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A SIMPLIFIED METHOD FOR DETERMINING HIATAL BIOMETRY

Hypothesis / aims of study:
The levator hiatus is the largest potential hernial portal in the human body and of importance both for childbirth and for pelvic organ support. It is associated with progress in labour[1] and with pelvic organ prolapse[2] and may be an independent risk factor for prolapse (unpublished own data). Hiatal biometry to date has been determined in single plane images obtained at the plane of minimal hiatal dimensions[3], but this may not always be appropriate since the true plane of minimal dimensions is non- Euclidean, i.e. warped. We undertook a study to determine whether rendered volumes may be more valid and repeatable in the determination of minimal hiatal dimensions since measurements in a rendered volume could account for the non-euclidean shape of the true plane of minimal dimensions.

Study design, materials and methods:
This study is a prospective analysis of previously obtained 4D ultrasound volume datasets of patients seen in a tertiary urogynaecology service. They underwent a clinical assessment including ICS POP-Q and assessment of the levator ani by palpation, as well as free uroflowmetry and translabial 4D ultrasound (GE Kretz Voluson 730 expert with RAB 8-4 Mhz transducer). Datasets comprised 4D ultrasound data obtained supine and after voiding, at rest, on maximal Valsalva, and on maximal pelvic floor muscle contraction. Offline analysis was undertaken at a later date, blinded against all clinical data. Hiatal measurements were obtained in sectional planes (SP, Method A) firstly as previously described[3], and secondly by measuring the same parameters in rendered volumes (RV, Method B) of 1- 2 cm thickness, with the centre of the rendered volume close to plane of minimal hiatal dimensions, with the second series of measurements blinded against the first. The thickness of the rendered volume was optimised visually to produce as clear an image of the hiatus as possible before measuring. We tested the repeatability of both methods in interobserver series; validity was tested by analysing the association between hiatal area on Valsalva and pelvic organ descent. This study was an extension of an HREC- approved parent project.

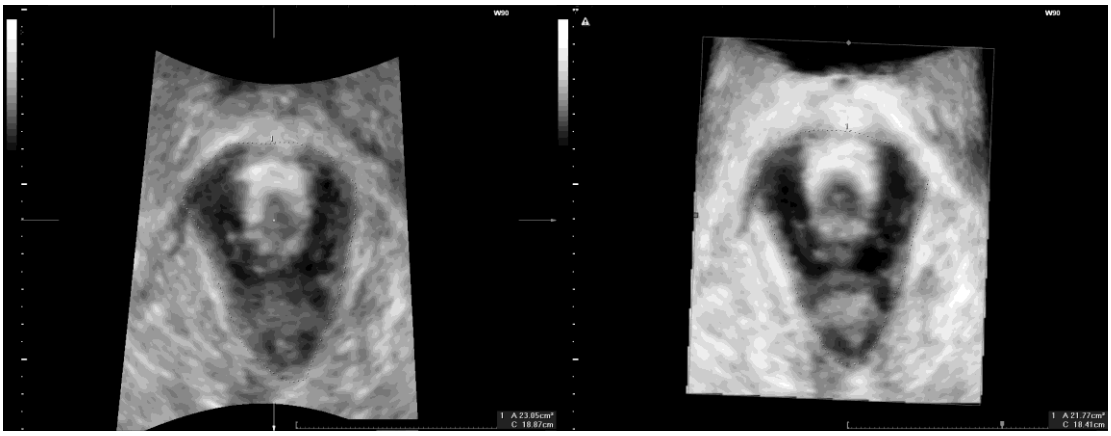

Figure 1: Hiatal area measurements using single plane (A, area =23.05 cm2) and rendered volume methods (B, area= 21.77 cm2).

