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REPRODUCIBILITY OF INTRA-ABDOMINAL PRESSURE MEASURED DURING PHYSICAL ACTIVITIES VIA A WIRELESS VAGINAL TRANSDUCER

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Abstract

Aims—In the urodynamics laboratory setting, a wireless pressure transducer, developed to facilitate research exploring intra-abdominal pressure (IAP) and pelvic floor disorders, was highly accurate. We aimed to study reproducibility of IAP measured using this transducer in women during activities performed in an exercise science laboratory.

Methods—Fifty seven women (mean $\pm$ SD: age 30.4 ± 9.3 years; body mass index = 22.4 ± 2.68 kg/m²) completed two standardized activity sessions using the same transducer at least three days apart. Pressure data for 31 activities were transmitted wirelessly to a base station and analyzed for mean net maximal IAP, area under the curve (AUC) and first moment of the area (FMA.)

Activities included typical exercises, lifting 13.6 to 18.2 kg, and simulated household tasks.

Analysis for test-retest reliability included Bland-Altman plots with absolute limits of agreement (ALOA), Wilcoxon signed rank tests to assess significant differences between sessions, intraclass correlations, and kappa statistics to assess inter-session agreement in highest vs. other quintiles of maximal IAP.

Results—Few activities exhibited significant differences between sessions in maximal IAP, or in AUC and FMA values. For 13 activities, the agreement between repeat measures of maximal IAP was better than ± 10 cm H₂O; for 20 activities, better than ± 15 cm H₂O. ALOA increased with mean IAP. The highest quintile of IAP demonstrated fair/substantial agreement between sessions in 25 of 30 activities.

Conclusion—Reproducibility of IAP depends on the activity undertaken. Interventions geared towards lowering IAP should account for this, and maximize efforts to improve IAP reproducibility.

Keywords

intra-abdominal pressure; test-retest reliability; limits of agreement; reproducible; pressure transducer

INTRODUCTION

Increased intra-abdominal pressure (IAP) may predispose women to new or recurrent pelvic floor disorders (PFDs). Many clinicians discourage strenuous activity in women at risk for PFDs. Understanding the potential association between IAP and PFDs requires an instrument that can measure IAP in women during real-life activities. IAP is measured indirectly during urodynamics testing and during certain clinical scenarios, notably in intensive care units to diagnose abdominal compartment syndrome. IAP has been studied during activities performed by women tethered to a urodynamics machine. (1–3) To overcome limitations of such wired devices and to improve participant comfort, we developed a wireless vaginal (rather than rectal) pressure transducer to measure IAP during physical activities. (4–6) In the laboratory, this transducer has an accuracy of $0.7 \pm \text{SD } 3.35$ cm H₂O when compared against a reference pressure transducer with a NIST-traceable calibration over the measurement range of 0–350 cm H₂O.) (5, 6)

There are many potential sources of variation when measuring IAP in a laboratory protocol. Though a transducer may have excellent reliability on bench testing, many factors may cause variation in IAP measured in women doing 1 different activities in succession, such as displacement, signal density, awkward or unfamiliar tasks, body position, different degrees of effort, or different techniques used to accomplish a task. (7–10).

We recently reported the range of values of the intra-abdominal pressures produced by this transducer and various ways of analyzing the measurements (11); in the current paper, we focus on the repeatability of measurements. The aim of this study is to use the wireless vaginal pressure transducer and associated software we have developed to determine the test-retest characteristics, at least three days apart, of IAP in women during a variety of activities. Because we do not know, at this time, whether sporadic high-amplitude peaks (high pressure events) or multiple, sustained lower-amplitude peaks (continuous pressure) in IAP are more likely to impact the pelvic floor, we assessed the reproducibility of the standard maximal IAP plus two other constructs of IAP: area under the curve (AUC) and first moment of the area (FMA)(12). AUC equally weights time and amplitude of pressure. FMA takes time into consideration and prioritizes pressure amplitude. (12) Testing these

constructs in future clinical populations will allow differentiation of the impact of different patterns of IAP. For example, AUC differentiates a very short activity with a high pressure, such as a cough, from a short duration activity with the same maximal pressure such as slowly lifting a heavy object. High-pressure/short-duration activities can produce similar AUC results when compared to low-pressure/long duration activities. However, the FMA will differ as it prioritizes amplitude over time, rather than equally weighting amplitude and time.

