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First in Human Subjects Testing of the UroMonitor: A Catheter-free Wireless Ambulatory Bladder Pressure Monitor

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Full-length article available at https://doi.org/10.1097/JU.0000000000003451.

Study Need and Importance: Urodynamics is the standard method of diagnosing bladder dysfunction, but involves catheters and retrograde bladder filling. With these artificial conditions, urodynamics cannot always reproduce patient complaints. We have developed a wireless, catheter-free intravesical pressure sensor, the UroMonitor, which enables catheter-free telemetric ambulatory bladder monitoring (see Figure). The purpose of this study was to evaluate accuracy of UroMonitor pressure data and assess safety and feasibility of use in humans.

What We Found: With short-term use in 11 women undergoing urodynamics for suspected overactive bladder, we found that the UroMonitor did not significantly alter capacity, sensation, or flow during urodynamics. The UroMonitor was also easily inserted and removed in all subjects. The UroMonitor successfully captured 98% (85/87) of voiding and nonvoiding urodynamic events. All subjects voided with low post-void residual volume with the UroMonitor in place. Median ambulatory pain score with the UroMonitor was rated 0 (0-2). There were no post-procedural infections or changes to voiding behavior.

Limitations: This was a feasibility study designed to assess safety and accuracy while minimizing risk to human subjects. The study was not designed or powered to demonstrate superiority of the UroMonitor over urodynamics in terms of diagnostic capability. The UroMonitor in this current early prototype stage measures pressure only and does not include bladder volume or other diagnostic measures. Future versions will be designed to expand the scope of measured and transmitted parameters.

Interpretation for Patient Care: Current urodynamics methodologies have limitations including catheters and nonphysiological filling. This is the first report of measurement of catheter-free wireless bladder pressure data during ambulation and voiding in human subjects. Longer monitoring times in a patient's home have the potential to revolutionize our understanding of lower urinary tract function and could provide a more accurate, less distressing method of diagnosing lower urinary tract dysfunction.

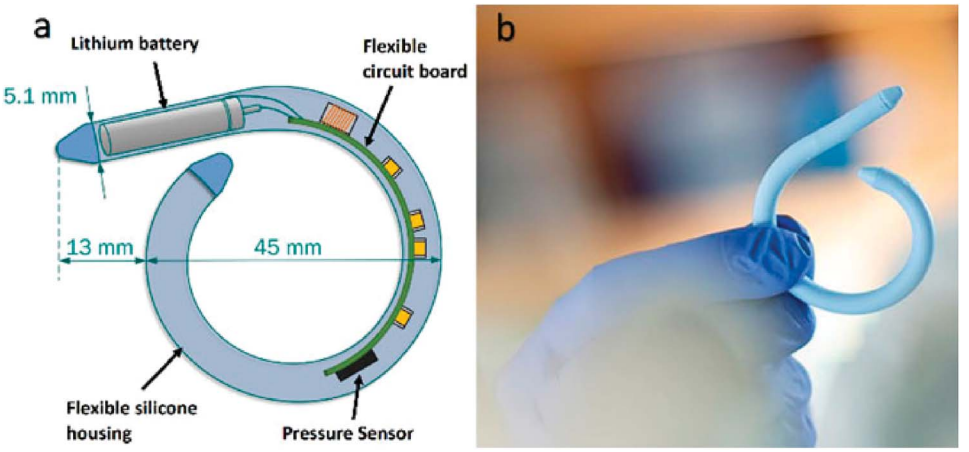

Figure. A, UroMonitor schematic with key components identified. B, Insertable UroMonitor device.

THE JOURNAL OF UROLOGY®

https://doi.org/10.1097/JU.0000000000003451
Vol. 210, 186-195, July 2023
Printed in U.S.A.

