INTRA- AND INTER-OBSERVER REPRODUCIBILITY OF VAGINAL TACTILE IMAGING

Heather van Raalte[1], Vincent Lucente[2], Sonya Ephrain[2], Miles Murphy[2], Nina Bhatia[1], Noune Sarvazyan[3], Vladimir Egorov[3]*

[1] Princeton Urogynecology, Princeton, NJ; [2] The Institute for Female Pelvic Medicine, Allentown, PA; [3] Artann Laboratories, Trenton, NJ.

INTRODUCTION

Tactile imaging, a form of elastography, translates the sense of touch into a digital image and allows assessment of tissue elasticity and muscle strength. The female pelvic organs likely have varying viscoelastic characteristics across physiological states, healthy and diseased conditions. This makes the pelvic floor tissues amenable to evaluation by tactile imaging techniques, opening up new possibilities for the quantitative biomechanical assessment and monitoring of pelvic floor conditions [1]. The Vaginal Tactile Imager (VTI) allows a large body of measurements/markers [2] to evaluate individual variations in tissue properties and muscle function in patients with pelvic organ prolapse and stress urinary incontinence.

AIM

To assess intra- and inter-observer agreements for a set of vaginal tactile imaging markers characterizing the pelvic floor conditions and reproducibility of vaginal tactile imaging.

MATERIAL & METHODS

A vaginal tactile imaging probe that images the vagina, pelvic floor support structures and pelvic floor muscle contractions in real time was utilized [3]. The analyzed set of VTI markers consists of 10 parameters (pressure and pressure gradients) acquired in 8 clinical tests to assess the vaginal and surrounding support structures tissue elasticity at rest, with manually applied deflection pressures and with voluntary, involuntary muscle contraction, involuntary relaxation, and Valsalva maneuver. Each of 10 parameters was measured at 4 characteristic locations [2]. We enrolled 12 subjects into a reproducibility sub-study of larger observational case-controlled study (NCT02294383). The patients were studied with the vaginal tactile imaging probe in lithotomy position. Two measurements of the full set of VTI markers were obtained by two observers. Agreement within and between observers and between observers for VTI markers was analyzed using 95% prediction intervals, Bland-Altman plots with 95% limits of agreement and the intraclass correlation coefficient (ICC). Tactile imaging reproducibility was calculated as a median tactile imaging deviation (TID) according to equation (1) in [1] for VTI tests 1-3.

RESULTS

All 12 subjects were successfully scanned with the VTI four times; two scans were completed by each of two operators. Mean patient age was 39.0 years (range 26 to 60), pelvic floor conditions were from normal (10 subjects) to Stage I/II POP (one subject with Stage 1 and one subject with Stage II prolapse) and mean parity was 1.2 (range 0 to 2). We analyzed the data set with 1920 VTI measurement records (12 subjects x 10 parameters x 4 locations x 4 VTI scans).

Intra-observer ICCs were found in the range from 0.80 (test 8: cough) to 0.92 (test 3: probe rotation) with average value of 0.87. Figures 1 and 2 present results for VTI test 1 and 5. Inter-observer ICCs were found in the range from 0.73 (test 2; elevation pressure and test 8: cough) to 0.92 (test 3: rotation) with average value of 0.82 Intra-observer ICCs was found in the range from 0.80 (test 8: cough) to 0.92 (test 3: rotation) with average value of 0.87 for all 10 parameters. Intra-observer limits of agreement were in the range from ±11.3% (test 1) to ±19.0%% (test 8) with average value of ±15.1%. Inter-observer limits of agreement were in the range from ±12.0% (test 5: voluntary contraction) to ±26.7% (test 2: elevation) with average value of ±18.4%. The median values for TID (4 VTI scans) were found as 6.6% for test 1 (probe insertion), 15.6% for test 2 (probe elevation) and 11.2% for test 3 (probe rotation).

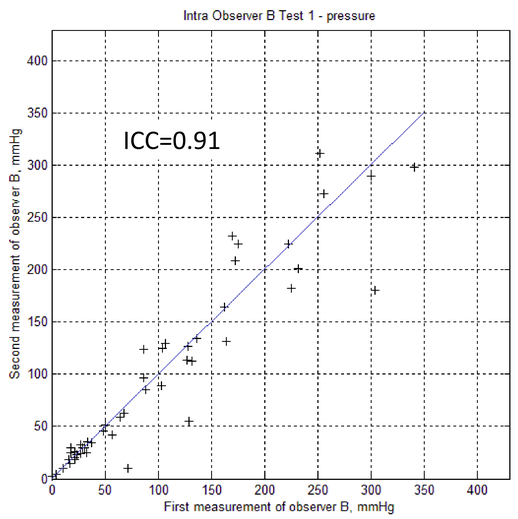

Figure 1. Intra-observer reproducibility, test 1

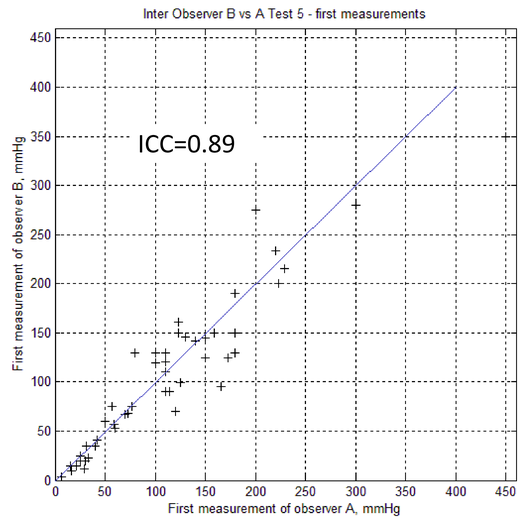

Figure 2. Intra-observer reproducibility, test 5

SUMMARY / CONCLUSION

There is reasonable intra- and inter-observer reproducibility for VTI measurements, though improved inter-observer reproducibility may be possible by additional operator training and consistency in VTI examination technique.

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Contact information: www.tactile-imaging.com

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