MATERIALS AND METHODS

The University of Utah Institutional Review Board approved this study, and all participants signed informed consent documents. Participants, women ages 18 to 54 years, who were regular participants in a strenuous activity and able to do 2 strenuous 1-hour sessions, were excluded if they responded positively to any question on the Physical Activity Readiness Questionnaire (13), were currently pregnant, within six months post-partum, reported sensations of a vaginal bulge, were unable to insert a tampon, or had an injury prohibiting completing the activities. Incontinence was not an exclusion.

Participants completed activity sessions when not menstruating, in the same temperature controlled indoor laboratory as previously described (11). Each woman completed two separate sessions, at least 3 days apart, using the same transducer. The same research assistant (NH, a certified athletic trainer with an MS in Exercise Science) led each session using a scripted protocol. Intra-abdominal pressures were not available to the research assistant during testing, although a non-quantified tracing of IAP was visible on the wirelessly connected computer screen, thus allowing the research assistant to know that the sensor was collecting data. This research assistant and the bioengineering PhD student (TC) operating the Matlab program were masked to previous IAP values when conducting/analyzing session 2. After voiding, women inserted the pressure transducer into the upper vagina, and the external antenna was taped to the abdomen. The standardized protocol included 31 activities (Table I) designed to include varying intensities of exercise tasks and simulated routine household activities that could be replicated in the exercise science laboratory. Walking and running tasks were done on a Quinton Q-Stress TM55 treadmill (Bothell, WA, USA); and cycling tasks, on a Monark 828E cycle ergometer (Vansbro, Sweden). Most activities required 20 to 40 seconds to complete. Participants were instructed to do 3 repetitions of coughing, Valsalva, lifting and carrying tasks; 8 repetitions of seated shoulder press; and 10 jumps to maximal height from the floor. For the remaining activities, women were instructed to continue the activity for 30 seconds as tolerated. For safety reasons, the activity order was consistent, beginning with gradual warm-up, progressing to higher intensity activities, followed by easier tasks to reduce heart rate, and ending with stretching. However, we placed Valsalva maneuver and jumping at the end, to avoid possible transducer displacement and consequent disruption of protocol flow.

Matlab software (R2009A, MathWorks; Natick, MA, USA) was used to create the variables of interest for analysis. Our methods for calculating IAP measures are described in detail elsewhere (12). Briefly, we measured maximal IAP as a function of a pre-specified number of peaks representative of the highest pressures during activity and calculated mean net

maximal IAP (from now on called maximal IAP) as the mean of the difference between the highest peaks and lowest troughs obtained from the pressure tracing for that activity. Net pressure was chosen to study the level to which activities increase intra-abdominal pressure rather than recalibrating to atmospheric pressure (zero) or determining a postural baseline for each activity.

AUC and FMA are time dependent variables, so for activities without a discrete number of repetitions, e.g., running, we calculated these for the duration of that activity segment and then standardized to a 10-second time period. For activities with a discrete, specified number of repetitions, e.g., lifting, we included only women who completed the required number of repetitions at both activity sessions.

The number of women with complete data for each activity for both sessions varies. Some women were unable to complete an activity, and in unusual instances, the transducer fell out of the vagina, or the base station did not appropriately receive the data. Six women were excluded because the transducers experienced technical problems, which caused anomalously high pressures. We elected to include all data for women who reported feeling slippage of the transducer, since this is a 'real-life' issue when measuring IAP using a vaginal transducer.

As we did not have pilot data for standard deviations for all IAPs, we planned a final sample size of 56 to fit several potential scenarios: this provided a 2-sided 95% confidence interval of width 0.1 for an expected intraclass correlation of 0.8; 80% power at the 5% significance level to test the null hypothesis that a Spearman correlation was no more than 0.6 versus an alternative hypothesis of 0.78 or greater; and 80% power at a 2-sided 5% significance level to detect an effect size of 0.38 in Bland-Altman t-tests. To account for potential drop-outs and possible non-normality, we enrolled 60 women.

