Perineal outcomes after practising with a perineal dilator

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Abstract

This article describes the outcomes for women who have used a perineal dilator before they have given birth. For the past four years, hundreds of women have exercised with a silicon inflatable perineal dilator in an attempt to avoid perineal trauma at birth in a birth environment where it is routine to undertake an episiotomy. The use of episiotomy has been shown to be harmful and should be discontinued. Its continued practice, particularly for first births, has necessitated women to take an active role in avoiding episiotomy and perineal trauma. The dilator is practised with at home in the weeks before labour begins. The device is inserted into the vagina by the pregnant woman herself, pumped up and pushed out, every day in a 10-minute practice session during the 37–40th week of pregnancy. The intended result is to stretch the perineum before labour in order to prevent perineal trauma during delivery. This article is about a descriptive, retrospective study that aimed to evaluate the pros and cons of the dilator by phone interviews with all women in Israel who bought it before 11 April 2002. The study compares the perineal outcomes of primipara women in Israel who practised with the dilator, with the published episiotomy rates for primipara women in the literature for the same time period. This study showed that the users of the perineal dilator had a lower episiotomy rate than published episiotomy rates. The majority of women also reported an increased confidence in their ability to birth, and most women, including the majority of women in the study group who underwent an episiotomy, felt that it prepared them for the sensations of pushing and birth.

END

Introduction

The practice of routine episiotomy is common practice in Israel and this is grounded on several theories proposing benefits which have been unequivocally refuted by randomised controlled studies (Thacker & Banta 1983, Eason *et al* 2000). Both of these review articles, as well as Carroli and Belizan (2000) conclude that, contrary to its suggested benefits, episiotomy actually increases damage to the perineum, takes longer to heal, does not prevent brain damage to the fetus even in the tiniest premature babies, nor does it prevent either long term stretching of pelvic floor muscles, cystocele, rectocele, urinary stress incontinence or prolapse of the uterus, and/or sexual dissatisfaction for the man or woman after childbirth.

In addition to having no evidence-based support for routine episiotomy, research has revealed additional drawbacks such as ‘more bleeding, more pain, more permanent vaginal deformity, more temporary and long-lasting difficulty with sexual intercourse’ compared with a natural tear (Wagner 1999). Episiotomy is associated with third and fourth degree extensions of the cut into the rectal tissue and muscles and a median episiotomy clearly promotes anal tears (Shiono *et al* 1990, Sultan *et al* 1993, Klein *et al* 1994, Labrecque *et al* 1997, Signorello *et al* 2000). Two large randomised controlled trials of liberal versus restricted use of medial lateral episiotomy show no prophylactic effect of its liberal use (Sleep *et al* 1984, Argentine Episiotomy Trial Collaborative Group 1993).

Martin *et al* (2001), in a retrospective cohort study of 3769 women, found that the risk of tearing on the second birth was higher in women with a previous episiotomy (45%) than in women with a spontaneous second-degree laceration during the first birth (36%). The study

concludes that avoiding episiotomy, in addition to increasing the rate of intact perineum, reduces the severity of perineal trauma at the next birth.

The perineal infection and abscess rate, mostly a result of episiotomies that extend into rectal tissue, is 0.5–3.0% of all episiotomies (Thacker & Banta 1983).

Taking an international perspective, although national figures are not available, the episiotomy rate is reported to have fallen substantially in the UK over the past 10 years (Department of Health 2002). The reported episiotomy rate in the US was 39.3% of deliveries in 1998 (Curtin & Martin 1999).

In Israel, the probability of a woman having an episiotomy is common, although it has decreased over the past 10 years. In 1990, the episiotomy rate at Hadassah Ein Kerem Hospital in Jerusalem was 91% for first births and 51% in general. In 2000, it was 51% for first births and 23% overall. The sutured tear rate was 18% in 1990, with no data available for 2000 (Cohain & Yoselis 2004). The 1995 Brookdale Institute Nationwide Survey, based on a sample of maternity patients proportionately from all parts of Israel, found a nationwide 81% episiotomy rate for first births and 54% overall episiotomy rate (Zalcberg *et al* 1999).

At present, 99.9% of births in Israel are in public hospitals and 0.1% are homebirths. Israel is a country of 6,000,000 people, which has universal health care coverage including prenatal care and labour and delivery services. All pregnant women in Israel are guaranteed the same free and easily accessible prenatal care, and free hospitalisation due to socialised medicine. The health care in a small country like Israel is fairly uniform. The 1984 National Perinatal census reported that 99.7% of all women received some form of prenatal care (Samueloff *et al* 1989).

