
ORIGINAL ARTICLE

Episiotomy and perineal tears presumed to be imminent: randomized controlled trial

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There is now firm evidence from several randomized controlled trials that routine use of episiotomy should be avoided (1–4). The Cochrane Collaboration's systematic review, last updated on 4 May 1999, combined data from six randomized controlled trials that compared the restricted use of episiotomies with routine use (5). The restricted use implicated significantly less trauma to the posterior perineum, fewer sutures and fewer complications of healing. However, restricted use of episiotomy was associated with more trauma to the anterior perineum. There was no difference in the incidence of severe

vaginal trauma, dyspareunia, urinary incontinence, or scores on measures of severe pain. The Cochrane authors concluded that restricted use of episiotomy has some benefits when compared to routine episiotomy. As a consequence, a considerable decrease in the practice of performing episiotomies has been documented (6, 7). There are, however, open questions concerning the indications of the restricted use of episiotomy in an assisted delivery, a preterm delivery, a breech delivery, in predicted macrosomia and in tears presumed to be imminent (5). We still do not know how beneficial an episiotomy may be, and

whether there is an association between episiotomy and pelvic floor disorders later in life, such as urinary or anal incontinence, and relaxation of the pelvic floor (8). Klein and colleagues demonstrated that early and 3-month postpartum perineal pain was least for women who gave birth with an intact perineum (9). Episiotomy discomfort worries many puerperal women more than anything else (e.g. labour pain) (10). We have conducted a prospective randomized trial and addressed the question of what is the indication for restrictive use of mediolateral episiotomy at tears presumed to be imminent. Is it possible to reduce the episiotomy rate in primiparous women by avoiding an episiotomy at a tear judged to be imminent and in this way to increase the rate of intact perineum and the rate of only minor perineal trauma without any adverse effects for mother and child?

Participants and methods

The study was conducted from January 1999 to September 2000 at the maternity unit of the University Hospital in Munich–Großhadern; study design and protocol were approved by the ethics and research committee of the medical faculty before the experiment. All participants were aware of the study and gave their consent to participate. Recruitment for the study took place at the outpatient department for pregnant women while they registered in advance for delivery at our hospital. Women were eligible for entry to the study if they were primiparous, >34 weeks of gestation with an uncomplicated pregnancy with a live

singleton fetus and were intending a vaginal delivery. They were not admitted to the study if any of the following criteria were present: previous surgery at the pelvic floor, or neurological disorder. During the 18-month study period 146 women were allocated at random to one of two management policies: (a) restrictive ($n=70$) – try to avoid an episiotomy even if a severe perineal trauma was judged to be imminent and only do it for fetal indications; (b) liberal ($n=76$) – in addition to fetal indications use episiotomy when a tear is judged to be imminent (Fig. 1). Random treatment assignments were carried out using two opaque envelopes with the different policies enclosed for every particular participant, ensuring a 50% chance for every participant to be assigned to one of the two groups. Of the 146 randomized participants 37 were excluded from analysis for the following reasons: delivery not at our institution (eight), preterm delivery (four), refusal to participate after randomization (one), cesarean section (24). Finally, 109 participants were included for analysis (restrictive use: $n=49$; liberal use: $n=60$). The groups were similar in several important obstetrical aspects (Table I).

All deliveries were conducted by the medical staff who would normally have been responsible (usually one obstetrician and one midwife). Episiotomies were mediolateral and were performed with scissors. A tear was judged to be imminent when the perineum was extremely thin and pale with the head visible during a contraction to a diameter of about 4–5 cm. Perineal trauma was repaired in a similar way by the obstetricians (at least 18 months professional experience). A continuous suture was used to repair the vagina, deeper perineal tissues, subcuticular and skin. When necessary, interrupted sutures were used for the deeper tissues.

Outcome measures were: reduction of episiotomies, increase of intact perineum and only minor perineal trauma (defined as first-degree tear or intact perineum), perineal pain in the postpartum period (100 mm visual analog scale, anchored with the words “not at all” and “very much”), percentage change in overall anterior perineal trauma (labial and