We scrutinized Bland-Altman plots and calculated absolute limits of agreement (ALOA) for each activity (average difference $\pm$ 2 standard deviations of the difference.) For example, an ALOA of 20 cm H₂O means that two IAP values would have to be more than 20 cm H₂O apart to represent a 'real' difference beyond test-retest uncertainty. Two IAP values closer together than the ALOA could be due to test-retest variability. Thus, we considered ALOA less than a difference of clinical interest to show adequate repeatability, if there was no significant mean difference between sessions. (14, 15) We also calculated standard intra-class correlations. We tested for significant differences between sessions with Wilcoxon signed rank tests, due to non-normality. As the results of this study can be used to guide future research on interventions that lower IAP, we conservatively chose to present nominal p-values, using the conventional 5% significance level, rather than making a correction for multiple testing.

To determine the test-retest agreement of "high" versus "not high" maximal net IAP between sessions, we faced the conundrum that there is no established cut-point or threshold that determines "high" IAP. Therefore, we tested the agreement of the upper quintile of pressure in each session ('high') vs. the other 4 quintiles combined ('low'), via a kappa statistic with p-values from the exact test and quintiles calculated separately for each session

for each activity except 9.1 kg shoulder press as only 8 women could do this. We tested symmetry of misclassification using McNemar's test. We considered kappa 0.4 to show adequate agreement of high vs. low IAP, as kappa is corrected for chance agreement.

RESULTS

Of 60 consented women (Figure 1), 57 completed two sessions and 51 remained after exclusions for technical issues. The mean age of the remaining 51 women was 29.2 years (SD 8.2, range 20–50) with mean body mass index 22.4 kg/m² (SD 2.59, range 17.7–28.9). Forty-one women (80%) were normal weight, 1 (2%) underweight, and 9 (18%) overweight; none were obese. Thirty-nine women (76%) were nulliparous; 11 (22%) had 1–3 live births, and one woman (2%) had more than three live births. Fourteen women reported that they felt the transducer location shift during one of the activity protocols, six into the lower vagina, four unspecified, and four into their underwear (two of these women withdrew and thus are not included.)

Table I displays means and standard deviations of maximal IAP, intraclass correlations, differences between sessions, and ALOA from Bland-Altman analysis. Figure 2 displays Bland-Altman plots for maximal IAP for more reproducible variables selected for a range of IAP. AUC was similar, and FMA was somewhat less reproducible (data available from the authors upon request.) Wilcoxon tests showed no differences between sessions ($P>0.05$) in maximal IAP, except for walking at 7% grade. In Bland-Altman plots, almost all data were within the limits of agreement, with 1–3 outliers; but outliers were far outside the limits for 14 activities.

Table II displays kappa values for the test-retest agreement of “high” maximal IAP (80th percentile for each activity). Kappas ranged from 0.00 to 1.00, with 25 of 31 above 0.4. Thus the great majority reflected fair to substantial agreement beyond chance (16). Results were similar for AUC and FMA, with kappas ranging from –0.20 to 0.86 and 20 of 31 kappas above 0.4, for each measure. There was no asymmetry of misclassification in evidence ($p>0.10$ in all activities by McNemar's test, data not shown).

DISCUSSION

In this study, we address the reliability of IAP measured in vivo, and not simply the reliability of the wireless vaginal transducer. Not surprisingly, IAP during specific activities varies when measured several days apart. While the device is highly accurate in bench testing, testing in women adds variability from many potential sources. However, from a clinical point of view, as seen in Table 1, the results generated by this device serve well to rank activities in terms of their impact on IAP.

Few activities exhibited statistically significant differences between sessions in maximal IAP, or in AUC and FMA values. For 13 activities, the agreement between repeat measures was better than ± 10 cm H₂O and for 20 activities it was better than ± 15 cm H₂O. “High” IAP for a given activity (upper 80th percentile) was generally reproducible between sessions; that is, women who exerted greatest pressure during the first session also tended to do so during the second session. The kappas for ‘high’ values of maximal IAP were moderate or

substantial, beyond chance, for most activities. None of the activities showed asymmetric disagreements between upper quintiles of the two sessions.

