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More complicated than it looks: The vagaries of calculating intra-abdominal pressure

Nadia M. Hamad, MS, ATC¹, Janet M. Shaw, PhD, FACSM¹, Ingrid E. Nygaard, MD, MS², Tanner J. Coleman, BS³, Yvonne Hsu, MD², Marlene Egger, PhD⁴, and Robert W. Hitchcock, PhD³

¹Department of Exercise and Sport Science, University of Utah College of Health

²Department of Obstetrics and Gynecology, University of Utah School of Medicine

³Department of Bioengineering, University of Utah

⁴Department of Family and Preventive Medicine, University of Utah

Abstract

Activities thought to induce high intra-abdominal pressure (IAP), such as lifting weights, are restricted in women with pelvic floor disorders. Standardized procedures to assess IAP during activity are lacking and typically only focus on maximal IAP, variably defined. Our intent in this methods paper is to establish the best strategies for calculating maximal IAP and to add area under the curve and first moment of the area as potentially useful measures in understanding biologic effects of IAP. Thirteen women completed a range of activities while wearing an intra-vaginal pressure transducer. We first analyzed various strategies heuristically using data from 3 women. The measure that appeared to best represent maximal IAP was an average of the three, five or ten highest values, depending on activity, determined using a top down approach, with peaks at least 1 second apart using algorithms written for Matlab computer software, we then compared this strategy with others commonly reported in the literature quantitatively using data from 10 additional volunteers. Maximal IAP calculated using the top down approach differed for some, but not all, activities compared to the single highest peak or to averaging all peaks. We also calculated area under the curve, which allows for a time component, and first moment of the area, which maintains the time component while weighting pressure amplitude. We validated methods of assessing IAP using computer-generated sine waves. We offer standardized methods for assessing maximal, area under the curve and first moment of the area for IAP to improve future reporting and application of this clinically relevant measure in exercise science.

Keywords

MAXIMAL INTRA-ABDOMINAL PRESSURE; AREA UNDER THE CURVE; STANDARDIZED IAP; MOMENT OF AREA; DATA ANALYSIS; WAVEFORM ANALYSIS

Corresponding Author: Nadia Hamad, MS, ATC, Department of Exercise and Sport Science, University of Utah, 250 S. 1850 East Rm. 241, Salt Lake City, UT 84112-0920, nmh10@utah.edu, Phone: (801)870-9712, Fax: (801)585-3992.

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Conflict of Interest

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INTRODUCTION

Pelvic floor disorders (PFDs) such as pelvic organ prolapse, urinary and fecal incontinence affect one in four women (20). Despite the high prevalence, the relationship between PFDs and a woman's activity level, especially as it pertains to exercise or heavy occupational work remains unclear (2). Clinicians often recommend activity restrictions for women with existing PFDs or after surgical repair for PFD (21), which is performed on 1 in 9 women in the US (22). A popular belief supported by virtually no clinical data is that there is a correlation between strenuous activities, intra-abdominal pressure (IAP) and PFDs. However, some activities commonly prohibited after surgery (such as lifting more than 10 pounds) appear to raise the abdominal pressure far less than unavoidable activities, like getting out of a chair (10, 27). Given the health benefits of physical activity, there is a clear need to understand the relationship between IAP, physical activity and pelvic floor disorders. Due to recently developed IAP monitoring systems, the study of this relationship is now more feasible.

IAP can be measured directly or indirectly. Direct IAP measurements are obtained by placing a catheter into the peritoneal cavity (for example, during laparoscopy). This type of invasive measurement is obviously not warranted for measuring IAP during physical activity studies. This leaves indirect measurement as the method of choice for IAP measurements in healthy, active women. Indirect measurements can be taken from the bladder, vagina, rectum and upper gastrointestinal tract and have been shown to accurately measure IAP, although pressures measured from each location reflects characteristics of the local environment (for example, smooth muscle pressure) as well as IAP (7, 16, 23).

In exercise settings, IAP has been measured to better understand how changes in IAP affect or are affected by spinal biomechanics (8, 9, 13), the use of weight lifting belts (12) and various exercise routines (11). Many exercise studies use a nasogastric manometer or rectal manometer coupled to the associative data collection instrumentation to measure pressure. The use of these types of measurement methods is uncomfortable and limits the types of activities the participants can perform. The data acquisition instruments used for these studies typically require the subjects to be tethered by a cable to a piece of laboratory equipment. In addition, the use of fluid coupled balloon manometric devices – those typically used for gastric and rectal measurements – has been shown previously by our group to suffer from poor dynamic response (17).

