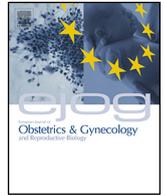




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Can we define excess vaginal space? - Genital hiatus size and prolapse severity are correlated with cube pessary size

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ABSTRACT

Objective: Prior studies demonstrated a positive association between increased genital hiatus (GH), advanced prolapse stage and levator ani muscle injury. Moreover wide GH is an established risk factor for recurrent pelvic organ prolapse (POP). Since excess vaginal space is not yet a dimension to estimate in Pelvic Organ Prolapse, we hypothesized that excess vaginal space has a positive correlation with increased GH and could be a new aspect for the assessment of the severity of POP and underlying pelvic muscle damage. We attempted to quantify excess vaginal space by different volumes of different cube pessary sizes.

Study design: In a prospective study, 716 symptomatic POP patients without any prior operations were enrolled from January 2011 to December 2017. All patients suffered from stage 2 POP or greater, where either the anterior, middle or posterior compartments or combinations of these were affected. As a conservative self-therapy, space-filling (Dr. Arabin[®]) cube pessaries were fitted. The size of each was individually adapted for each woman. For data analysis we used Spearman correlation test and Nonparametric statistical test.

Results: All patients included in the study were asymptomatic one week after fitting the pessary. We revealed a positive significant correlation between the genital hiatus (GH) and the size of the cube pessary ($\rho = 0.777, p \leq 0.001$). We also found a positive significant correlation between the size of the cube pessaries and the POP-Q stage. We also managed to find significant differences between cube pessary sizes and corresponding GH values.

Conclusions: Cube pessary sizes may indicate the amount of excess vaginal space. Since excess vaginal space significantly correlates with the increase of the genital hiatus, it could be considered - as well as GH - as a marker for advanced prolapse stage, and a risk factor for the recurrence of pelvic organ prolapse. More studies are needed to identify factors related to excess vaginal space.

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Introduction

Pelvic organ prolapse (POP) is a relatively common disease; it is described as a loss of anatomical support of the pelvic organs

Abbreviations: POP, pelvic organ prolapse; GH, genital hiatus; POP-Q, pelvic organ prolapse quantification system; IUGA, International Urogynecological Association; ICS, International Continence Society; SD, standard deviations; SEM, standard error of the mean.

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leading to the partial, or total downward displacement of the uterus and/or the different vaginal compartments and their neighboring organs such as bladder, rectum, or bowel into the vagina [1]. In the pathogenesis of the disease, several risk factors play a role, including menopause, genetic factors, chronically increased intraabdominal pressure, joint hypermobility and particularly obstetric pelvic floor trauma [2]. The positive associations between advanced prolapse stage, increased genital hiatus (GH), and levator ani muscle injury are well established [3–8]. Even though the pelvic organ prolapse quantification system (POP-Q) contains 9 objective parameters to assess defects [9], only GH was found to correlate with pelvic floor muscle injury [3,6]. Excess vaginal space is not yet a dimension for POP estimation. We hypothesized that excess vaginal space might be a new parameter to objectively assess the severity of POP and the underlying pelvic

muscle damage. Our assumption is based on observations that maximal normal vaginal space correlates with the volume of a full sanitary tampon (20 cm³); a larger intravaginal object in nulliparous women without POP leads to discomfort. If a patient with symptomatic POP feels comfortable with a dense, space-filling pessary, the difference between the volume of the pessary and the volume of a full sanitary tampon should be the excess volume of the vagina. Although the vaginal space is hard to determine—since the vagina does not have a rigid wall, therefore its size and volume are not constant—we aimed to objectively assess the extra vaginal space in POP with the help of different size and volume cube pessaries and find the correlation between the excess vaginal space and the increased GH measurements.

Materials and methods

Study population and data collection

This study was approved by the University of Pecs Institutional Ethical Review Board. In a prospective cohort study, 716 women suffering from symptomatic POP without any prior operations and who were intended to be treated with space filling cube vaginal pessary, as a first-line treatment were enrolled. Conservative therapy should be the first line option for all women with POP, since surgical treatment incurs the risk of complications and recurrence [10]. According to this recommendation, we advised our patients to try the pessary therapy as a first line treatment option, although at the same time, we also clarified the options for surgery, however the final decision was mainly related to the patient's preference.

The participants in the study were seen in an outpatient counselling setting in a private clinic at Győr, Hungary (Ladypower) from January 2011 to December 2017. All patients provided their written informed consent to participate. All women included in the study suffered from stage 2-or-higher POP of the anterior, middle or posterior compartment, or any combinations of those compartments. All patients reported a sensation of a bulge in the vagina with or without symptoms of urinary, bowel, or sexual dysfunction. Patients with active infections of the pelvis or vagina, such as vaginitis or pelvic inflammatory disease, patients who didn't use the fitted pessary after one week and patients who were noncompliant—including those who were not able to remove and reinsert the cube pessary on their own—or unlikely to follow up were excluded.

Baseline demographic data, parity, method of delivery, medical history and BMI were recorded.