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www.auajournals.org/journal/juro

First in Human Subjects Testing of the UroMonitor: A Catheter-free Wireless Ambulatory Bladder Pressure Monitor

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Purpose: Urodynamics is the standard method of diagnosing bladder dysfunction, but involves catheters and retrograde bladder filling. With these artificial conditions, urodynamics cannot always reproduce patient complaints. We have developed a wireless, catheter-free intravesical pressure sensor, the UroMonitor, which enables catheter-free telemetric ambulatory bladder monitoring. The purpose of this study was twofold: to evaluate accuracy of UroMonitor pressure data, and assess safety and feasibility of use in humans.

Materials and Methods: Eleven adult female patients undergoing urodynamics for overactive bladder symptoms were enrolled. After baseline urodynamics, the UroMonitor was transurethrally inserted into the bladder and position was confirmed cystoscopically. A second urodynamics was then performed with the UroMonitor simultaneously transmitting bladder pressure. Following removal of urodynamics catheters, the UroMonitor transmitted bladder pressure during ambulation and voiding in private. Visual analogue pain scales (0-5) were used to assess patient discomfort.

Results: The UroMonitor did not significantly alter capacity, sensation, or flow during urodynamics. The UroMonitor was also easily inserted and removed in all subjects. The UroMonitor reproduced bladder pressure, capturing 98% (85/87) of voiding and nonvoiding urodynamic events. All subjects voided with only the UroMonitor in place with low post-void residual volume. Median ambulatory pain score with the UroMonitor was rated 0 (0-2). There were no post-procedural infections or changes to voiding behavior.

Conclusions: The UroMonitor is the first device to enable catheter-free telemetric ambulatory bladder pressure monitoring in humans. The UroMonitor appears safe and well tolerated, does not impede lower urinary tract function, and can reliably identify bladder events compared to urodynamics.

Key Words: urodynamics, female, urethra, urinary catheters

Urodynamics (UDS) is the gold standard for functional assessment of the lower urinary tract (LUT).[1] Multichannel UDS requires the placement of transurethral and rectal/vaginal catheters in addition to surface electrodes for electromyography recording.[2,3] Although multichannel UDS provides objective data on LUT function, it also has several key limitations which may affect study results and accessibility, including retrograde bladder filling, catheter placement in an uncomfortable environment,[4,5] and the requirement of a skilled technologist and dedicated work space.

Telemetric ambulatory urodynamic monitoring (TAUM) is a novel approach for LUT assessment which enables

Submitted August 16, 2022; accepted March 28, 2023; published June 9, 2023.

Support: This research was supported in part by funds from the Research Program Committee of the Cleveland Clinic, Urology Care Foundation, and the Department of Veterans Affairs.

Conflict of Interest: Drs Majerus and Damaser have intellectual property in the UroMonitor technology, which has been licensed to a company for commercialization. Drs Majerus and Damaser were not involved with recruitment of subjects for this study. Dr Goldman is an investor in the company licensing the UroMonitor technology. Data collection and analysis for this study were completed prior to the license date and commencement of these competing interests.

Ethics Statement: This study received Institutional Review Board approval (IRB No. 19-072).

Author Contributions: Conceptualization: BTF, SJAM, SD, HBG, MSD; Designed the UroMonitor system: SJAM, MSD; Performed the experiment: BTF, SJAM, SD, ARW, HBG; Patient recruitment: BTF, SD, HBG; Experimental design: SD, HBG, MSD, SJAM; Performed urodynamics: ARW; Device assembly: BMB, SJAM; Data collection: SJAM, BTF, KCL, ARW; Data analysis: SJAM, MSD, SD, RSB; Performed statistical analysis: RSB; Interpretation of Urodynamics and UroMonitor data: BTF, SD, HBG, MSD, RSB, SJAM, KCL; Graphing of results: SJAM, KCL, BTF, BMB, RSB; Supervision: HBG, MSD; Writing—original draft: BTF, SJAM, SD, MSD; Writing—review and editing: BTF, SJAM, SD, KCL, ARW, BMB, RSB, HBG, MSD; Approved final version of the manuscript: BTF, SJAM, SD, KCL, ARW, BMB, RSB, HBG, MSD.

