

Benefit of vaginal dilatational balloons in pregnancy

Korzyści z zastosowania balonów rozszerzających pochwę w ciąży

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STRESZCZENIE

KORZYŚCI Z ZASTOSOWANIA BALONÓW ROZSZERZAJĄCYCH POCHWĘ W CIĄŻY

Cel pracy. Celem pracy było określenie wpływu stosowania balonów rozszerzających pochwę w ciąży na powstanie urazów porodowych lub wycieku moczu po porodzie. Ponadto znalezienie związku między stosowaniem balonów w ciąży a trudnościami seksualnymi po porodzie.

Materiał i metody. Badaniami objęto 394 respondenci, które stosowały lub nie stosowały Aniball lub Epi/no balloon w ciąży, a czas do porodu wynosił minimum pół roku. Badanie ilościowe zostało zrealizowane za pomocą niestandardyzowanego kwestionariusza ankiety własnej konstrukcji. Badania odbywały się w gabinetach ginekologicznych oraz za pośrednictwem przeglądarek internetowych. Poszczególne zmienne zostały poddane testom statystycznym za pomocą testu Chi-kwadrat i Fishera.

Wyniki. Na podstawie badań statystycznych stwierdzono, że istnieje związek pomiędzy stosowaniem balonów rozszerzających pochwę w ciąży a powstaniem urazu poporodowego w sensie ich zmniejszenia. U kobiet, które stosowały balonik dopochwowy stwierdzono mniejszą częstość występowania problemów z nietrzymaniem moczu.

Wnioski. Na podstawie badań empirycznych stwierdzono pozytywne korzyści z zastosowania balonów dopochwowych. Pozytywne korzyści stwierdzono w związku z powstaniem urazu poporodowego i rozwojem nietrzymania moczu po porodzie.

Słowa kluczowe:

poród, episiotomia, pęknięcie krocza, balonik rozszerzający pochwę, nietrzymanie moczu

ABSTRACT

BENEFIT OF VAGINAL DILATATIONAL BALLOONS IN PREGNANCY

Aim. Aim of research was to find out influence of using vaginal dilatational balloons in pregnancy on the origin birth injuries, leakage of urine after the childbirth. Apart from that, to investigate connection between using balloons in pregnancy and sexual difficulties after the childbirth.

Material and methods. The study contains 394 respondents, which used or did not use Aniball or Epi/no balloon in pregnancy and the time by their childbirth was minimum half of year. Quantitative research has been realized with the help of a non-standardized self constructed questionnaire. The research took place in gynecological clinics and through web browsers. Individual variables have been statistically tested with the help of Chi-square and Fisher's test.

Results. By statistical research have we found out that there exist the connection between using vaginal dilatational balloons in pregnancy and the origin postnatal injury in the sense of their reduction. Women, who used vaginal dilatational balloon, have experienced a lower incidence of incontinence problems.

Conclusions. In empirical research we have found positive benefit of using vaginal balloons. Positive impact has been also found in connection with the origin postnatal injury and the development incontinence after the childbirth.

Key words:

childbirth, episiotomy, perineum rupture, vaginal dilatational balloon, incontinence

INTRODUCTION

Vaginal balloons are considered as medical equipment for preparation of perineum for the childbirth. This article inquires into using two types of dilatation balloons, a German tool Epi-no and a Czech tool Aniball. Epi-no is a tool, which during exercise, encourages women to increase centimeters of circumference, followed by expulsion of the balloon from vagina. That is an aid to practice a dilatation of the vagina before the childbirth. Aniball is presented as a tool for activation of the pelvic floor for a prenatal training or for rediscovery the pelvic floor after the childbirth with the opportunity of use for rehabilitation already caused incurred functions of the pelvic floor.

Bohatá and Dostálka's study investigated the influence of antepartal methods to prevent episiotomy and rupture of perineum. As part of the comparison, there was a group of women using dilatation balloons during pregnancy and a control group; significantly more women with an undamaged perineum during the childbirth and significantly lower rate of episiotomies was also evident [2]. Zanetti and the team proved the influence of Epi-no balloon on the prevention of perineum injury [3]. Irini Papadopoulou, the German midwife, investigated the effects of three weeks exercise with Epi-no balloon with regard to the pelvic floor after the childbirth. The results show that a power of the pelvic floor has been increased of 60% and only 26% respondents still reported problems with urine leakage [4].

AIM

Aim of this study was to find out the influence of using dilatation balloons on the development of the childbirth injury, the presence of leakage of urine after the childbirth and the sexual difficulties after the childbirth. Sub-several targets were compiled from which there are based established hypotheses.