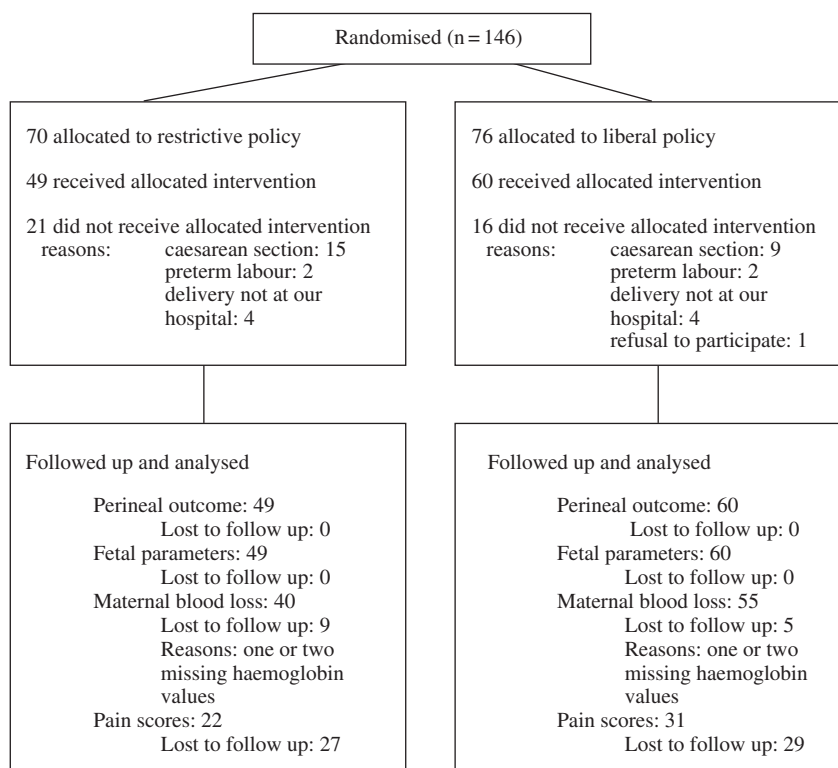


Fig. 1. Flow diagram.

Table I. Participants' variables

	Restrictive policy (<i>n</i> = 49)	Liberal policy (<i>n</i> = 60)
Mean (SD) maternal age (years)	28.3 (5.0)	28.6 (4.5)
Mean (SD) gestational age (weeks)	39.5 (1.3)	39.8 (1.2)
Epidural analgesia, <i>n</i> (%)	31 (63)	43 (72)
Birthweight (SD) (g)	3313 (455)	3535 (429)
Cephalic perimeter (SD) (cm)	34.8 (1.4)	35.2 (1.6)
Vacuum extraction, <i>n</i> *	4	9

*The difference is not statistically significant

vaginal tears), difference of the pH of the umbilical artery, percentage of umbilical artery pH less than 7.15, percentage of Apgar scores less than 7 at 1 min (assessed by the obstetrician or a pediatrician), maternal blood loss at delivery (assessed as mean changes in the hemoglobin concentration), percentage of severe perineal trauma (third-degree tear: extension through the anal sphincter or through the rectal mucosa).

The size of the study is sufficient to detect a 30% reduction of episiotomies (to 40%; with 90% power, two-tailed $\alpha = 0.05\%$), a 25% increase of intact perineum and a 25% increase of only minor perineal trauma (to 40%; with 80% power, two-tailed $\alpha = 0.05$). All analyses were on an intention-to-treat basis. Proportions were compared by using χ^2 -tests with Fisher's exact test when appropriate. The *t*-test or Mann-Whitney *U*-test was used for continuous variables.

Results

The results with respect to the perineal outcomes are summarized in Table II. The episiotomy rate was 41% in the group allocated to the restrictive policy and 77% in the liberal policy group. This difference reflected the different numbers of primiparous women in whom episiotomy was performed for a perineal tear judged to be imminent. The different episiotomy rates resulted in different rates of intact perineum: 29% in the restrictive group vs. 10% in the liberal group. There was a 26% increase in minor perineal trauma. There was no statistical difference with regard to the number of third-degree tears or anterior perineal trauma. However, five of the seven observed third-degree tears were related to the liberal policy group. There was no difference with regard to the mean time to discharge from hospital

Table II. Perineal outcome. Figures are numbers of participants (percentage in parentheses)

	Restrictive policy (<i>n</i> = 49)	Liberal policy (<i>n</i> = 60)	Relative risk (95% CI)	<i>p</i>
Episiotomy	20 (41)	46 (77)	0.47 (0.3–0.7)	<0.001
Intact perineum	14 (29)	6 (10)	2.9 (1.2–6.9)	0.023
Minor perineal trauma	19 (39)	8 (13)	2.9 (1.6–10.5)	0.003
Third-degree tear	2 (4)	5 (8)	0.43 (0.1–2.1)	0.46
Anterior trauma	27 (55)	25 (42)	1.1 (0.8–1.8)	0.25

{restrictive group: 4.2 days, liberal group: 4.4 days; difference [95% confidence interval (95% CI)]: -0.22 (-0.98 – 0.53); $p = 0.62$ } and with regard to the mean differences of the pre- and postnatal maternal hemoglobin concentrations as a measure of maternal blood loss. In both groups the mean hemoglobin concentration fell by 1.3 mg/dL [difference (95% CI): 0.02 mg/dL (-0.56 – 0.61); $p = 0.94$]. Forty-five percent of women in the restrictive group and 52% in the liberal group were assessed with regard to perineal pain in the postpartum period. There were no major differences in obstetrics parameters and perineal outcome in groups a and b for patients lost to follow-up compared to patients with follow-up. Women allocated to the restrictive policy group had significant lower mean pain scores at the different activities examined (Table III).