Data and Materials Availability: Individual patient data that underlie the results reported in this article, after deidentification, can be made available upon request. Figures 2-4 have associated raw data.

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https://doi.org/10.1097/JU.0000000000003451
Vol. 210, 186-195, July 2023
Printed in U.S.A.

continuous, catheter-free bladder pressure monitoring over a longitudinal time frame.[6-11] To date, no TAUM devices have been tested in humans. Our group has developed a wireless intravesical pressure sensor, the UroMonitor (UM), to perform telemetric, catheter-free ambulatory bladder pressure monitoring. The UM is placed in the bladder lumen transurethrally and can be maintained there, transmitting bladder pressure, until the attached transurethral suture is used to remove it. Bladder contractions are distinguished from abdominal pressure events using a novel adaptive signal processing model, enabling real-time detection of bladder events and obviating the need for a vaginal/rectal abdominal catheter.[12,13]

The primary objectives of this study were twofold: to evaluate the accuracy of UM pressure data as well as to assess the safety and feasibility of its use in humans. We hypothesized that UM-obtained pressure data would correlate with those from simultaneous multichannel UDS and that the UM could be safely placed, would be well tolerated and easily extracted, and would not disrupt normal LUT function.

MATERIALS AND METHODS

The UM

The UM consists of a custom, flexible electronic module powered by a lithium ion pin battery (Figure 1) and is packaged using custom-made housing made from an implant-grade silicone elastomer.[14] The electronic module includes a microcontroller running custom software, a data transmitting antenna, and a pressure sensor. Once activated, the UM has sufficient battery life to transmit pressure data 10 times per second (10 Hz) for over 135 hours. The UM does not measure bladder volume. Data are wirelessly transmitted from the UM to a 9-cm diameter loop antenna taped to the lower abdominal skin. The antenna is connected to a pager-like portable radio which records data on a microSD card and transmits data via Bluetooth to a PC (Figure 1). A sterile 0-silk suture threaded through 1 end cap of the UM enables transurethral extraction. Details of UM design and implementation are provided in the Supplemental Material (https://www.jurology.com).

Patient Selection

This was an observational pilot study which included 11 adult (18 years or older) female patients undergoing evaluation for overactive bladder with multichannel UDS. Women with a diagnosis of interstitial cystitis/bladder pain syndrome, neurogenic LUT dysfunction, recurrent urinary tract infection, stage 2b or greater pelvic organ prolapse, significant obesity with BMI >35, or a history of radical pelvic surgery were excluded from the study. Obese subjects were excluded to minimize issues with data transmission with the increased distance between the device and antenna. All patients were recruited between December 2019 and March 2021 following outpatient evaluation by 1 of 4 fellowship-trained FPMRS (Female Pelvic Medicine and Reconstructive Surgery) urologists at the Glickman Urological and Kidney Institute of Cleveland Clinic. All patients had a negative urine culture prior to any study-related procedures. Cleveland Clinic Institutional Review Board approval and patient consent were obtained prior to all study-related activity (IRB No. 19-072).

Study Procedures. On the day of the study, all patients had baseline, multichannel UDS. Further details on specific urodynamic practices and equipment used are included in the Supplemental Material (https://www.jurology.com). Following baseline UDS, the catheters were removed and post-void residual (PVR) volume was determined. An ethylene oxide gas–sterilized UM with a sterile suture attached was then inserted transurethrally into the bladder using sterile technique. The pre-curled, flexible silicone housing of the UM allowed the device to be straightened during insertion and return to a more circular shape upon entering the bladder. Flexible cystoscopy confirmed appropriate positioning of the UM and ensured there was no urethral or vesical trauma during insertion.

