

## Urinary and sexual function of puerperal women who used the vaginal balloon in preparation for vaginal birth – a cross sectional study

## Função urinária e sexual de mulheres puerperais que usaram o balão vaginal na preparação para o parto vaginal – um estudo transversal

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**ABSTRACT | INTRODUCTION:** Vaginal balloon can be an option to prepare the pelvic floor muscles for vaginal birth. Its implications for urinary and sexual functions need to be further studied. **OBJECTIVE:** To evaluate the implications of the vaginal balloon in preparation for vaginal birth on sexual and urinary functions. **METHODOLOGY:** Cross-sectional study was carried out in Belém do Pará, with primiparous women from vaginal births, aged between 18 and 40 years. Two groups were formed: the EG consisted of postpartum women who used the vaginal balloon during pregnancy from the Clínica Cafisio Mulher and the CG of postpartum women who did not use the vaginal balloon during pregnancy, from the Centro de Saúde Escola do Marco. A sociodemographic evaluation form, a questionnaire with questions about labor events, the International Consultation on Incontinence Questionnaire Short Form, and the Female Sexual Function Index were used. Excel software was used for data entry, preparation of tables, and descriptive statistical analysis of the variables. **RESULTS:** Most women had some urinary loss in both groups, with different impacts on quality of life. As for sexual function, both groups are below the cutoff point, which indicates sexual dysfunction. However, it was impossible to establish an association between urinary and sexual function between the two groups due to differences in sample size. **CONCLUSION:** The urinary and sexual functions of both groups were altered.

**KEYWORDS:** Pelvic floor. Pregnant women. Childbirth.

**RESUMO | INTRODUÇÃO:** O balão vaginal pode ser uma opção para preparar os músculos do assoalho pélvico para o parto vaginal. Suas implicações para as funções urinária e sexual precisam ser mais estudadas. **OBJETIVO:** Avaliar as implicações do balão vaginal na preparação para o parto vaginal nas funções sexual e urinária. **METODOLOGIA:** Estudo transversal realizado em Belém do Pará, com primíparas de partos vaginais, de 18 a 40 anos. Formou-se dois grupos: o GE se constituiu de puérperas que usaram o balão vaginal durante a gravidez provenientes da Clínica Cafisio Mulher e o GC de puérperas que não fizeram uso do balão vaginal durante a gestação, provenientes do Centro de Saúde Escola do Marco. Utilizou-se uma ficha de avaliação sociodemográfica, um questionário com perguntas acerca dos eventos do trabalho de parto, o International Consultation on Incontinence Questionnaire Short Form e o Female Sexual Function Index. Foi utilizado o software Excel para entrada dos dados, confecção das tabelas e análise estatística descritiva das variáveis. **RESULTADOS:** Em ambos os grupos, a maioria das mulheres apresentou alguma perda urinária, com impactos diferentes na qualidade de vida. Quanto à função sexual, ambos os grupos estão abaixo do ponto de corte, o que indica disfunção sexual. No entanto, não foi possível estabelecer uma associação entre a função urinária e sexual entre os dois grupos devido às diferenças no tamanho da amostra entre os grupos. **CONCLUSÃO:** As funções urinária e sexual de ambos os grupos estavam alteradas.

**PALAVRAS-CHAVE:** Assoalho pélvico. Mulheres grávidas. Parto.

## Introduction

The pelvic floor (PF) consists of muscles, ligaments, and fasciae with the important role of suspending and supporting pelvic organs and helping sexual function and maintain fecal and urinary continence.<sup>1</sup> However, certain situations tend to predispose this set of structures to anatomical physiological changes, as, for example, during the pregnancy-puerperium cycle.<sup>2</sup> The pressure exerted by the fetus, the effective uterine contractions during the repositioning of the fetus, and the force generated by the maternal expulsive effort may cause strain of the pelvic structure and even induce partial or total ruptures of the PF components, causing several types of lesions and functional harm.<sup>3</sup>

