Ballooning of the levator hiatus

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KEYWORDS: 3D ultrasound; levator ani muscle; levator hiatus; pelvic organ prolapse; perineal ultrasound

ABSTRACT

Objective The levator hiatus defines the ‘hernial portal’ through which female pelvic organ prolapse develops. Hiatal area may therefore be an independent etiological factor for this condition. In this retrospective study we defined ‘normality’ for hiatal area by assessing its relationship with symptoms and clinical signs of prolapse.

Methods Datasets of 544 women seen in a tertiary urogynecological unit were assessed. Patients had undergone an interview, clinical examination and three-/four-dimensional (3D/4D) pelvic floor ultrasound imaging. All analysis was performed off-line, blinded against clinical data.

Results Information on prolapse symptoms was available for 538 women and 171 (32%) of these complained of such symptoms. There was a strong statistical relationship between hiatal dimensions, both at rest and on Valsalva maneuver, and prolapse symptoms (all P < 0.001). Receiver–operating characteristics (ROC) curve analysis yielded an area under the curve of 0.65 (95% CI, 0.60–0.70) for hiatal area at rest and 0.71 (95% CI, 0.66–0.76) for hiatal area on Valsalva. Cut-offs of 25 and 30 cm² on Valsalva gave sensitivities of 0.55 and 0.34 and specificities of 0.77 and 0.86, respectively, for detecting symptomatic prolapse. Similar values were obtained when significant prolapse (Grade 2 or higher) was used as the state variable.

Conclusions Levator hiatal area as measured by 3D translabial pelvic floor ultrasound examination is strongly associated with symptomatic and clinical signs of prolapse. Based on the ROC curves that we obtained, we suggest that a hiatal area of ≥ 25 cm² on Valsalva be defined as abnormal distensibility or ‘ballooning’ of the levator hiatus. Copyright © 2008 ISUOG. Published by John Wiley & Sons, Ltd.

INTRODUCTION

The levator ani muscle is thought to be of central importance for pelvic organ support. It has recently been shown that trauma to this structure, i.e. detachment or ‘avulsion’ of the muscle from its insertion on the inferior pubic ramus and pelvic sidewall, predisposes women to prolapse, especially of the anterior and central compartments. In fact, levator trauma is likely to be the ‘missing link’ explaining the epidemiological association between childbirth and female pelvic organ prolapse, with prolapse patients showing a much higher likelihood of levator trauma, and with trauma conferring a near doubling of the risk of significant prolapse (Grade 2 or higher).

However, even in the absence of overt avulsion injury it is probable that the biomechanical properties of the levator ani muscle influence the likelihood of female pelvic organ prolapse as postulated in the form of the ‘ship in dock’ theory. Measuring hiatal distensibility of the levator ani is one of the most basic approaches to determining biomechanical properties of this muscle, although it is understood that many factors influence this parameter, not just passive compliance or stiffness. Regardless of the role of active factors such as striated muscle activation, excessive distensibility of the levator hiatus (‘ballooning’) is a striking observation on translabial ultrasound imaging in the axial plane. When we consider that the levator hiatus is a potential hernial portal it is not surprising that the phenomenon should affect pelvic organ mobility.

Highly significant correlations have been demonstrated between female pelvic organ prolapse and levator hiatal dimensions, agreeing with clinical data on dimensions of the urogenital hiatus. This relationship is not limited to hiatal dimensions on Valsalva maneuver, which may be explained as a passive phenomenon, but has also been confirmed for dimensions at rest, and it is true both for asymptomatic nulliparous women and patients symptomatic of pelvic floor dysfunction.
increases hiatal distensibility even in the absence of overt levator trauma\textsuperscript{10}, and hiatal dimensions in turn seem to influence the course of labor\textsuperscript{11,12}. It is therefore probable that hiatal distensibility is an independent etiological factor in the development of pelvic organ prolapse. However, to date there have been no published data on how to define ‘normal’ and ‘abnormal’ hiatal dimensions. We therefore conducted a retrospective study with the aim of defining ‘normality’ for the parameter of ‘hiatal area on Valsalva’ by assessing its relationship with the symptoms and clinical signs of pelvic organ prolapse.