All women were examined according to the International Urogynecological Association (IUGA) guidelines, and all terminology currently used refers to the recommendations of the International Continence Society (ICS). The level of pelvic anatomy alteration was assessed by using the pelvic organ prolapse

quantification system (POP-Q) [9]. During the study period, space-filling (Dr. Arabin[®]) cube pessaries were fitted. The sizes of the pessaries were 0, 1, 2, 3, 4 and 5, which correspond to diameters of 25, 29, 32, 37, 41 and 45 mm, respectively (which corresponds to volumes of 15, 24, 30, 42, 60 and 84 cm³). The size was individually adapted for each woman. Each pessary was large enough to resolve POP symptoms but small enough to avoid discomfort as previously described [11].

Statistical analysis

Statistical analyses were performed by using IBM SPSS Statistic 20 (IBM Corporation, Armonk, NY, USA) at the University of Pecs, Institute of Bioanalysis. The sample size (n) was 716. Continuous measurements were summarized and presented as averages and standard deviations (SD), while categorical data was presented as observed or as percentages. To determine the correlation between the pessary size and GH, PD—demographic parameters Spearman's rank correlation coefficient—was used. Mean data were reported ± standard error of the mean (SEM). For the independence analysis between the categorical variables, Fisher's exact test was performed. Statistical significance was set at $p < 0.05$, or $p < 0.1$.

Results

Demographic data

Seven hundred sixteen patients underwent insertion of pessaries due to symptomatic POP. The average age was 49 years ± 13 (min: 22, max: 85), and the mean parity per patient was 1.97 ± 0.78 (min: 0, max: 7) (Table 1). The study population had average weight and height, resulting in a mean BMI of 24.67 ± 3.62 kg/m² (min: 15.62; max: 39.06).

Correlation analysis between variables

The subjective symptoms of POP have decreased in all patients, and all patients reported themselves symptomless one week after the primary fitting. Spearman's correlation analysis found a significant positive correlation between the GH measurement and POP-Q stage ($\rho = 0.346$, $p \leq 0.001$). We found that as prolapse increases, GH measurements also increase until stage 4 prolapse, where mean GH is increased, although not significantly (Fig. 1A). In nulliparous women, the GH did not change significantly with increasing prolapse stage. We also calculated a positive significant correlation between the size of the cube pessary and the genital hiatus (GH) ($\rho = 0.777$, $p \leq 0.001$). Moreover, significant differences were noted between the GH measurements and the cube pessary sizes ($p < 0.01$; Fig. 1B). We revealed a positive significant correlation between the size of the cube pessaries and the total

Table 1
Demographic data of patients fitting various space-filling vaginal cube pessaries.

Variables	Vaginal cube pessary size (mean ± SD)					
	Size 1 (n = 128)	Size 2 (n = 256)	Size 3 (n = 268)	Size 4 (n = 56)	Size 5 (n = 8)	Sum (n = 716)
Age (years)	48 ± 4.66	48 ± 13	49 ± 12	51 ± 13	51 ± 8	49 ± 13
BMI* (kg/m ²)	24.21 ± .87	24.64 ± 3.67	24.71 ± 3.66	25.83 ± 3.30	24.56 ± 4.66	24.67 ± 3.62
Parity (n)	1.84 ± 0.87	1.96 ± 0.73	2.01 ± 0.76	2.06 ± 0.91	2.80 ± 0.83	1.97 ± 0.78
Vaginal delivery	1.78 ± 0.90	1.91 ± 0.74	1.99 ± 0.77	2.06 ± 0.91	2.80 ± 0.83	1.93 ± 0.79
Cesarean delivery	0.06 ± 0.26	0.05 ± 0.25	0.02 ± 0.17	0	0	0.04 ± 0.21
Macrosomic neonate (> 4000 g)	0.11 ± 0.51	0.02 ± 0.56	0.24 ± 0.58	0.23 ± 0.54	0	0.20 ± 0.56

* Body mass index.

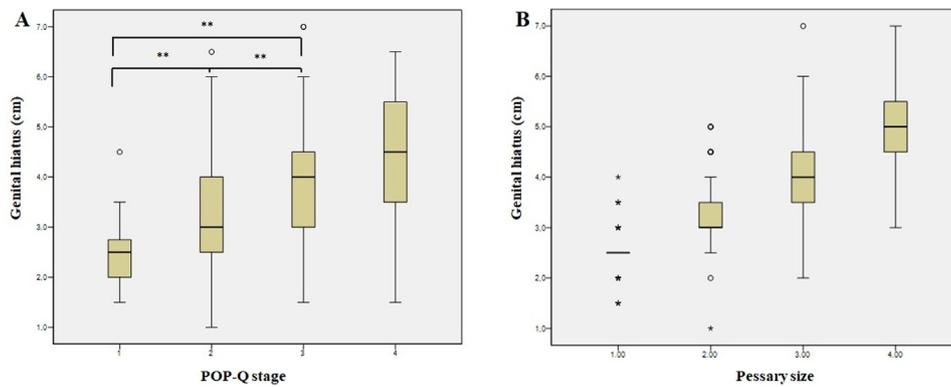


Fig. 1. Distribution of GH measurements (cm) and POP-Q stage (A), and GH (cm) and cube pessary size (B) with Kruskal-Wallis nonparametric test. In Fig. 1B, the data of women with pessary size 4 and 5 were pooled together due to the extremely low number of samples ($n = 8$) from the size 5 pessary group and demonstrated as group 4. In Fig. 1B, every group differed from each other significantly with p values of < 0.01 . On Fig. 1A, ** represents $p < 0.01$.