A second UDS was then performed with both the UDS catheters and UM simultaneously measuring pressure, allowing for comparison of simultaneous measurements between the 2 modalities. Next, the UDS catheters were removed and the subject ambulated while the UM transmitted bladder pressure. When she felt the need to void, each subject then voided in private with the UM in place. A voided urine sample was obtained from all subjects and sent for urine culture and heavy metal assay to assess device packaging integrity. Finally, the UM was manually extracted transurethrally via the pre-attached suture and a PVR volume was obtained. Visual analogue pain scales (0-5) were used to assess patient discomfort during each study phase. A follow-up phone call was made 2 days post-procedure to reassess for pain and for any changes in LUT symptoms.

Sample Size Calculation and Data Analysis

Sample size estimates were derived from data comparing ambulatory vs conventional urodynamics monitoring as previously reported by Heslington and Hilton.[15] It was determined that a sample size of 11 patients would provide 80% power with an alpha of .05 to compare 2 continuous measurements of vesical pressure, with UDS considered the gold standard. A repeated measures ANOVA was used to compare clinical UDS parameters before and after UM insertion. Repeated measures ANOVA was also used to compare patient-reported pain scores across the various study phases. Results are presented either as medians with ranges or interquartile ranges, or as mean with SD. A qualitative analysis of the simultaneously obtained UDS and UM pressure data was independently performed by 2 of the urologists involved in the study. Pressure data for each patient were also tested for correlation and agreement between UDS- and UM-measured pressures.[16] Details on the sample size calculation and the statistical methods are included in the Supplemental Material (https://www.jurology.com). Times to insert and extract the UM were recorded.

RESULTS

UDS and UM data from all 11 subjects were obtained (Figure 2). The median age of subjects was 67 years (range 44-83). Median BMI was 30.5 kg/m^2

