First clinical experiences with the new birth trainer Epi-no® in primiparous women

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Summary

In this prospective pilot study the efficiency of an inflatable, balloon-shaped vaginal dilatator (Epi-no®) was examined. This Birth Trainer is designed to gently mechanically expand the birth canal and to therefore reduce the episiotomy rate and improve the fetal outcome. 50 primiparae with a gestational age of 38 completed weeks aiming at a spontaneous birth participated in this Birth Training with the vaginal dilatator. 5 patients were subsequently excluded as a result of training times which did not comply with the study protocol.

In the comparison of episiotomy rates of matched-pairs a significant difference was found: 82% of the women in the Control-group (CG) delivered with episiotomy, whereas its percentage in the Epi-No® group (EG) was only 49%. Perineal tears of first and second degree occurred as frequent as in the EG (4% vs. 2%). Moreover children of trained mothers from the EG group showed significantly improved one-minute APGAR-scores. In addition to this we found a considerable reduction in the average duration of Second stage of labour in the EG (29min), in comparison with the CG (54min). Women in the EG also required by far less analgesics than those in the CG. By training with Epi-No® it was also possible to reduce the PDA rate from 36% to 16%. The probability of delivery without episiotomy rose with the number of training days: women without episiotomy had trained on average for 11 days – on average two days longer than women who had had an episiotomy.

Key words: Epi-no® - birth training - episiotomy - fetal outcome

First clinical experiences with the new birth trainer Epi-no® in primiparous women

Purpose: The effectiveness of a vaginal dilatator (Epi-no®) in avoiding episiotomies and improving the fetal outcome was examined.

Data sources and methods: Fifty pregnant women were included in our prospective study and took part in the prepartal birth training program with Epi-no® . Matched-pairs were compared for the rate of episiotomy and perineal tears, fetal APGAR score, average time of training, duration of labour and analgesia during delivery.

Results: We found a significant reduction in the rate of episiotomies in the group of women who participated in the birth training program with Epi-no® (EG: 49%) compared to women in the Control-Group (CG: 82%). Also the rate of perineal tears was twice as high in the latter (4% vs. 2%). Moreover, children of women of the EG showed better one-Minute-APGAR-scores. In addition to this we found a significant reduction in the average duration of the second stage of labour in the EG (29min) if compared with the CG (54min). Women in the EG had a lower rate of PDA (16% vs. 36%) and needed less analgesics than those in the CG. Women of the EG who delivered without episiotomy had trained on average two days longer than women who had had an episiotomy.

Conclusion: Birth training with Epi-no® decreases the rate of episiotomies in primiparous significantly.

Key words: Epi-no® – birth training – episiotomy – fetal outcome

Introduction

Episiotomy is the most frequent operation in the field of obstetrics. It is designed to facilitate operative delivery and prevent uncontrolled perineal tears. It is applied two to four times more frequently among primiparous than among multiparous [12]. All in all the incidence in the western industrialised nations is declining. The Bavarian Perinatal Statistics recorded for the year 1998 an episiotomy rate among primiparous of 63.7% (1997 it was 66.8% and 1990 69.2%). If only spontaneous deliveries of primiparous are considered and episiotomies after vacuum and forceps extractions are neglected, the episiotomy rate was even 66.8%. Even in the international comparison drastic differences are noticed with regard to the episiotomy rate . In Holland (1976) and France (1976), for example, episiotomy rates of 8% and 28% were documented [4, 14, 33]. Both rates lie by far below the German average; in

contrast to Denmark (1990) where episiotomy rates of 56% and in the USA (1979) of up to 63% [30, 36] were registered. An observation of the highly deviating prevalence of episiotomies not only in various countries, but also in different hospitals, presumes despite anatomical and medical substantiated indication for episiotomy the greater significance of additional factors, such as national and personal attitude, as well as training of obstetricians and midwives.