number of deliveries ($q = 0.086$, $p = 0.022$), as well as a positive correlation was found between the birth weight of the newborns ($q = 0.096$, $p = 0.011$) and vaginal parity ($q = 0.104$, $p = 0.004$). However, a negative correlation was revealed between the size of the cube pessary and caesarean delivery ($q = -0.083$, $p = 0.028$), confirmed by Spearman's correlation analysis. No correlation was observed between BMI and POP.

Discussion

To our knowledge, this is the first study which aims assessment of the dimension vaginal space in POP.

Vaginal space is something hard to standardize because the length and width of the non-muscular vaginal canal vary slightly for each person [12]. Not only that, but the size and shape are also dynamic and change throughout the cycle; the vaginal tissue can expand and then return to the same size. There are changes related to aging and childbirth, but the most notable changes are most likely due to alterations in the pelvic floor muscles [13]. Vaginal laxity and its correlation to pelvic floor musculature is also underlined from the perspective of sexual activity, due to the feeling of "tightness" during sex primarily being determined by the pelvic floor muscles around the vagina [14]. Moreover collagen disorders, such as joint hypermobility can also lead to laxity [2].

In the current study, we demonstrated vaginal cube pessaries are usable tools to appreciate the excess vaginal volume in pelvic organ prolapse. As excess vaginal space positive correlate with the increase of GH it could be a new, parameter for pelvic organ prolapse and for underlying pelvic muscle damage.

Our hypothesis was based on previously reported observations that there is a positive association between advanced prolapse stage, levator ani muscle injury and an increased GH [3,6]. Ghetti et al. demonstrated that GH measurements increase as prolapses increase. This finding is in contrast with PB measurements, which exhibited little or no change with advancing prolapse [6]. Moreover, increased GH measurements have been associated with levator ani muscle injury and pelvic organ prolapse on both clinical and ultrasound measurements [5–8].

In our current study, we found a positive significant correlation between cube pessary size and GH diameter, indicating that a higher GH measurement corresponded to a bigger cube pessary fit. As with Dunivan et al. [3], we too found that the GH did not change significantly in advanced prolapse stage in nulliparous women, and in these cases, a pessary size of 0–1 (16–24 mm³) was enough to meet the patients' needs.

In this study, we showed through the positive correlation between increased GH and excess vaginal space, that the latter

could be also correlated with levator ani muscle injury. This new information can be useful for the measurement of the effect of pelvic floor muscle rehabilitation. If the pelvic floor muscle rehabilitation is effective, the excess vaginal space will be decreased, as it was demonstrated previously, when complete recovery after severe postpartum genital prolapse was achieved after conservative treatment through the prospective downsizing of the cube pessary [15,16]. As wide GH is a well-established risk factor for recurrent pelvic organ prolapse [17,18], excess vaginal space could be a new one. Dietz et al. suggest that vaginal laxity may be considered a symptom of prolapse [18], although we believe that vaginal laxity could be the primary stage of POP based on our findings.

Strengths and limitations

The strengths of the study include its large population of more than 700 women examined due to stage 2 or more advanced POP. The prospective design of the study enabled us to reduce selection bias. Further advantages are the low study cost, blindly performed statistical analysis of all clinical data and a non-invasive approach.

The major limitation of our study is that the pelvic floor functional anatomy was only assessed by the POP-Q technique, and we did not use any imaging to evaluate levator ani injury. Instead, we concluded injury from the size of the genital hiatus; therefore, our plan is to measure the direct relationship between excess vaginal space and levator ani injury with 3D ultrasonography. Another limitation is that the study population consisted of Caucasian women, thus our results should not be extrapolated to the general population.

Conclusions

Cube pessary sizes may indicate the amount of excess vaginal space. Since excess vaginal space significant correlates with the increase of the genital hiatus, it could be consider - as well as GH - as a marker for advanced prolapse stage, and a risk factor for the recurrence of pelvic organ prolapse More studies are needed to identify factors related to excess vaginal space.

Authors' contributions

Z Nemeth: manuscript writing, project development, data collection.

N Farkas: statistical analysis.

B Farkas: project development, data analysis, manuscript writing/editing.

Declaration of Competing Interest

The corresponding author has multiple affiliations and has received financial support (salary) from the Hungarian Academy of Sciences (MTA), Budapest, Hungary. The remaining authors report no conflicts of interest with the present study.

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