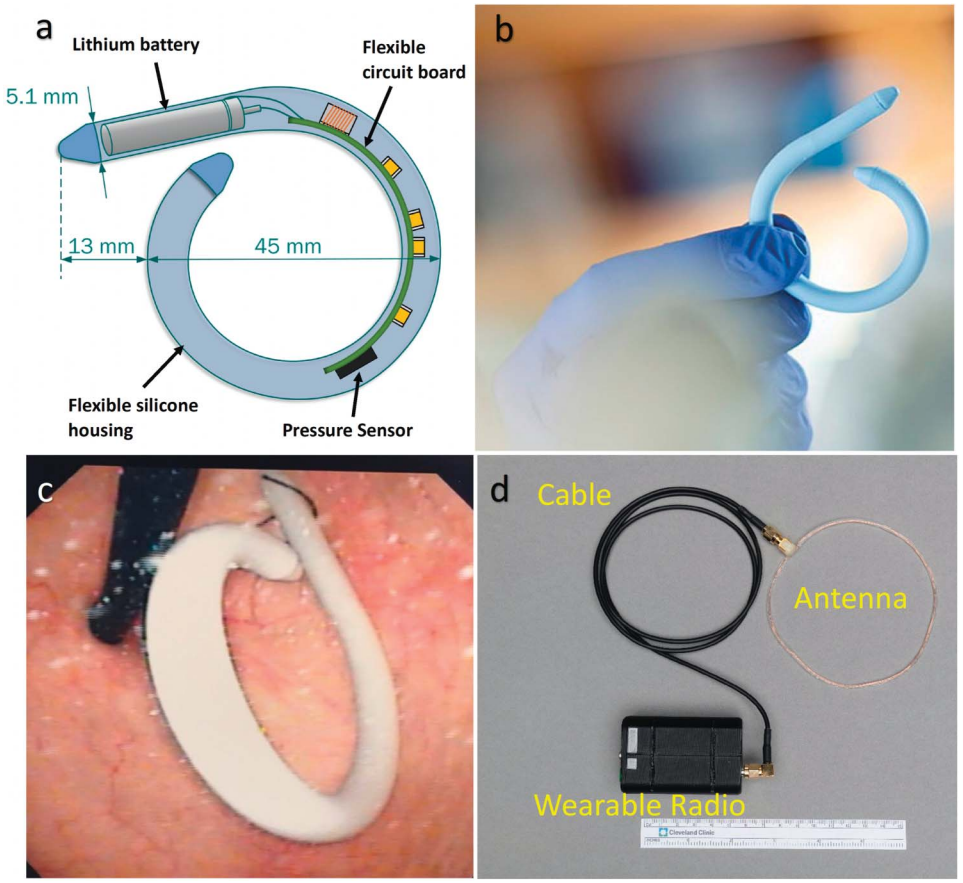

Figure 1. A, UroMonitor schematic with key components identified. B, Insertable UroMonitor device. C, Cystoscopic image of the UroMonitor within the bladder after insertion. D, UroMonitor system antenna with pager-like radio receiver.

(25.0-35.8). Median time for UM insertion was 17.5 seconds (7-66). The presence of the UM within the bladder did not lead to any statistically significant difference in clinical UDS parameters compared to baseline UDS. Likewise, the presence of the UM did not significantly alter volume at first desire to void, maximum voiding flow rate, detrusor pressure at the maximum voiding flow rate, capacity, voided volume, or PVR volume. One patient demonstrated worsening detrusor overactivity (DO) on UDS following UM insertion. No other new or concerning urodynamics findings were elicited with the UM in place. PVR volumes were not significantly different before and after UM insertion (Figure 3).

The pressure accuracy of the UM at low volumes did not correlate well with UDS; nonetheless, UM-recorded pressure events aligned in time and morphology with those from UDS (Figure 2). The UM accurately reproduced vesical pressure patterns during cystometry, capturing 98% (85 of 87) of voiding and nonvoiding urodynamic events (ie, DO, stress maneuvers, and voiding contractions) over all subjects. The 2 urodynamic events that were missed by the UM were due to failure of the radio to receive data during those events. This technical issue was resolved for later subjects by modifying the radio circuitry to improve reception. Subjects 4 and 6 were excluded from quantitative analysis due to radio interference encountered during the study, which corrupted the received data. Analyzing data from the remaining subjects showed that the mean of the difference in simultaneous UDS and UM pressure measurement was less than 1 cm H_2O (Figure 4) and the majority of pressure differences remained within 2 SDs of the mean (94%-99%) in each subject. The SD of differences ranged between 2.6 and 15.8 cm H_2O. UM pressure data correlated closely with those of UDS (Figure 4) and improved significantly after the first 3 subjects with technical improvements to the radio, resulting in mean r^2 of 0.51 (0.11-0.94) for all subjects and mean r^2 of 0.87 (0.72-0.94) for the final 6 subjects.

Subjects ambulated with only the UM in place for an average of 60 minutes (range 30-90). All subjects voided privately with the UM in place with a mean of 1 void (1-4 voids per subject). This is in contrast to 4 subjects who were unable to void with UDS catheters in place. Seventy-one percent fewer DO episodes were noted during the catheter-free phase than the UDS phase of the study (38 cumulative baseline UDS DO events vs 11 cumulative catheter-free DO events)