Classical indications of episiotomy

The aim and purpose of episiotomy is to facilitate delivery for the mother and the child by extending the birth canal, to avoid possible damage by a quick termination of delivery itself and to prevent pending dangers for the mother and child. That leads to the following classical indications of episiotomy [28]:

- Pending tearing of vagina and perineum – danger of degree III° and IV° perineal tears (DR) -
- vaginal-operative deliveries (forceps and vacuum extraction, complete extraction in particular in the case of primiparous) – often in the case of deliveries prior to the end of the 34th week of pregnancy (SSW)
- irregular head positions (e.g. HHL, deflection positions) and breech presentation
- need to quickly end the delivery to reduce risks for the mother and child
- prolonged Second stage of labour

Advantages and risks of episiotomy

In 1983 Thacker and Banta published a comprehensive overview of the literature which had been published in English since 1980 on the advantages and disadvantages of episiotomy [34]. They came to the result that the majority of surveys were not able to confirm the advantages of the perineal cut: Prevention of perinea tears III°, fetal injuries (hypoxic and mechanical) or trauma of the pelvis, descensus prophylactics, prevention of urinary incontinence and facilitated wound treatment. It was moreover, shown that the risks and disadvantages of episiotomy such as loss of blood , pain, oedema, infections, anal sphincter ruptures and dissatisfactory anatomic results are of greater clinical relevance than is generally assumed. A reserved attitude towards episiotomy is therefore recommended as well as an individual assessment of the medical indication, taking not only the texture of the tissue, but also the space and naturally the delivery situation into account [7, 19, 25, 26, 30, 31, 34, 35].

Method

The probability of a primipara to undergo episiotomy is greater than in the case of a multiparous. Whereas The Bavarian Perinatal Survey for the year 1998 registered an episiotomy rate of 36.6% in the case of multiparous with spontaneous delivery, this rate was 63.7% in the case of primiparous. This clearly lower episiotomy rate among multiparae is explained by the fact in the case of a multipara that there is less resistance opposed to the passing head of any further child as a result of extending the soft tissue of the birth canal during the first delivery.

These deliberations have led to the development of the insufflatable vaginal dilatator (Epi-No®). Training with the vaginal dilatator aims at transforming a primipara into a functional multipara by slowly and mechanically expanding the soft tissue of the birth canal.

Study design and issues

The *prospective pilot study* was implemented as a simple blinded study (midwives and obstetricians monitoring delivery were not informed of women'participipitation in the study). It aimed at answering the following questions:

- Is it possible to *gently expand the perineal region* and the birth canal with the *Birth Trainer Epi-No® without damaging the soft tissue* and to *lower the episiotomy and perineal tear rate* as a result?
- Does training with Epi-no® *have any effects on the length of Second stage of labour,* the *analgesics administered* resp. the *PDA-rate* and the *fetal outcome*?

The vaginal dilatator Epi-No®

The Vaginal Dilatator Epi-No® has been on the market in Germany since October 1999. It is sold in pharmacies and is the only device of this kind on the market.
The Birth Trainer consists of an inflatable balloon which is connected via a tube with a manometer (fig. 1). The balloon of silicon has the shape of an eight and consists of two differently inflatable ends between which a specially

Fig. 1
The Birth Trainer Epi-No®

reinforced part, the waist, lies. The distal end is inserted into a connecting tube through which compressed air is pumped. Before inserting the balloon into the vagina it is pumped up to 60 mmHg and coated with a lubricant to make it easier to insert it into the vagina. Only insert the balloon in the vagina to the extent up to the point where about 3cm are outside the vagina. The waist is located in the area of the hymenal border, whereby the balloon centres and positions itself at this place. Its special form prevents it from slipping further into the vagina during dilatation so that it does not touch the cervix uteri at any time. In pumping up the balloon the surrounding tissue is gently and slowly stretched.

The manometer fulfils two functions: On the one hand it serves as a pump to inflate the balloon, on the other as a manometer measuring the pressure as an indirect identification for the size of the inflated balloon.

Birth training with Epi-no®

By holding the tube with the index finger and middle finger at the link between tube and the balloon, it is possible to optimally position the balloon in the area of the birth canal exit so that it is positioned partly inside and partly outside the vagina. This is important as in particular the outer part of the vagina and the hymen border are to be expanded. This is the most sensitive and most endangered part of the female birth canal due to the danger of a perineal tear.