We have reported previously on a wireless intra-vaginal transducer for continuous IAP measurement (6, 14). These devices are well tolerated by the users and provide a continuous stream of data that accurately reflects intra-abdominal pressure during numerous activities including resistance exercises. The continuous and varied nature of the data coupled with a 32 Hz sampling rate requires custom software to process and evaluate the data. In the process of developing the software, we came to realize that no standard exists for calculating measures of IAP. The literature generally notes simply that maximal IAP was measured (4, 15), or that an average of the single highest pressure corresponding with a number of trials was used to determine maximal IAP (10, 11, 19, 27), but descriptions of how these values were determined or from what baseline they were calculated were generally not provided (4, 8, 13, 15). This variability is reflected in wide reported maximal IAP ranges; for example, mean maximal IAP during jumping was reported as 75, 127, 177 and 233 cmH₂O in 4 different studies that used different sensors and sensor locations (4, 9, 11, 27).

Thus, it is difficult to compare and utilize these values to guide clinician-based activity restrictions. Problems that we encountered were not only the number of peaks chosen, but

also from what baseline pressures were calculated, i.e. atmospheric or some type of positional baseline. Many reports described recalibrating sensors to zero when pressures were either not optimal or changed with body position. Some designated a single position, supine, as the point where the device is “zeroed”, others recorded a baseline, prior to activity, from which to calculate a net IAP while yet others re-calibrated before each activity (4, 11, 12, 19, 27). Meanwhile some studies do not indicate which baseline was used or calibration position (9, 10). Because of this ambiguity in IAP research, we feel it is necessary to provide a basic standard for calculating reported IAPs.

Clinicians have historically been concerned with activities that result in high IAP (4, 10, 25, 27), yet constant levels of relatively low IAP or brief excursions into higher pressure strata may also result in deleterious stress and strain on the pelvic floor. This question may be addressed by considering the pressure-time function rather than isolated measures of pressure amplitude. A standard approach for these types of IAP measurements does not exist. Prior reports have measured area under the curve (1) for IAP; however, they do not include measurement details sufficient for the development of custom software programs, nor do they incorporate a wide variety of activities (1, 11).

As we worked to develop a standardized, non-subjective, computerized approach to analyze IAP, we realized that guidelines were lacking and that various issues were more complex than we had anticipated. For example, simply choosing the single highest peak to describe maximal IAP was often not representative of the overall range of highest peaks during a specific activity. In addition, no consistent quantitative method has been previously described to determine IAPs from a large data set. Over the course of 12 meetings, our research group of exercise scientists, bioengineers, urogynecology clinicians and statisticians carefully considered various options that could be used to describe IAP maximums and AUC during different types of activities. We also analyzed the pressure waveforms for the first moment of the area (FMA), a measure that includes both pressure and time but places additional measurement emphasis on pressure amplitude. Our main goal was to apply a computerized method to detect maximal IAP values in pressure waveforms where there are tremendous variations in pressure profiles depending on subject and type of activity. In a broader sense, this work describes the development and validation of a method to capture maximal amplitudes of intra-abdominal pressure signals that is less vulnerable to measurement error because it decreases the bias from any single error in peak measurement.

METHODS

Experimental Approach to the Problem: Overview

To be consistent with existing literature and because upper vaginal pressure correlates well with IAP, we refer throughout to “IAP”, though the reader should note that we actually measure upper vaginal pressure. We also use the term “maximal IAP” to be consistent with the literature but note that more correct term for our method of calculating IAP would be “mean net IAP”, that is, the difference between maximal pressures and minimal pressures during a specific activity.

Our group visually, in 3 women, and quantitatively, in an additional 10 women, examined pressure tracings collected during subject activity sessions to best determine how to approach and calculate meaningful IAP measures. We considered many tactics for determining maximal IAP based on actual data tracings from the activity sessions (see Methods for Assessing Maximal IAP). The software algorithm we developed for calculating maximal IAP was compared to the single highest peak method and to the mean of all peaks method in a given pressure tracing to evaluate whether a clinically significant difference exists between these methods. To further assess the pressure waveform and to account for

the influence of time, measurements of AUC and FMA were calculated. The accuracy of the maximal IAP, AUC and FMA algorithms were finally validated using computer generated sine waves.

Subjects

Thirteen healthy women ages 20 to 43 years (mean $\pm$ S.D. 29.2 ± 8.1 years) who were not diagnosed with pelvic organ prolapse and who self-reported regular involvement in strenuous physical activity provided written, informed consent prior to engaging in this study. All study procedures were approved by the University of Utah Institutional Review Board.

Procedures

Laboratory Protocol—Subjects completed a series of activities as described by a laboratory protocol which was designed to include a variety of activities that women may perform on a routine basis or in exercise settings. The activities were limited to those that could be reproduced in an exercise laboratory setting. Activity sessions were completed on days when subjects were not menstruating and that were convenient to subjects and included morning, afternoon and evening times. All activity sessions were done in the same temperature controlled indoor laboratory. While the protocol was not excessively demanding, we did recommend that women not eat one hour prior to the protocol and to report to the laboratory well hydrated. Additionally subjects were instructed to void their bladder prior to inserting the intra-vaginal transducer. Data collection occurred during June through December 2011.

