Can ballooning of the levator hiatus be determined clinically?

Azar Khunda, MRCoG; Ka Lai Shek, PhD; Hans Peter Dietz, MD, PhD

OBJECTIVE: The objective of the study was to determine whether genital hiatus (gh) and perineal body (pb), measured using the pelvic organ prolapse quantification system of the International Continence Society, are predictive of an abnormally distensible levator hiatus on ultrasound and of objective prolapse and/or prolapse symptoms.

STUDY DESIGN: The design of the study included datasets of 188 urogynecology patients assessed in a cross-sectional retrospective study.

RESULTS: Gh and pb, as well as gh plus pb, were strongly associated with symptoms and signs of prolapse and with hiatal area on ultrasound. The sum of gh and pb was superior in predictive performance to individual measures for symptoms (P < .001) and signs of prolapse (P < .001). Gh plus pb equaled the hiatal area on ultrasound (area under the curve, 0.886; 95% confidence interval, 0.828–0.945 vs 0.867; 95% confidence interval, 0.808–0.926) for predicting objective prolapse. Optimal sensitivity (80%) and specificity (81%) was reached with a cutoff of 7 cm for gh plus pb.

CONCLUSION: A cutoff of 7 cm for gh plus pb measured on Valsalva is proposed as a clinical definition of excessive levator hiatal distensibility.

Key words: ballooning, levator hiatus, pelvic organ prolapse quantification system, 3-dimensional ultrasound, translabial ultrasound

The dimensions of the levator hiatus, that is, the space enclosed by the levator ani muscle, are strongly associated with prolapse. This is not surprising if one considers the levator hiatus as a hernial portal, the largest potential hernial portal in the abdominal envelope. Excessive distensibility of the levator hiatus may be congenital or acquired, due to avulsion of the puborectalis muscle or due to overdistension of a macroscopically intact muscle and is independently associated with prolapse and prolapse symptoms. It is plausible that the size of the levator hiatus may play a role in the etiology of female pelvic organ prolapse, which implies that there may be substantial benefit, both for research and clinical practice, in measuring hiatal dimensions.

To determine the size of the levator hiatus, it is necessary to use magnetic resonance or 4-dimensional (4D) ultrasound imaging, modalities that are neither cheap nor universally available. If it were possible to diagnose excessive distensibility of the hiatus clinically, this would allow clinicians to avoid more expensive imaging investigations and open up new opportunities for research and therapy.

The closest equivalent to the levator hiatus that can be measured clinically is the genital (or urogenital) hiatus, that is, the distance from the center of the external urethral meatus to the center of the fourchette. DeLancey and Hurd measured the urogenital hiatus using a ruler and found that pelvic organ prolapse was associated with the anteroposterior diameter of the urogenital hiatus and that this parameter was associated with surgical failure. The former finding has been confirmed independently by authors measuring the genital hiatus on pelvic floor muscle contraction. The genital hiatus, together with determination of the length of the perineal body, forms part of the pelvic organ prolapse quantification (POPQ) of the International Continence Society (ICS) and has been shown to be highly repeatable. Correlations for interobserver reliability were 0.913 and 0.514 for genital hiatus (gh) and perineal body (pb). The intraobserver reliability correlations for 25 subjects were 0.812 and 0.659 for gh and pb.

In this study we aimed to determine whether clinical estimation of the genital hiatus and perineal body on Valsalva, recorded as part of a routine clinical pelvic floor assessment using the ICS POP-Q, is predictive of an abnormally distensible hiatus (ballooning) as documented on pelvic floor ultrasound and prolapse/prolapse symptoms.
TABLE 1  
Associations between gh and pb measurements and ultrasound measures of hiatal dimensions

<table>
<thead>
<tr>
<th>Variable</th>
<th>Anteroposterior hiatal diameter on Valsalva, cm</th>
<th>Hiatal area on Valsalva, cm²</th>
</tr>
</thead>
<tbody>
<tr>
<td>gh, cm²</td>
<td>( r = 0.527 )( P &lt; .001 )</td>
<td>( r = 0.613 )( P &lt; .001 )</td>
</tr>
<tr>
<td>pb, cm</td>
<td>( r = 0.561 )( P &lt; .001 )</td>
<td>( r = 0.533 )( P &lt; .001 )</td>
</tr>
<tr>
<td>gh plus pb (cm)</td>
<td>( r = 0.673 )( P &lt; .001 )</td>
<td>( r = 0.722 )( P &lt; .001 )</td>
</tr>
</tbody>
</table>

Notes: \( r \) = Pearson’s correlation.
gh, genital hiatus; pb, perineal body.

Materials and Methods

This is a retrospective cross-sectional analysis of datasets of 188 patients seen at a tertiary urogynecology center for lower urinary tract symptoms and/or symptoms of pelvic organ prolapse between September 2010 and February 2011.