MATERIALS AND METHODS

For quantitative research a non-standardized self-constructed questionnaire has been used. The women provided a consent to be included in the research via signing informed permission. The ethics committee of this research was not implemented because consents for the research investigation were also obtained from the management of each institution prior to the commencement of the research investigation. During the research, the Charter of Fundamental Rights and Freedoms, the Nuremberg Code, the Declaration of Helsinki, the Tokyo Declaration, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects were respected. The questionnaire contained information about the characteristics of the content, instructions for filling in and 28 closed and semi-closed questions. The arrangement of the questions is based on previous research and evaluation of the available sources. According to the number of variation of answers of individual questions, there were chosen dichotomous questions (yes/no) which researched

the facts regarding the use of dilatation balloons e.g. if women used or did not use balloons during pregnancy and after the childbirth, if they had an injury during the childbirth, if they had leaking of urine or stool after the childbirth and others. The questionnaire contained polytomous questions with a bigger amount of answer variations and a bigger amount of choosing another variant. Those questions focused on women's parity, on the type of their injuries, on other problems associated with the injury or circumstances associated with leakage of urine or stool, and others. The questionnaire was adapted to distinguish women which used dilatation balloon Epi-no and Aniball. In the questionnaire research there were included women who used dilatational balloons during pregnancy, as well as women who did not use them. Data collection took place in selected gynecological clinics, where the questionnaire was distributed by clinics' staff and also online on social networking sites, in groups focused on experiences with the use of dilatational balloons.

The research file contained women in productive age who gave a birth and since their birth had passed no longer than half of year. The file contained 394 respondents. The criteria to classify in the file were as follows: 1. Women after vaginal birth, 2. Since they gave a birth had passed minimum half of year, 3. Women who used vaginal balloons Epi-no or Aniball, 4. Women who did not use any of the mentioned balloons, 5. Women who have reached to the age of 18.

The data obtained by the quantitative research were transferred to the Microsoft Office Excel 2016 with subsequent processing and evaluation. Individual data were for statistical processing numerically coded and a tabular and graphic representation of individual data obtained was created. After determining the individual variables, the obtained data of the set questions in the questionnaire were tested using descriptive statistics. For hypothesis testing, statistical formulas Pearson chi-square test and Fisher exact test were used. For both statistical tests a significance level $\alpha = 0.05$ (that is 5%) was determined. The questionnaire survey was conducted anonymously and together with subsequent data processing and their interpretation was subject to a strict criterion of no violation of personal data protection.

RESULTS

In the file there were most often present women between 26 and 30 years old (38.3%). The respondents had most often the highest university education (56.9%). The examined sample most often contained women who delivered for the first time – 56.3%. There were 248 (62.9%) women who used Aniball during pregnancy, 10 those who used Epi-no (2.5%).

At first, we evaluated the differences in the incidence of postnatal injuries in women related to the use of vaginal balloons (Tab. 1). Both set variables are dependent on each other. Without the use of vaginal balloons there is the possibility of occurrence of postnatal trauma in 80.4%, while with the use of balloons, the possibility of occurrence of postnatal trauma drops to 47.7%.

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■ Tab. 1. The difference between users of vaginal balloons in relation to the childbirth injury

Using vaginal balloons				
Postnatal injury	Yes N (%)	No N (%)	Chi-squared test	p-value
Yes	122 (47.7)	111 (80.4)	38.533	<0.001
No	134 (52.3)	27 (19.6)		

N - total number, % - number of percentages

■ Tab. 2. The difference between users of vaginal balloons in relation to the childbirth injury

Using vaginal balloons				
Leakage of urine	Yes N (%)	No N (%)	Chi-squared test	p-value
Yes	91 (39.1)	41 (25.5)	7.2947	0.007
No	142 (60.9)	120 (74.5)		

N - total number, % - number of percentages

■ Tab. 3. The difference between non-users of vaginal balloons in relation to the childbirth injury

The childbirth injury				
Leakage of urine	Yes N (%)	No N (%)	Chi-squared test	p-value
Yes	39 (32.0)	83 (68.0)	2.0829	0.149
No	31 (23.1)	103 (76.9)		

N - total number, % - number of percentages

■ Tab. 4. The difference between users and non-users of vaginal balloons in relation to difficulties in sex life after the childbirth

The childbirth injury				
The difficulties with sex life after the childbirth	Yes N (%)	No N (%)	Chi-squared test	p-value
Sex life has not changed	136 (53.1)	64 (46.4)	1.7212	0.423
Sex life has changed	43 (16.8)	25 (18.1)		
Yes	77 (30.1)	49 (35.5)		

N - total number, % - number of percentages

We evaluated the connection between using vaginal balloons and the leakage of urine (Tab. 2). The representation of women who did not have problems with the leakage of urine and had the childbirth injury was 25.5%. Respondents, who had problems with the leakage of urine, reported the incidence of the childbirth trauma in 39.1%.

