

**The possibility
of antepartal prevention
of episiotomy and perineal tears
during delivery**

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ABSTRACT

Study objective

To assess the effects of individual antepartal perineal tear prevention methods used in pregnancy on the prevention of birth trauma in primiparous women.

Study design

Retrospective study.

Setting

Český Krumlov Hospital, a.s.

Methods

Between February 2014 and November 2015, 315 primiparous women with singleton pregnancies and vaginal deliveries were asked to complete a questionnaire in order to establish whether they utilized any perineal tear prevention methods during pregnancy (vaginal dilatation balloons EPI-NO or Aniball, perineal massage, natural methods – raspberry leaf tea or linseed). The effects of these methods were evaluated by assessing the occurrence of an intact perineum, perineal tears and episiotomies in individual groups against a control group which did not utilize any of these methods. Differences in the incidence of spontaneous and operative vaginal deliveries in these groups were also observed.

Result

The antepartal use of vaginal dilatation balloons (VDBs) significantly increased the number of women who gave birth with an intact perineum in comparison with the control group (43.1 % vs. 14.1 %, $p < 0.001$). We also observed a statistically significant reduction in the number of episiotomies (29.3 % vs. 57.7 %, $p < 0.001$). No statistically significant effect on the prevention of perineal trauma was observed in the case of perineal massage or raspberry leaf tea and linseed consumption. A reduced risk of operative vaginal delivery was established in the case of women using VDBs compared to the control group ($p = 0.02$).

Conclusion

The use of vaginal dilatation balloons during pregnancy is clearly beneficial for the mother with respect to perineal trauma prevention during delivery. It also reduces the likelihood of operative vaginal delivery.

KEYWORDS

delivery, episiotomy, perineal tear, vaginal dilatation balloon, EPI-NO, Aniball, perineal massage, linseed, raspberry leaf

INTRODUCTION

Perineal trauma constitutes the most common vaginal delivery complication. It may be either spontaneous (perineal tear) or surgically induced (episiotomy). In the Czech Republic, the incidence of individual types of perineal trauma is subject to significant differences. These differences are caused by classification inconsistencies both between maternity hospitals and between obstetricians at individual workplaces [28]. In the past Czech literature primarily employed a three-tier classification scheme [29]. More recently, however, a four-level classification system has been adopted in accordance with British guidelines issued by the Royal College of Obstetricians and Gynecologists (RCOG) [7, 15]:

1. First-degree tear: Injury to perineal skin and/or vaginal mucosa.

2. Second-degree tear: Injury to the perineum involving perineal muscles but not involving the anal sphincter.

3. Third-degree tear: Injury to the perineum involving the anal sphincter complex: Grade 3a tear: Less than 50 % of external anal sphincter (EAS) thickness torn. Grade 3b tear: More than 50 % of EAS thickness torn. Grade 3c tear: Both EAS and internal anal sphincter (IAS) torn.

4. Fourth-degree tear: Injury to the perineum involving the anal sphincter complex (EAS and IAS) and anorectal mucosa.

However, in the Czech Republic and elsewhere, spontaneous perineal tears are less common than episiotomies. The term episiotomy is formed by a combination of two Greek words: *epíseion* (female external genitalia) and *témnō* (to cut) [5]. It is an operation (though nowadays it is not understood as an operation and no surgical protocol is required), which aims to facilitate the delivery of the fetus by artificially dilating the soft birth canal.

There are several types of episiotomy [3]:

1. Median – along the midline of the vaginal opening towards the anus. Advantages include easy suture and good healing, but it is an anal sphincter tear risk factor [11].

2. Mediolateral – from the midline of the vaginal opening diagonally towards the ischial tuberosity at a 45-degree angle. Compared to a median episiotomy, it may bleed more, but poses less risk of injury to the anal sphincter.

3. Lateral – the incision begins approximately 2 cm laterally from the vaginal opening and continues diagonally like a mediolateral episiotomy.

4. Radical lateral episiotomy (Schuchardt incision) – the incision begins in the same direction as the lateral episiotomy, but is more extensive. Suture is technically more demanding and healing is more difficult.

Around the world, episiotomy is the most commonly performed obstetric procedure [3, 9]. However, the percentage of episiotomies varies greatly, from 9.7 % in Sweden to almost 100 % in Taiwan [8]. In general, a trend towards fewer episiotomies has been observed over the past 30 years. According to the Institute of Health Information and Statistics of the Czech Republic, episiotomies were

performed in 60 % of all deliveries in the Czech Republic in 2003 (spontaneous perineal tears: 19.3 %), but only in 42.3 % of all deliveries in 2013 (spontaneous perineal tears: 22.8 %) [20, 21]. Previously, especially in primiparous women, episiotomies were performed almost routinely; however, a shift towards a selective approach is currently noticeable. In comparison with women who underwent routine episiotomy, women who underwent episiotomy selectively exhibited a lower incidence of posterior perineal trauma [2], lower need for suture [2], and fewer complications up to seven days postpartum [2]; no difference in the occurrence of pain or anal sphincter tear incidence were established [2] (with the exception of medial episiotomy [5, 11]). The positive effect of episiotomy on anterior perineal trauma prevention has been demonstrated, though this is not associated with potential urinary incontinence [1, 2, 11].