Pressure values were measured using a newly developed, wireless intra-vaginal transducer (IVT) whose design specifications and testing results have been previously described (5, 6, 14, 17). In brief, this system includes a pressure sensor sealed inside a gel-filled capsule that looks much like a tampon, a tether made of flexible polymer tubing that provides an atmospheric pressure reference and allows for IVT removal, and an antenna for communicating pressure data wirelessly to a base station. Atmospheric pressure readings were obtained for 30 seconds prior to the IVT being inserted by the subject.

Participants performed twenty-seven activities that fall into three categories: general exercise, routine activity, and those commonly done during urodynamics, a test of bladder function. Activities were performed in a laboratory equipped with a Quinton Q-Stress TM55 treadmill (Bothell, WA, USA), a Monark 28E cycle ergometer (Vansbro, Sweden), exercise dumbbells, an 8" exercise step, and a variety of household items for lifting and carrying activities. General exercise activities included walking with varying speed and grade, running, seated and standing cycling, stepping, shoulder press, various trunk exercises (full sit-ups, abdominal crunches, side-bridge, modified superman), push-ups, stretches (quadriceps, hamstring and low back), and jumping. Routine activities included walking with an 11.3 kg sack on one hip to simulate carrying a child, lifting and carrying 13 – 18 kg objects, scrubbing the floor, dusting, and sit to stand. Coughing and Valsalva maneuver (abdominal straining) were included as they are standard in urodynamic studies (18, 23). Most activities in the laboratory protocol required 20 to 40 seconds to complete. The order of laboratory activities was consistent with a standard exercise protocol that involved gradual warm up progressing to higher intensity activities (walking, running, cycling), followed by easier tasks to reduce heart rate (stepping, sit to stand), lifting and carrying tasks, and ended with stretching. The only exceptions to the trend above were Valsalva maneuver and jumping. These tasks were placed at the end of the protocol in the event they resulted in displacement of the sensor, which would have interrupted natural flow of the protocol.

Pressure Data—Each sensor was calibrated in the laboratory using a National Institute of Standards and Technology (NIST) traceable reference transducer from 0 – 350 cmH₂O and programmed with a unique identifier to prevent cross-talk with other wireless IVT devices. Pressure units of cmH₂O are used since they are standard for IAP assessment in urogynecology studies. Prior to the study, sensors were sterilized and pre-heated to body temperature (37°C) to minimize temperature induced offset of the sensor from room to body temperature. IAP pressure measurements were obtained at a frequency of 32 Hz with a wireless data packet being sent to the base station every 1.5 seconds. Each wireless packet contains header information including pressure values with associated time stamps, temperature, and internal battery status. Data are managed by a custom Graphical User Interface (GUI) program that allows the user to monitor the values of the sensor in real time. The output of the GUI is a structured text file. The text file is read by data converter software and subsequently converts the raw pressure count output of the wireless IVT based upon the calibration profile of the sensor. Pressure tracings for each baseline and activity were generated.

Methods for Assessing Maximal IAP—Maximal IAP should be representative of the highest pressures observed for any given routine or exercise activity in the laboratory protocol without bias from any single error in peak measurement. Our research group identified various possible means for identifying maximal IAP. One requirement was to sample as much pressure data from any given activity as possible to reduce the impact of potential measurement error due to one aberrant measurement; thus, we dismissed the strategy of assessing the single highest peak, despite its previous use in the literature (10, 12, 19, 27). We illustrate an example of a problem with the single-peak method of assessing maximal IAP in Figure 1. To identify the most robust means we began by visually inspecting the pressure tracings from six subject trials collected from three subjects who completed the protocol twice. Because of the variety of pressure tracings from the activities, we looked for patterns in the data. Some tracings from dynamic activities with repetitive motion such as walking, running, standing cycling and shoulder press, yielded somewhat predictable patterns. In these tracings, the highest-pressure values, which we label as peaks, were easy to visualize. However, to determine maximal IAP for the entire segment of data, the timing, height, range and number of peak values for any activity needed to be considered. These values varied even in the more predictable pattern activities. In some activities, there were multiple upward inflections contained in one peak, which a computer software program would recognize as separate, individual peaks. Therefore, we imposed a timing rule, such that peaks must be at least one second apart to reduce sampling bias (Figure 2). In addition, several activities have peaks that are one second apart, but are considerably lower in magnitude than others. A computer software program would necessarily include these in a calculation of mean maximal IAP if all peaks during a time period were averaged. We defined these as “peaklets” and did not wish to include these in our calculation of maximal IAP (Figure 3).

From this visual inspection, we then developed five initial strategies for capturing maximal IAP: 1) average of three highest peaks, 2) average of ten highest peaks, 3) average of all peaks, 4) average of peaks above a 75% threshold, and 5) average of peaks above a 50% threshold. The average of three highest peaks strategy was based on previous methodology (11, 27). For all measures, we added the caveat that included peaks must be separated by at least 1 second. Similar to the three peak strategy, the ten peak strategy first required identifying the ten highest peaks greater than 1 second apart, from which a mean value was calculated.