By activating the manometer the balloon is individually inflated, i.e. according to the subjective feeling of expansion of the pregnant women. The mother-to-be should leave the inflated balloon for at least 10 minutes in her vagina before trying to press it out of her vagina by actively pressing with the help of her stomach and pelvic muscles. This processes is demonstrated graphically in fig. 2.

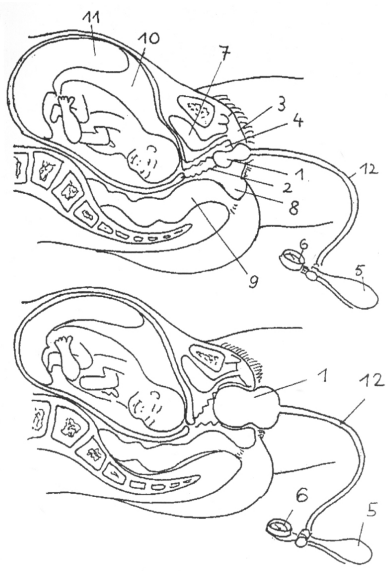

Fig. 2
a: Inserted balloon in a non-dilatated condition.
b: Inserted balloon inserted in inflated condition
1= balloon,
2= vagina,
3= vulva,
4= hymen border area,
5= hand pump,
6= manometer,
7= bladder,
8= M. sphincter ani,
9= rectum,
10= amnion,
11= placenta,
12= connecting tube
(derived from the patent application for Epi-No®)

By increasing the extent to which the balloon is pumped up daily, its diameter gradually gets closer to that of the baby's head and the pregnant woman succeeds in pressing a greater volume out of her vagina day by day.

The pregnant women were instructed to boil the balloon in hot water before and after each training unit. Before each training unit the women had to determine the pH value of the vagina using pH indicator strips. In the case of a measured pH value ≥5.0 bacteriological smears would have had to be taken to differentiate and treat the bacteria. This case, however, never occurred in our collective of patients. Training was only permitted in the event of a guaranteed non-existence of any infection.

Data acquisition

On the basis of partograms, birth booklet and questionnaire the following data were collected and analysed creating matched-pairs separately for women in the EG and CG. As criteria for creating matched-pairs the circumference of the baby's head (±0.5cm) and the birth weight (±150g) were applied. The two groups were compared with regard to the following criteria:

- Rate of deliveries with intact perineum (without episiotomy and without perineal tear)
- Episiotomy and perineal tear rate
- Analgesics administered to the mother during delivery and PDA rate
- Length of parturition phase
- Baby's APGAR-Scores

Statistical evaluation

The computer-supported statistical evaluation of the data was performed using the SPSS®-Software (Version 8.0) for MS-Windows. The program Excel® (Version 97) was used for the mathematical calculation of the median, minimum, maximum and mean values as well as the standard deviations of certain parameters required for descriptive statistics. The calculations of significance were performed using the Chi-Quadrat-Test, the T-Test for independent samples as well as the Mann-Whitney-U-Test. As significance level a standard $\alpha \leq 0.05$ was requested.

The collective of patients

From May 1998 to August 1999 50 pregnant women were registered as participants in the study (primiparae and functional primiparae e.g. condition after primary caesarean section resp. after miscarriage prior to 21st week of pregnancy who came either to the hospital Klinikum rechts der Isar in Munich or to the gynaecologist's surgery of Dr. W. Horkel in Starnberg for regular prophylactic pregnancy

check-ups. Participation in the study was offered to all primiparae who complied without exception with the inclusion criteria listed below and for whom no single exclusion criterion was applicable. The following women were therefore excluded from participation in the study:

- Women giving birth to their second child and multiparous
- Women with at least one risk factor which would make a vaginal delivery improbable (diabetes mellitus of the mother - also gestation diabetes -, breech or torso presentation of the fetus, multiple birth, pelvic anomaly, suspected misratio, placenta praevia)
- vaginal infections
- Following amniotomy
- With a gestational age less than 38th weeks
- In the case of an indicated latex allergy

That led to the following obligatory inclusion criteria:

- Spontaneous delivery
- Primiparae and functional primiparae after primary caesarean section at the birth of the first child resp. miscarriage prior to the 21st week of gestation
- Low-risk group for vaginal delivery on the grounds of anamnestic findings
- No given vaginal infections

Women who had trained less than three days with the Birth Trainer Epi-no® were subsequently excluded.

