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Original Article

Prospective randomised multicentre trial with the birth trainer EPI-NO® for the prevention of perineal trauma

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Background: In several non-randomised trials training with EPI-NO® increased the rate of intact perineum and decreased episiotomy rates, shortened the second stage of labour and lowered use of pain killers.

Aims: To verify the preliminary results with EPI-NO® in a prospective randomised trial.

Methods: Randomised, single-blind multicentre trial in four university hospitals in Germany including 276 primigravidae.

Results: After training with EPI-NO® we observed a significant increase in the incidence of intact perineum (37.4% vs 25.7%; $P = 0.05$) and a tendency towards lower episiotomy rates (41.9% vs 50.5%; $P = 0.11$). We found no significant differences between the two groups regarding incidence of perineal tears, duration of second stage of labour, use of pain relief and rate of vaginal infection.

Conclusions: Training with EPI-NO® increases significantly the likelihood of having an intact perineum and reduces the episiotomy rate.

Key words: birth trainer, EPI-NO®, episiotomy, perineal trauma.

Introduction

Perineal trauma during childbirth is associated with substantial short- and long-term morbidity. Short- and long-term morbidities like urinary and faecal incontinence, dyspareunia, high blood loss and persistent pain after perineal trauma require continuous and cost-effective surgical, conservative and psychological treatment for these women.[1–4] Primiparity, instrumental delivery (forceps in special), high birthweight, III–IV degree tears and episiotomy are known risk factors for perineal trauma.[3,5–9] Several techniques (for example perineal massage before or during labour, whirlpool bath, perineal lubrification, perineal injection of hyaluronidase, etc.) have been proposed to prevent episiotomy or other kinds of perineal trauma.[10–14] In randomised trials only perineal massage during the weeks before childbirth and recently perineal injection of hyaluronidase had a noticeable effect on perineal integrity.[10,15–17]

EPI-NO – a new birth and vaginal training device – was created to reduce the number of episiotomies and increase the incidence of an intact perineum by training with the device. It consists of an inflatable silicone balloon connected to a hand pump. EPI-NO is designed to dilate the vagina with the aim of adaptation of vagina and perineum to the penetrating fetus. Furthermore women can train pelvic floor muscles and are able to develop a feeling for pushing process during labour. First results of a retrospective German trial demonstrated not only a significant decrease of perineal trauma (42%) and much lower episiotomy rates (33%) but also a significant reduction of analgesics, patient anxiety of birth and shortening the duration of second stage of labour after training with EPI-NO.[14] Similar experience was reported by Kok *et al.*[18] who reported in a retrospective trial a significant reduction of episiotomies and a tendency towards lower rates of injured perineum (90% vs 96.6%). Similar results of a significant higher rate of intact perineum and a lower rate of perineal tears were observed in a prospective Australian trial.[19]

With the objective of verification of the promising results of a prevention of perineal damage by using the birth training device EPI-NO we performed a prospective randomised multicentre trial. Primary objective were rates of episiotomies and intact perineum. Secondary objectives were the influence on the length of second stage of labour, use of analgesics and vaginal infections.

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Methods

After approval by the ethics committee of the Technical University Munich the trial was conducted between February 2000 and 2002 in four university hospitals in Munich and Ulm with a total of 5000 births per year. Three hospitals recruited patients: two from their outpatient clinics and one on referrals by private office colleagues. Two hospitals undertook examinations of the pelvic floor before and six months after delivery. Separate ethic approvals were obtained from each hospital. An independent data monitoring group was established to advise the research group.