We also considered calculating maximal IAP based on a percentage of the range of pressure values in any given tracing, in contrast to calculations based on a predetermined number of

peaks. The calculated percentage of the range is added to a previously reported positional pressure to determine a threshold and only peaks above this threshold are evaluated. In two separate strategies, 75% or 50% of the calculated range between the highest and lowest pressure values are added to the positional pressure and a mean maximal IAP is calculated by averaging all peaks at least one second apart above this threshold.

Evaluating Strategies to Determine Maximal IAP—We visually analyzed tracings for all activities in the laboratory protocol using the initial three subjects to determine how well each strategy captured maximal IAP (Figure 4). The three peak strategy was a good fit for two activities, but not a good representation for others that had multiple peaks over the course of the activity (Figure 4 A, B). The average of all peaks did not reflect maximal peaks well because the software recognized “peaklets,” or fluctuations in IAP, as peaks. This strategy was a marginally good fit for two activities (Figure 4-C) but a poor fit for most others (Figure 4-D). The ten peak strategy was a good fit for eleven activity groups, such as running, and levels of walking and cycling, providing a consistent representation of maximal IAP but did not work well for the most physically demanding activities in our protocol, such as heavy lifting (Figure 4-E). Sometimes the assessment of IAP was limited by a subject’s ability to perform the activity for the entire time segment allotted and ten peaks were not clearly identifiable (Figure 4-F). Furthermore, some activities required the subject to perform a particular activity a set number of times at increasing intensities. For example, dumbbell shoulder press consisted of three sets of 8 repetitions using progressively greater weight for each set. In this activity, the number of peaks that represented maximal IAP was limited to the number of repetitions completed per subject.

In both the 75% and 50% threshold strategies, the calculation of maximal IAP depended on two factors that varied for each activity and subject; the range of pressure in any given segment and the positional pressure. If the range of pressures was large, such as in stepping, and the lowest pressures were below the positional pressure, the calculation of maximal IAP was nearly impossible since very few or no peaks were identified above the predetermined threshold (Figure 5-A). Alternatively, if an activity had a relatively narrow range of pressures such as side bridge, and the lowest pressures were above positional pressure, then almost all of the peaks in the tracing would be included in the calculation of maximal IAP (Figure 5-B). The 75% threshold strategy was a good fit for only three of the fourteen general activity groups (Figure 5-C). The 50% threshold strategy was also highly variable. It often included too many peaklets (Figure 5-D). It was a good fit for three activities and a poor fit for fourteen of the activity groups. Overall, the use of a threshold did not seem to be a good strategy for determining maximal IAP.

Based on our preliminary visual analysis of methods to determine maximal IAP, we chose three peak and ten peak averages as methods that seemed to consistently reflect maximal IAP. However, in applying these strategies to additional activity tracings, we realized that an additional group was needed to analyze certain activities that consistently produce only a mid-range of peaks (i.e. 4–9). This was the case for six activities, including those that often resulted in premature fatigue by our subjects (i.e. shoulder press, full sit-ups). To accommodate these activities, we added an average of five peaks group.

The activities we studied thus fell into the following groups: three peak: coughing and Valsalva maneuver; five peak: lift and carry, curl ups, sit ups, side bridge, stand to sit, shoulder press (all); and ten peak: walking (all), running, slow stepping, cycling (all), erasing the board, scrubbing the floor, superman pushups, jumping, hamstring stretch, low back stretch, and quadriceps stretch. An example of points determined for a ten peak activity is demonstrated in figure 6.

A computer program was developed using Matlab software (R2009A, MathWorks; Natick, MA, USA) to discern the highest three peaks, highest five peaks and highest ten peaks at least 1 second apart using a top down approach; meaning that the software identified the peaks starting with the highest, second highest and so forth. Collectively we refer to this approach as the mean top down approach to calculating maximal IAP.

In addition to positional changes, expected when assessing IAP, we also observed baseline fluctuations during some activities in some women that appeared unrelated to position. This led us to re-evaluate the sensor again in ideal laboratory conditions. We found that the sensitivity of the device does not change to a clinically significant extent from initial calibration to after human testing was conducted. The offset of the sensor was found to change daily and although the offset is initially set to atmosphere, there still exists an offset from the measured pressure of the wireless device and the true peritoneal IAP. Therefore, confirming accuracy of the sensor itself, we concluded that these fluctuations were due to physiologic changes in the upper vagina (for example, sensor movement, vaginal smooth muscle contraction, small bowel peristalsis, etc). Rather than arbitrarily recalibrating to zero, as is commonly done in clinical situations, or choosing a pre-set baseline, we chose to instead report net IAPs as differences between maxima and minima. Minima are obtained similarly to maxima: the three, five or ten trough pressures are averaged, and the net pressure is a result of the difference between the highest averaged pressures and the averaged low pressures (Figure 6).

