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Clinical Evaluation of a Wireless Intra-Vaginal Pressure Transducer

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Abstract

Objective—To describe the development, feasibility and validity of a wireless intra-vaginal pressure transducer (IVT) which can be used to measure intra-abdominal pressure in real-world settings.

Study Design—A feasibility study was conducted in sixteen physically active women to determine retention and comfort of various IVT prototype designs during activity. A criterion validity study was conducted among women undergoing urodynamic testing to determine the accuracy of the IVT prototypes when compared to accepted clinical standards.

Results—A final prototype wireless IVT was developed after four design revisions of the second generation model. The feasibility study found that women reported the final prototype comfortable to wear and easily retained during physical activity. Intra-abdominal pressure measurements from the final prototype IVT compared favorably to standard urodynamic transducers, thus confirming evidence of its utility.

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K Heintz: Protocol/project development, data collection, Manuscript editing

Yvonne Hsu has served as a consultant in the past for American Medical systems.

Robert Hitchcock is a shareholder in Catheter Connections, Inc and a consultant to Navigen Inc. None of the other authors have disclosures.

Conclusion—We have successfully advanced the design of a wireless, intra-vaginal pressure transducer which provides accurate measures of intra-abdominal pressure. The final wireless IVT is better tolerated by patients and overcomes limitations of traditional urodynamic testing while laying the foundations for intra-abdominal pressure monitoring outside of the clinic environment.

Keywords

Wireless intravaginal pressure transducer; intra-abdominal pressure; pelvic organ prolapse

Introduction

A popular belief supported by scant clinical data is that strenuous physical activity and the associated load from increased intra-abdominal pressure (IAP) on the pelvic floor leads to pelvic floor disorders (PFD) such as pelvic organ prolapse and urinary incontinence ^{1,2}. Due to the assumed relationship between IAP and activity, clinicians often recommend drastic long-term activity restrictions for women with existing PFD or after surgical repair ³. Studying the potential association between IAP and PFDs has been hampered by our inability to measure IAP in real-world settings.

Our group has previously reported on a prototype intra-vaginal transducer (IVT) which correlated well with IAP readings from traditional rectal balloons, yet had less measurement error and noise ⁴. It had fewer design limitations compared to both the fluid-coupled rectal transducers and the micro-tip bladder transducers ⁵. However, this proof of principal device lacked user mobility, electronic durability and an extended shelf life. It could be used only in a laboratory setting and women were limited in mobility as it was connected by cables to the data monitoring device. The overarching aim of our research is to develop a wireless remote abdominal pressure sensor (“WRAPS”) which can then be used to measure IAP in various real-world settings. The aim of the current study is to describe the development, feasibility and validity of the second generation wireless intra-vaginal pressure transducer (IVT).

Materials and Methods

Similar to the first generation intravaginal pressure transducer (IVT), the second generation IVT was also designed to be placed and retained in the upper one third of the vagina, but needed to house additional circuitry to transmit wireless signals. Additional components needed to achieve wireless telemetry included a signal conditioner, microcontroller, battery, and supporting radio telemetry components. The electronic package was sealed in a gel filled elastomeric capsule which transfers externally applied pressures to the sensor. During the development process, multiple revisions to the capsule design were tested to maximize user comfort, retention during activity, and accuracy of IAP measurement.

In the development process of the wireless IVT, a wired second generation IVT was built for testing. This wired second generation device was an important transition step to the development of the wireless IVT because it allowed the design team to make substantive design changes to the capsule and gel while developing the wireless capabilities in parallel. The wireless IVT circuitry was subsequently developed and evaluated. A detailed description of the engineering processes, components and circuitry used in developing the second generation wireless IVT has been previously described ⁶.

To test the retention of the varying capsule shapes and sizes, mock prototypes were built. The mock devices consisted of a gel filled capsule with a plastic or aluminum cylindrical tube inside to mimic the rigidity of the proposed electronic package. For device removal, a length of nylon string was tied to the cylindrical tube and sealed in place with silicone

elastomer. The devices were cleaned with isopropanol and sterilized with ethylene oxide prior to use. Study approval was granted from the University of Utah Institutional Review Board and informed consent was obtained from volunteers.