The reproducibility of activities is particularly important to consider when planning interventions designed to lower IAP during a specific activity. The precision of the device cannot overcome the lack of precision introduced by the human body and its environment. We found that in general, variability increases as mean IAPs for activities increase. For example, the ALOA for lifting 18.2 kg from floor to counter, an activity with mean IAP of 49.6 cm H₂O in the first session, was + 27.9 cm H₂O. Minimal variation in IAP may make a big clinical difference in diagnosing and managing abdominal compartment syndrome (17), but it is biologically implausible that small changes in IAP impact PFDs. Similar to studies exploring various performance indices, (18) we found that some of the activities with greatest ALOA are those that are more difficult to standardize: the ALOAs are much lower for shoulder press than for extemporaneous lifting and lower for seated cycling than for standing cycling.

To tell whether or not a measurement has changed meaningfully on a second occasion requires knowing that the difference between the two measurements is clinically interesting, statistically significant, and has small measurement uncertainty compared to the change. Based on our data, for some activities, larger improvements may be needed to see an effect beyond the test-retest uncertainty. For example, using our data, how would we demonstrate that a new approach to strengthen abdominal muscles decreases IAP compared to standard sit-ups (upper ALOA of 34.1 cm H₂O)? The new approach would need to decrease IAP from a mean of 62 cm H₂O for sit-ups to 28 cm H₂O, to overcome the inherent test-retest variability, if no further measures were taken to limit variability. We standardized the activity protocol, but in order to capture the all potential sources of variability in IAP, we did not standardize body position, effort, technique differences, baseline strength, or familiarity with activities. We included data from women in whom the transducer slipped into the lower vagina during activity; as we did not perform pelvic exams, we do not know whether this occurred more frequently in women with worse vaginal support. When researchers test the effect of interventions intended to lower IAP, we suggest that they attempt to standardize, to the degree possible, these myriad factors that might impact IAP.

We studied reliability of two newer IAP measures, AUC and FMA, in addition to maximal IAP. It is not yet clear which measure is best suited to study associations between IAP and pelvic floor disorders but our data suggest similar levels of agreement when IAP is measured with any of these three methods, though uncertainty is more pronounced with FMA. This transducer's IAP correlated well with those simultaneously obtained via the traditional gold standard, transrectal urodynamics catheter. (5, 6) Others have also shown that pressures in the upper vagina approximate those measured via rectal or bladder transducers (19, 20) and that rectal and bladder pressures approximate true intra-abdominal pressure (21, 22). However, measuring from the vagina likely adds unknown pressures from viscera, vaginal smooth muscle, and other unknown sources, which may contribute to variation. Other study limitations included a non-prolapsed, non-elderly, non-obese study population (age 20–50, BMI 17.7–28.9, 24% parous). We did not collect data on

incontinence. Women with prolapse may not be able to insert the device. Thus, the device is viewed as facilitating the measurement of risk factors.

As far as we know, this is the first study to assess test-retest reproducibility of IAP during standardized activity sessions done on different days. Kruger and colleagues (2013) demonstrated high repeatability for maximal IAP with another intra-vaginal transducer in 14 women who performed three consecutive sets of activities (23). In addition to differences in the transducer used, the activity protocols and the separation in time between sessions, Kruger et al. manually selected starting and ending points to create each measure, similar to marking urodynamic events. We used MATLAB software developed to automate this process to facilitate future research in real-life settings. Similar to Kruger et al., in our study, each woman wore the same device twice. It is not feasible to assess the reliability of IAP measured by two different intra-vaginal devices in the same woman at the same time. Thus these results apply only to longitudinally repeated measurements where the woman wears the same device in repeated measurements.

In conclusion, these results suggest that IAP data generated using this wireless vaginal transducer helps to understand the mean IAP during activities of a population. Some activities do not produce the same IAP consistently. Activities with higher maximal IAP tend to have greater variability between sessions. Women who express high IAPs during specific activities tend to do so consistently. Research designed to test the effects of interventions that lower IAP on PFDs should take such variability into account. However, there is moderate agreement of the upper quintiles of IAP in these activities, suggesting that such cut-points can be used in future research.