All patients had undergone an interview and a clinical examination using the ICS POP-Q, including measurement of the genital hiatus and perineal body at maximal Valsalva using a wooden, disposable, calibrated ruler (PopStix; Endoventure, Auckland, New Zealand). Translabial 3-dimensional (3D)/4D pelvic floor ultrasound was performed using GE Kretz Voluson 730 expert systems (GE Kretz Medizintehnik, Zipf, Austria) with RAB sound was performed using GE Kretz (A.K., who was blinded to all other data. All quantitative data were found to be normally distributed on Kolmogorov-Smirnov testing. Pearson’s correlation was used to compare clinical examination measurements and 3D/4D ultrasound measurements. Receiver operating characteristics (ROCs) curve analysis was used to examine the relationship between gh, pb, and signs (prolapse stage 2 POPQ or greater) and symptoms of prolapse.

The Human Research Ethics Committee of the Sydney West Area Health Service approved this research project (IRB code, NBMLHN 11/13). Because this was a retrospective analysis of data obtained during normal clinical practice, informed consent was not required. The manufacturer donated the PopStix (Endoventure).

Results

Interobserver reliability data (n = 20) was obtained for hiatal area on Valsalva (intraclass correlation [ICC], 0.89; 95% confidence interval [CI], 0.73–0.95) and for anterior-posterior diameter on Valsalva (ICC, 0.85; 95% CI, 0.62–0.94), indicating excellent repeatability between A.K. and H.P.D.

Both clinical and ultrasound measures of hiatal dimensions were normally distributed. Mean age was 56.8 (range, 21.5–85.6), median parity was 3 (range, 0–10), mean body mass index was 29.4 (range, 17.3–59.5).

Patients presented with stress incontinence (n = 138); urge incontinence (n = 137); frequency (n = 65); nocturia (n = 85); symptoms of voiding dysfunction such as hesitancy, straining to void or poor stream (n = 55); and symptoms of prolapse such as a vaginal lump or a dragging sensation (n = 96). One hundred sixty-eight were vaginally parous, and 48 had forceps/vacuum deliveries. Fifty women reported a previous hysterectomy and 37 incontinence or prolapse surgery.

The gh on Valsalva was measured at a mean of 4.1 (range, 1.5–8) cm, and mean pb was 3.8 (range, 2–7) cm. Adding both genital hiatus and perineal body, we obtained a mean of 7.8 (range, 4.2–13) cm. The mean hiatal area on Valsalva was 27.4 (range, 9.7–59.1) cm²; the mean antero-posterior dimension of the hiatus was 6.7 (range, 3.7–9.1) cm. Both genital hiatus and perineal body measurements on Valsalva showed moderate to substantial correlation with hiatal measurements (Table 1), but the sum of both (gh plus pb) showed the strongest correlation with ultrasound measures of hiatal size.

Ultrasound and clinical measures of hiatal dimensions demonstrated significantly larger measurements in the patients with signs and symptoms of pelvic organ prolapse compared with those without such signs and symptoms (Table 2).

On using ROC characteristics to describe the predictive performance of measurements for symptoms and signs of prolapse, we found that the combination of gh and pb on Valsalva was superior in performance to the individual measures and that gh plus pb equalled hiatal area on ultrasound in its predictive performance (area under the curve [AUC], 0.886; 95% CI, 0.828–0.945 vs
0.867; 95% CI 0.808 – 0.926 for the area on Valsalva).

To define clinical ballooning of the levator hiatus, we examined the ROC curve of gh plus pb vs significant (ICS POPQ stage 2 or greater) prolapse on clinical examination. Optimal sensitivity (80%) and specificity (81%) was achieved with a cutoff of 7 cm for gh plus pb (Figure).

**COMMENT**

This study suggests that the sum of gh and pb measurements obtained during a clinical examination using the ICS POPQ is a strong predictor of symptoms and signs of prolapse. Most interestingly, the sum of gh plus pb was even stronger a predictor than the individual measurements.

We also confirmed the results of previous studies showing that hiatal dimensions determined by translabial ultrasound are strongly associated with symptoms and signs of prolapse. In parallel with the definition of hiatal ballooning on ultrasound (≥25 cm² on maximum Valsalva), we propose that ballooning of the levator hiatus on clinical examination be defined as gh plus pb of 7 cm or more on Valsalva.

The ICS POPQ was introduced in 1996 as an objective means of determining pelvic organ descent. Since then, several reports have shown that it has good reproducibility; reliability seems independent of examiner experience. Measuring the gh and pb is accepted as a standard part of the ICS POPQ; however, it is frequently unclear as to whether this measure should be obtained at rest, on Valsalva or on pelvic floor contraction, and there are very few reports of clinical or research use of this parameter.