Clinical testing proceeded in two phases. The first phase was a feasibility study in which healthy, physically active women reported on the comfort and retention of the various mock prototype devices during exercise and other strenuous activity. The second phase was a criterion validity study in which all prototype IVT pressure measurements were compared to results obtained during standard urodynamic testing. The criterion validity study was conducted in women who were scheduled for urodynamic testing but who did not have evidence of pelvic organ prolapse

We established three acceptance criteria for our device: 1. the device had to be retained during physical activity 2. the subjects had to feel comfortable wearing the device and 3. the device had to measure and record pressure changes in accordance with predetermined specifications. A difficulty for device testing is the lack of a true gold standard for the measurement of intra-abdominal pressure⁷. Urodynamics is one accepted clinical gold standard however standardization is difficult to achieve uniformly⁸. This is especially a problem for determination of “true” baseline since urodynamics baselines are often obtained with adjustments to the device and transducer during the set-up for the study. However, the response of the device to changes of pressure can be compared between our device and urodynamic measurements to establish criterion validity since this is not dependent on baseline. A less than 5% change from the ideal was determined to be valid. Although no specific clinical accuracy standards exist for urodynamic pressure measurements this 5% change was selected by our team as a subjective comparison benchmark. As described previously, the wired and wireless IVT’s are bench tested and calibrated using NIST traceable standards and meet or exceed the overarching AAMI standard for physiologic pressure transducers which includes accuracy^{5,6,9}.

Women were included in the feasibility study if they were ≥ 21 years of age, were regularly engaged in strenuous physical activity and provided negative responses to questions about pelvic organ prolapse on the Pelvic Floor Distress Inventory¹⁰. Women were excluded if they were pregnant, within 6 months postpartum, or had a history of pelvic or vaginal surgery other than hysterectomy. Eligible participants were not menstruating when they completed feasibility study procedures.

Height, weight, age, parity, history of hysterectomy and the Pelvic Organ Prolapse Quantification (POP-Q)¹¹ measurements were recorded for participants in the feasibility study. Women were given simple, pictorial instructions for the insertion and removal of the device. They were instructed to insert the IVT into the top of the vagina and requested to wear the device during strenuous physical activity or exercise. Common activities women performed while wearing the IVT prototype included running, climbing, and aerobics. They reported on the ease of device insertion and removal, comfort, and whether the device was retained during activity.

For the criterion validity study, wired and wireless IVT devices were built to evaluate device performance against a standard urodynamic rectal balloon catheter. Pressure sensors were calibrated to 350 cm H₂O using a National Institute of Standards and Technology (NIST) traceable reference transducer, cleaned with isopropanol, and sterilized using ethylene oxide prior to human use.

The criterion validity study was conducted in women undergoing standard urodynamic testing as part of routine clinical care. Women were included if they were ≥ 21 years of age and were not currently menstruating. Women with a history of pelvic or vaginal surgery

other than hysterectomy, or who were pregnant were excluded. Women were also excluded if they had prolapse of the apical, anterior or posterior compartment beyond the hymen.

After uroflowmetry, the urodynamics nurse placed a Life-Tech #6 French water-filled catheter into the bladder along with a Laborie #10 French balloon catheter into the rectum past the internal anal sphincter to measure IAP. The rectal balloon catheter was filled with 5ml of sterile saline and both catheters were then connected per standard practice to a cystometry machine (Aquarius, Laborie Medical Technologies). The wired IVT was connected to a DAQ card (NI USB-6211, National Instruments) that was controlled by a laptop running a custom LabView 8.0 program. Pressure readings at zero (atmospheric) were recorded for 30 seconds prior to insertion. The IVT data was captured at a frequency of 120 Hz. A member of the clinical research team then inserted the IVT into the vagina. Routine filling cystometry testing then progressed in which the rectal and bladder catheters were zeroed to atmospheric pressure. Discrepancies between the rectal and urethral pressure was corrected in the usual fashion by either flushing or repositioning the catheters. The IVT was not adjusted to correct for discrepant pressures during setup; rather, this adjustment was made post hoc (Figure 3). Bladder and rectal measurements were collected at 15 Hz with standard clinical cystometry software (Laborie Medical Technologies). At a bladder volume of 200ml, each participant performed a series of seated cough and Valsalva maneuvers followed by a series of standing coughs and Valsalva maneuvers. The relative changes in pressure of both the rectal balloon catheter and the IVT were plotted and compared.