**PATIENTS AND METHODS**

We retrospectively analyzed the data of 544 women seen in a tertiary urogynecological unit for symptoms of pelvic floor and/or urinary tract dysfunction. A subset of this population had previously been studied for the prevalence of levator trauma\textsuperscript{2}. All patients had given a medical history and undergone clinical examination for prolapse (International Continence Society (ICS) pelvic organ prolapse quantification (POP-Q) grading) and levator integrity and function (modified Oxford Grading), as well as three-/four-dimensional (3D/4D) pelvic floor ultrasound using Medison SA 8000 (Medison, Seoul, Korea) and GE Kretz Voluson 730 Expert (GE Medical Systems, Zipf, Austria) systems. Symptoms of pelvic organ prolapse were defined as ‘the sensation of a lump in the vagina’ and/or ‘a dragging sensation in the vagina’. Ultrasound data acquisition was performed as described previously\textsuperscript{9}, with data acquired after bladder emptying, supine, at rest and on maximal Valsalva maneuver. Great care was taken to avoid levator co-activation\textsuperscript{13}. Acquisition angles were set to the system-specific maximum (70° for the SA 8000 and 85° for the Voluson 730 Expert).

Analysis of data was performed off-line using the 4D View v 2.1–5.0 software (GE Medical Systems), weeks to months following clinical assessment, blinded against all clinical data. Hiatal dimensions were determined according to a previously published methodology\textsuperscript{9} (Figure 1), which has been shown by several authors to be highly repeatable\textsuperscript{14–16} and probably superior to magnetic resonance imaging\textsuperscript{17}. Figure 2 illustrates different degrees of hiatal ballooning. We focused on hiatal area since it is clearly a more inclusive measure of levator biometry. Axial diameters have the advantage that they can be obtained by two-dimensional ultrasonography, but the relationship between axial diameter on Valsalva with prolapse and prolapse symptoms is less strong (own unpubl. data), probably owing to the effect of avulsion injury, which impacts much less on axial diameters in comparison to area. Coronal diameters are another potential choice, but the ‘warped’ nature of the plane of minimal dimensions is likely to act as a potential confounder.

This study is an analysis of data obtained in a parent study undertaken for a different purpose and approved by the institutional Human Research Ethics Committee (SWAHS ref 05/029). Statistical analysis was undertaken using SPSS v. 14 (SPSS Inc., Chicago, IL, USA) and Minitab v. 13 (Minitab Inc., State College, PA, USA). All quantitative data were found to be normally distributed on Kolmogorov–Smirnov testing. We used \( t \)-tests to evaluate the relationship between pelvic organ descent and prolapse symptoms, and receiver–operating characteristics (ROC) curve analysis to examine the relationship between hiatal dimensions and reported symptoms of prolapse, in order to obtain a plausible estimate of ‘normality’ for hiatal dimensions.

Figure 1 Translabial three-dimensional ultrasound images in the midsagittal plane (a) and oblique axial plane (b) showing identification of the plane of minimal hiatal dimensions on Valsalva maneuver. (a) The horizontal line illustrates the identification of the plane of minimal hiatal dimensions in the midsagittal plane and is equivalent to the vertical line in b. (b) The dotted line illustrates the minimal hiatal area on Valsalva, which was measured at 19 cm\(^2\), indicating normal distensibility of the hiatus.
RESULTS

The mean age of the study population was 53.2 (range, 17–89) years, and median vaginal parity was 2 (range, 0–8). Information regarding prolapse symptoms was available for 538 women, with 171 (32%) complaining of such symptoms. Objective clinical examination revealed: 185 Grade 1, 102 Grade 2 and 68 Grade 3 cystoceles; 61 women with Grade 1, 16 with Grade 2 and eight with Grade 3 uterine prolapse; and 187 Grade 1, 81 Grade 2 and 29 Grade 3 rectoceles. In a total of 250 women (46%) we found prolapse of Grade 2 or higher. In 497 out of 538 women we were able to correlate hiatal dimensions with clinical prolapse grading. The other 41 cases were accounted for by corrupt or inadequately identified ultrasound datasets (n = 29), which occurred almost exclusively during the first few months of the study period; a patient’s inability to perform an adequate Valsalva maneuver (n = 11); and operator difficulties in evaluating the volume dataset (n = 1).

