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INTRA- AND INTER-READER VARIABILITY OF TRANSVAGINAL ULTRASOUND BLADDER WALL THICKNESS MEASUREMENTS: RESULTS FROM THE SHRINK STUDY

Hypothesis / aims of study

Previous studies suggest that bladder wall thickness (BWT), measured using transvaginal ultrasound, is increased in women with overactive bladder (OAB) or detrusor overactivity (DO), compared with women with normal urinary function or stress urinary incontinence (1,2). The SHRINK study investigated the effect of solifenacin on BWT in women with OAB and DO. This analysis aimed to evaluate the extent of intra- and inter-reader variability in BWT measurements from the SHRINK study (clinicaltrials.gov identifier: NCT01093534).

Study design, materials and methods

The SHRINK study was conducted at 79 centres in 20 countries across Europe, the Middle East and the USA. The study randomised 547 subjects 1:1:1 to solifenacin 5 mg, 10 mg or placebo, and bladder wall images were taken from 501 patients after voiding (PVR <30 mL) at baseline, Week 6 and/or Week 12 or at time of discontinuation. Images were assessed by two blinded central readers at three locations (anterior, dome and trigone), and a mean BWT was derived per subject. Images were assessed by a third reader in cases of significant variability between the two readers ($p<0.05$, based on Bland-Altman limits of agreement) (3). For assessment of intra-reader variability, the same subset of 40 images was assessed twice by each of the three readers and the mean difference (with standard deviation, 95 % CI and paired t-test) was calculated for each reader. Inter-reader variability was assessed as the mean differences between readers for a total of 1544 images from all time-points.

Results

Intra-reader variability: The mean difference between the first and second reading of the 40 images was <0.2 mm for both reader 1 and 3 ($p=0.575$ and $p=0.186$, respectively) and -0.4 mm for reader 2, which reached statistical significance both for mean BWT ($p=0.013$; Table) and at all three locations. Inter-reader variability: An image was considered readable when a central reader could measure at least two locations. Reader 1 and 2 agreed on image readability for > 91% of 1544 images. The mean difference in average BWT between the two main central readers was 0.4 mm (Table) and the largest difference was observed between readers 1 and 3, at 1.1 mm. Measurements of reader 1 and reader 3 were similar for anterior and dome, but smaller for the trigone, while measurements for reader 2 were similar for all three locations.

Interpretation of results

Variability in BWT measurements was observed between readers, with the greatest differences occurring between readers 1 and 3. Differences in measurements for the trigone versus anterior or dome may show more variability and be affected by factors including poor demarcation of the trigone and focal plane.

Concluding message

Intra-reader variability in BWT measurements was generally low, and although inter-reader variability was higher, differences were still small. We conclude that transvaginal ultrasound is a reliable method of assessing BWT in women with OAB and DO.

Summary of average BWT measurements (mean of anterior, dome and trigone)

		No. Images	**Mean BWT in mm (SD)**	**95% confidence interval**
Reader 1	Session 1	39	4.740 (1.114)	4.384, 5.096
	Session 2	40	4.684 (1.099)	4.333, 5.036
	Difference	39	-0.056 (0.626)	-0.256, 0.144
Reader 2	Session 1	40	5.432 (1.252)	5.032, 5.833
	Session 2	40	4.996 (1.254)	4.595, 5.397
	Difference	40	-0.437 (0.799)*	-0.692, -0.181
Reader 3	Session 1	39	5.585 (1.368)	5.141, 6.028
	Session 2	40	5.395 (1.231)	5.001, 5.789
	Difference	39	-0.158 (0.732)	-0.395, 0.079
Reader 1 vs 2		1425	-0.391 (1.068)	-2.485, 1.702
Reader 1 vs 3		160	-1.126 (1.717)*	-1.394, -0.858
Reader 2 vs 3		150	0.325 (1.801)*	0.034, 0.615

*$p<0.05$

References

1. Br J Obstet Gynaecol 2002; 109:145–8.
2. Neurourol Urodyn 2011; 30:325–8.
3. Lancet, 1986; 327: 307-10.

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