

Short review

Reviewing the Impact of Antenatal Pelvic Floor Training Using a Novel Vaginal Balloon Device on the Childbirth-Related Health Outcomes in Czech Women

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Abstract

Vaginal delivery is a known risk factor for various negative outcomes significantly influencing both short-term and long-term aspects of women's health. Many methods and techniques mitigating these negative outcomes are being studied. Vaginal balloon devices designed for antenatal training are among these methods. In our study, we prospectively examined the effects of antenatal training with the Aniball® device in nulliparous women with cephalic vaginal delivery at term on several defined outcomes - primarily, the Levator Ani Muscle (LAM) avulsion rate and secondarily, the episiotomy rate, any perineal tear rate and the duration of the second stage of labor. Except the episiotomy rate, which was significantly reduced among women training with Aniball® in comparison with women who did not train ($p = 0.007$; RR 0.58, 95 % CI 0.39-0.86), the use of Aniball® was not associated with a significant difference in any other outcome.

Keywords: Aniball; Avulsion; Birth trauma; Childbirth; Levator ani muscle; Pelvic floor

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Introduction

Vaginal birth is an established risk factor for pelvic floor trauma [1,2]. This trauma may be defined as the macrotrauma of the Levator Ani Muscle (LAM) - avulsion from the inferior pubic ramus - or microtrauma - irreversible LAM overdistension [2]. Pelvic floor trauma is most frequently caused by LAM overdistension during the second stage of labor, primarily affecting the pubococcygeus muscle [1,3]. The incidence of LAM avulsion ranges between 10 and 35 % based on the current literature [2,4]; the use of forceps significantly increases the risk involved [5]. In terms of additional risk factors, LAM avulsion is associated with obstetric anal sphincter injury, prolonged second stage of labor [4] or the application of pressure on the uterine fundus during the second stage of labor known as the Kristeller expression [6].

Both LAM macro- and microtrauma represent serious long-term health issues for the affected women. Mainly LAM avulsion contributes to the development of Pelvic Organ Prolapse (POP): 55 % of women with POP have identifiable LAM avulsion compared to 16 % of women with normal pelvic organ support [7]. In addition to its impact on women's health and quality of life, POP is also one of the most common indications for surgery. In countries of the Organization for Economic Cooperation and Development, an average of 14 women out of 10,000 undergo POP surgery each year; this number translates to approximately 7,000 annual operations in the Czech Republic alone [8]. Given the significant health and economic impacts, preventive measures designed to reduce the incidence of LAM avulsion and the associated risk factors are thus needed.

This short review aims to summarize our last publication entitled "Investigating antenatal pelvic floor training using a vaginal balloon device in Czech women", which presented the effects of antenatal pelvic floor training using a novel vaginal balloon device, Aniball®, on several childbirth-related women's health outcomes [9]. Primarily, the Levator Ani Muscle (LAM) avulsion rate and secondarily, the episiotomy rate, any perineal tear rate and the duration of the second stage of labor.

Materials and methods

This was a prospective cohort intervention study, in which a total of 200 nulliparous women at their 32nd week of gestation were originally enrolled. 100 women were enrolled in the intervention group, hereinafter referred to as "cases", and provided with the Aniball® device along with written instructions (manual) for use from 36 weeks of gestation while 100 women did not use the device (i.e., the control group, hereinafter referred to as "controls"). It was not a randomized controlled trial, women were assigned to each group based on their personal preferences towards training with Aniball®. The only exclusion criterion for study inclusion was the existence of a personal history of pelvic injury, e.g., following a car accident.

The clinical staff taking care of women in labor were blinded to the women's participation in the study and participants were explicitly instructed not to mention this fact. No additional restrictions were implemented. After completing the six weeks postpartum period all women were contacted by phone and basic information about their

births was established (type of birth, gestational age at birth, spontaneous or instrumental birth). Of these, only women who self-reported their birth as vaginal with cephalic presentation after week 37 + 0 without the use of a vaginal extraction method were selected for further analysis.

A total of 123 women in both study groups (64 women who had exercised with Aniball® device prior to birth - “case” group - and 59 women who had not - “control” group) who met the inclusion criteria for further analysis received a translabial ultrasound examination of the pelvic floor in the lithotomy position 10 weeks after birth; clinical data associated with birth were recorded.

Results

There were no statistically significant differences observed in the means of obstetric characteristics and pregnancy pathologies between the two groups of women included for further analysis. Primarily, no difference in the rate of LAM avulsion was identified between women who had used the Aniball® device and those who had not ($p = 0.82$). Secondly, no difference in the duration of the second stage of labor was found between women who had used Aniball® and those who had not ($p = 0.63$). Women who had used Aniball® had a lower number of episiotomies than those who had not [cases: 34 % (22/64) vs. controls: 59 % (35/59); $p = 0.007$; RR 0.58, 95 % CI 0.39-0.86]. There was no significant difference in the incidence of perineal tears ($p = 1.0$) as well as other birth injuries not defined as perineal tears ($p = 0.50$) observed. An obstetric anal sphincter injury occurred only in one case (grade 3A) among women not using Aniball®.

Discussion

In the context of what is known there is only one other vaginal balloon device that has been studied in several clinical trials [2,10-15]. Although results of the first trials had shown benefits of antenatal training in regard to pelvic floor trauma [10,15], no protective effect was confirmed in more robust randomized controlled trials [2,13]. Similar situation occurred in the matter of the duration of the second stage of labor - firstly positive [10], then negligible benefits [2,16] or the perineal injury rate - also initially positive [11,12], then negligible effects [2,14].

The Aniball® device showed no benefit in regard to the LAM avulsion rate, the duration of the second stage of labor or any perineal tear rate. Nevertheless, the association between its use and the episiotomy rate reduction observed in this study was in line with previously published data [17]. Our study has laid an important groundwork for better understanding the relationship between the use of vaginal balloon devices, vaginal delivery and its outcomes as well as significant background information for further research with respect to the Aniball® device.

Conclusion

The antenatal use of Aniball® in nulliparous women with cephalic vaginal birth at term is not associated with better pelvic health outcomes or shortening the duration of the second stage of labor. However, the antenatal use of Aniball® might reduce the frequency of episiotomies. Further research based on more robust trials is needed to confirm these results.

Conflict of Interest Statement

The authors declare that they have no conflict of interests.

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