DeLancey and Hurd have proposed a different method for estimating the urogenital hiatus by measuring the distance between the posterior symphseal margin and the fourchette at rest, using digital palpation and a ruler. On correlating these measurements with prolapse, they concluded that increasing pelvic organ prolapse is associated with increasing urogenital hiatus size; the hiatus is larger after several failed operations. Vakili et al also showed an association between the recurrence of prolapse after surgical correction and genital hiatus, using the gh measurement of the ICS POPQ in a large series of patients at a median follow-up of 5 months.

Other investigators have shown a moderate correlation of gh on Valsalva (r = 0.5) and digitally estimated levator hiatus on maximum pelvic floor muscle contraction (r = 0.5) with prolapse severity; however, correlations were weaker for the sum of gh and pb (r = 0.3). Although most of the scarce data in the literature seem to agree with the data presented in our study, this latter finding is in contrast with our results. We found generally higher correlations with prolapse than those reported by others for both gh and pb, and in our data the optimal predictive performance was achieved by the sum of gh plus pb (AUC, 0.886). Ghetti et al postulated that the perineal body is not within the levator hiatus. This is clearly inaccurate, especially on Valsalva, because the entire perineal body will be within and caudal to the levator hiatus on maximal Valsalva unless the levator hiatus is very narrow, which is very unusual in women with significant prolapse.

One of the main weaknesses of this study is its retrospective nature. The nature of our population limits conclusions because this dataset was obtained in mostly white patients with urogynecological conditions, implying selection bias. Hence, our conclusions are limited to this population. In addition, it could be argued that we should have used validated symptom questionnaires. However, the authors have found that compliance with questionnaire use is suboptimal in our population. Measurements were correlated with symptoms of prolapse, which were defined as either a

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**TABLE 2**

**Comparison between ultrasound and clinical measurement for hiatus and signs and symptoms of prolapse**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Symptoms of prolapse</th>
<th>Prolapse stage 2 or greater on POPQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anteroposterior hiatal diameter</td>
<td>6.32 vs 7.08, P &lt; .001</td>
<td>5.77 vs 6.99, P &lt; .001</td>
</tr>
<tr>
<td>Hiatal area on ultrasound</td>
<td>23.47 vs 31.14, P &lt; .001</td>
<td>18.6 vs 29.99, P &lt; .001</td>
</tr>
<tr>
<td>gh</td>
<td>3.65 vs 4.45, P &lt; .001</td>
<td>2.91 vs 4.4, P &lt; .001</td>
</tr>
<tr>
<td>pb</td>
<td>3.59 vs 3.93, P = .011</td>
<td>3.19 vs 3.93, P &lt; .001</td>
</tr>
<tr>
<td>gh plus pb</td>
<td>7.25 vs 8.38, P &lt; .001</td>
<td>6.12 vs 8.33, P &lt; .001</td>
</tr>
</tbody>
</table>

gh, genital hiatus; pb, perineal body.


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**FIGURE**

**ROC estimates of gh plus pb**

<table>
<thead>
<tr>
<th>AUC</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.886</td>
<td>0.867</td>
</tr>
</tbody>
</table>

ROC estimates the predictive performance of A, gh plus pb and B, hiatal area on Valsalva for significant (ICS POPQ stage 2 or greater) prolapse on clinical examination.

AUC, area under the curve; gh, genital hiatus; ICS, International Continence Society; pb, perineal body; POPQ, pelvic organ prolapse quantification; ROCs, receiver operator characteristic curves.

sensation of bulge and/or a dragging sensation, symptoms that are highly predictive of objective prolapse.\textsuperscript{15,18,19}

Our results support the use of gh and pb as part of the routine assessment of women with symptoms of pelvic floor dysfunction. Findings are valid and repeatable, and they are clearly a clinical measure of the distensibility of the levator hiatus, similar to hiatal dimensions determined on ultrasound. Hence, ballooning of the levator hiatus can be determined clinically, using gh and pb, preferably by combining the 2 measurements.

Why should an assessment of hiatal distensibility be part of prolapse assessment? Because it is a strong predictor of signs and symptoms of prolapse, it is not surprising that patients with clinical ballooning seem more likely to experience recurrence of prolapse after pelvic floor reconstruction surgery.\textsuperscript{7,17} If so, can we justify using mesh implants in women with ballooning on clinical examination or ultrasound to reduce the likelihood of recurrence? Should we attempt to permanently or temporarily reduce the size of the hiatus at the time of prolapse surgery to lower recurrence rates?\textsuperscript{20} We may not be able to optimize the treatment of high-risk patients or target hiatal distensibility surgically unless we determine hiatal dimensions in clinical practice.

In conclusion, this study illustrates that the sum of gh and pb is a strong predictor of symptoms and signs of prolapse. A cutoff of 7 cm has a sensitivity of 81% and specificity of 80% for significant prolapse and could be used to define excessive distensibility of the levator hiatus (ballooning) clinically.

REFERENCES