interesting and useful journal.

Episiotomy is a marker for a range of other procedures, approaches, and attitudes that have been characterized as "modern" maternity care.[16] The next task is to join with consumers to devise methods for promoting behavioral change within the dominant culture and to introduce and evaluate these methods. Armed with solid information, consumer self-advocates may increasingly push the system until a paradigm shift occurs, not only with regard to episiotomy use, but for a range of interventionist techniques as well.

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In the face of such a protracted and exhausting process, the most important resource is the personal support of family, friends, and colleagues. During the more than 10 years from conceptualization to first publication, I was sustained by many people. At the beginning, Murray Enkin, a McMaster obstetrician, shared his original rejected protocol and encouraged me to rethink the methodology and "give it a try." Later, he urged me to submit to the Online Journal. Diana Elbourne, of the National Perinatal Epidemiology Unit in Oxford, and Bill Fraser, a Quebec obstetrician, consistently provided both methodological advice and moral support. Larry Reynolds, Tony Reid, and Michel Labrecque of the Canadian Family Practice Obstetrical Interest Group and NAPCRG, and Mindy Smith, Carol Herbert, and Stefan Grzybowski and others from NAPCRG, and many research colleagues from the Society of Teachers of Family Medicine, provided moral support and practical methodological help.

With good humor, Cheryl Levitt and my colleagues from the Herzl Family Practice Centre in Montreal accepted my obsession while giving concrete help and enrolling their patients in the trial. Along with the Montreal obstetrical nurses, they fully engaged in the research because they saw the questions as worth answering and appreciated the symbolic place of episiotomy in the maternity care system.

Bonnie Klein deserves appreciation for helping me keep perspective, and, along with our children, Seth and Naomi, was a good enough sport to tolerate endless discussions at the dinner table about episiotomy.

The paper published in the Online Journal of Current Clinical Trials received the 1994 Research Paper Award by the Society of Teachers of Family Medicine for the best research by a family physician in the world literature, a much appreciated and sustaining recognition by our peers.

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