Therefore, to avoid lesions in the region and keep the maximum of its ligament and muscle functions, we understand that the pelvic floor muscles (PFM) need to be tonic to sustain the baby during pregnancy, although they also need to be elastic to stretch during delivery adequately.<sup>4</sup> For tonicity, the Kegel protocol can be used to exercise the perineal musculature and work their hypotonia, while for elasticity, there are other strategies, e.g., vaginal balloons, such as Epi-No.<sup>5,6</sup>

Epi-No is a vaginal dilator formed by an inflatable silicone balloon connected to a pressure gauge and a hand pump so that, when pressed, it provides compressed air that makes the balloon grow and expand. It is believed that this expansion, within the tolerance threshold of each woman, causes an elongation of the perivaginal and perineal structures, which, in turn, would favor the passage of the fetus through a greater distention of the birth canal. It also aims to train the mother for the expulsion phase, having the potential to reduce the time in this stage of labor and, consequently, the necessity of using analgesics for pain relief.<sup>7</sup>

The effectiveness of this tool to extend the vaginal canal during pregnancy has already been observed<sup>6</sup> without changing the resistance of the PFM. However, there are few data and studies regarding the implications on urinary and sexual functions, so that an explanation about these aspects would be

enriching for the academic and professional context, as well as for the puerperal women themselves, as it would increase the array of available resources for quality preparation for delivery.

As such, this study aimed to evaluate the implications of the vaginal balloon on the sexual and urinary functions of puerperal women that used it as a preparation for delivery.

## Material and methods

This is a cross-sectional observational study approved by the Ethics Committee for Research with Human Beings of the Center of Biological and Health Sciences of the University of the State of Pará (CAAE: 09087419.8.0000.5174, Report No. 3.333.014), conducted in the Physical Therapy clinic CAFISIO Mulher and the Centro de Saúde Escola do Marco (CSE-Marco), both in Belém, Pará, Brazil.

Data collection occurred from September 2019 to October 2020 and targeted primiparous puerperal women who had a vaginal delivery and did or did not use a vaginal balloon during pregnancy. Therefore, we formed two groups: EG (Experimental group) and CG (Control group). EG consisted of puerperal women that used the vaginal balloon during pregnancy and were selected at the clinic Cafisio Mulher. In contrast, CG consisted of primiparous puerperal women that did not use a vaginal balloon during pregnancy and were selected at the CSE-Marco.

Sampling was by convenience, so that, for the EG group, we consulted a list of women of CAFISIO-Mulher that prepared for vaginal delivery with a vaginal balloon, and we selected those that fitted the inclusion criteria of the study. Afterward, we contacted the women by telephone and invited them to participate in the study, and those who accepted should go to the clinic for evaluation. For CG, the puerperal women were approached while waiting for their appointment at the CSE-Marco, and those that accepted were referred to a private room to apply the questionnaires.

We included in both groups primiparous puerperal women aged 18 to 40 so that EG included those that used the vaginal balloon during pregnancy for vaginal delivery, and CG included those that did not use it. We excluded from both groups puerperal women who had a risk of multiple pregnancies.

Both groups answered a sociodemographic evaluation form created by the researchers and a questionnaire with questions about the events during labor. To evaluate the urinary function, we used the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF), which is a simple, brief, and self-manageable questionnaire consisting of two identification questions, three questions about the amount and frequency of urine loss, and one question about the situations in which urine loss occurs, so that the higher the score, the more is the urinary function compromised.<sup>8</sup>

Finally, to investigate the sexual function of the puerperal women, we adopted the Female Sexual Function Index (FSFI), responsible for evaluating the sexual desire, arousal, vaginal lubrication, orgasm, satisfaction, and pain. The scores of each domain are summed up and multiplied by a factor that homogenizes the influence of each domain. In the end, the total score is reached (Chart 1), in which the higher the value, the better the function, with 26.55 being considered the cut-off score for the presence or not of sexual dysfunction.<sup>9</sup>