Data analysis revealed statistically significant relationships between reported symptoms of prolapse and pelvic organ descent, both on ultrasound (Table 1) and on clinical examination (all P < 0.001). There was also a strong statistical relationship between reported prolapse symptoms and hiatal dimensions both at rest and on Valsalva (all P < 0.001, Table 2). ROC analysis confirmed this relationship, with an area under the curve (AUC) of 0.65 (95% CI, 0.60–0.70) for hiatal area at rest and 0.71 (95% CI, 0.66–0.76) for hiatal area on Valsalva. Cut-offs of 25 and 30 cm² on Valsalva gave sensitivities of 0.55 and 0.34 and specificities of 0.77 and 0.86, respectively (Figure 3).

Table 1 Relationship between reported symptoms of prolapse and pelvic organ descent (as determined by translabial ultrasound)

<table>
<thead>
<tr>
<th>Type of descent</th>
<th>Yes</th>
<th>No</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystocele</td>
<td>−9.6 ± 19.5</td>
<td>−0.1 ± 19.5</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Uterine</td>
<td>−3.2 ± 14.7</td>
<td>+4.5 ± 13.1</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Rectocele</td>
<td>−6.9 ± 17.1</td>
<td>+0.9 ± 17.2</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

All measurements are in mm, given as mean ± SD relative to the inferior margin of the symphysis pubis, as described previously. *Student’s t-test.

Table 2 Relationship between reported symptoms of prolapse and levator hiatus parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Yes</th>
<th>No</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anteroposterior diameter</td>
<td>5.70 ± 0.88</td>
<td>5.37 ± 0.86</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Coronal diameter at rest</td>
<td>4.44 ± 0.60</td>
<td>4.07 ± 0.59</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Hiatal area at rest</td>
<td>14.79 ± 5.03</td>
<td>14.98 ± 4.26</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Anteroposterior diameter</td>
<td>6.63 ± 1.12</td>
<td>6.01 ± 1.15</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>on Valsalva (cm)</td>
<td>5.36 ± 0.88</td>
<td>4.67 ± 0.80</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Coronal diameter on</td>
<td>27.14 ± 8.69</td>
<td>21.01 ± 7.82</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Valsalva (cm²)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Values are mean ± SD. *Student’s t-test.

When significant objective prolapse (POP-Q Grade 2 or higher) was tested against hiatal area at rest and on
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Valsalva, similar ROC statistics were obtained. There was a fair relationship between area at rest and prolapse (AUC 0.64, 95% CI, 0.59–0.69), but the AUC on Valsalva was much higher (0.76, 95% CI, 0.72–0.80; Figure 3). A cut-off of 25 cm² on Valsalva yielded a sensitivity of 0.52 and a specificity of 0.83 for detecting significant prolapse as diagnosed on clinical examination. The respective figures for a cut-off of 30 cm² were 0.35 for sensitivity and 0.93 for specificity.

On the basis of our results we propose that a hiatal area on Valsalva of 25–29.9 cm² can be defined as ‘mild’, 30–34.9 cm² as ‘moderate’, 35–39.9 cm² as ‘marked’ and ≥ 40 cm² as ‘severe’ ballooning. In our dataset, this stratification resulted in 60 women having ballooning classified as ‘mild’, 50 as ‘moderate’, 29 as ‘marked’ and 22 as ‘severe’. Table 3 shows the prevalence of maximal prolapse stages in each subgroup.

### Table 3 Prevalence of pelvic organ prolapse stages (maximal stage for any compartment) relative to hiatal ballooning in 497 women for whom both clinical prolapse assessment and hiatal imaging on Valsalva maneuver were available