The most common indications for episiotomy are prevention of third- and fourth-degree perineal tears [5, 9], acceleration of labor in the event of fetal hypoxia [5, 9, 27], prolonged duration of the second stage of labor [5, 9], prolapse prevention [5] and urinary incontinence [5]. However, no study has confirmed these supposed benefits [26]. Other common indications include operative vaginal delivery [3, 5, 9, 11, 27], spontaneous breech delivery [3, 5, 9], a presumed large fetus [3, 5], or, conversely, a small immature fetus [3]. Episiotomy is associated with a number of complications: major blood loss [26], hematoma [15], infection [15, 26], dehiscence [15], pain [26], and edema [26]; it may also result in long-term conditions such as dyspareunia [27]. Performing a medial episiotomy increases the risk of an anal sphincter tear [5, 26].

Historically, protecting the perineum from injury was a key priority for midwives. The first written record mentioning perineum care appears in a treatise entitled *Γυναικεία* (Gynaecia – Women) written by the Greek physician Soranus of Ephesus (98–138 AD) specifically for midwives [4]. For centuries afterwards, the subject is not mentioned in any existing records. Throughout Europe all significant books were destroyed by the church, with Byzantine medical texts the only exception; obstetrics was well-developed here and perineal care is described in detail. During the 12th century, several texts known as the Trotula [4] were published in Salerno, Italy, covering women's issues from gynecology to obstetrics to cosmetics. The texts list several types of perineal injuries as well as describing the process of suturing using silk thread. Written records are otherwise rare in Europe until the 17th century. The first surviving description of an episiotomy comes from A Treatise on Midwifery written by Sir Fielding Ould in 1742 [16]. Simultaneously, a shift from perineal tear prevention to intentional surgery took place. In the early 20th century, Joseph DeLee, a prominent Chicago obstetrician, even proposed to significantly shorten the second stage of labor by promoting routine episiotomy and forceps delivery under general anesthesia in order to minimize risk to the fetus [4]. At the same time, another American obstetrician, Ralph Hayward Pomeroy, called the newborn's head a "battering ram" and defended the routine episiotomy procedure, saying "Why not open the gates and close

them after the procession has passed?" [4]. Such was the dominant obstetrics approach until the year 1980.

More recently, a renaissance of perineal care has resurfaced in much of the developed world. However, while women in the Czech Republic regularly attend various pregnancy courses and exercises and frequently obtain extensive knowledge of breathing during labor, etc., perineal trauma prevention has yet to receive sufficient →

attention. Perineal trauma risk factors during delivery include primiparity [1, 7, 10, 22], operative vaginal (primarily forceps) delivery [7, 10, 11, 22, 27], shoulder dystocia [7], advanced maternal age [22], fetal malpresentation [1], and Asian ethnicity [7]. Perineal trauma risk further increases with increased fetal birth weight [1, 7, 10] and larger head circumference [1].