**Table 1.** Scores according to the FSFI

Domain	Question	Score variation	Factor	Minimum score	Maximum score
Desire	1,2	1 – 5	0.6	1.2	6.0
Arousal	3, 4, 5, 6	0 – 5	0.3	0	6.0
Lubrication	7, 8, 9, 10	0 – 5	0.3	0	6.0
Orgasm	11, 12, 13	0 – 5	0.4	0	6.0
Satisfaction	14, 15, 16	0 (or 1) – 5*	0.4	0.8	6.0
Pain	17, 18, 19	0 – 5	0.4	0	6.0
Total score				2.0	36

\*Variation for item 14 = 0–5; for items 15 and 16 = 1–5.

The vaginal balloon used during pregnancy was the model Epi-No, used from 32 weeks until delivery, once a week for 5 to 10 minutes, in practice with a physical therapist. The balloon was gradually inflated until a diameter of 0.5 to 1 cm on average in each session. The were women trained with the balloon in dorsal decubitus until the 35th week and bipedestation until delivery (protocol of Cafisio Mulher).

We used the software Excel for data input, table preparation, and descriptive statistical analysis of the variables, which were presented through relative frequency and central tendency measures (mean).

## Results

Fifteen puerperal women participated in the study, 4 in the EG group and 11 in the CG group. Table 1 presents the sociodemographic profile of the sample, highlighting a mean age of  $36.5 \pm 5.0$  years for the EG and  $28 \pm 6.7$  years for the CG. In both groups, most participants were married, had some occupation, and had eight or more years of formal education (Table 2).

**Table 2.** Sociodemographic profile of the sample

Variables	Relative frequency	
	GE (n=4)	GC (n=11)
<b>Age (Mean and SD) in years</b>	36.5 ± 5.0	28 ± 6.7
<b>Marital status</b>		
Single	-	20.0%
Married	100.0%	60.0%
Divorced	-	20.0%
<b>Occupation</b>		
Liberal professional	75%	54,5% <sup>o</sup>
Autonomous	25%	18.1%
Student	-	18.1%
Formal work		27,3%
<b>Religion</b>		
Catholic	72.7%	27,3%
Evangelical	9.1%	36,4%
Others	18.2%	36,4%
<b>Color</b>		
White	12.5%	8,3%
Brown	50.0%	50,0%
Yellow	37.5%	25,0%
Black	-	16,7%
<b>Education level</b>		
Complete High School	-	56,0%
Incomplete undergraduate	-	20,0%
Complete undergraduate	46,2%	24,0%
Graduate	53,8%	-

(-) Numerical data equal to zero.

In the obstetric history of the participants, we observed that most did not suffer any abortion, having had only one pregnancy. All had prenatal care, with a mean of 9.06 appointments. However, we observed a great disparity between both groups regarding preparation with a physical therapist because while 100% of the EG had some sort of physical therapy preparation, the opposite occurred with the CG (Table 3).

**Table 3.** Obstetric history of the sample

Variables		Relative frequency	
		GE (n=4)	GC (n=11)
<b>Abortion</b>	Yes	33.3%	9.1%
	No	66.7%	90.9%
<b>Number of pregnancies</b>	1	66.7%	90.9%
	2	33.3%	9.1%
<b>Number of weeks since delivery</b>	36 - 38	75.0%	54.6%
	39 - 42	25.0%	45.5%
<b>Prenatal appointments</b>	6-10	100.0%	9.1%
	11-14	-	15.2%
	30-43	-	18.2%
<b>Preparation with physical therapy</b>	Yes	100%	-
	No	-	100%
<b>If no, was there any other type of preparation?</b>	Yes	-	10.0%
	No	-	90.0 %
<b>Would you have prepared your body if you had the opportunity?</b>	Yes	-	100.0%
	No	-	-

(-) Numerical data equal to zero.