The background to the dilator:

The idea for using an inflatable intravaginal perineal dilator was adapted from a similar practice in Uganda. In Mbarara, Uganda the midwives instruct mothers-to-be to practise with a series of gourds, called calabashes, with increasing diameters, to stretch the pelvic floor as a preparation for the oncoming birth and to prevent perineal injury. In Uganda, especially in rural areas, a tear in the perineum is considered a severe injury since doctors or midwives are either not available or not equipped to treat them. After using the wood-like gourds, the gourds are sterilised in boiling water and hung up again on the wall to dry.

A silicon version of the wood-like gourds is available in Israel for US$100. This perineal dilator is an inflatable sausage-shaped silicone balloon, 15 cm long by 5 cm wide, with a slightly indented middle. The user inserts it half way, up to the indentation, so that when it is inflated, the largest diameter will be at the introitus. The balloon is attached to a rubber pumping bulb and pressure manometer exactly like the pump and meter on the device that is used to measure blood pressure manually. After the user inserts the silicone balloon into the vagina, she pumps the rubber bulb and the balloon slowly inflates. She attempts to increase the size to which she inflates the balloon in each practice session. The balloon can be inflated to 10 cm which imitates the diameter of the fetal head at birth. At the end of the 10-minute practice session, she pushes the balloon out of her vagina. After the balloon is removed, the user is instructed to measure the diameter of the balloon so she knows how many centimetres her perineum has been stretched.

Perineal dilators are currently sold primarily as a device to stretch the perineum before birth in order to avoid perineal trauma. They are also marketed as a device to strengthen the ‘Kegel’ muscles in order to improve urinary incontinence in non-pregnant women. This study is designed to test whether practice with a perineal dilator

affects perineal trauma during birth. It also examines women's assessment of the device. There is only one previous article in the literature evaluating the intravaginal perineal dilator (Hillebrenner *et al* 2001). That study was carried out by the company which sells the product and therefore was subject to researcher bias. In addition, in that study only 45 women tested the device. The dilator has been sold worldwide since 1999. As a Class I device, it is exempt from US FDA 510(k) notification requirements. Therefore, the FDA in the US did not approve this device but it received FDA clearance on 24 September 2001 as a low-risk, low-tech device found to be substantially equivalent to other products already on the market.

Research into use of the perineal dilator

Methods

There is only one distributor of the dilator in Israel. The distributor, a midwife herself, was interested in the usefulness of it. To that end, she asked every buyer whether she would be willing to participate in research after using the dilator, ie a phone interview after she gave birth. All women who purchased the device were anxious to be part of the study and gladly gave their phone numbers, which were recorded on the receipts. For this study, all the women who bought an intravaginal perineal dilator in Israel from October 2000 – 11 April 2002 were eligible to take part in the study. The distributor gave the researcher copies of receipts for all the purchases between October 2000 and 11 April 2002. Those with a legible, working phone number were then approached by phone by an independent midwife researcher, unconnected to the distributor, to take part in a telephone interview.

The women were called between the hours of 10:00 and 18:00, excepting 14:00–16:00 which is the rest period in Israel. On calling the women, I gave my name and said that I was a certified nurse-midwife researching the outcomes after use of the dilator. I emphasised that I was not affiliated with any institution or organisation, but rather wanted women in the future to have some objective data about the outcomes of using the device and therefore was doing this research at my own expense. I asked the woman if, for the sake of research, I could ask her ten questions about the device and her birth; the interview would be completed in one minute and would be entirely anonymous. I waited for a yes or no answer and, if she was busy with child care, I often called back at another time. No one refused to be interviewed. I asked the following questions using exactly the same words each time:

1. Did you use it more than three times? [Inclusion criteria of previous study (Hillebrenner *et al* 2001)].
2. Was it your first, second, third birth?
3. In which hospital did you deliver?
4. Was it a spontaneous birth, instrumental or caesarean section?
5. Did you have an epidural?
6. Gestation age in weeks at delivery?
7. Birth weight of the baby?
8. Did you have an episiotomy, or a tear, and any subsequent stitches?
9. Did you have a vaginal infection around the time of the birth?
10. Do you have anything to add about your experience using the device?

Results

From 269 purchase receipts, 36 (13%) had a phone number that was either too illegible to read or was a non-working number. This left 233 receipts in which the phone number was correct.

Four women were excluded because they had practised less than three times; one woman was excluded because she had twins; and one was postmenopausal using it to strengthen her urethral sphincter muscles, leaving a study group of 227. A further 18 women (8%) who had home deliveries were not included in the analysis of the data but their perineal outcomes are presented separately. The group of women who used the dilator and had homebirths are self-selected on two counts — homebirth and perineal dilator use — so it may be argued that they should be analysed separately from the Israeli population delivering in hospital. Therefore, there was a total study group of 209 women who reported having delivered at one of the 15 major hospitals located all over Israel as public patients. Thirteen of those 209 users were multiparous women with previous vaginal births whose outcomes are described separately, leaving 196 primiparous and multiparous women having their first vaginal birth (three had a previous caesarean section). The outcomes of these *users* are shown in Table 1.

