167

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CAN BALLOONING OF THE LEVATOR HIATUS BE DETERMINED CLINICALLY?

Hypothesis / aims of study

The dimensions of the levator hiatus, the space between the pelvic floor muscles, is a strong predictor of prolapse(1), and probably also of prolapse recurrence after pelvic reconstructive surgery. In order to determine the size of the levator hiatus it is necessary to use magnetic resonance or 4D ultrasound imaging(2), modalities that are not cheap and not universally available. In this study we aimed to analyse existing data obtained in the context of routine clinical practice to determine whether clinical estimation of the genital hiatus and perineal body, recorded as part of a routine clinical pelvic floor assessment using the prolapse quantification system of the International Continence Society(3), is sufficiently predictive of a) an abnormally distensible hiatus (ballooning) and b) prolapse and/ or prolapse symptoms to potentially replace imaging. If it were possible to diagnose excessive distensibility of the hiatus clinically, then this would allow clinicians to avoid imaging investigations, especially prior to surgery designed to reduce hiatal dimensions.

Study design, materials and methods

We undertook a retrospective analysis of 188 datasets of consecutive patients seen at a tertiary urogynaecology unit between September 2010 and February 2011. Patients underwent an interview, a clinical examination using the ICS POP-Q, including measurement of the genital hiatus (gh) and perineal body (pb) at maximal Valsalva, translabial 4D ultrasound using a Voluson 730 expert system with RAB 8-4 Mhz transducer, and multichannel urodynamic testing. Archived ultrasound datasets were analysed at a later date by the first author, blinded to all other data. Anteroposterior diameter and hiatal area were measured on maximal valsalva in the plane of minimal hiatal dimensions(2), see Figure 1. Gh, pb and gh+pb were tested against measurements of hiatal dimensions. Both ultrasound and clinical measurements were then tested for their predictive value for symptoms and signs of prolapse. We did not perform formal power calculations due to lack of pilot data.

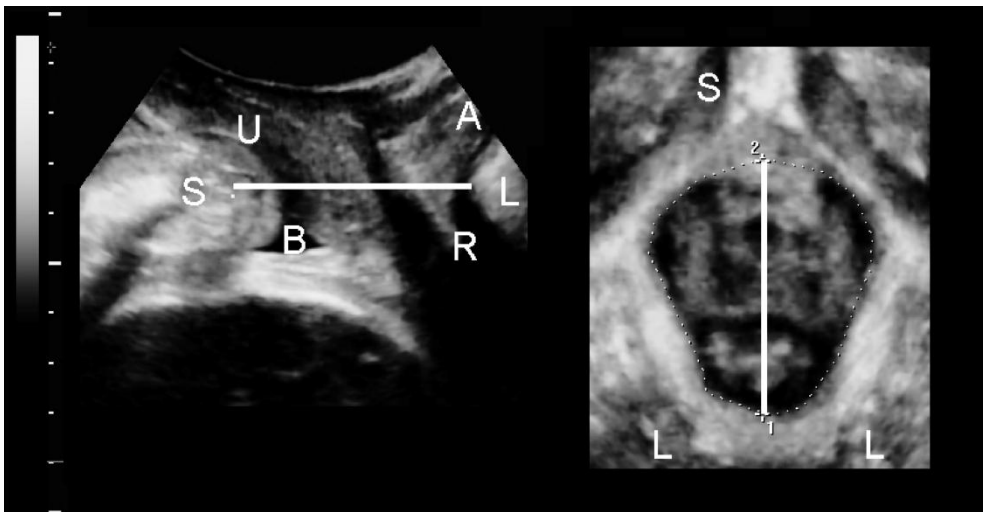

Figure 1: *Determination of hiatal dimensions by axial plane translabial ultrasound on Valsalva. The horizontal line in A and the vertical line in B identifies the ap diameter of the hiatus. The vertical line dotted line on the right show the measurement of hiatal area. S=symphysis pubis, U= urethra, B= bladder, R= rectum, A= anal canal, L= levator ani.*