Area under the curve—Maximal IAP reflects the highest pressures achieved during an activity, but it does not take into consideration the duration of the pressure over time. Clearly there is a difference in a rapidly increasing and decreasing pressure such as a cough versus a high-pressure activity with a longer time duration such as slowly lifting a heavy object. We considered area under the curve, a measure that includes both the pressure amplitude as well as time (reported as $\text{cmH}_2\text{O}\cdot\text{s}$) to characterize the time associative properties of pressures between activities. However, a simple AUC is limited in that pressure and time are weighted equally and the result does not describe potential amplitude contribution to the overall measure. For example, high-pressure activities over short duration could produce similar AUC results when compared to low-pressure activities over long duration as shown in Figure 7.

Other measures of the pressure waveform over time include higher order moments such as the first moment of the area (FMA). The FMA is a finite measure of a small area multiplied by the y-axis component, in this case cmH_2O . Since we are interested in how IAP from various physical activities may strain pelvic floor structures, we considered this additional method to distinguish high pressure/low duration activities from low pressure/long duration activities. These differences are illustrated in Figure 7. Both AUC and FMA will be calculated from the calculated baseline pressure for each individual for each activity.

Analysis

Quantitative Analysis of Maximal IAP—As noted previously, we used mean net IAP, that is, the difference between maxima and minima, to reflect maximal IAP. We compared the IAP calculated using our mean top down approach to 1) IAP reported by identifying the single highest peak and 2) IAP calculated using the mean of all peaks in a given pressure tracing, including peaklets. In our comparisons, we used an accuracy range of 5 cmH_2O as a standard, since this magnitude of pressure difference is considered clinically meaningful (23). Using pressure data from ten additional subjects whose data were not used in the visual inspection described, IAP was calculated using our newly developed software algorithm from the following representative activities: three peaks (coughing, Valsalva maneuver),

five peaks (sit to stand, 3.6 kg seated shoulder press), and ten peaks (cycling at 2 kp, walking at 4.8 kmh and running at 8–9.6 kmh). To preserve an overall 5% significance level per activity, we used a Bonferroni-corrected 1.7% significance level for tests comparing pairs of methods for a single activity.

We compared the different measurement techniques using two different statistical methods. We recognized that these IAP measurement methods are naturally ordered, i.e., within a single subject, the maximal IAP as determined by measuring the single highest peak is as high or higher than IAP determined from the mean top down approach, which, in turn, is as high or higher than the mean IAP of all peaks. Thus, the first analysis utilized three one-sided, Bonferroni-adjusted t-tests to test whether the population average of maximal IAP, as determined by each method, exceeded the others by at least 5 cmH₂O. Rejection of the null hypothesis implies that a pair of methods is significantly different by > 5 cmH₂O. However, failure to reject the null hypothesis does not prove equivalence. We conducted further equivalence analyses (3) in which two methods are considered equivalent if a two-sided confidence interval on the mean differences between them falls entirely into the interval from 0 to 5 cmH₂O. That is, we would have 98.3% confidence that all the plausible values for the population mean difference between a pair of methods were between 0 and 5 cmH₂O, and an overall 95% confidence that all three methods were equivalent, if all three confidence intervals comparing methods fell into this specified interval.

Validating Software Algorithm for IAP Measures—To validate our software algorithm, we generated three waveforms with known pressure – time values. These three sinusoidal waveforms were analyzed by Matlab software to determine the accuracy at which the software algorithm could detect the highest peaks and calculate AUC and FMA. The equations for these sine waveforms were:

1. Maximal IAP: sine waveform 1) $3x \cdot \sin(3x) + 3x$;
2. AUC: sine waveform 2) $3x \cdot \sin(12x) + 3x$ and
3. FMA: sine waveform 3) $3x \cdot \sin(25x) + 3x$.

Each waveform was analyzed by our custom Matlab program from 0–30 seconds in intervals of 0.031 seconds. A random number generated waveform was developed to create another set of artificial pressure data. This data was generated using a random number function in Excel (2010, Microsoft; Redmond, WA) and consisted of 968 data points with each point constrained to a pressure value between 0 and 200 cmH₂O.

Two of the computer generated sine waveforms (sine waveforms 1 and 2) and the random number generated waveform were used to validate the accuracy of our software algorithm for assessing maximal IAP. The sine waves and random waveform were processed by a custom Matlab program, to determine the three, five, and ten highest peaks for the appropriate tracing. The identified peaks were then compared to the known values for the generated waveforms and percent error was calculated. These algorithms were considered valid if the calculated maximal pressure was within 2% of the known values for the waveforms.