Perineal outcomes of primiparous *non-users* of the dilator in public hospitals (spontaneous and instrumental births) were obtained from the literature: this identified 81% of women who experienced an episiotomy in the National Hospital survey in 1996 (Zalcberg *et al* 1999) and 51% of 772 randomly selected primiparous women had an episiotomy at the Hadassah Hospital, Jerusalem in 2000 (Cohain & Yoselis 2004). Where users had homebirths, 15 were primiparous and three were multiparous. Of the 15 primips who delivered at home, none had an episiotomy, three had sutured tears and for the remaining twelve, the perineum was intact. None of the multiparous women had tears or episiotomies although they all had previous episiotomies.

Birth weights ranged from 2400 gs to 4650 gs. The average birth weight of the primiparas was 3320. The reported average birth weight for primiparas in the hospital where the author did extensive research is 3180 (Cohain & Yoselis 2004).

All of the multiparous women (13 women) who used the dilator for second or third births delivered over an intact perineum (100%). They all chose to use it because of 'traumatic' experiences from episiotomies from either their previous or both previous births.

Epidural anaesthesia was used by 44% (72/163) of the women having first births in hospital. The National Hospital reported an epidural rate for primiparas of 54% (Zalcberg *et al* 1999). The reported national vacuum rate in Israel is 11% (Zalcberg *et al* 1999).

One women reported a yeast infection after using the dilator eight or nine times and stopped using it. She is included in the study group.

Several first-time mothers reported a 15-minute pushing time whereas others reported pushing for an hour and a half.

Ninety-eight percent of the women would recommend the use of an inflatable intravaginal perineal dilator after their experience and five women would not. These women said that it hurt a lot to use and it did not help. Women gave a range of responses to their experiences of using the device:

'*It gave me confidence*'.

'*It taught me how to push*'.

'*You see progress, you learn to exercise the muscles*'.

'*Wonderful, I am sure it helped me a lot*'.

'*Worth all the effort*'.

'*Sorry I didn't use it enough!*'.

'*Helped the recovery after birth*'.

'*I had bad stitches twice and on this birth — none!*'.

'*I had a VBAC with no episiotomy! I am very happy!*'.

Several women who had episiotomies said, '*I know it helped. I didn't really need the episiotomy. The midwife*

did not know any other way', or '*It was the end of the shift and the midwives just wanted the baby out*' (in Israel, midwives do not suture), or '*The doctor cut an episiotomy but he said it was a smaller episiotomy than it would have been if I hadn't used it*'. One woman who had twins used it and believed it helped her as she had only a very small episiotomy. Several first birth users said their midwives commented that '*their perineum seemed to be like a woman who has already delivered a baby vaginally*'.

One primipara delivered a 3100 g breech baby over an intact perineum despite vaginal breech birth protocol which calls for a routine episiotomy for breech births. This woman was very assertive and insisted that the doctor write in her chart that she refused episiotomy. She is convinced that this is why he did not cut her.

Several women said it was hard to keep the dilator in place while practising. One woman had the following advice: *Do not lubricate it very much and lay on your side with your legs together to help hold it in before you pump it up.*

Discussion

Since the human body is wired for pain avoidance, the users and non-users both consist of women who would prefer to avoid unnecessary perineal trauma. The study group was motivated to spend $100 on a device that is marketed to prevent perineal trauma. No demographic or socioeconomic data was collected about the women since there is no established association between episiotomy and either status. The users may or may not differ from the general population in terms of motivation. It is not known how many women in the general population used techniques such as massaging the perineum, meditation, herbs, prayer and/or other techniques to avoid perineal trauma, and this is a limitation of the study.

The parturient factor in episiotomy rates has barely been explored. No study has yet looked at whether assertiveness or compliance, or a little of both, work best to motivate practitioners to practise evidence-based protocols at birth. Studies examining perineal self-massage during pregnancy have differed in their conclusions as to its influence on perineal outcomes (Shipman *et al* 1997, Labrecque *et al* 2000). No one has scientifically examined what happens when a woman directly asks the practitioner not to cut an episiotomy. The dilator in this study had a positive influence on perineal outcomes. Possibly the device gave the woman the confidence to ask in such a way that sometimes she succeeded in not being cut. Some primipara women mentioned very short second stages — perhaps the pre-labour practice shortened the second stage. The episiotomy rate has been shown to increase directly proportionally to the length of the second stage. Shortening the second stage by 15 minutes incrementally decreased chances of episiotomy by a proportionate percentage (de Leeuw *et al* 2001). The second stage could be shortened either because the tissue stretched more easily or the woman pushed more effectively, or both or neither. The birth weights were slightly above average reported primiparous birth weights, so it was not

because of smaller babies. Several primipara women reported posterior babies, one weighing 3700 g, delivered over intact perineums. A third hypothesis is that practice actually stretches the perineum, perhaps the way a multipara is stretched, in such a way as to stretch more easily at birth.