Table 3 highlights the events that occurred with the participants during labor. Regarding the use of episiotomy, we did not observe differences between both groups, as half of the participants of the EG were subjected to an incision during labor and, in the CG, episiotomy occurred in 6 women, a little more than 50%, so that the data were very similar in both groups. A discrepant variable was the position adopted during labor. Most women in the CG 8 (72.7%) delivered in the conventional position of dorsal decubitus with flexed legs, but vertical postures, such as sitting/reclined or squatting, were also recorded. On the other hand, 100% of the EG adopted the dorsal decubitus position.

**Table 4.** Events of the sample's labor

Variables	Relative frequency	
	GE (n=4)	GC (n=11)
<b>Weeks of pregnancy</b>		
36	25.0%	9.1%
37	-	9.1%
38	50.0%	36.4%
39	25.0%	18.2%
40	-	9.1%
41	-	9.1%
42	-	9.1%
<b>Episiotomy</b>		
Yes	50.0%	54.5%
No	50.0%	45.5%
<b>Position during labor</b>		
Lying on one's back with raised legs	100.0%	72.7%
Sitting/reclined	-	18.2%
Squatting	-	9.1%

Regarding the urinary function of the participants, in both groups, most women experienced some urine loss. However, it is important to mention that most of the records of urine loss correspond to only small amounts according to the participants' perception, a situation that was similar in both groups. However, although urine loss seemed to be similar between groups, the repercussion was very heterogeneous, as 100% of the EG stated that these events did not affect their life (no impact), while 45.5% of CG reported suffering from this scenario, with a mean of 7.45, which is a severe impact (Table 5).

**Table 5.** Urinary function of the sample

Variables	Relative frequency	
	GE (n=4)	GC (n=11)
<b>Frequency of urinary loss</b>		
Never	25.0%	27.3%
Once a week or less	50.0%	36.4%
Two or three times a week	-	9.1%
Once a day	25.0%	18.2%
All the time	-	9.1%
<b>Amount of urinary loss</b>		
None	25.0%	27.3%
A small amount	75.0%	63.6%
A large amount	-	9.1%
<b>Situations in which loss occurs</b>		
Never	25.0%	27.3%
Before I reach the toilet	-	18.2%
When I cough or sneeze	50.0%	45.5%
When I am doing physical activities	25.0%	-
<b>How much this loss affects life - mean</b>	0	7.45
<b>ICIQ-SF score - mean</b>	2.75	4.27

Regarding sexual function, the mean general score for women who used the vaginal balloon was 22.3, while that of women who did not use the device was 24.3. Thus, both groups are below the cutoff point, which is >26.55. Regarding the general score of each participant, 46.6% of the women had a score below the cutoff point, which indicates sexual dysfunction (Table 6).

**Table 6.** Mean of the scores per domain and total of the questionnaire FSFI

Domains	Mean of each domain	
	GE (n=4)	GC (n=11)
Desire	3.9	4.41
Arousal	3.45	4.17
Lubrication	4.27	4.8
Orgasm	2.8	4.47
Satisfaction	2.6	4.94
Pain	4.4	4.69
Mean total score	22.3	24.3

## Discussion

This study aimed to verify the influence of the vaginal balloon, used in preparation for delivery, on the urinary and sexual function of primiparous women. In general, there was no influence of the vaginal balloon on the urinary and sexual outcomes of primiparous women that used it concerning those that did not use it.

Urinary incontinence (UI) is a frequent phenomenon during pregnancy, with an estimated occurrence of about 75%, but it can vary according to the study type and investigated period and the socio-cultural characteristics of a population.<sup>10</sup> Supporting this argument, in the study of Santini et al.<sup>11</sup>, of the 950 interviewed women, 472 reported some urine loss, indicating a prevalence of 49.68% of UI.

