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ORIGINAL ARTICLE

How to determine "ballooning" of the levator hiatus on clinical examination: a retrospective observational study

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Abstract
Introduction and hypothesis Dimensions of the levator hiatus determined on imaging are strong predictors of symptoms and signs of female pelvic organ prolapse (FPOP) and of FPOP recurrence. A clinical equivalence can be recorded as genital hiatus (Gh) + perineal body (Pb) using the ICS prolapse quantification system. The objective of this study was to stratify the Gh+Pb measurement to provide clinicians with clinical diagnostic criteria similar to those available on imaging.
Methods A retrospective study of the data sets of 477 patients seen in a tertiary urogynecological clinic.
Results On average, Gh was 4.2 (range, 1.5–8.5) cm, Pb 3.8 (range, 2.0–7.0) cm, Gh+Pb 7.9 cm (range, 4.2–13.0). The sum of Gh+Pb was strongly associated with symptoms ($p<0.001$) and signs ($p<0.001$) of FPOP. On receiver–operator characteristic statistics, the area under the curve was determined as 0.707 (0.658–0.755) in predicting symptoms of FPOP, and as 0.890 (0.854–0.925) for predicting FPOP≥stage 2, using 7 cm as the optimal cut-off for Gh+Pb. Using the data sets of 309 patients with abnormal (i.e. ≥7 cm) Gh+Pb measurements, we stratified abnormal hiatal distensibility, or "ballooning", into mild, moderate, marked and severe as Gh+Pb=7.0–7.99 cm, 8.0–8.99 cm, 9.0–9.99 cm and 10 cm or more respectively, as the optimal compromise between easily remembered cut-off numbers and quartiles.
Conclusions The sum of Gh+Pb measurement may allow clinicians to determine the degree of excessive hiatal distensibility or 'ballooning' without requiring imaging assessment.

Keywords Ballooning · Female pelvic organ prolapse · Genital hiatus · Levator hiatus · Levator trauma

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Introduction

The size of the levator hiatus, that is, the central opening of the levator plate, has been shown to be strongly associated with both signs and symptoms of female pelvic organ prolapse (FPOP) [1] and FPOP recurrence [2]. This is not surprising, given that the levator hiatus represents the largest potential hernial portal in the human body, with FPOP and rectal intussusception/prolapse [3] interpretable as herniations. There are a number of potential explanations for excessive distensibility of the levator hiatus ("ballooning") including congenital [4] or acquired [5] causes. The latter may occur secondary to avulsion of the puborectalis muscle [6], where the muscle has detached from its bony insertion; or "microtrauma", i.e. irreversible overdistension of the levator hiatus, which may be the result of the hormonal effects of pregnancy [7] or secondary to vaginal delivery[5].

Hiatal dimensions have been determined using imaging techniques including magnetic resonance or 3-/4-dimensional (3D/4D) ultrasound imaging [8]. Given that there are both technical and cost limitations of using imaging, assessing hiatal dimensions may prove difficult to those without access to such facilities. The closest clinically measurable equivalent to the levator hiatus is thought to be the genital hiatus, that is, the distance from the centre of the external urethral meatus to the centre of the fourchette as per the ICS pelvic organ prolapse quantification system (POP-Q) [9]. It has been shown that the genital hiatus, and even more so, the sum of the genital hiatus and perineal body measurements on Valsalva (Gh+Pb) are strongly associated with symptoms and signs of FPOP [10–12]. Furthermore, there is evidence that the anteroposterior diameter of the genital hiatus may be associated with prolapse recurrence after pelvic reconstructive surgery [12]. Confirming such clinical data by ultrasound, it has recently been shown that the degree of abnormal hiatal distensibility is associated with the risk of prolapse recurrence[2].

In this study we aimed to stratify Gh+Pb measurements on Valsalva, recorded as part of a routine clinical pelvic floor assessment using the ICS POP-Q [9], to allow a clinical diagnosis of mild, moderate, marked and severe hiatal over-distensibility or "ballooning" equivalent to ultrasound diagnostic criteria [1]. We also aimed to validate stratified clinical diagnosis against hiatal area determined on translabial ultrasound and against levator trauma (avulsion).