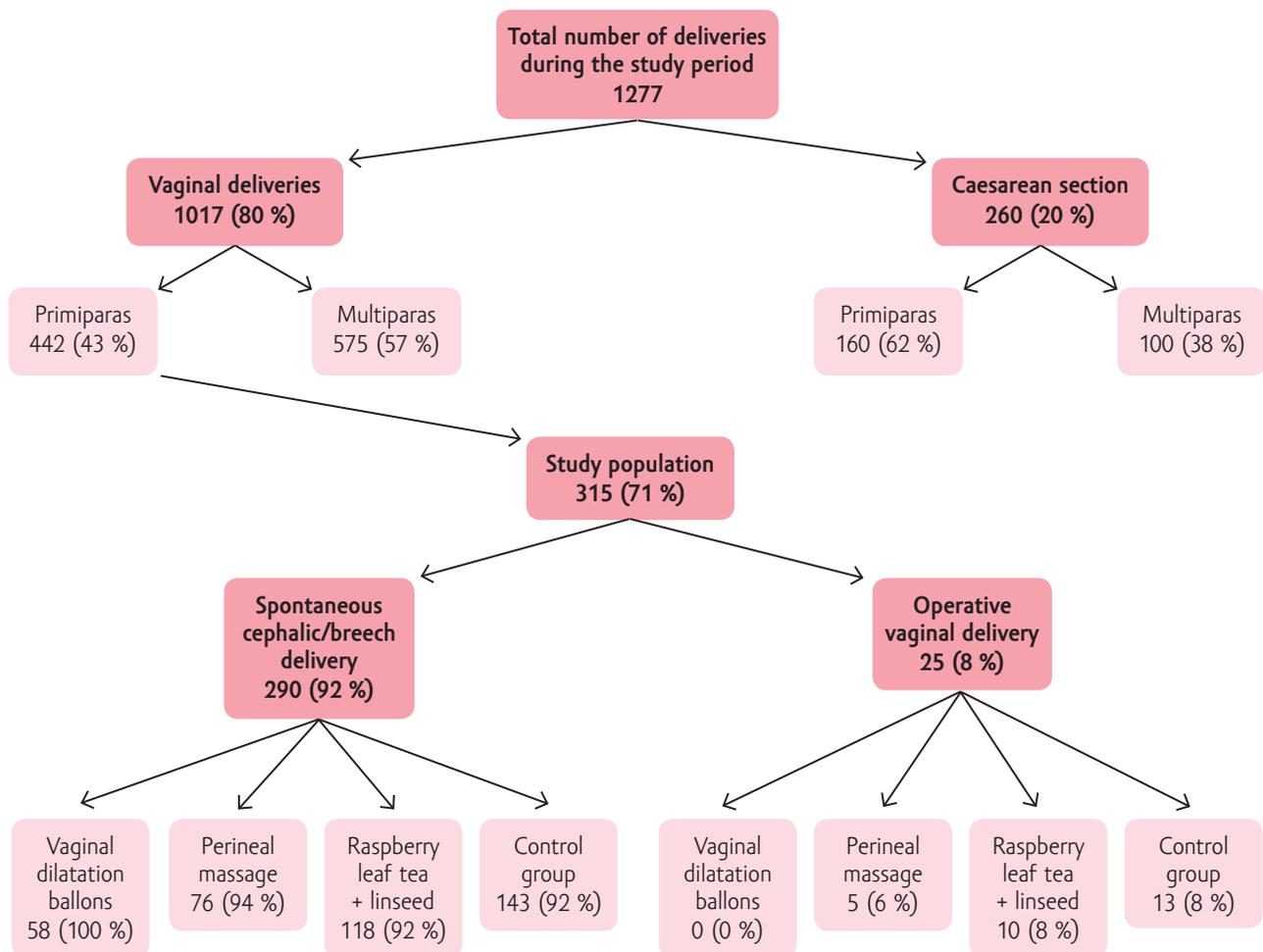


Fig. 1 Overview of births and PTP methods used at Český Krumlov Hospital during the study period.

This study aims to examine the effect of individual perineal trauma prevention methods used in pregnancy (vaginal dilatation balloons, perineal massage, and natural methods – raspberry leaf tea and linseed) on birth trauma incidence in primiparous women. In the following text, we wish to test the hypothesis that, given their action mechanism (see below), mechanical perineal trauma prevention methods (vaginal dilatation balloons and perineal massage) have a statistically significant positive effect on the perineum. We further hypothesize that subject groups using these methods may also experience a reduction in the number →

of operative vaginal deliveries. By contrast, we do not expect a significant reduction in the number of episiotomies or an increase in the number of intact perineum deliveries in groups using natural methods (raspberry leaf tea and linseed). While linseed and raspberry leaf do contain substances which help relax smooth muscle, they are, we believe, not present in sufficient quantities so as to significantly affect the results. We thus do not expect any effects on delivery method in this case.

	n	Maternal age ± SD	Newborn weight (g) ± SD	Newborn weight (cm) ± SD	Gestational age at delivery (weeks) ± SD
Minimum		16	2200	45	31
Maximum		24	4480	54	42
Study population average	315	28.0±5.1	3300 ±423	50.2±1.8	40.1±1.4
Control group average	156	26.6±5.3	3230 ±422	49.8±1.8	39.9±1.5
VDB group average	58	30.2±4.1	3288 ±414	50.2±1.7	40.3±0.9
Perineal massage group average	83	29.8±4.2	3357±386	50.5±1.6	40.0±1.5
Natural methods group average	128	29.2±4.4	3369 ±395	50.6±1.7	40.3±1.3

Table 1. Basic study population characteristics

STUDY POPULATION AND METHODOLOGY

Český Krumlov Hospital is a district hospital with approximately 700 deliveries per year. The study was conducted at our department from February 2014 to November 2015. During the study period, 1,277 deliveries took place, of which 1,017 (80 %) were delivered vaginally and 260 (20 %) by caesarean section. Of the vaginal delivery group, 422 (43 %) women were primiparous (Figure 1). A total of 226 (51.1 %) episiotomies were performed in this group of women. Only women meeting the following criteria were included in the study:

- 1) primiparous or so-called functionally primiparous women (women with a history of caesarean section, but giving birth vaginally for the first time, women who have had an abortion prior to week 21 of pregnancy),
- 2) cephalic or breech presentation, vaginal delivery,
- 3) singleton pregnancy. Women with multiple pregnancies and women who gave birth by caesarean section, whether planned or unplanned, were excluded.