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Figure 1.
Participant Flow Diagram

Figure 2.
Bland-Altman plots of maximal IAP for more-reproducible activities spanning low to high values of mean IAP
Note: ICC=intraclass correlation, K=Kappa

Table 1
Characteristics of maximal IAP in a panel of activities performed at each of two sessions

Activity	Session Means and SDs					Differences Between Sessions			Absolute Limits of Agreement		
	N ₁	Mean ₁	SD ₁	N ₂	Mean ₂	SD ₂	ICC	Mean _{diff}	SD _{diff}	P Value (Signed Rank)	± ALOA
Lower back stretch	51	5.97	2.07	49	5.9	2.29	0.37	0.01	2.45	0.79	4.9
Seated cycling 450kg·m·min ⁻¹	51	8.16	2.02	51	8.45	3.68	0.44	-0.29	3.14	0.62	6.27
Seated cycling 600 kg·m·min ⁻¹	51	10.74	2.49	51	11.24	3.06	0.69	-0.50	2.19	0.05	4.38
Side lying quadriceps stretch	51	10.48	4.19	49	9.61	3.89	0.30	0.96	4.76	0.30	9.52
Seated hamstring stretch	50	10.02	3.95	49	10.41	3.67	0.51	-0.32	3.76	0.86	7.52
Erasing board, dusting	50	10.92	4.55	49	10.93	5.11	0.74	0.01	3.50	0.93	6.99
Scrubbing floor on hands and knees	51	12.15	8.09	50	12.2	7.88	0.70	0.06	6.25	0.64	12.49
Seated shoulder press, 3.6 kg	39	10.12	4.71	40	10.44	6.95	0.50	-0.48	5.93	0.70	11.86
Seated shoulder press, 4.5 kg	42	12.74	6.41	41	12.03	5.27	0.83	0.77	3.37	0.17	6.73
Seated shoulder press, 5.5 kg	36	11.48	4.94	34	12.89	5.36	0.39	-0.97	5.61	0.26	11.22
Seated shoulder press, 6.8 kg	11	12.21	3.63	11	15.42	5	0.37	-3.40	4.48	0.06	8.96
Seated shoulder press, 9.1 kg	8	21.82	9.82	7	18.78	4.2	0.73	2.02	5.33	0.56	10.66
Isometric side bridge	50	16.48	8.38	48	15.04	7.73	0.81	1.47	4.80	0.08	9.61
Push-ups from knees	51	15.97	6.87	48	16.78	7.71	0.63	-0.41	6.23	0.80	12.47
Modified superman	50	21.32	8.45	47	20.27	8.24	0.74	0.79	5.93	0.55	11.85
Walk 4.8km·h ⁻¹ , 0% grade	51	24.63	4.08	51	24.15	3.56	0.73	0.48	2.80	0.31	5.6
Walk 4.3 km·h ⁻¹ , 0% grade, with 11.4 kg weight	50	26.98	5.39	51	26.5	4.98	0.38	0.50	5.77	0.25	11.55
Walk 4.8 km·h ⁻¹ , 7% grade	51	29.09	5.48	51	27.94	4.52	0.75	1.14	3.45	0.01	6.89
Walk 5.6 km·h ⁻¹ , 7% Grade	51	35.62	6.7	51	33.71	6.14	0.68	1.91	4.94	<0.01	9.88
Stepping, 20 cm Step	50	30.79	7.02	51	29.72	6.56	0.72	1.10	5.00	0.12	9.99
Abdominal curl ups	51	22.11	14.91	49	20.75	15.45	0.78	1.63	10.07	0.16	20.15
Stand to sit	49	36.81	15.15	48	39.69	30.72	0.52	-2.84	23.42	0.95	46.83
Standing cycling 900 kg·m·min ⁻¹	50	42.78	10.56	51	41.55	12.67	0.56	0.83	10.97	0.85	21.94
Lift 13.6 kg, floor to counter & back	50	34.4	9.01	50	34.13	9.39	0.60	0.51	8.19	0.57	16.39
Lift 18.2 kg, floor to counter & back	49	49.59	18.69	50	50.35	19.38	0.73	-0.71	13.96	0.83	27.92
Run 8-9.7 km·h ⁻¹ , 0% grade	50	66.02	13.72	51	62.67	14.82	0.59	3.42	12.78	0.09	25.57
Full sit ups with feet held	51	62.89	23.37	50	61.44	25.56	0.76	2.08	17.05	0.55	34.09