UI can affect women of all ages, but its incidence tends to increase with age, which may be related to the weakening of the PF and the bladder structures, as aging leads to a reduction in the number of collagen fibers and a decrease in hormone levels.<sup>12</sup> In our work, although the women in the EG were older and 75% of them had UI, in the CG, the youngest puerperal women experienced episodes of urine loss, while some older women never lost urine.

Regarding sexual function, Faisal-Cury et al.<sup>13</sup> stated that postpartum brings clear physical and psychological changes, and not all women adapt positively to them. One proof is that, in their study, two-thirds of the women experienced a significant reduction of sexual function six months after vaginal delivery.

Primiparous women tend to have a greater disturbance in orgasm, which may be explained by a weakening of the PFM either during pregnancy or during labor, leading to sexual dysfunctions such as hypoesthesia and anorgasmia.<sup>14</sup> This reality was found in the sample evaluated in our work, especially among the women that used the balloon, who had this dysfunction as the second most common complaint, the first being about satisfaction, while dyspareunia was not frequent. In the CG, the most prevalent dysfunctions were related to desire and arousal. Holanda et al.<sup>15</sup>, in a study with 200 puerperal women, also identified dyspareunia with higher frequency, followed by vaginismus, desire dysfunction, orgasm dysfunction, and, finally, dysfunction in the arousal phase.

Vaginal delivery can have a negative impact on the sexual function in the puerperium, mainly due to the occurrence of spontaneous tears and episiotomy.<sup>16</sup> This relationship between the presence of dyspareunia, instrumental delivery, second- and third-degree spontaneous tears, episiotomy, and sexual dysfunction was observed by O'Malley et al.<sup>17</sup> in their cohort work with 832 primiparous women.



Pelvic physical therapy has effective strategies for restoring PF functionality due to changes promoted by pregnancy and postpartum. In the study of Marques et al.<sup>18</sup>, the training of the PFM was compared in nulliparous women during the 28th week of pregnancy and puerperal women. They found a greater reduction in urinary urgency and frequency, nocturia, and urgency UI in the group of pregnant women and concluded that physical therapy, especially when applied early, promotes positive results in both muscle function and sexual and urinary functions.

It is important to mention that the stretching of the perineal region does not seem to prevent incontinence or sexual dysfunctions, but it can have a relevant role in preventing tears during labor. Thus, dilators of the vaginal balloon type, such as Epi-No, were designed to gradually increase the diameter of the perineum in the final phase of pregnancy to reduce perineal trauma and indiscriminate episiotomy.<sup>19</sup>

Similarly, Kok et al.<sup>21</sup> conducted a study with 31 primiparous women who used Epi-No in the prenatal period, starting at the 37th week and for 15 minutes, and compared it to 60 women who did not use the device. At the end of the study, it was observed that the group that used the vaginal balloon had a significantly smaller episiotomy rate (50% vs. 93.3%), besides a less severe extension of the tear, which in turn has an important influence on the reduction of urinary and sexual repercussions.

As a limitation of our study, we highlight the small sample, which did not allow for more robust analyses. There was also no control of other factors that interfere in the sexual and urinary function, such as the mother's age, fetus weight, obesity, and chronic diseases. Another limitation was the protocol of use of the vaginal balloon performed by the GE group, which is not validated. Thus, we suggest that future studies compare groups with pelvic floor preparation, including a group that only used the balloon, a group isolating another technique, such as perineal massage, and a third group combining both techniques, to observe their effects on the sexual function of women, especially using larger samples.

## Conclusion

In our study, there were negative repercussions in the urinary and sexual functions of puerperal women in both groups, without significant influence of the vaginal balloon on the urogynecological outcomes of the participants, which the small sample size can justify.

## Authors' contributions

Latorre GFS was responsible for the conception and design of the research. Fernandes CA, Cavalcante IL, Araújo NS were responsible for data collection and writing of the scientific article. Soares ACN was responsible for the literature review. Serrão CCA was responsible for analyzing the results. Almeida PSM, Nunes EFC were responsible for reviewing the article.

## Competing interests

No financial, legal, or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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