Data were collected by means of printed questionnaires distributed to women in the postnatal ward after delivery. Therefore, the obstetrician did not know at the time of delivery whether or not the mother used any perineal trauma prevention (PTP) method; the possible performance or non-performance of an episiotomy thus could not be influenced in any way. The completed questionnaire was returned by 315 mothers; the remaining women either did not wish to participate in the study or refused to complete the questionnaire. Women willing to participate in the study gave →

informed consent for the anonymous disclosure of the data provided. Individual questions included general information about the mother such as age at delivery and date of delivery along with the mother's initials. These data were subsequently used to identify the mother. Further details were obtained from birth records: newborn birth weight, length and sex, gestational age at delivery, delivery method and whether or not perineal trauma occurred. Additional questionnaire items focused on PTP methods (whether the mother had used any of them before delivery and, if so, which one, where had she learned about the method in question, and, in the case of the Aniball and EPI-NO dilators, the achieved dilatation). When evaluating the data, the perineum was considered intact in case no suture was needed. Conversely, even a minor laceration which required suturing was classified as a first-degree perineal tear.

Statistical significance calculations were performed for categorical variables using the χ^2 test at the significance level of $p = 0.05$. Continuous variables were compared using an independent t-test or one-way analysis of variance (ANOVA) in Statistica 12. Birth trauma incidence (none vs. tear vs. episiotomy) and delivery method (spontaneous vs. operative vaginal) in correlation with the employed preventive methods were also tested by redundancy analysis (RDA) using Canoco v. 4.5 (terBraak and Šmilauer, 2002). Analysis significance was tested by a Monte Carlo permutation test using 499 permutations.

OVERVIEW OF EVALUATED PTP METHODS

Vaginal dilatation balloons: EPI-NO and Aniball

EPI-NO is a German product (TECSANA GmbH, Munich), which has been on the world market since 1999 and has been available in the Czech Republic since 2009. It is recommended for daily use from the 37th week of pregnancy until delivery for approximately 30 minutes per day. It consists of a figure eight shaped silicone balloon and a hand pump with or without a pressure gauge. The device is first inserted into the vagina where it helps strengthen the pelvic floor by providing resistance as muscles are contracted and relaxed for approximately 10 minutes. The balloon is then inflated to the point of stretching and comfort and remains inflated in the vagina for another 10 minutes. In the final phase the pelvic floor muscles are relaxed, which allows the inflated balloon to gently expel itself from the vagina. The target achieved dilatation is 8–10 cm in diameter. Greater dilatation is neither necessary nor recommended [19].

Aniball is a Czech product, which has been available since 2014 (RR Medical, s.r.o., Troubsko). Its shape is inspired by the African gourd – the calabash, which has supposedly been used by African women for the same purpose. Aniball use is recommended from the 36th week of pregnancy and the training procedure is carried out analogously to the EPI-NO. The goal is to achieve dilation to a balloon circumference of 28–30 cm [18].

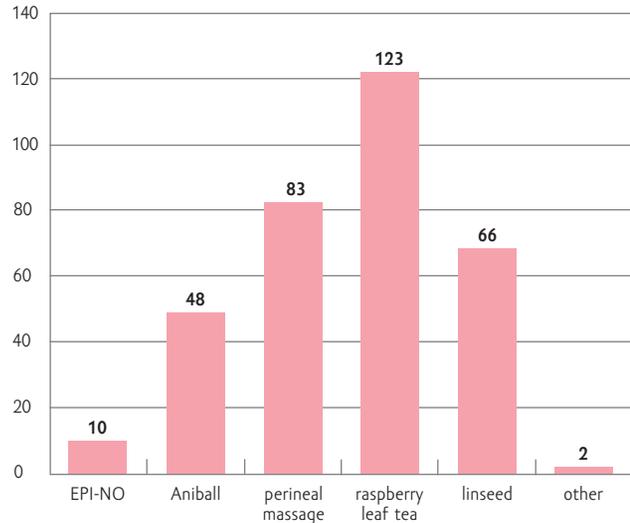
Perineal massage

Perineal massage increases perineal muscle flexibility and reduces resistance; during delivery the perineum is thus dilated in an injury-free manner. The perineum may be massaged by the pregnant woman herself or with the help of a partner from the 35th week of pregnancy using oils (olive, almond, etc.). The massage procedure is performed once a day; two fingers inserted into the vaginal opening perform a U-shaped movement, massaging the lower part of the opening (the section from 3 o'clock to the 9 o'clock position on an imaginary clock face) [23].

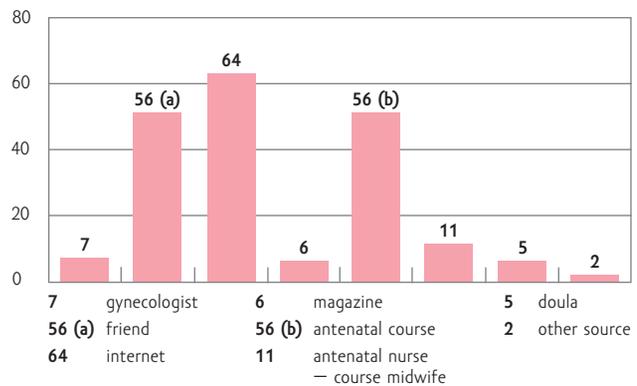
Natural methods – raspberry leaf tea and linseed

Raspberry leaf stimulates smooth muscle contractions and should thus positively influence delivery and shorten labor. It is recommended to drink 1–2 cups daily from the 36th week of pregnancy. It also helps contract the uterus after delivery and promotes lactation [17, 24]. Linseed relaxes smooth muscle, thus helping to open the cervix. Thanks to its phytoestrogen content, it is also supports lactation. Linseed may be consumed either in the form of a decoction or as whole seeds, mixed e.g. with yoghurt. The recommended dosage is several times a day from the second half of pregnancy. The maximum dose should not exceed three teaspoons per day [25].