The Control-group (CG) consisted of all pregnant women who had delivered spontaneously and not operatively in the same period (May 1998 to August 1999) at hospital Klinikum rechts der Isar in Munich. They were subject to the same inclusion resp. exclusion criteria as those applying to pregnant women who took part in the training (EG).

Beginning of training and length of training

Participants in the study began to train at the earliest at the end of their 38th week of gestation (38+0). From the first day of training on the women were to train daily with Epi-No® about 10 minutes up to the date of delivery.

Results

Episiotomy and perineal tear rates

As fig. 3 shows there is a significant difference ($p<0.001$) in comparing the episiotomy rates in both groups. Whereas the episiotomy rate in CG was at 82% (37/45), only 47% of the women in EG (21/45) had an episiotomy. This corresponds to a reduction of the episiotomy rate in EG of 43% (odds ratio: 0.21). The rate of perineal tears I° and II° was also reduced to the half (EG: 1; CG: 2). Due to the low incidence of perineal tears in both groups these results are, however, insignificant ($p=0.40$).

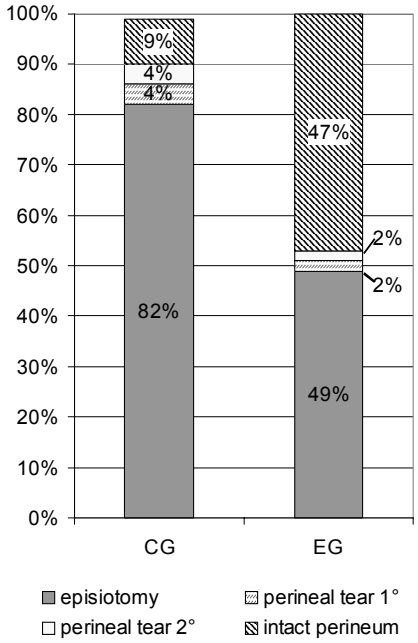

Fig. 3 Overview of episiotomy and perineal tear rates

If women with intact perineum after delivery are examined, there are only 4 of 45 women in the CG (9%), who had neither episiotomy nor a spontaneous perineal tear. The percentage of these in the EG was 49% (22/45), corresponding to an increase in deliveries with intact perineum by 5.5 times.

Fetal outcome

The fetal APGAR scores are used as a parameter for assessing the health status of the baby and the stress the baby is exposed to during delivery. In the EG the mean APGAR scores were higher than in the CG. This trend becomes especially obvious in comparing the one-Minute-APGAR scores ($p=0.024$).

For the 5- and 10-minute- APGAR-Score a trend towards significantly higher APGAR scores was noticed in the EG.

Average duration of training

As it was proven that by training with Epi-No® the episiotomy rate can be drastically reduced, the question arises to the interrelation between the protective effect of the vaginal dilatator and the training period. For this purpose the group of spontaneously delivering women was split up into a group with and a group without episiotomy and a comparison of numbers of their prepartal training days . It was noticed that not only the median but also the mean value of the training period in the group without episiotomy was by far higher than in the group of women with episiotomy. These results, however, did not reach significance ($p=0.174$) (tab. 1; fig. 4).