Mothers-to-be were asked to participate during pre-admission examinations before birth in three university hospitals. They received information material about the trial and a check for vaginal infection with pH and vaginal smear was routinely done in every women. Women who agreed to participate in the trial met the research physicians during 35 to 37 week gestational period to survey their baseline characteristics and obstetric history and to let check inclusion and exclusion criteria. Inclusion criteria were primigravidity and single pregnancy, exclusion criteria were multiparity, multiple pregnancy, uncertain dates, water birth, pelvic anomalies, multiple sclerosis, collagenosis or other chronic disorders affecting collagen, placenta praevia, previous vaginal or perineal surgery, estimated birthweight over 4000 g, acute or chronic vaginal infection, premature rupture of membranes, diabetic neuropathy, drug or alcohol abuse and paraplegia. After written consent to take part in the trial the women were randomly assigned to study or control group. Randomisation was carried out by phone by an independent organisation. There was no stratification across the three centres. Immediately after randomisation participants completed first questionnaires about their actual anxiety of birth and their general pelvic floor condition. The questionnaire for the evaluation of the function of pelvic floor was developed in-house and is in validation. For evaluation of anxiety we used two validated standard questionnaires (Geburts-Angst-Skala GAS[20] and State-Trait–Anxiety Inventory STAI-G X1[21]). All participants in both groups were asked to repeat the questionnaire at specific times before and after delivery. The anxiety questionnaires were to fill in once weekly, while questionnaires for the evaluation of pelvic floor function were to fill in at randomisation and six months after delivery. In addition, all women were asked to measure their vaginal pH values daily. In case of a pH increase women were requested to contact the study's attending physician.

Participants in study group were instructed in the technique of training with EPI-NO® by the study physician. A minimum of 15 min daily training should start at 37 + 1 weeks of gestation. First, after the balloon is slightly inflated and moistened with gel, it is smoothly inserted into the vagina until only 2 cm of the balloon are still visible. After insertion the balloon should be inflated until below the pain threshold. Afterwards participants were asked to contract and relax their pelvic floor muscles. At the end of the session participants should slowly ease the balloon out to simulate childbirth. This could be assisted in the beginning by gently guiding the balloon out by hand. The study group participants received a training questionnaire and were requested to note their daily duration of training, number of training days, the circumference of the balloon at the beginning and at the end of each training session and any problems during use of the device. After use, the balloon was washed with soap and water and then used again the following day.

As part of the safety discussion in Germany we had to demonstrate that there is no harm for the mother by a vaginal infection that could lead to infection of the newborn as well.

To encourage compliance and to detect problems the study group participants were telephoned four days after starting their training.

Woman in both groups received the usual obstetric care and were asked to contact their respective hospitals if any problems occurred.

Upon admission to the delivery ward, all study and control group participants received a vaginal examination for pH value and a group B *Streptococcus* smear. Birth attendants as well as midwifes were blinded to the use of EPI-NO®. Trialists were asked not to disclose the training with EPI-NO® to the midwife or accoucheur. Regarding vaginal operative delivery, indications (fetal, maternal, combined) for ventous or forceps were overlapping. Each hospital was allowed to use its favourite and common technique and to do an episiotomy if necessary.

All obstetric data were collected from the hospital charts and entered in the patients' case files. For the classification of birth injuries we used the nomenclature recommended by Sultan.[22] All hospitals that took part agreed to this nomenclature and use it in daily routine. All injuries were assessed. If labial tears occurred without other injuries perineum was considered to be intact.

Within three months from the assumed birth date any study group participant who had not returned her questionnaire was contacted and asked to complete and return it.

Part of our trial was the evaluation of the effects of the training with the EPI-NO® device on the pelvic floor function six months after delivery (pelvic floor muscle strength, urinary and anal incontinence, perineal pain, bladder neck mobility, occult anal sphincter tears). The researchers analysed the data on completion of the data entry and after all participants had been followed up for at least six months. Another objective was the safety evaluation of the training device EPI-NO regarding vaginal infection. Since it is foreign body, there might be a risk of a vaginal infection that could lead to an infection of the newborn as well.

In a small pilot study an increase of 42% for intact perineum and a decrease of 33% for episiotomies were obtained. When planning the actual trial a sample size calculation was performed based on these data. Assuming a background episiotomy rate of 60% a sample size of 225 patients in the study group and 225 in the control group was calculated to allow the detection of a statistical difference in the episiotomy rate of 15% on significance level of $P < 0.05$ with a power of 80%. However, because of a delayed recruitment the trial only reached a total sample size of 276 patients. We present results of an intention to-treat analysis. Continuous variables are presented as mean and standard deviation (SD) and compared

Table 1 Baseline characteristics of women (upper part) and factors confounding perineal integrity (lower part) according to the groups. Various rare cephalic presentations (for example face, brow, sinciput presentation) are summarised under 'Other'