Materials and methods

This is a retrospective study utilizing 477 data sets, obtained at a tertiary urogynecological service, of women presenting with symptoms of pelvic organ prolapse and/or lower urinary tract symptoms, between September 2010 and February 2012. All patients had undergone a standardized local interview, clinical examination and 4D translabial pelvic floor ultrasound [13]. Clinical examination was performed using the ICS POP-Q [9] and included measurement of the genital hiatus (Gh) and perineal body (Pb) on maximal Valsalva of at least 5 s duration, by the senior author, or by staff under his direct supervision, using a wooden, disposable, calibrated ruler (PopStix; Endoventure, Auckland, New Zealand; Fig. 1). Translabial 4D pelvic floor ultrasound was performed using GE Kretz Voluson 730 expert systems with RAB 8–4 MHz transducer (GE Kretz Medical Ultrasound, Zipf, Austria) as previously described [14]. Levator strength and integrity were also determined by palpation [14].

Symptoms of pelvic organ prolapse were ascertained from every patient using the same standardised wording querying a "sensation of a lump" and/or a "dragging sensation in the vagina". Archived 4D translabial ultrasound data sets were analysed offline for hiatal dimensions at a later date by the first author (BG) using proprietary software (GE Kretz 4D View, version 10; GE Kretz Zipf, Austria) blinded to all clinical data. Hiatal coronal and anterior–posterior diameters and area on maximum Valsalva were measured at the plane of minimal hiatal dimensions. This plane is identified in the mid-sagittal plane as the minimal distance between the symphysis pubis and the anterior margin of the central aspect of the puborectalis muscle [15]. This methodology has been shown to be highly repeatable (Fig. 1) [8, 16, 17]. Levator avulsion had been diagnosed at the time of clinical assessment, using multislice or tomographic ultrasound imaging (TUI) on volumes obtained at pelvic floor muscle contraction as previously described [18, 19]. Using TUI a set of 8 slices are obtained at 2.5-mm slice intervals, from 5 mm below to 12.5 mm above the plane of minimal hiatal dimensions. An avulsion is diagnosed if at least the reference slice and two slices cranial to this show a clearly abnormal muscle insertion on the pubic ramus [19].

All quantitative data were found to be normally distributed on Kolmogorov–Smirnov testing. Gh+Pb measurements were tested against symptoms (vaginal lump/bulge or dragging sensation) and signs (ICS POP-Q stage 2 or greater) of FPOP. Using receiver–operator characteristic statistics (ROC), we determined the optimal cut-off value for predicting symptoms and signs of FPOP. Patients with abnormal Gh+Pb measurement were then further stratified into "mild", "moderate", "marked" and "severe" clinical ballooning analogous to the ultrasound diagnosis of ballooning [1]. This stratification was validated against symptoms, signs, ultrasound measurement of hiatal dimensions and the prevalence of levator avulsion using ANOVA and Mantel–Haenszel Chi-squared tests. Multiple logistic regression was used to control for potential confounders. A subset of 188 data sets contained in this study has been utilised for a prior publication [11].

Ethics approval was obtained from the Human Research Ethics Committee of Nepean Blue Mountains Local Health District (IRB code NBMLHD 11–13). Informed consent was not required given the retrospective analysis of data collected during normal clinical practice.

Results

A total of 477 patients were seen during the inclusion period of September 2010 and February 2012. Ultrasound volume data sets were missing because of equipment unavailability in 42 and clerical error in 3, leaving 432. Mean age was 56.7 years (19–86), mean BMI was 29.1 (17.3–55.7). Patients complained of stress incontinence (73 %), urge incontinence (73 %), frequency (29 %), nocturia (43 %), symptoms of voiding dysfunction (31 %) and prolapse (51 %). Most were vaginally parous (91 %), 31 % had had a previous hysterectomy, 21 % a previous incontinence or prolapse procedure. On examination, 79 % of patients had a significant prolapse (ICS POP-Q≥stage 2), which included a cystocele in 64 %, uterine prolapse in 12 %, an enterocele in 5 % and a rectocele in 54 %. In 13 cases Gh+Pb could not be determined owing to a lack of equipment, omission, absence of the anus, or access problems, leaving 419 data sets. All subsequent analysis relates to those 419 data sets.