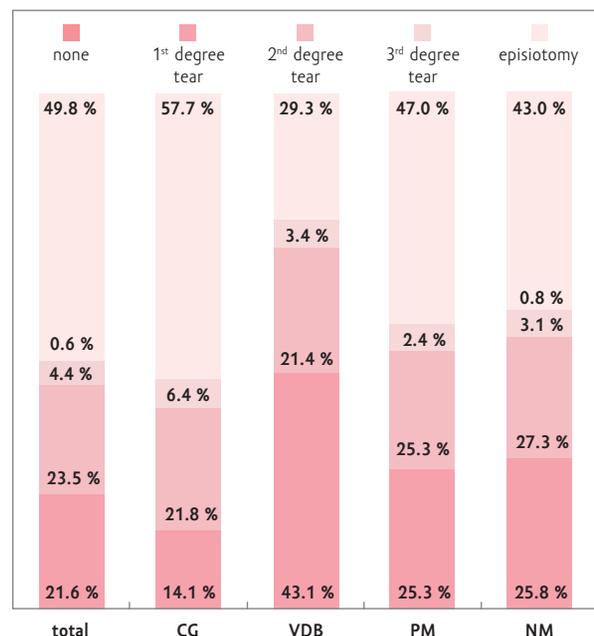
A group of women who did not use any of the described PTP methods were included in the study as a control group (CG). Less frequently reported PTP methods listed in response to our questionnaire included e.g. Chinese herbs and homeopathy; however, we did not evaluate their effect on perineal trauma due to the small number of such instances in the study population.



Graph 1. Representation of individual PTP methods in the study population



Graph 2. Perineal trauma prevention information sources



Graph 3. Trauma occurrence in individual groups

RESULTS

A total of 315 primiparous women were included in the study. The basic characteristics of the study population are provided in *Table 1*. The data set met the conditions of homogeneity and normality of distribution. Average maternal age was 28 years and average birth weight was 3,300 g. Mothers gave birth on average in the 40th week of gestation.

The basic subject population breakdown clearly indicates that dilatation balloons were used more frequently by older women (VDB group average: 30.2 years vs. CG average: 26.6 years). However, age alone did not significantly affect the probability of birth trauma in individual groups ($F_{2,312} = 0.107$, $p = 0.898$), and this fact should therefore not affect other results. Similarly, gestational week at delivery ($F_{2,312} = 1.265$, $p = 0.284$) did not affect the incidence of individual trauma types.

Graph 1 includes the absolute numbers of women using each of the studied PTP methods. Some women reported using multiple methods simultaneously. Study subjects most frequently learned of a given PTP method from the internet; other common sources of information included antenatal courses and information provided by friends (*Graph 2*). Some mothers acquired information from multiple sources.

Trauma was subdivided into three groups (none, first to third degree perineal tear, and episiotomy). No trauma occurred in the case of 21.6 % of the study population, episiotomy was performed in 49.8 % and perineal tears were diagnosed in 28.5 % of all cases. The distribution of perineal trauma types in individual groups is →

shown in *Graph 3*. The success rate of individual methods was determined by the presence or absence of birth trauma.

Of the entire study population, 58 women (18.4 %) used vaginal dilatation balloons (VDBs). Average VDB use duration was 27 days and average achieved dilatation (circumference) was 27 cm. As the mechanism employed by the two devices is identical, the results were calculated for EPI-NO and Aniball together. In the VDB group, significantly more women gave birth with an intact perineum ($p < 0.001$) compared to the control group, and significantly fewer women underwent episiotomy ($p < 0.001$). VDBs were the only method to significantly reduce the incidence of birth trauma ($p < 0.001$) even when the influence of all other methods was excluded (*Table 2*). A significant difference was also observed in the group of mothers using natural methods compared to the control group ($p = 0.013$ for no birth trauma and $p = 0.014$ for deliveries without episiotomy). Perineal massage also significantly increased the chance of delivery with an intact perineum ($p = 0.03$) but did not significantly affect the number of episiotomies (*Table 3*). None of the PTP methods statistically significantly affected the incidence of perineal tears. A significant reduction in birth trauma incidence in the VDB group was observed in women who achieved a minimum dilatation of 24 cm ($p = 0.0005$, *Table 4*). *Graph 4* indicates that the greater the achieved dilatation, the greater a woman's chance of delivery without birth trauma.