Baseline characteristics	With EPI-NO ($n = 135$)	Without EPI-NO ($n = 137$)
Maternal age (years)		
Mean value ± SD	31.3 ± 4.2	31.3 ± 4.4
Marital status		
Unmarried	36 (26.7%)	37 (27.0%)
Married	95 (70.4%)	91 (66.4%)
Divorced	0	2 (1.5%)
Widowed	0	1 (0.7%)
NA	4 (3.0 %)	6 (4.4%)
Gestational age at birth (weeks) ± SD	40 ± 3.9	40 ± 1.3
Epidural anaesthesia	71 (52.6 %)	68 (50.4%)
Length of first stage of labour	445.3 ± 301.2	449 ± 265
Position of head at birth		
Occiput anterior position	121 (89.6%)	121 (88.3%)
Occiput posterior position	4 (3.0%)	4 (2.9%)
Other	5 (3.7%)	8 (5.8%)
Birthweight	3372.7 ± 389.3	3291 ± 405.2

NA, not available; SD, standard deviation.

Table 2 Comparison of the modes of delivery according to the groups

	Vaginal deliveries with		Vaginal deliveries without		
	EPI-NO	($n = 107$)	EPI-NO	($n = 105$)	*P*-value
Intact perineum	40	(37.4%)	27	(25.7%)	***0.05***
Episiotomy	44	(41.1%)	53	(50.5%)	0.11
I/II degree laceration	22	(20.6%)	26	(24.8%)	0.81
III/IV degree laceration	6	(5.6%)	5	(4.8%)	0.51
All others	40	(37.4%)	27	(25.7%)	***0.05***

with the *t*-test; categorical variables are given as counts and percentages and were compared with the Fisher's exact test. *P*-values below 0.05 were defined as statistically significant.

Results

A total of 276 nulliparas were included in the trial. In only four cases a follow up was unobtainable. Of the remaining 272 participants, 135 were randomised into the study group and 137 assigned to the control group. Baseline characteristics between the two groups showed no significant difference (Table 1, upper part).

Comparing the mode of delivery there was no significant difference between the study and the control groups (Table 2).

Regarding our primary objectives we found in the group using EPI-NO® a significant higher incidence of intact perineum (37.4% vs 25.7%; $P = 0.05$) (Table 3) and a tendency towards a decreased episiotomy rate (41.9% vs 50.5%; $P = 0.11$) after spontaneous and operative vaginal delivery (Table 3). Investigation of an influence of the training on the incidence of perineal tears we found no significant differences between study and control group (Table 3).

Analysis of training with the EPI-NO® device showed a mean of 15 training days (15.1 ± 7.7 days) and an average of 18.5 min duration per day (18.5 ± 6.0 min). Mean circumference of the device at the end of training period was 24.3 cm (24.3 ± 4.4 cm). We found no correlation between final circumference and incidence of intact perineum or the duration of training and the incidence of intact perineum. The following problems during training with the device were reported: bleeding (8.2%), pain (8.9%), contractions (1.5%) and dislocation of the balloon from the vagina (15.6%). Eight patients (6%) cancelled training (after up to 20 days training).

Analysis of the duration of first and second stage of labour of spontaneous vaginal deliveries failed to show significant differences between the groups (Table 4).

On examination of the obstetrical outcome after spontaneous vaginal delivery we observed a statistically significant higher head circumference in the study group ($P = 0.05$). Position of head at birth, birthweight, length, APGAR score and pH value of the umbilical artery showed no significant differences between the two groups (Table 5).

In the use of peridural anaesthesia (52.6% vs 50.4%, Table 1) and analgesics (pethidine, meptazinol, piritramid) we found higher percentages in the study group, reaching no statistical significance.