Tab. 1 Training duration [d]

Training duration [d]	Episiotomy	No episiotomy
Minimum	3	3
1. Quartile	4	7
Median	9	12
Mean value	8,9	11,0
3. Quartile	12	15
Maximum	21	20

Length of birth

With an average duration of Second stage of labour of 29 ± 25 min the mean length of delivery in the EG was

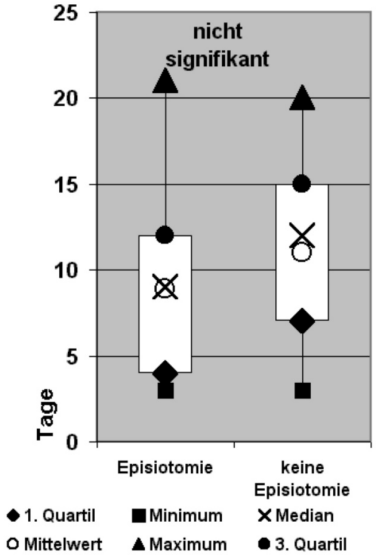

Fig. 4
Duration of training with EPI-No by women with and without episiotomy

significantly under Second stage of labour of non-trained women with 54 ± 55 min (p=0.014). Not only the median, but also the

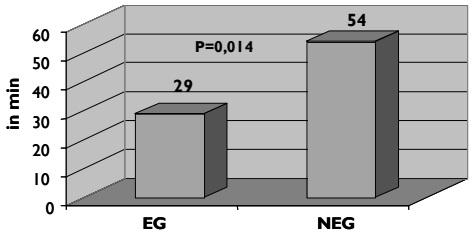

Fig. 5
Average time of Second stage of labour of Control-group (CG) and the Epi-NO group (EG)

Tab.2 Length of Second stage of labour in the Control-group and in the Epi-NO group (EG) [min]

Training duration [d]	Episiotomy	No episiotomy
Minimum	10.0	3.0
1. Quartile	19.0	10.3
Median	38.0	26.5
Mean value	53.7	28.8
3. Quartile	69.5	38.8
Maximum	192	120

mean value of the parturition phase were by far lower than in the CG (fig. **5**; tab. **2**).

Medication during birth

As an indirect measure for the stress the mother is exposed to we assessed the analgesics administered to the mother during delivery We examined the average consumption of Dolantin and the administration of further pain killers in both groups of the match collective. A lower consumption of these drugs were assessed in the EG (fig. 6).

PDA-Rate

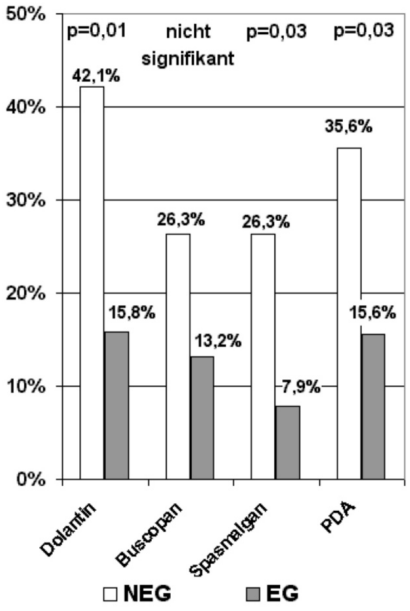

Fig. 6
Administration of analgesics and PDA rate of Control-group (CG) and the EPI-NO group (EG)

In comparing the peridural anaesthesia rate a significant difference was noticed between the CG and the EG (p=0.029). The PDA rate in the CG with 36% (16/45) was almost twice as high as in the EG (16%, 7/45).

Acceptance

The participants in the study were questioned in subjective questionnaires on their readiness to further recommend this Birth Trainer. A high acceptance of training was registered among the women as this readiness was high resp. very high among 84% (61/73) of the women interviewed.

Discussion

Episiotomy and perineal tear rates

In the EG a significant reduction in the episiotomy rate was achieved in comparison with the CG. The low case

statistics have to be made responsible for the fact that there was no significant distinction between the I° and II° perineal tear rates between the EG and CG. An increase in perineal tears would, however, have been expected in our training group, if an indirectly proportionate relationship between low-level perineal tears and episiotomies, as they are described by Hermsteiner and Künzel, had been assumed [12]. The identifiable trend among our participants in the study – reduced episiotomy and perineal tear rate (I° and II° perineal tear) – was not able to identify this relationship. As in the case of primiparous the risk of perineal tears of a higher degree is twice as high as among multiparous [15, 22, 30], it is important to ensure that the reduction in the episiotomy rate by the birth training with Epi-No® is not achieved at the cost of a higher perineal tear rate.