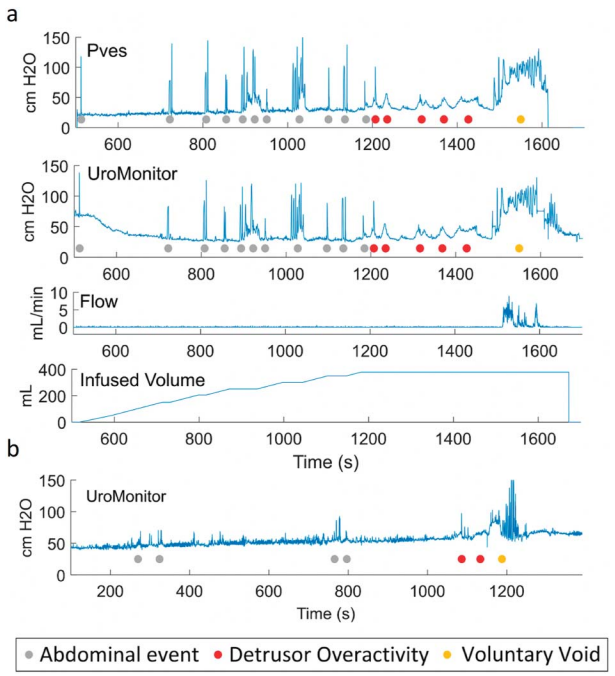

Figure 2. A, Simultaneous vesical pressure data obtained from urodynamics catheters and the UroMonitor during multichannel urodynamics. The top row displays intravesical pressure (Pves) via a transurethral catheter. UroMonitor-measured pressures are displayed just below, followed by the flow rate during voiding and infused volume. B, UroMonitor-measured vesical pressure is also shown during natural filling and voiding in an ambulatory patient free of catheters. All pressure values are reported in cm H_2O and urodynamics-relevant pressure events are annotated with color-coded dots below, with gray indicating an abdominal-generated bladder pressure change event such as a cough or Valsalva, red indicating detrusor overactivity, and yellow indicating a voluntary void. Clinical urodynamics parameters before (gray) and after (blue) UroMonitor insertion were not significantly different.

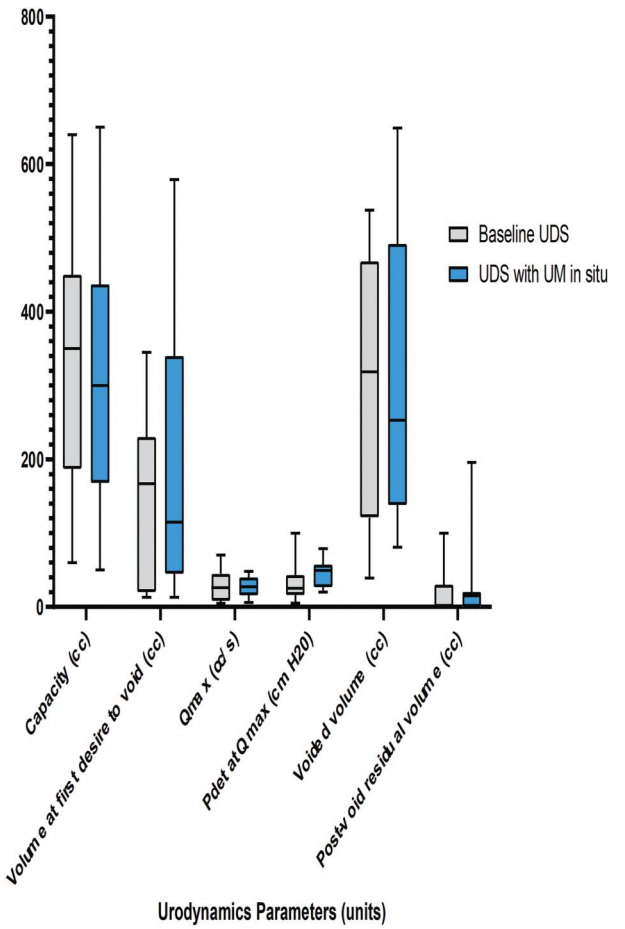

Figure 3. Box and whisker plot demonstrating the urodynamics (UDS) parameters comparing baseline UDS and UDS with the UroMonitor (UM) in situ. The line within the box represents the median distribution. The top and bottom of the box represent the interquartile ranges, and whiskers denote minimum and maximum ranges. Pdet indicates detrusor pressure; Qmax, maximum voiding flow rate.

in the 5 subjects with DO observed in baseline UDS, despite almost 2 times the duration of monitoring (103 minutes cumulative baseline UDS time vs 205 minutes cumulative catheter-free ambulatory UM monitoring time). Median PVR during UDS with UM in situ (0 cc [0-196]) and during the catheter-free, ambulatory phase (4.5 cc [0-50]) was not significantly different from PVR during baseline UDS (0 cc, [0-100]; $P = .56$ and $P = .38$, respectively; Figure 3). Two patients voided the UM completely out, 1 shortly after insertion during the pre-cystometry uroflow and the other during a private void in the ambulatory phase, but neither reported pain associated with this. A second sterile UM was replaced in both instances to complete the study.