	VDB (n=11)			PM (n=17)			NM (n=36)			CG (n=156)	
	n	%	p	n	%	p	n	%	p	n	%
None	6	54.5	0.0005	5	29.4	0.10	9	25.0	0.11	22	14.1
Tear	1	9.1	0.17	4	23.5	0.68	11	30.6	0.78	44	28.2
Episiotomy	4	36.4	0.17	8	47.1	0.40	16	44.4	0.15	90	57.7

Table 2. Comparison of trauma incidence in individual groups (cleaned data) and in the control group

	VDB (n=58)			PM (n=83)			NM (n=128)			CG (n=156)	
	n	%	p	n	%	p	n	%	p	n	%
None	25	43.1	0.000005	21	25.3	0.03	33	25.8	0.013	22	14.1
Tear	16	27.6	0.93	23	27.7	0.94	40	31.2	0.58	44	28.2
Episiotomy	17	29.3	0.0002	39	47.0	0.11	55	43.0	0.014	90	57.7

Table 3. Comparison of trauma incidence in individual groups and in the control group

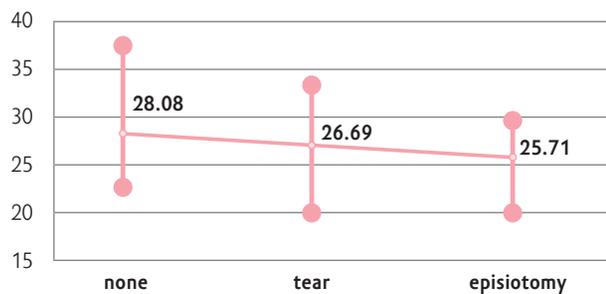
Dilatation (cm)	VDB (n=58)			CG (n=156)			p
	n	none	%	n	none	%	
< 24	7	2	28.6				0.24
24-29	39	15	38.5	156	22	14.1	0.0005
≥ 30	12	8	66.7				0.000005

Table 4. Achieved dilatation in the VDB group compared to the CG

Of the entire study population, 58 women (18.4 %) used vaginal dilatation balloons (VDBs). Average VDB use duration was 27 days and average achieved dilatation (circumference) was 27 cm. As the mechanism employed by the two devices is identical, the results were calculated for EPI-NO and Aniball together. In the VDB group, significantly more women gave birth with an intact perineum ($p < 0.001$) compared to the control group, and significantly fewer women underwent episiotomy ($p < 0.001$). VDBs were the only method to significantly reduce the incidence of birth trauma ($p < 0.001$) even when the influence of all other methods was excluded (Table 2). A significant difference was also observed in the group of mothers using natural methods compared to the control group ($p = 0.013$ for no birth trauma and $p = 0.014$ for deliveries without episiotomy). Perineal massage also significantly increased the chance of delivery with an intact perineum ($p = 0.03$) but did not significantly affect the number of episiotomies (Table 3). None of the PTP methods statistically significantly affected the incidence of perineal tears. A significant reduction in birth trauma incidence in the VDB group was observed in women who achieved a minimum dilatation of 24 cm ($p = 0.0005$, Table 4). Graph 4 indicates that the greater the achieved dilatation, the greater a woman's chance of delivery without birth trauma.

VDB success rate was affected neither by fetal sex ($p = 0.78$) nor by postterm pregnancy ($p = 0.62$). The study population was divided into five subgroups according to newborn weight and VDB efficiency was compared to the control group. While a significant reduction in birth trauma incidence was observed in the over 3,000 g subgroup ($p < 0.05$), the reduction was most notable in the 3,000–3,499 g subgroup ($p < 0.001$) (Table 5).

Of the entire study population, a total of 289 (91.7 %) deliveries featured a spontaneous cephalic presentation and one (0.3 %) →



Graph 4. Average, minimum and maximum achieved dilatation (in cm) in the VDB group, listed by trauma type

a spontaneous breech presentation; a vacuum extractor was used in 21 (6.7 %) cases, and four (1.3 %) cases involved a forceps delivery. We believe that the higher incidence of operative vaginal deliveries in the study population was caused by the group consisting of primiparas, who are more likely to require an instrumental delivery than multiparas.

All women in the study population who used VDBs gave birth spontaneously. Logically, the risk of operative vaginal delivery in this group was thus significantly lower compared to the control group ($p = 0.02$, Table 6). Operative vaginal deliveries were more frequently carried out in the case of younger mothers (26.1 years vs. 28.2 years for spontaneous deliveries, $p = 0.05$). Neither fetal weight ($p = 0.68$) nor gestational age ($p = 0.23$) had any effect on delivery method. A summary of the above is also shown in Figure 2 (RDA, $p = 0.02$).