Possible effects of training on the pelvic floor represent a further important viewpoint.

Whereas a sudden dilation leads to a spontaneous tearing of muscle fibres causing considerable pain, the gradual expansion is as a rule free of pain. In literature specialists agree that the vaginal birth represents in itself a risk factor for muscle, neuromuscular and tissue-related damage to the pelvic floor of varying extents [9, 29]. It can even lead to damage of peripheral nerves innervating the Mm. levator et sphincter ani. Handa and her colleagues assume that as a result of delivery the pelvic nerves are stretched and compressed and that that leads to a temporary denervation of the muscles of the pelvic floor, which lasts until the surrounding intact nerves branch in to resupply the denervated muscles [9].

According to the PNTML (pudendal nerve terminal motor latency) it was possible to detect that a denervation is not registered after a primary caesarean section [32], whereas it is often registered after a secondary caesarean [1]. That means that the sudden and extreme expansion of the pelvic floor during delivery is causally involved in the damaging of these nerves and also of the pelvic floor muscles.

Fascia and tissue can also be damaged during the vaginal delivery. Postpartally the damaged tissue is replaced by new collagen. As redeveloped collagen never has the same firmness as the original tissue [23], tissue and fascia are weaker after delivery than before. The consequences hereof can be descensus and urinary incontinence. As the M. levator ani plays a decisive role in fixing the pelvic organs in the physiological anatomic position, it is likely that damaged muscles of the pelvic floor can lead to a descensus of these organs.

Fynes et al found out that among primiparae the risk of sphincter damage is highest, but that however, with an in general rising number of vaginal deliveries, above all in the case of occult injuries, there is a cumulative damage and therefore an increasing problem of incontinence. Further risks for sphincter damage are vaginal operative delivery, an extended Second stage of labour as well as peridural anaesthesia which may lead to a longer Second stage of labour. In the case of incontinence problems caused by a sphincter damage as a result of previous vaginal deliveries, a primary caesarean is postulated [7].

If these deliberations are taken into account it is quite feasible that by gently and gradually stretching the tissue with Epi-No® it is not only possible to reduce episiotomies, but also long-term consequences, such as stress incontinence and further consequences of denervation of peripheral nerves after vaginal deliveries. This, however, can only be completely avoided by a primary caesarean section.

To avoid a genital prolapse Kegel recommends to train the muscles of the pelvic floor [16, 17]. Nielsen et al. were also able to prove in their study that in the case of primiparae, training the muscles of the pelvic floor during their pregnancy was able to significantly enhance the ability of the women to contract their muscles postpartally to a significant degree [13].

Based on their tests using a condom filled with fluid and connected to a manometer Gordon and Logue found out that by starting off training the muscles of the pelvic floor at an early point of time it was possible to avoid a genital prolapse [8]. Other authors believe that well trained muscles make the pelvic floor too rigid and therefore make a vaginal delivery more strenuous and longer [6]. Others indicate a facilitated delivery by prepartal muscle, because the woman has learnt to directly apply the muscles involved by training the muscles of her pelvic floor [5]. Training with Epi-No® is – in comparison with the method of training the muscles of the pelvic floor propagated by Kegel – no active training which serves to create muscle mass. It moreover passively stretches the muscles and cannot lead to an aggravated delivery as a result of excessive muscle build-up. Nevertheless the woman learns how to directly apply her muscles to press. Training therefore combines the postulated advantages of pelvic floor training, however, without having to accept the potentially associated disadvantages.