The three computer generated sine waves were used to validate AUC and FMA. Exact values of AUC (equation 1.0), and FMA of generated sine waves (Equation 1.1) were calculated by integration. Measurements were validated using three sine waves since integration with the random number data curve is less accurate because there is no defined equation to integrate. The AUC of the computer generated sine waves was calculated using the trapezoidal approximation in a custom Matlab program. The FMA was determined by

the trapezoidal approximation of the square of the pressure in a uniform grid (time interval of .031 seconds) divided by two (Equation 1.2).

$$\text{Area Under the Curve} = \int_a^b f(t) dt \approx (b - a) \frac{f(a) + f(b)}{2} \quad \text{Equation 1.0}$$

$$1st\text{Moment} = \frac{1}{2} \int_0^{30} (\text{Generated sine wave})^2 dx \quad \text{Equation 1.1}$$

$$1st\text{Moment approximation} = \frac{\frac{.031}{2} \sum_{k=1}^{968} (\text{Pressure}_{k+1})^2 + (\text{Pressure}_k)^2}{2} \quad \text{Equation 1.2}$$

Due to the constraint of the 0.031 second time interval which limits the resolution of the sine wave analysis, we considered the calculated values of AUC and FMA to be valid if they were within 2% of the known or indicated value. After validating the AUC and FMA calculations, further analyses were carried out on three data sets that included coughing, sit to stand, and running profiles.

RESULTS

Quantitative Analysis of Maximal IAP

Table 1 displays sample averages and SDs of IAP, as calculated by each of the three selected IAP measurement methods, for the seven activities and 10 subjects in the present study. Table 2 compares maximal IAPs (expressed as mean net IAP, or in the case of single peak analyses, as net IAP), as calculated by each of the three selected IAP measurement methods in 10 women. As noted, for some activities, IAPs are statistically significantly different between measurement techniques, while for others they are statistically equivalent within 5 cmH₂O and for others they are indeterminate (i.e., neither null hypothesis was rejected).

Validating Software Algorithm: Maximal IAP

Sine waveforms 1 and 2 as well as a random number data curve were used to compare calculated peak heights as determined by the custom Matlab algorithm to actual values. The Matlab algorithm correctly identified all peaks for the sine waveforms 1 and 2 as well as random number data curves (Table 3) with 0.00% error. In addition, the custom Matlab algorithm was used to calculate the three, five, and ten maximal peaks on coughing, sit to stand, and running data sets respectively (Table 3).

Validating Software Algorithms: AUC and FMA

Sine waveforms 1, 2 and 3 were used to compare AUC and FMA results between known values and the Matlab algorithm. The trapezoidal approximation, a built in function of Matlab, was used to estimate the AUC. This measurement displayed accuracy within 0.00% when compared to results calculated with integration (Table 4). The AUC values were determined for coughing, sit to stand, and running IAP profiles as well (Table 4). The FMA approximations of sine waveforms 1–3 using the Matlab algorithm showed a 0.00%, 0.00%, and (-)0.01% error from integral values (Table 4). The AUC was calculated for the same three activity profiles as shown in Table 3.

DISCUSSION

Assessing IAP during physical activity seems simple but in fact is a challenging undertaking. Results can differ dramatically depending on type of sensor used, position of sensor, how often and when sensor is calibrated to zero, software used for analysis, type of baseline used and physiological phenomena other than IAP that influence results.

We have developed an appropriate sensor to allow for comfortable, safe and accurate IAP measurement during a variety of activities and have developed data analysis software to allow computer analysis of large volumes of data. After a successful sensor design and testing phase, our group realized that we also had to overcome the limitations inherent in using software to calculate measures of IAP. After comparing various potential methods used to calculate IAP qualitatively, through visual inspection of data from 3 participants, we conducted quantitative analyses to compare methods in 10 additional women. Based on this evaluation, we chose the mean top down approach, a strategy that calculates maximal IAP based upon the number of peaks representative of maximal IAP observed during a given activity.

Our results indicate that maximal IAP measured by the mean top down approach is not identical to the single peak method nor the method of all peaks. Within a single subject, these three methods produce different-sized measures of IAP: IAP measured as a single peak is always as large or larger than IAP measured by the mean top down approach, since the single largest peak is averaged with other values to obtain the mean top down IAP; similarly, IAP measured by the method of all peaks includes as components the values used in the mean top down approach and is always smallest. Using a 5 cmH₂O difference as one that is clinically significant, we found statistically significant differences by approach in IAPs during some but not all activities. This requires that a clinical judgment be made in terms of which IAP calculation has best face validity. We believe the mean top down approach adheres to sound principles of measurement practice, as it does not rely on one value that may represent artifact and it does not include submaximal peaks as does averaging all peaks. No matter the method, for some activities it is difficult to judge how IAP is best measured. For example, in the side-lying quadriceps stretch IAP is generally low but rises dramatically when the participant changes position to stretch the contralateral leg. We concurred that while change in body position is part of the side lying quadriceps stretch and should be included in the calculation of IAP, it should not be the sole reflection of the maximal IAP as would be the case in using data from only the single highest peak. In a similar manner, lifting tasks, depending on the relative magnitude of the load, can result in variable IAP peaks by repetitions considering inputs from trunk stabilization and Valsalva. We did not see statistical differences beyond 5 cmH₂O between the calculation of maximal IAP from the single highest peak and the mean top down approach in the shoulder press task, and in fact these methods were determined statistically equivalent in the second analysis for the same task. Yet, the results may be different in real world application of these methods outside of the laboratory when women are lifting weights on their own terms and in a less controlled environment.