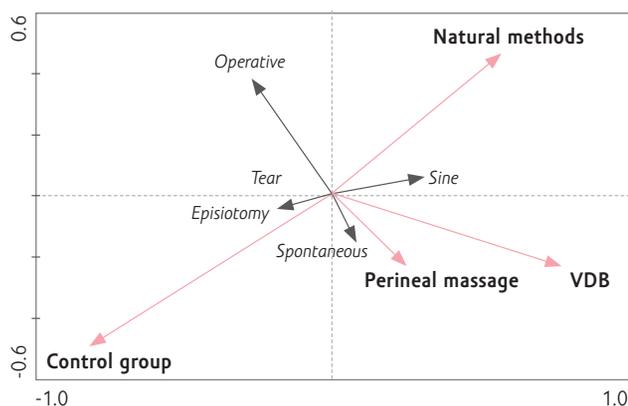


Fig 2. Birth trauma incidence and delivery method according to the utilized PTP method (RDA)

Newborn weight	VDB (n=58)			CG (n=156)			p
	n	none	%	n	none	%	
2,000–2,499 g	1	0	0.0	7	1	14.3	0.69
2,500–2,999 g	14	6	42.9	39	8	20.5	0.10
3,000–3,499 g	27	12	44.4	71	8	11.7	0.0003
3,500–3,999 g	14	6	42.9	32	5	15.6	0.05
4,000–4,499 g	2	1	50.0	7	0	0.0	0.05

Table 5. Comparison of “no trauma” deliveries between the VDB group and the control group by newborn weight subgroups

	VDB (n=58)			PM (n=83)			NM (n=128)			CG (n=156)	
	n	%	p	n	%	p	n	%	p	n	%
Spontaneous delivery	58	100	0.02	78	94.0	0.49	118	92.2	0.87	143	92.7
Operative vaginal delivery	0	0		5	6.0		10	7.8		13	8.3

Table 6. Delivery methods in individual groups compared to the control group

DISCUSSION

The increasing number of requests for primary caesarean section may be linked to potential morbidity associated with vaginal delivery. Consequently, demand for an effective method which has been shown to reduce the risk of perineal trauma during delivery has also increased. The lower incidence of perineal trauma has clear advantages for the mother: less pain and discomfort in the early postpartum period, speedier recovery and thus improved newborn care conditions. The following text presents the expected action mechanism of individual PTP methods and a comparison of our results with existing international studies.

Vaginal dilatation balloons

Perineal trauma occurs more commonly in women during their first vaginal delivery than in women who have previously given birth vaginally. This is explained by the fact that multiparous women have lower tissue resistance to head penetration than primiparous women as the soft tissues of the vagina and perineum have already been dilated during the first delivery. This consideration led to the development of an inflatable vaginal dilator. The use of a dilatation balloon mechanically expands the soft birth canal tissues, effectively turning a primipara into a “functional multipara” [9]. In addition, VDB use also helps women train the pelvic floor muscles, thus enabling them to push better and more efficiently. We found a total of four international studies evaluating the effect of VDBs on the perineum in primiparous women. Unlike ours, all of these studies were prospective. The authors asked women to use an EPI-NO vaginal dilatation balloon prior to delivery, and subsequently evaluated the incidence of birth trauma as well as additional parameters. We found no Czech studies dealing with this issue. The very first study of this topic was published in Germany in 2001 and showed a statistically significant reduction in the number of episiotomies ($p < 0.001$) in the EPI-NO group (45 primiparous women). In this study Hillebrenner et al. [9] evaluated not only the effect of the balloon on the incidence of birth trauma, but also the analgesic dosage in labor, the duration of the second stage of labor (describing its significant reduction in women using EPI-NO, $p = 0.014$) and the Apgar score of newborns. The results of the possible effect of the balloon on the pelvic floor are of interest. According to Hillebrenner, gradual soft tissue dilation using EPI-NO may help reduce episiotomy incidence as well as the long-term consequences of vaginal delivery including stress →

incontinence and pelvic organ prolapse [9]. An Australian study published in 2004 focused on 39 women using EPI-NO. The study results indicated that women using EPI-NO were significantly more likely to have an intact perineum ($p < 0.0001$) and significantly less likely to have experienced perineal rupture ($p < 0.05$); a discernible but not statistically significant ($p = 0.286$) reduction in the number of episiotomies during vaginal delivery was also observed [13]. In the same year, another study was also published in Singapore, where episiotomies are routinely performed in the case of primiparous women. In a group of 29 primiparous women using EPI-NO, episiotomy incidence was significantly lower than in the control group (65 % vs. 93.3 %, $p < 0.0001$); however, very few deliveries were entirely injury-free (6.9 % vs. 3.3 %) [12].

The most recent and, in terms of the number of women training with EPI-NO, also the most extensive study to date was conducted in Germany and published in 2009 [22]. This study focused on episiotomy rate and intact perineum incidence, the duration of the second stage of labor, analgesic dosage and vaginal infection incidence in a group of 135 women using EPI-NO before delivery and a control group of 137 women. The results of the study showed a statistically significantly higher number of intact perineum deliveries in the EPI-NO user group compared to the control group (37.4 % vs. 25.7 %; $p = 0.05$, in our study 43.1 % vs. 14.1 %, $p < 0.0001$). While fewer episiotomies were performed, the result was not significant (41.9 % vs. 50.5 %; $p = 0.11$). By contrast, the number of performed episiotomies was found to be statistically significantly lower in our study (29.3 % vs. 57.7 %, $p < 0.001$). The authors of the German study did not establish a correlation between an intact perineum and achieved dilatation. In our case, such a dependence was observed: a positive effect on the intact perineum was significant in the VDB user group beginning with an achieved dilatation of 24 cm. A reduced risk of operative vaginal delivery was established in the case of women using VDBs compared to the control group ($p = 0.02$). Furthermore, Ruckhäberle et al. observed neither a higher incidence of vaginal infections nor an increased risk of fetal infection in EPI-NO users compared to the control group. They found no negative effect of EPI-NO on the pelvic floor. While a lower need for analgesics was observed in the EPI-NO group, this result did not reach statistical significance [22].