There were no significant differences in neonatal outcome (Table IV). Mean umbilical artery pH was almost identical in both groups. One baby (pH 7.10) in the restrictive group and four babies (pH 7.07; 7.11; 7.13; 7.14) in the liberal group had an umbilical artery pH below 7.15. Three (6%) babies in the restrictive group and seven (12%) in the liberal group had Apgar scores below 7 at 1 min.

Discussion

This randomized controlled trial was designed to answer one of the open questions with regard to the restricted use of episiotomy: Should we avoid an episiotomy when a perineal tear is judged to be imminent? Random allocation generated two groups of participants who were similar in several important aspects (Table I). The newborns in the liberal group were slightly heavier. This small difference of about 200 g is not the result of a selection bias because proper randomization was performed throughout the study. In addition, this difference is not likely to influence the results because cephalic perimeters were symmetrically distributed. The episiotomy rate of 41% in the restrictive group is within the range reported in

Table III. Mean (SD) maximum perineal pain in the postpartum period (1–5 days) at different activities (in mm of the 100 mm visual analog scale anchored with the words "not at all" at the left and "very much" at the right side)

	Restrictive policy (<i>n</i> = 22)	Liberal policy (<i>n</i> = 31)	Difference (95% CI)	<i>p</i>
Bedrest	22 (21)	39 (28)	16 (2–30)	0.025
Sitting	51 (25)	69 (23)	18 (5–31)	0.009
Walking	37 (24)	56 (24)	19 (6–33)	0.005
Defecation	21 (21)	36 (30)	15 (0–30)	0.048

Table IV. Fetal outcome measures: number (%) Apgar scores less than 7 at 1, 2, 5 and 10 min, number (%) pH < 7.15 of the umbilical artery, mean (SD) pH of the umbilical artery

	Restrictive policy (n = 49)	Liberal policy (n = 60)	Odds ratio (95% CI)	p
Number (%) Apgar at 1 min <7	3 (6.1)	7 (11.7)	2.03 (0.49–8.29)	0.51
Number (%) Apgar at 2 min <7	0 (0)	1 (1.7)	*	1
Number (%) Apgar at 5 min <7	0 (0)	0 (0)	*	NS
Number (%) Apgar at 10 min <7	0 (0)	0 (0)	*	NS
Number (%) pH <7.15 of the umbilical artery	1 (2)	4 (6.7)	0.29 (0.032–2.70)	0.38
Mean (SD) pH of the umbilical artery	7.25 (0.06)	7.24 (0.06)	0.01 (–0.01–0.04)†	0.30

*Statistics cannot be calculated

†mean difference

other prospective trials with restricted episiotomy policies for primiparous deliveries: 8–53% (1,2,4, 11,12). Nevertheless, the episiotomy rates are relatively high even in the group of restricted use. It is likely that the diagnosis of “suspected fetal compromise” in both groups and “imminent perineal tears” in the liberal group is overestimated, possibly due to our institution’s formerly routine episiotomy policy. Reducing the episiotomy rate within an institution is obviously associated with a learning curve with respect to the indications for its use. Our study demonstrates that in clinics with a high episiotomy rate, this rate can be significantly reduced. In our liberal group, 23% of the women did not have an episiotomy. This reflects the fact that we did not examine routine use of episiotomy. In the routine groups of other studies with comparable data the reported rates are usually much higher. In the study of the Argentine episiotomy trial, for example, the episiotomy rate in the routine group for primiparous women was 91%.

Restrictive use of episiotomy only for fetal indications resulted in a 36% decrease in the episiotomy rate, which was accompanied by a threefold increase in both the rate of intact perineum and the rate of minor perineal trauma. This is of major importance, because women whose infants were delivered over an intact perineum or with only a first-degree tear reported in a recent study the best outcomes overall with regard to postpartum sexual functioning (13). In addition, in the study published by Klein et al., at 3 months postpartum those delivered with an intact perineum had the strongest pelvic floor musculature, and early and 3-month perineal pain was least among those women (9).