Post-trial bench top testing was performed on sensors to determine accuracy and performance. It was determined that the sensitivity of the device does not change to a clinically significant extent from initial fabrication to after the trials were performed. The offset was found to change daily. The offset is initially set to atmosphere however there still exists an offset from the measured pressure of the wireless device and the true peritoneal IAP based on the anatomical influences, location of the sensor etc. In a previous study, the pressure profiles of a rectal balloon catheter and the wireless IVT were found to be displaced by an offset error (14). In that study, an offset correction was imposed on the wireless IVT

to account for this difference, which is synonymous with established urodynamic techniques of adjusting the rectal balloon catheter to establish a baseline. In the present study no external reference could be used to establish an offset correction since the device is fully positioned with the vagina. Future device development work will center on establishing a reliable offset measurement for baseline activities.

We raised pressure-time analyses as important constructs to consider when describing the potential effect of IAP on the pelvic floor. In the literature, there is little use of AUC as a measure of IAP, and rationale for use is almost nonexistent (1, 12). Understanding the potential association between pelvic floor disorders and strenuous physical activity is grossly hampered by the lack of tools with which to measure and calculate relatively high IAPs during exertion. By assessing several ways to evaluate IAP (maximal pressures, AUC and FMA measures), in future work, we will be able to determine whether one type of measure best reflects changes in the pelvic floor (for example, downward displacement of the bladder during activity assessed during ultrasonography). Given the paucity of using AUC to describe IAP in the exercise science and urogynecologic literature, we debated the merits of measuring the entire AUC above atmospheric pressure vs. choosing an arbitrary threshold as a cut-point. There is as yet no IAP cut-point that is known to place women at higher risk for pelvic floor disorders. Therefore we measured AUC and FMA from the same average of low-pressure (trough) data points per individual activity and participant.

Understanding the role strenuous activity may play on women's health, both positive and negative, is important. Despite scant data, many physicians currently discourage various types of physical activity in women. The American Urogynecological Society, an organization devoted to the care of women with pelvic floor disorders, recommends that to prevent pelvic floor disorders, women should "avoid increased pressure inside the abdomen," "avoid heavy lifting" and "avoid repetitive strenuous activities (26)." In addition to this recommendation to limit strenuous exercise in women are others such as the 2005 statement by International Ski Federation president Gian Franco Kasper, an International Olympic Committee member, who said "he didn't think women should ski jump because the sport 'seems not to be appropriate for ladies from a medical point of view (24).'"

The ultimate goal of our research is to understand whether there are certain types of activities associated with upper ranges of IAP that may, in fact, be deleterious to the pelvic floor, such that women can be appropriately counseled with facts rather than opinions. We have now developed a wireless vaginal pressure sensor (6), herein describe methods for calculating maximal IAP, AUC and FMA using objective computer software, and will next assess the reproducibility of these values in a large sample of women performing a variety of activities. In future work, we will then be able to assess whether women that routinely engage in activities with higher IAP, AUC or FMA are more or less likely to manifest pelvic floor disorders or to experience recurrence after treatment.

PRACTICAL APPLICATIONS

IAPs described in the literature to date vary widely during similar activities. Standardizing IAP is essential to understand the primary exposure thought to relate lifting and other physical activity to pelvic floor disorders in women. To this end, we have developed a novel wireless device that will allow future IAP assessment in women during activities that are not regulated in a laboratory setting. In this manuscript, we present a standardized method for evaluating IAP using computer software and encourage inclusion of AUC and FMA as potentially useful constructs in understanding the impact of physical activity on pelvic floor function. This will enable appropriate recommendations for activity restrictions for women who are predisposed to or have pelvic floor disorders, without unnecessarily restricting

activities that promote health. While current sentiment in exercise science suggests that strenuous activity is safe for women, a rigorous approach to understanding IAP associated with lifting and other forms of physical training and sport will further guide evidence-based activity recommendations for women.

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Figure 1.

Example of side lying quadriceps stretch, an activity where single highest peak includes artifact from a position change that would increase the error in maximal IAP. Position change also demonstrates a change in baseline. Copyright © Hamad 2012.

Figure 2.