Whereas existing international studies focusing on VDB use only evaluated the EPI-NO device, a majority of our study population used the relatively new Czech product Aniball. As the action mechanisms are identical and the function and shape of the two devices very similar, we believe that the results of studies evaluating the effect of EPI-NO on the perineum are valid for Aniball as well. This notion is supported by the facts that most women in our VDB group used Aniball and that the conclusions of our study are similar to those featured in existing international studies. The results of our study, as well as all available international studies, show a significantly lower perineal trauma incidence during childbirth in women using a vaginal dilatation balloon prior to delivery. An added benefit may be that women using a VDB have already experienced the pressure that the balloon creates inside the vagina. As a result, they were not afraid when the fetal head exerted the same pressure: they knew how best to push and were not worried about the head passing through the birth canal. As a point of interest, the mother of the heaviest newborn in our study population (4,480 g) used a dilatation balloon (Aniball) before childbirth and subsequently delivered with an intact perineum.

Perineal massage

Several existing international studies also focus on antenatal perineal massage. A British study from 1997 observed that the probability of an intact perineum was higher in women performing perineal massage. However, the results were only significant for primiparous women over 30 years of age [23]. The authors of two Canadian studies [6, 14] also concluded that perineal massage before delivery increases the chances of trauma-free birth in primiparas, as did an Australian study summarizing the results →

of four studies involving 2,497 women [1]. In our study, we also observed a significantly higher number of women with an intact perineum in the perineal massage group compared to the control group (25.3% vs. 14.1%, $p = 0.03$); however, after excluding other PTP methods, the result was no longer significant. This difference may be due to the vastly smaller number of women performing perineal massage in our study population compared to other studies. In addition, the potential increase in perineal flexibility thanks to massaging cannot (unlike in the case of VDBs) be assessed objectively; finally, the quality of the massage performed by individual women might not have been the same.

Natural methods (raspberry leaf tea and linseed)

While two Australian studies evaluating the effect of raspberry leaf on the course of delivery did not find that the consumption of raspberry leaf tea shortened the first stage of labor, it was shown to shorten the second stage. No adverse effects of raspberry leaf on the mother or fetus have been reported [17, 24]. However, the studies did not evaluate the effect of raspberry leaf on birth trauma. Likewise, we were unable to locate any studies examining the effects of linseed intake on birth trauma. In our study, natural methods significantly increased the number of deliveries with an intact perineum ($p = 0.013$) and decreased the number of episiotomies ($p = 0.014$). However, this result is certainly influenced by the fact that of the total number of natural method users (128), 45 women also used VDBs and 64 performed perineal massage. Once we excluded the influence of these methods (Table 2), no positive significant effects on the perineum were observed in the remaining 36 natural method users.

CONCLUSION

The results of our study show that the antepartal use of vaginal dilatation balloons leads to significantly higher chances of an intact perineum during delivery. We also observed a statistically significant reduction in the number of episiotomies and operative vaginal deliveries in the group of women using dilatation balloons. Based on these outcomes, we conclude that VDB usage is advantageous not only for mothers, but may also be beneficial for maternity hospitals, where it might lower costs associated with the use of e.g. vacuum extractors, suture materials, analgesics, etc.

According to the findings of our study, women who achieved a dilatation of at least 24 cm and delivered a baby weighing 3,000 g or more benefit most from the use of VDBs. We believe that our study is the first of its kind in the Czech Republic and the second largest in terms of the number of women using vaginal dilatation balloons (58) in comparison with existing studies carried out abroad.

In the case of the other methods (perineal massage and natural methods) evaluated in our study, a positive effect on the perineum at delivery was demonstrated only when the influence of the individual methods on each other was not taken into account. →

Once we excluded other PTP methods, neither perineal massage nor natural methods showed a statistically significant effect on the prevention of perineal trauma. Our hypothesis was therefore only partially confirmed, as we expected better results in the perineal massage group; on the contrary, we were surprised by the influence of natural methods. However, this was certainly influenced by the use of other PTP methods, and especially VDBs. A reduction in the need for instrumental deliveries in the VDB group, though not in the perineal massage group, was thus confirmed. We also confirmed that natural methods do not affect the method of delivery.

The results of the comparison of all of these groups with the control group indicate that any antepartal perineal trauma prevention method is better than none at all, but that only the use of VDBs provides a clear benefit for the mother.

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