Activity	Session Means and SDs					Differences Between Sessions			Absolute Limits of Agreement	
	N ₁	Mean ₁	SD ₁	N ₂	Mean ₂	SD ₂	ICC	Mean _{diff}	SD _{diff}	± ALOA
Jumping	44	87.91	25.15	46	87.3	29.61	0.59	1.48	24.28	48.57
Coughing	43	100.28	34.76	45	98.32	31.7	0.81	-3.60	19.49	38.99
Lying Valsalva	49	91.16	32.59	48	87.55	39.34	0.77	2.63	23.99	47.98
Seated Valsalva	50	124.81	41.74	49	119.51	48.03	0.82	6.91	26.19	52.39

IAP =intra-abdominal pressure; N₁, N₂, N_{diff}=number of participants to complete a given activity with adequate data in sessions 1, 2 and their difference, respectively; Mean₁, Mean₂, Meandiff, SD₁, SD₂, SD_{diff}=means and standard deviations of maximal IAP (cmH₂O) in sessions 1, 2 and their difference, respectively; P Value (Signed Rank)=P-value from the Wilcoxon signed rank test of the difference between sessions; ALOA=absolute limits of agreement=the smallest change that would be likely to be real for this activity, e.g., an ALOA of ±4.9 for maximal IAP means that the smallest change that would be likely to be real would be less than -4.9 or greater than +4.9 cm H₂O

Table II

Test-retest agreement of upper quintile classification for maximal IAP measures

Activity	Percentile		Session 1 vs Session 2	
	Session 1 80th%	Session 2 80th%	Kappa(K)	
Lower back stretch	7.64	8.05	0.05 [†]	
Seated cycling 450kg·m·min ⁻¹	9.62	9.66	0.50	
Seated cycling 600 kg·m·min ⁻¹	12.26	13.03	0.63	
Side lying quadriceps stretch	14.3	12.63	0.15 [†]	
Seated hamstring stretch	13.27	13.43	0.41	
Erasing board, dusting	14.49	13.45	0.67	
Scrubbing floor on hands and knees	14.16	16.21	0.50	
Seated shoulder press, 3.6 kg	14.46	13.1	0.59	
Seated shoulder press, 4.5 kg	15.74	15.08	0.84	
Seated shoulder press, 5.5 kg	14.58	17.57	0.52	
Seated shoulder press, 6.8 kg	15	20.05	1.00	
Seated shoulder press, 9.1 kg	31.17	20.33	0.00 [†]	
Isometric side bridge	19.72	18.21	0.59	
Push-ups from knees	20.67	20.36	0.54	
Modified superman	28.62	26.74	0.59	
Walk 4.8km·h ⁻¹ , 0% grade	26.54	26.75	0.50	
Walk 4.3 km·h ⁻¹ , 0% grade, with 11.4 kg weight	30.6	31.33	0.38	
Walk 4.8 km·h ⁻¹ , 7% grade	32.14	30.82	0.50	
Walk 5.6 km·h ⁻¹ , 7% Grade	40.11	38.66	0.50	
Stepping, 20 cm Step	36.84	34.53	0.50	
Abdominal curl ups	28.65	28.61	0.41	
Stand to sit	43.98	41.42	0.73	
Standing cycling 900 kg·m·min ⁻¹	52.69	52.91	0.13 [†]	
Lift 13.6 kg, floor to counter & back	41.98	41.45	0.41	
Lift 18.2 kg, floor to counter & back	60.8	62.69	0.41	

Activity	Percentile		Session 1 vs Session 2	
	Session 1 80th%	Session 2 80th%	Kappa(K)	
Run 8–9.7 km·h ⁻¹ , 0% grade	76.6	73.65	0.63	
Full sit ups with feet held	78.98	82.51	0.63	
Jumping	107.73	113.36	0.53	
Coughing	127.51	125.68	0.73	
Lying Valsalva	117.8	113.55	0.31 [†]	
Seated Valsalva	157.22	163.95	0.59	

[†] No statistically significant agreement beyond chance.

Note: IAP =intra-abdominal pressure