The most painful portion of the procedural intervention was flexible cystoscopy, with a median pain score of 3 (range 0-5). Ambulation with only UM, UM removal, post-procedure, and 48 hours after the procedure all had median pain scores of 0 (Figure 5). Median time for UM removal was 2.0 seconds (1.5-3). There were no post-procedure urinary tract infections or detection of heavy metals within the urine. There were no adverse events or peri-procedural complications. There were no significant changes to baseline voiding behaviors 48 hours post-procedure.

DISCUSSION

Multichannel UDS is done over a brief period of time utilizing nonphysiological retrograde filling of the bladder and does not always reproduce patients' symptoms.[17,18] While ambulatory urodynamics addresses some of these limitations, it is still reliant on urinary and rectal catheters, which are distressing for patients and may affect the resultant data.[7,8] This study reports the first ever use of a catheter-free, wireless ambulatory bladder pressure monitoring device in humans. The UM system seeks to address these critical limitations by utilizing an intravesical, catheter-free device, allowing for continuous bladder pressure monitoring during natural bladder filling

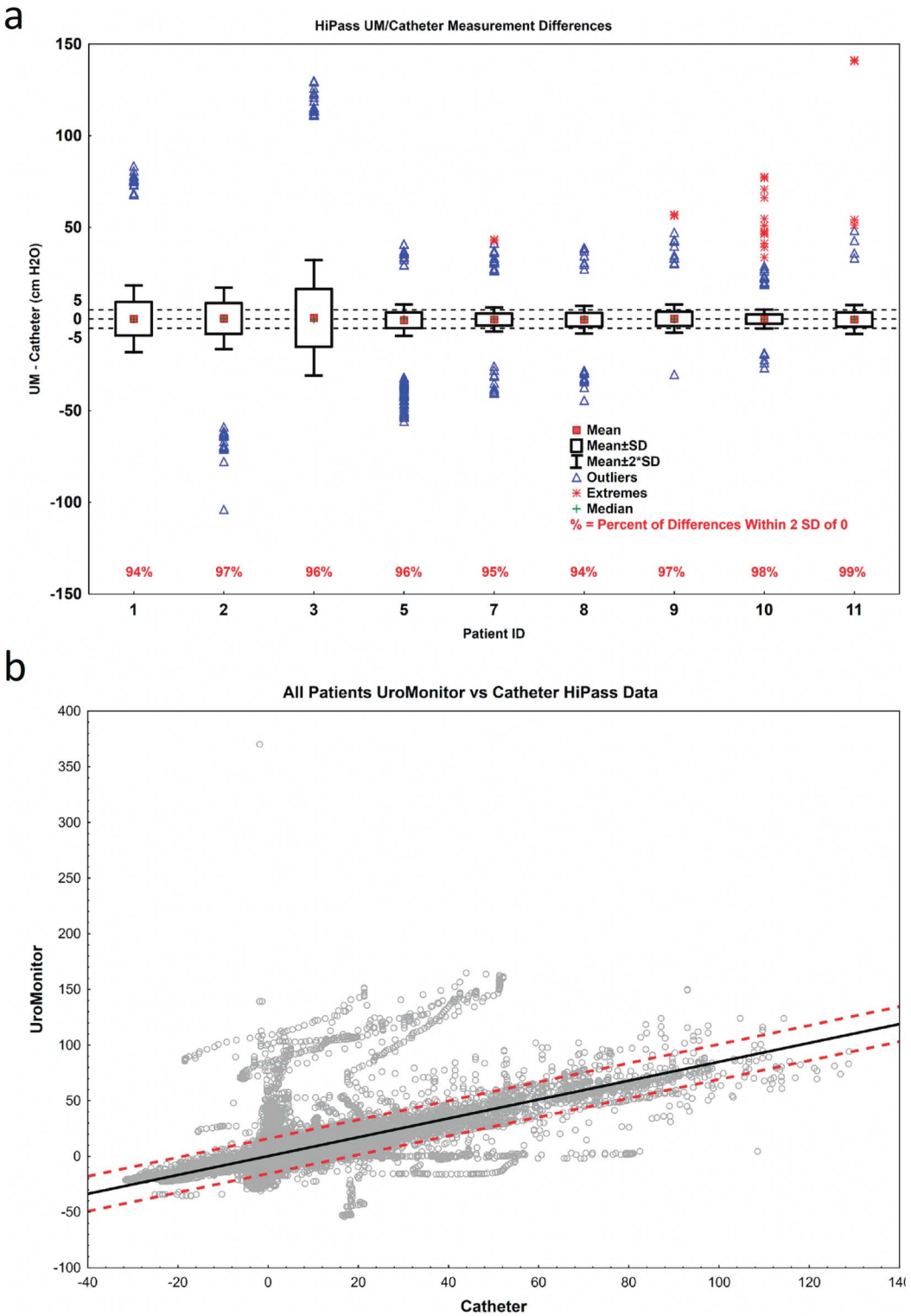

Figure 4. A, Box and whisker plot depicting differences based on mean and standard deviation (SD) between simultaneous UroMonitor (UM) wireless and urodynamics catheter–based measured pressures for individual study participants. For each participant, the box limits represent 1 SD from the