Each version of the second generation wired IVT was tested. This included 3 capsule versions of the second generation wired IVT. The final version (revision 4) was used as the design for the wireless IVT.

This final version of the IVT design was found to be retained, was comfortable and had criterion validity. The wireless components were then built into the final version of the IVT (Figure 1). Wireless urodynamic comparisons were collected from additional volunteers undergoing standard urodynamic testing using this final version. The standard urodynamic testing protocol was followed as described above. The wireless IVT was programmed to sample at 30 Hz and transmitted data packets to a base station (ZLE70101BADA Applications Development Kit, Zarlink) every 1.5 seconds. Prior to the study an atmospheric measurement was taken by sampling the pressure of the device for 30 seconds. The changes in pressure recorded during Valsalva and coughs of both the rectal balloon catheter and the wireless IVT were plotted and compared. Correlation coefficients and percentage change from ideal were calculated. An ideal 1:1 curve with slope equal to 1 was used to signify the best case scenario in which all relative peak pressure changes from the wireless IVT was also recorded by the rectal balloon catheter. Percent change in measurement between the rectal balloon catheter and the IVT was calculated by plotting a straight line through the data while setting the intercept of the line equal to zero. A plot was generated relating the slope of the line to the percent error in measurement from the ideal 1:1 curve. A seventh order polynomial was used to fit the relationship between the slope and the percentage error from the ideal graph. Using the seventh order polynomial, percent error was then calculated based upon the slope of each data set.

Results

Feasibility study

16 women with a mean age of 41 years (range 24 to 61 years) were enrolled in the retention study. The mean parity of enrolled women was 1.5 (range 0–4), and average body mass index was 24.6 kg/m² (range 17.1–29.7 kg/m²). Two participants had undergone hysterectomy. Pertinent mean (range) POP-Q points (available for 14 of 16 participants)

were: TVL 9 (range 8 to 11), Ba -0.86 (range -2 to 1), Bp -1.36 (range -3 to 1) and C -5.93 (range -7 to -3). Some study participants tried multiple IVT devices.

Revision 1: The original wired prototype (first generation wired IVT) was packaged in the revision 1 capsule (Table 1 Rev 1) which was modeled after female hygienic devices. While this device performed well in terms of comfort, retention and accuracy, we needed to modify the dimensions to incorporate wireless components. We ultimately developed three subsequent capsule designs to accommodate the new components while maintaining retention and comfort.

Revision 2: The initial modification to the original design was an increase in the capsule size to accommodate the wireless electronics (Table 1 Rev 2). While accurate when tested in the laboratory (described further below), it was not retained during activity by any of the four women in whom it was tested.

Revision 3: The design was further modified by shortening the overall length and increasing diameter, in order to improve retention (Table 1 Rev 3). Retention with the revision 3 design was improved; five of seven women retained the device during activity. However, revision 3 proved inaccurate in subsequent urodynamics comparisons (described further below).

Revision 4: This was a modified hybrid of the revision 2 and revision 3 designs (Table 1 Rev 4). Five of five women retained revision 4 device during activity. It also had good criterion validity in the urodynamics laboratory.

Participants described revision 1, 2, 3 and 4 as easy to insert and comfortable to wear. Only revision 3 was noted as difficult to remove (Table 1).