	Ap hiatal diameter on Valsalva (cm)	**Hiatal area on Valsalva (cm2)**
genital hiatus (gh), in cm	r= 0.527 P<0.001	r=0.613 P<0.001
perineal body (pb), in cm	r= 0.561 P<0.001	r=0.533 P<0.001
gh+pb, in cm	r= 0.673 P<0.001	r=0.722 P<0.001

Table 1: *Associations between gh and pb with ultrasound measures of hiatal dimensions.*

Results

Interobserver reliability data (n=20) was obtained for hiatal area on valsalva (ICC 0.89, CI 0.73-0.95) and for anterior-posterior diameter on valsalva (ICC 0.85, CI 0.62- 0.94), indicating excellent repeatability. 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 BMI 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), voiding dysfunction (n=55) and symptoms of prolapse (n=96). 168 were vaginally parous, 48 had forceps/ vacuum deliveries. Fifty reported a previous hysterectomy, 37 incontinence or prolapse surgery. The genital hiatus on Valsalva (gh) was measured at a mean of 4.1 (range, 1.5-8) cm, mean perineal body (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 anterior-posterior dimension of the hiatus was 6.7 (range 3.7-9.1) cm. Both genital hiatus and perineal

body measurements correlated highly significantly with hiatal measurements (see Table 1), but the sum of both (gh+pb) showed the strongest association with ultrasound measures of hiatal size.
On testing ultrasound and clinical measures of hiatal dimensions against symptoms and signs of prolapse, we found that, as previously described, ultrasound measures were strongly associated with symptoms (AP diameter, 6.32 vs 7.08, P < 0.001; hiatal area, 23.47 vs 31.14, P < 0.001) and signs of prolapse (AP diameter, 5.77 vs 6.99, P < 0.001; hiatal area, 18.6 vs 29.99, P < 0.001). Clinical measures of hiatal dimensions were also associated with symptoms (gh, 3.65 vs 4.45, P < 0.001; pb, 3.59 vs 3.93, P = 0.011, gh+pb, 7.25 vs 8.38, P< 0.001) and signs of prolapse (gh, 2.91 vs 4.4, P < 0.001; pb, 3.19 vs 3.93, P<0.001, gh+pb, 6.12 vs 8.33, P< 0.001). 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 was superior in performance to the individual measures, and that gh+pb was comparable to hiatal area on ultrasound in its predictive performance (AUC 0.886 [CI 0.828-0.945] and 0.867 [CI 0.808-0.926] respectively for objective prolapse stage 2+). In order to define 'clinical ballooning' of the levator hiatus, we examined the ROC curve of gh+pb vs. significant (ICS POP-Q stage 2+) prolapse on clinical examination (see Figure 2). Optimal sensitivity (80%) and specificity (81%) was achieved with a cut-off of 7 cm for gh+pb.

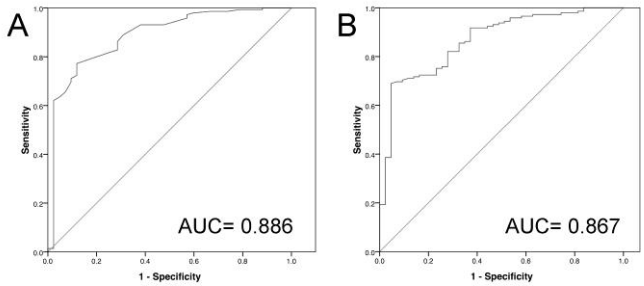

Figure 2: *Receiver operator characteristics (ROC) curves estimating the predictive performance of gh+pb (left, A) and hiatal area on Valsalva (right, B) for significant (ICS POP-Q stage 2+) prolapse on clinical examination.*

Interpretation of results
The combination of genital hiatus and perineal body measured on Valsalva is a strong predictor of symptoms and signs of prolapse, stronger than the individual measurements. A cut- off of 7 cm is proposed which provides sensitivity of 80% and specificity of 81% for significant (stage 2+) prolapse.

Concluding message
We propose that 'ballooning' of the levator hiatus on clinical examination be defined as gh+pb=>7 cm on maximal Valsalva.

References
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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**SWAHS HREC No (11/13)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**