

Levator hiatal ballooning prevalence in pelvic organ prolapse patients and its relation to levator ani muscle strength

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Abstract

Ballooning of the levator hiatus is a unique phenomenon of hyperdistention seen during the Valsalva maneuver in Pelvic Organ Prolapse (POP) patients. Although it is related to the weakness of pelvic floor muscles, there is only limited evidence of its effect on Levator Ani Muscle (LAM) strength, especially in Indonesia. The aim of this study was to describe the prevalence of levator hiatal ballooning in POP patients and its effect on LAM strength. A cross-sectional study was done on POP patients at Cipto Mangunkusumo National General Hospital, Jakarta, Indonesia, from July 2019 to June 2021. Subjects who could not perform the Valsalva maneuver or perineometer and those having a history of perineal rupture were excluded. Subjects were grouped into hiatal ballooning and non-ballooning group based on the maximum hiatal genital length measured using ultrasound examination. Clinical characteristics, hiatal ballooning status, and LAM strength were compared between groups. A total of 99 subjects (47 ballooning and 52 non-ballooning) were recruited during the study. The prevalence of hiatal ballooning in POP patients was 47.5%. There was significantly lower LAM strength in the ballooning group measured by perineometer ($p = 0.018$). There was a significant relationship between the perineometer result and Modified Oxford Grading Scale result in both groups ($p < 0.001$). Lower LAM strength was observed in POP patients with hiatal ballooning.

Introduction

The Levator Ani Muscle (LAM) is the most important component of the pelvic floor muscles because of its role in supporting the pelvic organs. The normal LAM have a constant contraction tone to support

the abdominopelvic organs except during micturition, defecation, and delivery. The strength of the LAM is critical in preventing stretching of the pelvic ligaments and fascia.^{1,2}

It is estimated that as many as 3% of all women in the United States complain of symptoms of vaginal bulging.³ However, there is a much higher prevalence of Pelvic Organ Prolapse (POP) detected by physical examination compared to the subjective complaints (41-50% vs 3-6%), suggesting a higher prevalence of POP in the community.³ A study in Indonesia showed as many as 15.4% of patients experienced levator ani weakness at 3 months following vaginal delivery.⁴

Ballooning of the levator hiatus is a phenomenon in which there is an excessive distensibility of the levator hiatus seen during the Valsalva maneuver. Many instruments are used in assessing hiatal ballooning, such as clinical examination based on Genital hiatus plus Perineal body (Gh+Pb) values or maximal levator hiatus length measured using Pelvic Organ Prolapse Quantification (POP-Q) examination or ultrasound imaging.^{1,5} The overdistension is thought to be a factor further weakening the strength of the levator and pelvic floor muscles. Moegni *et al.* (2021) found lower levator ani contraction strength in POP patients compared to general patients.⁶ One of which factors causing the muscle weakness was thought to be hiatal ballooning.⁶ However, only a few cases of POP are complicated by levator hiatal ballooning. Moreover, clinicians in regions with limited infrastructure may have difficulties in measuring the levator ani contraction strength due to the absence of a perineometer, thus relying on digital examination.⁷ It is especially important in Indonesia which has many underdeveloped regions. As of today, the incidence of ballooning in POP cases has never been studied in Indonesia before.

This study aims to describe the prevalence of levator hiatal ballooning in POP patients and its effect on LAM strength.

Materials and Methods

This study was a cross-sectional study done to determine the prevalence of levator hiatal ballooning and its effect on LAM strength measured by perineometer and digital examination in Cipto Mangunkusumo National General Hospital, Jakarta, Indonesia from July 2019 to June 2021.

The inclusion criteria for this research were all POP patients aged ≥ 18 years old, examined with ultrasound examination, per-

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Key words: Levator ani muscle strength; levator hiatal ballooning; pelvic organ prolapse; perineometer.

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Availability of data and materials: The data used in this study may be requested from the corresponding author upon reasonable request.

Conflict of interest: The authors have no conflict of interest to declare.

Ethics approval and consent to participate: The present study had been approved by the Research Ethics Committee of Faculty of Medicine, University of Indonesia with ethical clearance letter number KET-398/UN2.F1/ETIK/PPM.00.2/2022. All patients who were included in this study had given informed consent prior to the study.

Informed consent: Written informed consent was obtained from the Research Ethics Committee of the Faculty of Medicine, University of Indonesia for anonymized patient information to be published in this article.

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ineometer, and digital palpation. Subjects with other gynecologic problems such as anatomical deformity could not be examined using a perineometer probe, or could not perform the Valsalva maneuver were excluded from the study. The subjects were consecutively recruited into the study.