Criterion validity study

The wired devices (revisions 2–4), were tested against the conventional urodynamics balloon catheter placed in the rectum. Before use, each wired IVT was calibrated in a pressure chamber in the range of 0 – 350 cmH₂O. The revision 2 IVT correlated well ($r=0.98$) with rectal catheter data with an error of 0.1% (Fig. 2) but subsequent retention studies failed (Table 1). In contrast, the revision 3 IVT also measured a high correlation coefficient ($r=0.94$) but measured a lower relative change in abdominal pressure than the conventional balloon catheter contributing to the 29.1% error. The revision 4 wired IVT pressure changes correlated well ($r=0.99$) with peak pressures measured by the rectal catheter and had an error of 14.6%.

After evaluating the retention and criterion validity results, the revision 4 design was selected to move forward as the best candidate design for wireless integration. Once developed, these wireless revision 4 designs were also compared to the conventional urodynamics balloon catheter placed in the rectum. The wireless device with the revision 4 capsule correlated well for changes in pressures with the rectal balloon catheter ($r=0.97$) with a low error of 1.5% compared to the ideal 1:1 line. Examples of relative pressure changes obtained with the device compared to the rectal balloon during coughing and Valsalva maneuvers are shown in Fig. 3. The baselines between the analog and wireless Rev4 design and the rectal balloon ranged in error between 1.3% to 46.7% or 0.2 cmH₂O-17.3 cmH₂O.

Discussion

We successfully developed a wireless version of an intravaginal pressure sensor. This required close collaboration between the engineering and clinical teams. The clinicians were

initially disappointed that we would be unable to use the shape and dimensions of the revision 1 prototype because this had been well tolerated in our earlier work⁴. The main engineering factor driving the size increase was the size of the Zarlink Wireless chip. Unfortunately, the Revision 2 device failed the retention study likely because the diameter did not allow it to be maintained in the upper third of the vagina. While the final Revision 4 IVT is longer and wider, all participants in the retention study found it to be comfortable, easy to insert and easy to remove.

In developing versions 3 and 4 of the IVT, we considered dimensions of various sources, including various menstrual tampons, Colpexin sphere pessaries¹², and vaginal measurements. When Revision 2, to our surprise, could not be retained, we brought a simulation pelvic model and modeling clay into our multi-disciplinary design meeting and the engineers, urogynecologists and exercise scientists brainstormed about various possibilities using the clay models. While the engineers had seen many figures and photographs of pelvic anatomy, the simulation model was very helpful for them to understand the vaginal axis, position of cervix, posterior fornix, etc. We emphasized that the final model had to be easy for the woman to insert herself and had to be positioned in the upper vagina.

In addition to the wireless technology and changes in dimension, other improvements made to the first generation IVT include the integration of a silicone gel as well as changes made to the capsule which increased the tensile strength and tear strength properties as well as increased the durability of the wireless IVT. These modifications advance the IVT towards a design capable of tracking IAP associated with daily activities outside of the laboratory environment.

In existing studies of intra-abdominal pressure, investigations have focused on measuring how certain activities increase intra-abdominal pressure in a urodynamic setting with the goal of determining activity restrictions in the post-operative period. While there is a great deal of variability, pelvic surgeons often recommend significant restrictions in exercise and lifting post-operatively. Even one year after surgery, women who had undergone abdominal sacrocolpopexy cited physician advice as a reason for interference for physical activity³. Although there are limited data, surgeons make these recommendations for a plausible reason. By limiting activities that increase intra-abdominal pressure, they hope to decrease failure as a result of excess loading on the pelvic floor. However, investigators have found that lifting from certain positions do not increase intra-abdominal pressure substantially¹³ and that many unavoidable or uncontrolled physiologic functions such as coughing and Valsalva are associated with increases in intra-abdominal pressure in access of activities that patients are warned about^{14, 15}.