On average, Gh was measured at 4.2 (range, 1.5–8.5) cm, Pb at 3.8 (range, 2.0–7.0) cm, giving a sum of 7.9 cm on average (range, 4.2–13.0) for Gh+Pb. The sum of Gh+Pb was strongly associated with symptoms (t test, $p<0.001$) and signs (t test, $p<0.001$) of FPOP. This association remained true even after adjusting for

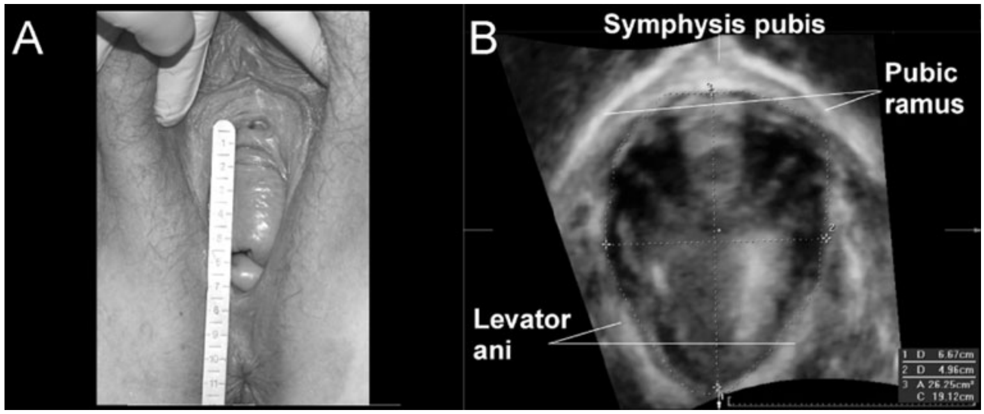

Fig. 1 Determination of **a** Gh+Pb using the POPStix ™ disposable wooden ruler and **b** of hiatal dimensions on axial plane translabial ultrasound

previous surgery, using multiple logistic regression. The area under the curve was determined as 0.707 (0.658–0.755) in predicting symptoms of FPOP, and as 0.890 (0.854–0.925) for predicting objective FPOP of stage 2 or higher (Fig. 2), with 7 cm giving a sensitivity of 80 % and a specificity of 81 % for the latter. We then stratified the 309 patients with measurements at or over this cut-off into mild, moderate, marked and severe ballooning (Table 1). This implied compromising between easily remembered cut-off numbers and quartiles, but this was easily accomplished and validated against ultrasound hiatal area measurements and the diagnosis of avulsion on tomographic imaging (Table 1).

Discussion

Female pelvic organ prolapse (FPOP) is a highly prevalent condition [20–22] that has a significant impact on women's quality of life. The lifetime risk of surgery for FPOP has been estimated to be between 10 and 20 %, with up to 30 % repeat procedures [20, 23]. The high recurrence rate after pelvic reconstructive surgery may partially be due to a lack of understanding of the pathophysiology of this common condition. Recent developments in diagnostic imaging, specifically magnetic resonance and 4-dimensional (4D) ultrasound[14], have enabled us to "rediscover" levator trauma as a potential missing link between childbirth and FPOP [24] and as an important risk factor for prolapse recurrence after surgery with or without mesh [1, 25, 26]. It has been shown that both levator avulsion and abnormal distensibility of the levator hiatus ("ballooning"), are independent risk factors for prolapse development and recurrence [2]. Preoperative assessment for avulsion and ballooning may therefore be useful for patient counselling and surgical planning, in particular with regard to mesh use [2]. Any recommendation derived from such information could then be tested in randomised controlled trials.

Both levator avulsion and abnormal distensibility of the hiatus can be determined clinically. While digital palpation for levator defects may require substantial training [14], a Gh+Pb measurementof ≥8.5 cm may help to identify women with avulsion. On the other hand a cut-off of 7 cm for Gh+Pb has been shown to