The subjects were examined using ultrasound examination (Voluson® 10, GE Healthcare, USA) for POP characteristics. The degree of POP was measured according to the Pelvic Organ Prolapse Quantification

(POP-Q) system. Perineometer used in this study was Peritron™ (Peritron™, Cardio-Design, Australia) hand-held clinical biofeedback Perineometer with a range of pressure of 0 to 300 cmH₂O. Digital palpation for LAM strength was done using the Modified Oxford Grading Scale (MOS) criteria with the interval limit being 0 and 5.^{7,8} A single urogynecologist acted as the evaluator for all subjects in this study.

The subjects were grouped into ballooning or non-ballooning group. Levator hiatal ballooning was defined as having either a maximum hiatal genital area of ≥ 25 cm², Gh+Pb (genital hiatus + perineal body) length of ≥ 7.0 cm, or hiatal AP length of ≥ 6.0 cm on POP-Q examination.

This study followed the Guidelines for Good Clinical Practice and had been approved by the Research Ethics Committee of the Faculty of Medicine, the University of Indonesia with ethical clearance letter numbered KET-398/UN2.F1/ETIK/PPM.00.2/2022. All patients included in this study were provided with informed consent before the study.

Collected data were then analyzed using SPSS for Macintosh ver. 25. Characteristics of subjects and examination results were analyzed descriptively. This study used a 5% error bound and 95% confidence interval limit, with the power of the test considered to be 90%. The difference in LAM strength between study groups was analyzed using either an unpaired t-test or Mann Whitney U test. Correlation between examinations was calculated using the Spearman test.

Results

During this study, a total of 110 subjects POP subjects came to the study location and were consecutively recruited. However, a total of 11 subjects were excluded due to their inability to perform the Valsalva maneuver. Therefore, 99 subjects were included in the study, consisting of 47 ballooning and 52 non-ballooning subjects, resulting in the prevalence of ballooning in this study being 47.4%. The baseline characteristics of subjects in this study can be found in Table 1.

Following the baseline characteristics analysis, the LAM strength of each subject was measured using both a perineometer and digital palpation. The results of the analysis can be found in Table 2 and Figure 1. Based on the analysis, lower muscle strength was observed in the ballooning group on measurement using a perineometer ($p = 0.018$). However, there was no difference in measurement using digital palpation ($p = 0.282$).

Based on the analysis, the LAM contraction strength is weaker in patients with more severe form of ballooning. The muscle contraction strength for each hiatal ballooning grade could also be found in Table 3. Furthermore, the correlation between LAM strength measurement using both perineometer and digital palpation was compared, both in all subjects, ballooning group, and non-ballooning group. The results can be observed in Table 4.

Based on the analysis, it could be observed that there was a significant correlation between perineometer and digital palpation measurement results in all subjects, ballooning group, and non-ballooning group. However, a lower perineometer

result was observed in the ballooning group compared to the non-ballooning group.

Discussion

A total of 47.4% prevalence of levator hiatal ballooning was observed in this study. There are limited studies on the prevalence of levator hiatal ballooning. Dietz et al (2008) reported that 32% of women with prolapse symptoms complained of a bulging sensation.¹ Meanwhile, there were no other studies with levator hiatal ballooning prevalence analysis using clinical measurements. However, the high prevalence in this study signifies that many women are suffering from levator hiatal ballooning. Therefore, prompt diagnosis and treatment are essential.

Previously, Dietz *et al.* (2008) first introduced the “ballooning” term through pelvic floor ultrasound imaging.¹ Afterward, a prior study by Khunda *et al.* (2012) showed that the occurrence of levator hiatal ballooning might be diagnosed by clinical (digital) examination.⁹ Previous studies by Moegni *et al.* (2021) had also shown that the use of LAM strength might also be beneficial for determining the degree of injury for those having levator hiatal ballooning.⁶ These studies show that early diagnosis of levator hiatal ballooning, even using only clinical examinations, is a feasible option.

In this study, we can conclude that there was lower LAM strength observed in the ballooning group. Furthermore, the muscle strength is lower the higher the grade of levator hiatal ballooning. A study by Taylor *et al.* (2020) using a pelvic floor muscle model found that the size of the levator hiatus

Table 1. Baseline characteristics of the subjects.

Variables	Ballooning (n = 47)	Non-ballooning (n = 52)	p
Age (years)	62 (35-79)	64 (45-77)	0.214*
Parity (%)			0.438**
Nulliparous	0	1 (1.9)	
Primiparous	5 (10.6)	3 (5.8)	
Multiparous	42 (89.4)	48 (92.3)	
POP degree (%)			0.306**
1	3 (6.4)	6 (11.5)	
2	6 (12.8)	9 (17.3)	
3	15 (31.9)	21 (40.4)	
4	23 (48.9)	16 (30.8)	
Largest birth weight (grams)	3.300 (2.500-4.200)	3.400 (2.500-4.200)	0.960*
Levator avulsion (%)			0.103**
Yes	3 (6.4)	0	
No	44 (93.6)	52 (100)	

* Mann Whitney U test, ** Chi-square test.