<table>
<thead>
<tr>
<th>Extent of ballooning</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 25 cm² (normal)</td>
<td>82 (24)</td>
<td>140 (42)</td>
<td>76 (23)</td>
<td>38 (11)</td>
<td>336</td>
</tr>
<tr>
<td>25–29.9 cm² (mild)</td>
<td>6 (10)</td>
<td>17 (28)</td>
<td>24 (40)</td>
<td>13 (22)</td>
<td>60</td>
</tr>
<tr>
<td>30–34.9 cm² (moderate)</td>
<td>5 (10)</td>
<td>9 (18)</td>
<td>20 (40)</td>
<td>16 (32)</td>
<td>50</td>
</tr>
<tr>
<td>35–39.9 cm² (marked)</td>
<td>1 (3)</td>
<td>3 (10)</td>
<td>13 (43)</td>
<td>12 (41)</td>
<td>29</td>
</tr>
<tr>
<td>≥ 40 cm² (severe)</td>
<td>0</td>
<td>2 (9)</td>
<td>7 (35)</td>
<td>13 (65)</td>
<td>22</td>
</tr>
<tr>
<td>Total</td>
<td>94</td>
<td>171</td>
<td>140</td>
<td>92</td>
<td>497</td>
</tr>
</tbody>
</table>

Values are n (%).

**DISCUSSION**

The levator hiatus defines the largest potential hernial portal within the envelope of the abdominal cavity. Consequently, the static and dynamic properties of this muscle are likely to matter for the etiology and pathogenesis of any form of herniation through this portal. The most common forms of such herniation are subsumed under the term ‘female pelvic organ prolapse’, although rectal intussusception and rectal prolapse also constitute herniation through the levator hiatus. Levator hiatus dimensions are likely to reflect aspects of muscle compliance or elasticity, that is, they probably describe components of the biomechanical properties of this muscle.

We feel that any parameters describing the size and distensibility of the hiatus should be investigated more closely. This retrospective study was undertaken to define ‘normality’ for the parameter ‘hiatal area on Valsalva’, the measurement of which has been shown to be highly reproducible by the authors and others and which seems to be strongly associated with pelvic organ mobility, and this was again confirmed in this cohort of women.

Two standard approaches to determining ‘normality’ are:

- to use a normal population and determine the 95th centile or, alternatively, to use the mean plus two standard deviations;
- to determine optimal cut-offs with the help of ROC curves using symptoms attributable to the phenotypic observation in question.

On the basis of previously obtained data in young nulliparous women, a purely mathematical definition
of the upper limit of normality (mean + 2 SD) yielded a figure of 25.8 cm². In this study we have attempted to define a cut-off for normality on the basis of symptoms of pelvic organ prolapse and of objectively determined significant (POP-Q Stage 2 and higher) pelvic organ prolapse, the presumptive main manifestation of excessive distensibility of the levator hiatus. We do not propose hiatal area on Valsalva as a test for prolapse (this would be nonsensical); the purpose of using ROC statistics was exclusively to determine normality. Interestingly, the optimal cut-off proved to be 25 cm², yielding a sensitivity of 0.53 and specificity of 0.77, with an AUC of 0.71, for predicting symptoms of female pelvic organ prolapse, and a sensitivity of 0.52 and specificity of 0.83 (AUC 0.76) for predicting objective prolapse on examination (Figure 3).

On the basis of the ROC curves and patient symptoms we therefore suggest that a hiatal area of ≥ 25 cm² on Valsalva maneuver be defined as abnormal distensibility or ‘ballooning’ of the levator hiatus. As already mentioned, our clinical experience would suggest that a hiatal area on Valsalva of 25–29.9 cm² can be defined as ‘mild’, 30–34.9 cm² as ‘moderate’, 35–39.9 cm² as ‘marked’ and ≥ 40 cm² as ‘severe’ ballooning. While it is understood that any such stratification is necessarily arbitrary, it has performed well in approximately 1000 clinical assessments in our unit to date, is easy to remember and seems to describe increasing degrees of abnormality as demonstrated by a progressively stronger association with pelvic organ prolapse (Table 3). Future studies should focus on the determinants of excessive distensibility of the levator hiatus and its use as a predictor (e.g. of recurrence after prolapse surgery) or as a surrogate outcome parameter in intervention studies aimed at altering the biomechanical properties of this muscle.

In conclusion, we have defined ‘normality’ for the biometric parameter ‘area of the levator hiatus on maximal Valsalva’ by using ROC analysis of the association between this parameter and the symptoms and clinical signs of female pelvic organ prolapse. We suggest a cut-off of 25 cm² for ‘normal’ distensibility of the levator hiatus.

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