Regarding pelvic floor function we found no significant differences with regard to bladder neck mobility (introital

Table 3 Incidences of intact perineum, episiotomies, perineal lacerations and other perineal injuries (vaginal or labial tears) among woman with spontaneous and vaginal operative deliveries according to the study group. Perineal injuries were classified according to Sultan.[22] Multiple answers are possible. We did not differentiate between mediolateral and midline episiotomy

	With EPI-NO ($n = 135$)		Without EPI-NO ($n = 137$)		
Mode of delivery	*n*	%	*n*	%	*P*-value
Spontaneous	83	61.5	79	57.7	0.30
Vaginal operative	24	17.8	26	19.0	0.66
Ventouse	20		22		
Forceps	4		4		
Caesarean total	28	20.7	32	23.4	0.75
(primary caesarean)	4	3.0	3	2.2	
(secondary caesarean)	24	17.8	29	21.2	

Table 4 Duration of certain stages of labour in study and control groups. First stage of labour is defined as time from the beginning of regular active contractions until the cervix is fully dilated. Second stage of labour starts with the complete dilation of the cervix and ends with birth. The pushing starts when the fetal head passes midpelvis and ends when the baby is born

	With EPI-NO ($n = 83$)	Without EPI-NO ($n = 79$)	*P*-value
First stage of labour			
Mean value ± SD	445.3 ± 301.2	449 ± 265	0.94
Second stage of labour			
Mean value ± SD	62.1 ± 51.0	74.6 ± 59.6	0.154
Pushing			
Mean value ± SD	21 ± 20.2	22.1 ± 15.8	0.698

SD, standard deviation.

Table 5 Neonatal outcome after spontaneous vaginal delivery according to groups

	With EPI-NO ($n = 83$)		Without EPI-NO ($n = 79$)		*P*-value
Birthweight					
Mean value ± SD	3372.7 ± 389.3		3291 ± 405.2		0.2
Head circumference					
Mean value ± SD	35.1 ± 2.3		34.5 ± 1.3		0.05
Length					
Mean value ± SD	51.8 ± 2.9		52.1 ± 2.3		0.49
pH value	*n*	%	*n*	%	
≥ 7.20	75	90.4	74	93.7	
< 7.20 ≥ 7.10	6	7.2	3	3.8	0.89
< 7.10	0	0	1	1.3	
NA	2	2.4	1	1.3	
APGAR score 5 min	*n*	%	*n*	%	
> 7	82	98.8	78	98.7	0.74
NA	1	1.2	1	1.3	

NA, not available; SD, standard deviation.

sonography), incidence of occult anal sphincter trauma (endoanal sonography) or with regard to anal pressure at rest or during squeezing as well as the maximum pelvic floor contraction strength (Oxford Score) between the two groups.

Another secondary objective was the incidence of vaginal infection. We found no significant differences in rates for group B *Streptococcus* infection (three cases in the EPI-NO® group versus one case in the control group) and vaginal pH–value of ≥ 4.7 (one case in the EPI-NO® group versus two cases in the control group) in the two groups, and in two cases of the study group we diagnosed a vaginal infection while training with the device.

Discussion

Over the last two decades both women's and obstetricians' interest in strategies for the prevention of perineal injuries during delivery has increased. Several authors report on a significant increase in short- and long-term morbidity following childbirth.[2–4] Risk factors for perineal trauma and consequent problems are null parity, episiotomy (midline episiotomy in particular), higher age of the mother, vaginal operative deliveries and high birthweight.[1,3] Contrary to the former school of thought that the routine use of episiotomy avoids perineal injury during delivery, many reports over the last 20 years verify an increase in the likelihood of perineal trauma.[1] Therefore, the restrictive use of an episiotomy was postulated and is reflected in declining rates of episiotomy over the last 15 years.[23–25] Several techniques, for example perineal massage before and during labour, whirlpool baths, head flexion and restraint, perineal compresses and other forms of lubrification, have been proposed to avoid episiotomy and severe perineal and vaginal tearing.[11]