Table 2. LAM contraction strength.

Measurement	Ballooning (n = 47)	Non-ballooning (n = 52)	p
Perineometer (cmH ₂ O)	14.8 (0 – 47.7)	20.9 (0 – 68.3)	0.018*
MOS	2 (0-4)	2 (0-4)	0.282*

* Mann Whitney U test.

Table 3. LAM strength of different ballooning grade.

Ballooning grade	Perineometer result	p*
Mild (n = 9)	20.9 (3.7 – 47.7)	0.002
Moderate (n = 15)	16.35 (8.8 – 39.0)	0.002
Marked (n = 36)	11.55 (0 – 17.2)	0.002
Severe (n = 39)	4.1 (0 – 26)	0.002

* Kruskal Wallis test

Table 4. Correlation between Perineometer and Digital Palpation.

Digital palpation	All subjects Perineometer result (cmH ₂ O)	r (p-value)	Digital palpation	Ballooning group Perineometer result (cmH ₂ O)	r (p-value)	Digital palpation	Non-ballooning group Perineometer result (cmH ₂ O)	r (p-value)
0	0 (0 – 2.32)	0.683	0	0 (0 – 2.32)	0.594	0	0 (0 – 0)	0.746
1	10.7 (3.7 – 16.9)	(p < 0.001)	1	8.3 (3.7 – 16.9)	(p < 0.001)	1	12.2 (4.3 – 13.6)	(p < 0.001)
2	16.2 (1.2 – 68.3)		2	16.2 (2.8 – 35.67)		2	17.1 (1.2 – 68.3)	
3	30.9 (0 – 53)		3	24.4 (0 – 47.7)		3	31.1 (12.4 – 53.0)	
4	41.5 (37.1 – 61.5)		4	49.0 (37.1 – 43.1)		4	51.2 (39.2 – 61.5)	
5	N/A		5	N/A		5	N/A	

affects the strength of pelvic floor muscle contraction.¹⁰ Using the same amount of force, the strength of pelvic floor muscle contraction would be lower in the population with a large levator hiatus than in the population with a small levator hiatus. This phenomenon would result in lower measurement results on the perineometer. Therefore, smaller levator hiatus size is associated with stronger pelvic floor muscle contractions.¹⁰ There is a significant correlation between the LAM strength measurement using both digital and perineometer on all groups. Moreover, a lower perineometer result was observed in the ballooning group compared to the non-ballooning group. The result in this study is in accordance with other studies of digital palpation using the MOS for POP patients.^{7,8} However, lower estimation of perineometer results might be attributed to several factors, namely central distribution bias in performing the estimation, or even the use of other pelvic floor muscles as compensation for LAM weakness.

The significant correlation between measurement methods in this study signifies the fact that digital examinations could be a useful option for clinicians with limited infrastructures, especially those located in underdeveloped areas without perineometers. A previous report by United Nations Children's Fund (UNICEF) had already elucidated the importance of sufficient maternal healthcare in Eastern Indonesia, where people had inadequate access to maternal care due to unique geographical barriers.¹¹

The limitation of this study lies on the nature of its single-center and retrospective study. Due to the single-center nature, a risk of bias occurring from similar demographic characteristics between subjects could not be avoided. However, the risk of bias was minimized by performing an analysis of the baseline characteristics of the subjects. Moreover, there is no data regarding the distance in years between vaginal delivery and eventual vaginal tear. A follow-up study regarding the distance between vaginal delivery and vaginal tear may be beneficial

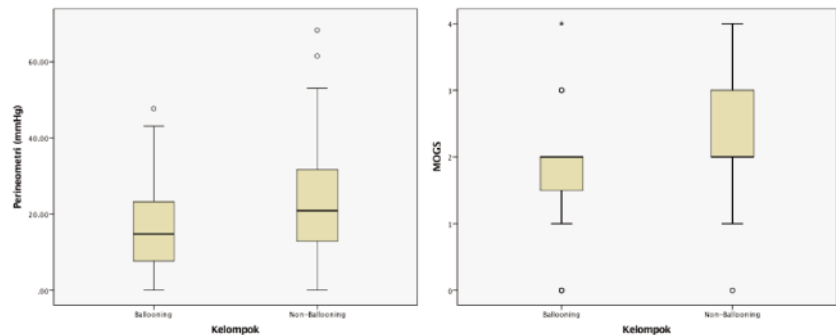


Figure 1. LAM strength measured by (a) perineometer (b) MOS.

for future workups for patients in clinical practice.

Conclusions

It is concluded in this study that lower LAM strength was observed in POP patients with hiatal ballooning.

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