The posterior vaginal vault is an accepted location for measuring IAP and results between rectal and vaginal IAP measurements are comparable¹⁶. However the same report acknowledges that these measurements require careful setup and continuous surveillance and adjustment of the measurement devices to obtain quality recordings. In addition to setup, subject position can play a large role in abdominal pressure and in the correlation between rectal and vaginal IAP measurements^{16, 17, 18, 19}. Absolute comparisons between rectal and vaginal IAP measurements are dependent on multiple factors including subject, transducer type, transducer setup and measurement technique^{16, 20}. Given these vagaries, we considered the International continence Society (ICS) criteria for ensuring quality control of pressure recordings: 1) resting values for Pabd, Pves and Pdet are in a typical range, 2) the Pabd and Pves signals have only minor variations caused by breathing or talking and should be similar for both signals 3) coughs ensure that Pabd and Pves respond equally¹⁶. When we applied these recommendations to the wireless IVT, we determined that the

wireless IVT provides quality IAP despite any bias or offset between the rectal and vaginal measurements.

The primary limitation of the current device is that it cannot be used in women with significant apical prolapse as it will likely fall out. For our feasibility study, we required that women have no symptom of a bulge. While we did not exclude women based on POP-Q results, none of our participants had more than Stage II prolapse. In addition, our wireless version currently requires a base station that is not easily portable to acquire data. Therefore, we are still limited to exploring IAPs during activities that can be done in the same room as the base station. We are now in the process of designing wearable base stations that will be the size of a pager and able to store wireless IAP measurements for the device to be truly portable.

Lastly, we were not able to determine the accuracy of our device in measuring absolute pressures since there is not a clinical gold standard for measurement of intra-abdominal pressures. Therefore, we are not able to determine if differences in baseline measurements between our devices and the rectal balloon are due to differences in device function, accuracy or location.

We are currently conducting a test-retest reproducibility study of the wireless second generation device in the exercise laboratory setting during a variety of activities. The final wireless remote abdominal pressure system (WRAPS) can then be used for long term measurements of IAP during real world activities. Such a tool, until now lacking in our research armamentarium, will allow exploration of the association between IAP, activities and pelvic floor disorders.

We have successfully advanced the design of a wireless vaginal pressure transducer which allows accurate measures of intra-abdominal pressure directly in the vagina. This is better tolerated and overcomes limitations in traditional urodynamic measures of intrabdominal pressure. Compared to a previous wired design, we are closer to measuring the role that physical activity plays in incidence, progression and reoccurrence of pelvic floor disorders.

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Figure 1.

Picture of a wireless generation 2 Rev 4 IVT. The electronics package is sealed in a gel-filled Rev 4 elastomeric capsule. An external antenna with a chip antenna is used to transmit wireless data packets to the base station receiver. The tether system allows for easy removal of the IVT after use.

Figure 2.

Combined correlation of peak pressures with the analog and wireless IVT compared to the rectal balloon catheter during coughing and Valsalva maneuvers as part of a standard urodynamics test. The ideal line shown above indicates the ideal case in which the rectal and the intra-vaginal transducer report the same IAP. Percent from ideal measurements were based upon the slope of the best fit line through the data points compared to the ideal line.

Figure 3. Pressure tracings of Rev4 wireless IVT and rectal transducer of both recorded pressures (A) and pressure tracings with baselines adjusted to match (B).

Table 1

Feasibility study results

Capsule	Dimensions Length/Diameter	Retention	Prior Hysterectomy	Insertion of the device was easy?	Device was comfortable to wear?	Removal of the device was easy?
Rev 1	27.4 mm/12.7 mm	Retained in 3 out of 4 subjects. Retention considered success	1/4	3 Strongly Agree 1 Agree	1 Strongly Agree 2 Agree 1 Neutral	2 Strongly Agree 2 Agree
Rev 2	35.6 mm/15.9 mm	Failed retention on 4 of 4 subjects. Retention considered failure	0/4	4 Strongly Agree	4 Strongly Agree	2 Strongly Agree 2 Agree
Rev 3	27.9 mm/23.8 mm	Retained in 5 out of 7 subjects. Retention considered success	1/7	3 Strongly Agree 4 Agree	3 Strongly Agree 4 Agree	1 Strongly Agree 3 Agree 2 Disagree 1 Strongly Disagree
Rev 4	37.3 mm/23.8mm 15.9mm	Retained in 6 out of 6 subjects. Retention considered success	1/6	6 Strongly Agree	6 Strongly Agree	3 Strongly Agree 3 Agree