There are some interventions which are problematic for random sampling because many people would be unwilling to undertake the procedure and such dilemmas apply to the device being studied. This means that those women who choose to take part in a study such as this may introduce bias as they are likely to be highly motivated and self-selected respondents, as opposed to those included in the study from a random sample. Science insists that the proof that the dilator itself is effective can only come from randomised controlled trials (RCTs). Nonetheless, such studies are likely only to take place once the promising observational data (such as presented in this study) has been published. If female mutilation in the form of routine episiotomy is removed from hospital protocol, this would facilitate further research about the effectiveness of the dilator and this would be more straightforward. Possible expected outcomes of dilator use may be: a lowering of the tear rate, less severe tears, and/or a lowering of the vacuum extraction rate perhaps users and non-users had the same practitioners who were the midwives working at all the major hospitals in Israel. The percentage of women in the study group who had an epidural (44%) and the percentage who underwent a vacuum delivery was 11.7%. Both of these are close to the reported national average and supports the author's view that the study sample is comparable to the Israeli population as a whole. The caesarean section rate of 6% is lower than the reported caesarean section rate of 10.5% for low risk primipara women (Cohain & Yoselis 2004). This may be explained by the fact that women only buy the device at the end of pregnancy, which eliminates some women who become high risk during pregnancy, or it may reflect selection bias.

Several doctors at Assafe Rofe Hospital, Tel Aviv, Israel, have already told the author that the perineal dilator is very dangerous because it causes 'dangerous bleeding and premature rupture of membranes'. No such problems were found in this or in the previous Hillebrenner study. The distributor reported that among the 552 devices sold in Israel between 12 April 2002 and 12 January 2003 since the study was completed, one (and only one) woman came to the distributor for a refund reporting that practice with the device caused her a vaginal abrasion for which she went to the emergency room, but it did not require any suturing.

Although the device demanded significant expenditure, time and discomfort, 98% of the users were very enthusiastic about it during the phone interview and recommended that women use it. Since protocol in all Israeli hospitals calls for episiotomy with instrumental births, the perineal outcomes after dilator use for vacuum births were an improvement over current statistics.

The use of the intravaginal perineal dilator showed a 29% primiparous episiotomy rate for vaginal births. The episiotomy rate is an improvement over the current national statistics in Israel but is still more than double the World Health Organization's recommendation for an episiotomy rate of 10% based on the 1984 Sleep *et al* article (WHO 1996). Exceptional episiotomy rates of 0.5% (homebirths) 1% (hospital births) (Slome 2002), 1.4 % (Murphy & Feinland 1998), 3.8% (Janssen *et al* 2002), and 4 % (Wagner 1994) have been documented by motivated one-to-one care midwife practices and might be a goal to which to aspire. The national episiotomy rate for the Netherlands is 8% (Wagner 1999).

In their telephone interviews, the women implied that they had derived much empowerment from taking part in the preparation for birth. Goldberg *et al* (2002) suggests three reasons for the lowering of the episiotomy rate in his facility: one being improved patient education and

participation in decision making (the other two being the body of research against routine episiotomy and decreased use of forceps). In this study, both the users and the non-users had the same prenatal care. Future studies should control for and compare how women in each group educated themselves before birth and participated in decision making at birth.

Summary

In this preliminary study, 233 women who used an inflatable intravaginal perineal dilator to prepare for birth were interviewed by telephone. The rate of intact perineums reported for spontaneous vaginal births to primiparous women and women having vaginal births after a caesarean for their first births was 48% with another 28% having tears, half of those minor. *The episiotomy rate was 23%. This is a higher percentage of episiotomy than would be expected if evidence-based protocols were in place, but was at least a 50% improvement over the present statistics for non-users of the device in Israel.* Although the users were aiming to avoid episiotomy, 86% of the women who practised with the device and had an episiotomy felt positive about their experience since it taught them how to push and gave them confidence, and they believe it helped. Three possible theories are suggested; the perineal dilator may increase intact perineal outcomes in primiparous women by shortening the second stage as a result of improved labour advice to women, by stretching the perineal tissues before birth, and/or it may empower women to participate in the decision not to perform an episiotomy.

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