We evaluated the difference between the women who non-user vaginal balloons in relation to the childbirth injury and the leakage of urine (Tab. 3). The result is the independence of the leakage of urine after childbirth due to the childbirth injury by respondents not using Aniball/ Epi-no balloons during pregnancy. Respondents, who did not suffer from the leakage of urine and did not have the childbirth trauma, accounted for 103 (76.9%), compared to the women who did have the childbirth trauma – 31 (23.1%). There were 39 (32%) respondents who did have problems with the leakage of urine and the childbirth injury and 38 (68%) of those who did not have the childbirth injury.

We evaluated the connection between using vaginal balloons during pregnancy and sexual difficulties after the childbirth (Tab. 4). We assumed the independence of sexual difficulties on using vaginal balloons during pregnancy. In the group of respondents who did use aids is the presence of complaints about sexual difficulties after the childbirth in 30.1% compared to the group of women who did not use aids during pregnancy, in whom incidence of sexual difficulties increases to 35.5%.

DISCUSSION

The vaginal childbirth is the most significant risk factor for pelvis floor disorders with decrease of its strength up to 22-35% after the childbirth [1,5,6]. One of the studies, concerned with exercise with Aniball, which evaluated the effect of methods for preventing perineum injury during the childbirth, proved a significantly lower incidence of intact perineum and performing an episiotomy by women who did use balloons. According to the study, vaginal balloons reduced the incidence of childbirth injuries ($p < 0.001$) [2]. The pilot study by Freitas et al. included 20 respondents who proceeded to analyze. The number of 40% of respondents who did use balloons mentioned intact perineum [9]. The study by Kamisana et al. evaluated effects of Epi-no balloon on the development of the childbirth injury. They came to the conclusion that they did not proved protective effect of using Epi-no balloon during pregnancy on the pelvic structures primary women during the childbirth. They diagnosed the perineum rupture and the injury of an anal sphincter by 50.1% and 6.2% women. They came by statistical evaluation to insignificant differences between control and intervention groups ($p=0.61$ and 0.41) [10]. This finding is supported by a systematic review by Schreiner et al. [11], who found that the Epi-No balloon showed no benefit in minimizing birth injury. However, a pilot study by Kubotani et al. [12] confirms the positive effect of using the Epi-No balloon. The Epi-No balloon increased pelvic floor distensibility in women with twin pregnancies, which was confirmed by transperineal 3DUS and epinometry. This device supported an increase in perineal distensibility with a single use [12].

The main aim of this research was to find out influence of using vaginal dilatational balloons in pregnancy on the origin birth injuries, leakage of urine after the childbirth.



The sub-objective of research was to determine the dependence of exercises with vaginal balloons during pregnancy on the development of leakage of urine after the childbirth. The incidence of leakage of urine by women exercising with balloons was 27.3%, and by women who did not exercise it was 44.9%. The resulting finding is that women using aids may have a significantly lower risk of developing leakage of urine after the childbirth. The study published in 2012 presented the prevalence of urgent incontinence (5.5%), stress incontinence (22%) and combination incontinence (4.3%, stress and urgent) 6 months after the vaginal childbirth. As long as 12 months after the childbirth they again investigated the prevalence and mentioned

that urgent incontinence was in 8.2%, stress in 25.9% and combination in 6.7% [13]. The study presented in 2019 included 393 respondents. The authors reported that 84 respondents (21.4%) experienced the development of leakage of urine after the vaginal childbirth [14]. A long-term study investigating the leakage of urine after the childbirth with a range of up to 12 years was published in 2015, the results pointing up to the incidence urinary incontinence in 33.1% 3 months after the childbirth (1247 women from 3763 respondents), 6 years after the childbirth the incidence was in 46.8% and after 12 years after the childbirth the incontinence was found in 52.7% [15]. The sub-objective of research investigated the connection between the childbirth injury and the leakage of urine after the childbirth. We investigated the connection of the childbirth injury and the urinary incontinence between women who did not use vaginal balloons. As a result of investigation, we found out that the urinary incontinence is not dependent on the childbirth injury in both investigated groups. The study from year 2016 mapped the reality of the childbirth injury and its influence on the pelvic floor after the childbirth. The resulting opinion proves that childbirth injuries are not associated with the occurrence of urinary incontinence after the childbirth. We generally evaluated all urinary incontinence in groups of women with the childbirth injury and without the childbirth injury (59.8% vs. 53.1%) [16]. The effect of episiotomy on the pelvic floor and sexuality after the childbirth was researched in the study published in year 2019, their results point to incontinence by women with cut-in perineum after the childbirth – 15.2% [17]. Our resulting stand during comparing respondents is the same, it points to the independence between the childbirth injury and urinary incontinence. Respondents with the leakage of urine had the childbirth injury in 32% and without the childbirth injury in 68%.

CONCLUSIONS

Exercising with health aid such as Aniball or Epi-no balloon can help women to improve the quality of life. Recommending using dilatation balloons during pregnancy by doctors and midwives can be an affective strategy in preventing the above mentioned disorders or complications and this may prevent subsequent surgical interventions of the urogenital tract.

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