An intra-abdominal pressure tracing obtained during a jumping activity that demonstrates the need for the 1-second rule to rule out multiple upward inflections in one peak. Copyright © Hamad 2012.

Figure 3.

A jumping activity intra-abdominal pressure tracing demonstrating the need to eliminate “peaklets.” Copyright © Hamad 2012.

Figure 4.

Representation of intra-abdominal pressure tracings and appropriateness of some of the strategies tested to determine maximal IAP for: three peak strategy (**A**) (**B**); Peaks above baseline strategy (**C**) (**D**); and ten peak strategy (**E**) (**F**). Peaks selected in each rule are demonstrated by arrows. In the three peak and ten peak cases, the software is programmed to select the highest peak, followed by the next highest peak at least 1 sec apart, followed by the next highest peak, etc. Copyright © Hamad 2012.

Figure 5.

The 75% and 50% strategies applied to 4 different activities: Graphs **A** and **B** demonstrate a poor fit for both the 50% and 75% strategies. Graph **C** demonstrates a good fit for the 75%, but a poor fit for the 50% strategy. Graph **D** demonstrates a good fit for the 50%, but a poor fit for the 75% strategy. Copyright © Hamad 2012.

Figure 6.

Intra-abdominal pressure tracing for jumping, demonstrating the mean top-down approach for calculating maximal IAP. * represent minima and represent maxima used to determine maximal IAP. Copyright © Hamad 2012.

Figure 7.
 Demonstration of three IAP tracings that each has the same calculated area under the curve (2). While AUC is the same, First moment of area is very different between each of the tracings. Copyright ©Hamad 2012.

Table 1

IAP by Three Measurement Methods (n=10)

(n=10)	Single Peak Method		Mean Top Down Method		Method of All Peaks	
	<i>Sample Average</i>	<i>SD</i>	<i>Sample Average</i>	<i>SD</i>	<i>Sample Average</i>	<i>SD</i>
Cough	125.1	29.0	113.5	28.8	23.3	10.5
Lying Valsalva	88.3	33.6	83.3	33.0	34.6	19.0
Stand/Sit	41.4	15.7	37.4	14.8	20.8	6.2
8 lb. shoulder press	11.2	4.7	8.9	3.7	4.7	2.1
Walking 3 mph	31.7	6.3	27.0	4.5	19.1	3.3
Running	73.5	17.6	68.5	17.1	54.9	13.0
Seated Cycling	12.9	2.3	10.7	2.0	6.2	1.1

Statistical equivalence results

Table 2

	Single Peak Method vs. Mean Top Down Approach	Mean Top Down Approach vs. Method of All Peaks	Single Peak Method vs. Method of All Peaks
Cough	D (P=0.0042)	D (P<0.0001)	D (P<0.0001)
Lying Valsalva	I -	D (P<0.0001)	D (P<0.0001)
Stand/Sit	I -	D (P=0.0016)	D (P=0.0006)
8 lb. shoulder press	E (p<0.017)	I -	I -
Walking 3.0 mph	I -	D (P=0.0086)	D (P=0.0003)
Running	I -	D (P=0.0032)	D (P=0.0003)
Seated Cycling	E (p<0.017)	I -	D (P=0.0030)

D= population average *differences* exceeding 5 cmH₂O between IAP measurement methods, beyond chance; E=population average *equivalence* within 5 cmH₂O between IAP measurement methods, beyond chance; I=indeterminate: unable to determine from the present study.

Table 3

Peak analysis of generated and activity plots.

	Number of Peaks Correctly Identified	Known Maximal IAP (cmH ₂ O)	Calculated Maximal IAP (cmH ₂ O)	% Difference
Waveform				
Sine Wave 1	3/3	166.5	166.5	0.00%
Sine Wave 2	5/5	166.9	166.9	0.00%
Random number waveform	10/10	146.6	146.6	0.00%
IAP Tracing				
Coughing	3	--	54.8	--
Stand to sit	5	--	27.6	--
Running	10	--	63.6	--

IAP= Intra-abdominal pressure

Table 4

Area under the curve and first moment of area analysis of generated and activity plots

Waveform	Integral AUC (cmH ₂ O) ² s	Trapezoidal Approximation AUC (cmH ₂ O) ² s	% Difference	Integral FMA (cmH ₂ O) ² s	Trapezoidal FMA (cmH ₂ O) ² s	% Difference
Sine Wave 1	1359.79	1359.78	0.00%	61946.0	61944.6	0.00%
Sine Wave 2	1348.04	1348.04	0.00%	60624.2	60624.1	0.00%
Sine Wave 3	1348.49	1348.46	0.00%	60673.6	60668.6	-0.01%
IAP Tracing						
Coughing	--	106.9	--	--	1910.0	--
Stand to Sit	--	306.4	--	--	2486.5	--
Running	--	775.8	--	--	16452.0	--

IAP= Intra-abdominal pressure, AUC= Area under the curve, FMA= First moment of the area