Fetal outcome

Despite the fact that in the given literature it is substantially ascertained that the APGAR scores of children born with or without episiotomy do not reflect any differences [2, 10, 19, 24, 27, 31, 35], we were nevertheless able to detect significant differences in our study in the one-Minute APGAR scores among children delivered with resp. without episiotomy. Children delivered without episiotomy had significantly better APGAR scores after one minute than

children delivered by women with episiotomy (p=0.014 resp. p=0.037). This assumes that there is reduced stress for the child as a result of the shortened delivery process after training with Epi-No® . It is feasible that training with Epi-No® also secondarily contributes to reducing the perinatal morbidity. A short delivery from the mother's viewpoint and also due to the reduced perinatal morbidity of the child is therefore desirable.

The large scattering range of the permissible delivery period is the consequence of various factors. On the one hand parameters, such as the property of the pelvic bone, the child and birth management have an effect on the length of delivery itself, to which the woman is not able to make any contribution. On the other hand the coordinated labouring activities and the condition of the mother resp. of the soft tissue play a decisive role [18]. These factors can be improved by actively involving the pregnant woman resp. by training on the days prior to delivery. It is possible to draw the conclusion that prepartal expansion training involving the soft tissue surrounding the birth canal, as is performed with the vaginal dilatator Epi-No® will relieve and accelerate delivery itself.

Menticoglou et al. came in their study to the result that a longer parturition phase leads to a deterioration in the fetal outcome. As this study shows, the probability of birth of a child with a lower APGAR (<7) [21] score rises with an increasing length of Second stage of labour. A reduction of the parturition phase therefore seems an appropriate measure to improve the fetal outcome. Our study results document this theory. In the case of mothers in the EG a reduced average time of Second stage of labour paired with an improvement in the fetal APGAR scores was detected. This reduction in the parturition phase in the group of women who had trained with Epi-No® is comprehensible. By expanding the birth canal the child faces less resistance on its way down and that reduces the delivery period. Moreover, women benefited from the pressing exercises after training with Epi-No® and that was also noticed in other forms of birth training [13].

One other aspect we noticed was that after an episiotomy the Second stage of labour was nevertheless significantly longer, despite the fact that numerous studies had demented the influence of episiotomy on the duration of birth [11, 20, 25, 26]. It is, however, feasible, that in some of these cases episiotomy was applied to terminate an already prolonged birth. This could explain the interrelation between an increased episiotomy rate and a prolonged average parturition phase.

Administration of analgesics

There are various possibilities to explain the lower consumption of analgesics (Dolantin, Buscopan and Spasmalgan), the lower PDA rate during delivery and the drastically raised number of women in our training group who delivered without requesting the administration of any kind of medication: on the one hand it seems to be plausible that by a prepartal expansion the birth canal is more easily adapted to the pressure and tensile forces arising during delivery and that therefore the pain stimuli are lower. As greatest pain is stimulated in the region of the cervix, vagina and perineum [3], the already effected gentle expansion of the vagina and perineum in the EG may explain the reduced analgesics required by the trained women in the EG.

Moreover the experience of trained pressing and the familiarity with the birth canal may have led to an anxiolysis which may also be expressed in lower pain killer requirements. The woman comes to the delivery room with a more relaxed and relieved feeling. In training she has become aware of the fact that the birth canal has been expanded sufficiently to allow the passage of her baby. She has been able to practise pressing and feels prepared for the oncoming birth of her child. This reassurance eliminates her fear and tension which can also lead to a further sensitisation of the pain threshold.

Hetherington reported that women who had prepared themselves in a birth training course required less analgesics during delivery [13]. Baumgarten and Cretius [3] also described pain relief by psycho-prophylactic birth preparation. A general psychological alleviation of delivery pains is described in a similar way in a book on obstetrics by Kyank, Schwarz and Frenzel [18]. The authors of this study proceed on the assumption that a systematic sensitisation – in this case daily training with Epi-No® - enhances the confidence in one's own body, this controls the intensity of sensitive stimulation afferrences from the periphery and lowers the pain threshold . By reflecting these deliberations the lower consumption of pain killers in the EG seems quite plausible.

In summary the results of the pilot study among primiparae reflect an advantageous influence of birth training with the vaginal dilatator. In a multi-center study the next step is now to verify these results prospectively in a larger collective of patients.

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