There was no significant difference with regard to third-degree tears, although five of the seven observed third-degree tears were in the liberal group. To detect the observed difference of 4% (from 8 to 4%) as statistically significant, 739 women per group would have to be included in the study (with 90% power, two-tailed $\alpha = 0.05\%$).

For that reason, the study is underpowered to draw conclusions from the rate of the observed third-degree tears. However, it is not very likely that the different third-degree rates reflect a real difference, because other studies with larger sample sizes did not show any influence of mediolateral episiotomy on the rate of severe perineal trauma of primiparae (1,5). Anterior lacerations were slightly more common in the restrictive group, consistent with comparable data of other trials (1,4). In practice, however, anterior lacerations are not associated with known clinically significant adverse outcomes. Blood loss, assessed as mean difference of the pre- and postpartum hemoglobin concentrations, was the same in both groups. This suggests that episiotomy does not influence peripartum blood loss. This is in contrast to one retrospective study where episiotomy turned out to be one factor for postpartum hemorrhage (14). Women in the restrictive group had considerably lower perineal pain scores in all activities assessed during the first 5 days postpartum. These findings are generally consistent with previously reported trials (1,12). With regard to postpartum perineal pain, follow-up was possible in only 45% of women in the restrictive group and 52% of the liberal group. However, there were no major differences in obstetrical parameters and perineal outcome in groups a and b for patients lost to follow-up compared to patients with follow-up. In addition, the people who handed out the self-reporting sheet (with the visual analog scales for the pain parameters) and the patients themselves usually were not aware of the allocated group, indicating that there was no relevant selection bias.

In our study we did not find a difference concerning fetal outcome. The mean umbilical arterial pH did not differ between both groups suggesting that avoiding episiotomies at tears judged to be imminent does not put additional stress on the newborn. The same is true for the Apgar scores, which were not worse in the restrictive group.

Conclusion

Our data make it very likely that performing mediolateral episiotomies at tears judged to be imminent causes perineal pain and does not have any demonstrable benefit for mother or child. Therefore, a tear judged to be imminent is no indication for mediolateral episiotomy and should be avoided.

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References

1. Argentine Episiotomy Trial Collaborative Group. Routine vs selective episiotomy: a randomised controlled trial. *Lancet* 1993; 342: 1517–18.
2. Harrison RF, Brennan M, North PM, Reed JV, Wickham EA. Is routine episiotomy necessary? *Br Med J (Clin Res Ed)* 1984; 288: 1971–5.
3. Klein MC, Gauthier RJ, Jorgensen SH, Robbins JM, Kaczorowski J, Johnson B et al. Does episiotomy prevent perineal trauma and pelvic floor relaxation? *Online J Curr Clin Trials* 1992; Doc 10.
4. Sleep J, Grant A, Garcia J, Elbourne D, Spencer J, Chalmers I. West Berkshire perineal management trial. *Br Med J (Clin Res Ed)* 1984; 289: 587–90.
5. Carroli G, Belizan J. Episiotomy for vaginal birth. *Cochrane Database Syst Rev* 2000; 2: CD000081.
6. Goldberg J, Holtz D, Hyslop T, Tolosa JE. Has the use of routine episiotomy decreased? Examination of episiotomy rates from 1983 to 2000. *Obstet Gynecol* 2002; 99: 395–400.
7. Klein MC. Use of episiotomy in the United States. *Birth* 2002; 29: 74–6.
8. Thacker SB. Midline versus mediolateral episiotomy. *Br Med J* 2000; 320: 1615–16.
9. Klein MC, Gauthier RJ, Robbins JM, Kaczorowski J, Jorgensen SH, Franco ED et al. Relationship of episiotomy to perineal trauma and morbidity, sexual dysfunction, and pelvic floor relaxation. *Am J Obstet Gynecol* 1994; 171: 591–8.
10. Reading AE, Sledmere CM, Cox DN, Campbell S. How women view postepisiotomy pain. *Br Med J (Clin Res Ed)* 1982; 284: 243–6.
11. Eltorkey M, Al Nuaim M, Kurdi A, Sabagh T, Clarke F. Episiotomy, elective or selective: a report of a random allocation trial. *J Obstet Gynaecol* 1994; 14: 317–20.
12. House M, Cario G, Jones M. Episiotomy and the perineum: a random controlled trial. *J Obstet Gynaecol* 1986; 7: 107–10.
13. Signorello LB, Harlow BL, Chekos AK, Repke JT. Postpartum sexual functioning and its relationship to perineal trauma: a retrospective cohort study of primiparous women. *Am J Obstet Gynecol* 2001; 184: 881–8.
14. Stones RW, Paterson CM, Saunders NJ. Risk factors for major obstetric haemorrhage. *Eur J Obstet Gynecol Reprod Biol* 1993; 48: 15–18.

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