Results:
One hundred and four consecutive patients were identified. In four cases 4D volumes were irretrievable, leaving 100 datasets. All subsequent data (except the test- retest series) relates to those 100 patients, but in a few patients volumes on Valsalva (n=3) or on PFMC (n=2) could not be assessed. A test – retest series in 20 patients showed similar repeatability for both methods, with an Intraclass correlation (ICC) of 0.85 (CI 0.81- 0.88) for Method A (SP) and of 0.88 (CI 0.85-0.9) for Method B (RV). Mean age was 54.8 (range 17.6- 83). Stress incontinence was reported by 78%, urge incontinence by 71%, frequency by 49%, nocturia by 60%, symptoms of prolapse by 46%. Ninety- one women were vaginally parous, and the median number of vaginal deliveries was 3 (1-9). Twenty- nine women had had a hysterectomy, and 24% an incontinence or prolapse procedure. A significant prolapse (stage 2 or higher) was detected in 54%; most commonly this was a cystocele (38%) or a rectocele (33%). In a total of 20 women we detected an avulsion injury that was right- sided in 16 women, left-sided in 12, and bilateral in 8 women.

Parameter	**Method A**	**Method B**	**t-test**	**Limits of agreement**	**Bias**	**r**
Sagittal diameter, rest in cm	5.64 (0.79)	5.62 (0.84)	P=0.5	-0.913 to 0.852	-0.03	0.85
Coronal diameter, rest in cm	4.34 (0.66)	4.30 (0.72)	P=0.4	-0.914 to 0.842	-0.04	0.79
Area at rest in cm^2	17.68 (4.95)	17.26 (4.79)	P=0.085	-5.114 to 4.279	-0.42	0.88
Sagittal diameter on Valsalva in cm	6.78 (1.14)	6.71 (1.18)	P=0.32	-1.276 to 1.151	-0.06	0.86
Coronal diameter on Valsalva in cm	5.42 (1.0)	5.34 (1.04)	P=0.1	-1.021 to 0.860	-0.08	0.89
Area on Valsalva, cm^2	27.86 (9.1)	27.04 (9.56)	P=0.005	-6.224-4.595	-0.82	0.96
Sagittal diameter, PFMC in cm	4.95 (0.87)	4.76 (0.80)	P=0.009	-1.577 to 1.168	-0.21	0.65

Coronal diameter, PFMC in cm	4.17 (0.69)	4.08 (0.74)	P=0.2	-1.43 to 1.24	-0.1	0.55
Area on PFMC in cm^2	14.76 (4.38)	13.96 (4.01)	P=0.044	-8.481 to 6.781	-0.85	0.58

Table 1: *Limits of agreement and bias for hiatal measurements (n=100) obtained by methods A and B. N=100 at rest, n=97 on Valsalva, and n=98 for PFMC.*

On comparing data for the two methods, there was a general trend for measurements taken from rendered volumes to be lower. This reached significance for area on Valsalva (P= 0.005) as well as sagittal diameter and area on pelvic floor contraction (P= 0.009 and P= 0.044). Table 1 provides limits of agreement and bias for hiatal biometry. Pearson's correlations demonstrated a high concordance for biometric measures, especially for measurements on Valsalva (r= 0.857- 0.957) and at rest (r= 0.792- 0.88). In order to validate the two different methodologies we tested hiatal area on valsalva, previously described as a strong predictor of symptoms and signs of prolapse. Method B seemed more strongly associated with symptoms of prolapse than method A (P= 0.008 vs. P= 0.027). This was confirmed on validating both methods against significant prolapse (ICS POP-Q >=2), with the RV method performing slightly better (SP, T=-6.64, P< 0.001 vs. RV, T= -6.95, P< 0.001). On average, women with significant prolapse had an area on Valsalva that was 50% larger than those without.

Interpretation of results

Levator hiatal biometry can be determined in rendered volumes obtained by 4D translabial ultrasound. Such measures are strongly correlated with diameters and areas obtained in sectional planes. Compared to sectional plane measurements, this simplified methodology may be more strongly associated with symptoms and signs of prolapse, supporting the validity of the method. This may be due to the fact that the plane of minimal hiatal dimensions is not a Euclidean plane, but non- Euclidean, i.e., warped. Repeatability appears similar for both methods. In view of the simplicity and theoretically higher accuracy we recommend that levator hiatal diameters and areas be obtained from rendered volumes of the hiatus.

Concluding message

In view of the simplicity and theoretically higher accuracy we recommend that levator hiatal diameters and areas be obtained from rendered volumes of the hiatus.

References

1. Aust NZ J Obstet Gynaecol 2007, 47(3):176-180
2. Ultrasound Obstet Gynecol 2008, 31:676-680
3. Ultrasound Obstet Gynecol 2005, 25:580-585

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**SWAHS HREC**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**