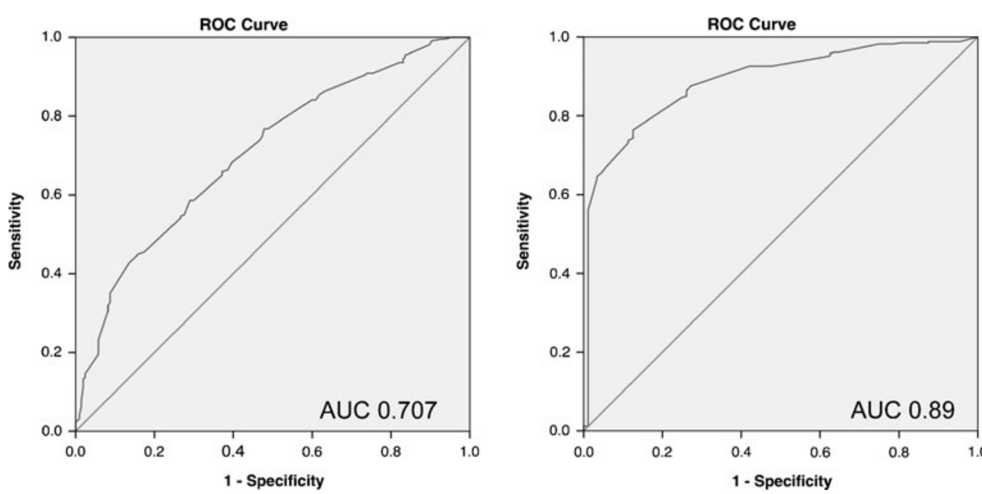

Fig. 2 Receiver–operator characteristic (ROC) curves for the association between Gh+Pb measurements on Valsalva vs symptoms of prolapse (*left*) and significant prolapse (ICS POPQ stage 2 or higher; *right*); n=419

Table 1 Stratification of degrees of clinical ballooning (n=419) against symptoms and signs of prolapse, prevalence of avulsion and hiatal area on Valsalva measured by translabial ultrasound

Category	n	Symptoms of prolapse (%)*	Clinical prolapse stage 2 or above (%)*	Levator avulsion (%)*	Mean hiatal area on Valsalva (cm^2)*
Normal (<7 cm)	110	32	44	7	20.5
Mild ballooning (7–7.99 cm)	89	47	79	10	27.3
Moderate ballooning (8–8.99 cm)	98	50	98	20	31.5
Marked ballooning (9–9.99 cm)	67	76	100	37	35.1
Severe ballooning (10 cm or higher)	55	78	98	53	41.9

*p value <0.0001

be useful in determining clinical ballooning [11], and the results of this study, an extension of Khunda et al. [11], confirm those data.

In order to provide a more useful clinical diagnosis and to allow better estimation of the risk of prolapse recurrence, stratification of clinical ballooning may prove to be useful in clinical practice. An analogous stratification of ultrasound hiatal area assessment has proven to be of high utility in everyday practice in our unit. Hence, we decided to perform the same process of stratification for Gh+Pb measurements. Based on this study we propose that mild ballooning be defined as Gh+Pb=7.0–7.99 cm, moderate ballooning as 8.0–8.99 cm, marked ballooning as 9.0–9.99 cm and severe ballooning as 10 cm or more. As shown in Table 1, increasing degrees of clinical "ballooning" are associated with increasing likelihood of symptoms and signs of FPOP, with increasing prevalence of levator avulsion, and increased hiatal area on Valsalva. Hence, it is very likely that increasing degrees of clinical "ballooning" should be predictive of an increasing risk of recurrence following surgical repair [2], but of course such a hypothesis will need to be tested prospectively.

The main weaknesses of this study include its retrospective nature and the fact that most of our patients were of Caucasian background and had symptomatic urogynaecological complaints, which implies selection bias. Consequently, conclusions apply primarily to similar populations. Future efforts will be needed to validate the proposed stratification in other ethnic groups. Furthermore, it could be argued that validated symptom questionnaires should have been used to define the symptoms of prolapse. However, measurements were validated against symptoms of prolapse, which were defined as either a sensation of bulge and/or a dragging sensation, definitions that have been shown to be highly predictive of objective prolapse [11, 27–29]. While one could criticise that we did not perform power calculations, the study was obviously sufficiently powered to allow for validation of the proposed stratification. Finally, only one of the parameters against which we validated the proposed stratification (hiatal area on Valsalva) was obtained in a blinded fashion. At the time of Gh+Pb measurements, the examiner was not consistently blinded against symptoms and other ICS POP-Q measurements, and at the time of avulsion diagnosis there was no consistent blinding against Gh+Pb. This shortcoming is due to the retrospective study design, which only allowed us to blind hiatal area measurement against all other data. However, it is evident from Table 1 that all chosen measures, whether obtained in a blinded fashion or not, served to validate the proposed stratification.

In conclusion, the sum of Gh+Pb measurements obtained on Valsalva is a valid clinical equivalent of hiatal ballooning observed on ultrasound imaging. We propose to stratify abnormal hiatal distensibility or "ballooning" into mild (Gh+Pb=7.0–7.99 cm), moderate (Gh+Pb 8.0–8.99 cm), marked (Gh+Pb 9.0–9.99 cm) and severe (Gh+Pb 10.0 cm and higher).

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Conflicts of interest B. Gerges, I. A. Kamisan and K. L. Shek have no conflicts of interest. H. P. Dietz has received an unrestricted educational grant from GE Medical.

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