In the mid-90s EPI-NO®, a new birth and vaginal training device was designed with the intention to tenderly stretch vagina and perineum before birth, to simulate the sensation of the birth feeling and to avoid an episiotomy or perineal laceration. In a first retrospective trial a significant 33% reduction of the episiotomy rate and an increase of 42% in the incidence of intact perineum were observed.[14] Furthermore, a significant reduction in the use of analgesics and peridural anaesthesia, a shortening in the duration of second stage of labour and a reduction in the patient anxiety of birth were reported. The results of our randomised trial confirmed these results of a significant increase in the rate of intact perineum and a tendency towards lower incidences of episiotomy, a shortening duration of second stage of labour and a reduction in anxiety of birth after training with the device. In contrast to our pilot trial, we observed no reduction of pain medication in the study group. We observed neither a negative influence on the pelvic floor nor an increase of vaginal infection during the training and thus consider the method and the device to be safe. Additionally there we confirmed a lack of negative influence of the training with EPI-NO® in the six-month follow-up examination of the pelvic floor.[26] A conclusive explanation for the trend towards a reduction in the episiotomy rate without reaching the significance level is the low number of patients. Following the sample size calculation we aimed for 450 patients. Because of low recruitment we were only able to randomise 276 patients. Prejudices of midwifes and obstetricians against this new device were some factors for the low recruitment. Interestingly, even with lower sample size a significant benefit for the perineum throughout the training was observed. Other drawbacks were the retrospective realisation of the pilot trial, the overall reduction of episiotomies in Germany from 60% in 2000 to 37% in 2002 and the wider variation in the number and qualification of midwives and physicians between the university hospitals. The last fact seems to be of outstanding importance. There is a great variety of manoeuvres used by midwifes (that do usually perineal prevention during labour in Germany) including compresses with various lubricants, perineal massage, head restraint and Ritgen manoeuvre that can have an influence of perineal integrity and could have biased our results. The less restrictive use of pain medication, including peridural anaesthesia, in a university hospital could also explain differences between the trial results. Furthermore differences in the policy of perineal prevention and execution of vaginal operative manoeuvres (routine episiotomy versus not) between various hospitals could bias the results of our trial and explain differences between the pilot and the multicentre trial. Since we failed to observe significant differences in the length of second stage of labour and pushing period between the two groups, we do believe in a bias in the German retrospective pilot trial by higher rates in active management of labour (with augmentation) leading to faster deliveries. There exist great differences in the policy of labour management not only in Germany but in other countries as well.[27,28] The more interesting are our results of no significant differences between the groups indicating that the policy did not differ too much between various hospitals.

Similar results of an increase of intact perineum, no significant reduction in episiotomies and an additional significant reduction in perineal tears was observed in a prospective, case–control study from Australia.[19] Authors reported on more confidence in the ability to cope with the passage of the baby during second stage of labour what we observed too in our collective.

In contrast, results of a trial in Singapore[18] have shown a significant reduction of episiotomies but no significant decrease of perineal trauma after training with EPI-NO®. Discrepancies to our results might be explained in part by racial differences between European and Asian population,[29] differences in delivery techniques and management of labour and, ultimately, differences in the implementation and realization of the trials (randomisation versus matched pair analysis). In addition there maybe a bias that might evolve from intensive matter with prevention of perineal injury.

In comparison with other randomised trials of perineal massage we found a similar reduction in the relative risk of perineal trauma after training with EPI-NO® and after massage in the weeks before birth, and lower risks compared to massage during birth. In a recent Cochrane database meta-analysis[17] perineal massage was associated with a lower risk of perineal injury requiring suture, but the difference was significant only for primigravidae. In addition antenatal perineal massage reduced the risk of an episiotomy by 15% (relative risk 0.85; 95% confidence interval 0.75 to 0.97). Another approach is the perineal injection of hyaluronidase. In a recent randomised pilot trial,[12] this procedure demonstrated significant risk reduction for perineal trauma and higher degree lacerations. Further investigation is underway to evaluate this technique.

All these results demonstrate that training with the EPI-NO® device increases the likelihood of an intact perineum and helps to prevent episiotomies. In concurrence with the reported experiences of the massage trials, we observed an increase in the women's feelings of self-control and satisfaction to proactively prepare her for birth and to prevent perineal

injury due to pre-birth training. Training with EPI-NO® is easy to handle and not time-consuming. Regarding cost-effectiveness we assume a price of 50 euros for the device and accessories relatively low compared to the possible higher direct and indirect costs associated with surgical and psychological treatment.

Conclusions

Our results demonstrate that training with EPI-NO® is safe for both mother and child, easy to use, helps to avoid unnecessary episiotomies and increases the likelihood of having an uninjured perineum. The question of a further improvement of these results by means of combining EPI-NO® and perineal massage should be evaluated.

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