mean and whiskers denote 2 SDs. Each box and whisker represents 2,637-18,689 data points. Boxplot outliers are data points between 2 and 3 times the 2-SD spread and are depicted in blue. Boxplot extremes are data points greater than 3 times the 2-SD spread and are depicted as a red asterisk. Only the outliers and extremes are shown as individual data points for clarity. Subjects 4 and 6 were excluded from quantitative analysis due to poor transmission of pressure data from the UM to the external radio. B, Summative linear regression analysis comparing all available simultaneously collected urodynamic and UM-measured pressure data. The line fit to all data (black line) had $R^2 = 0.51$ and $P < .0001$. The red dashed lines indicate the 95% confidence interval for the data. Box and whisker plot depicting visual analogue pain scores (0-5) during various study phases. HiPass indicates application of a high pass filter to both data sets as detailed in the Supplemental Material (https://www.jurology.com).

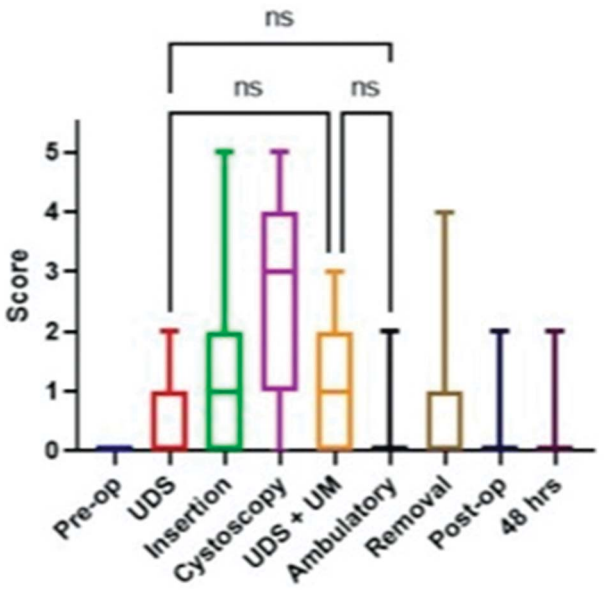

Figure 5. Box and whisker plot demonstrating the median pain scores at each part of the study. The line within the box represents the median pain score. The top and bottom of the box represent the interquartile range with whiskers denoting a 95% confidence interval. There were no statistically significant differences in pain/distress ratings between baseline urodynamics (UDS) and the ambulatory phase of the study. ns indicates not significant; UM, UroMonitor.

and emptying without impeding activities of daily life.

A unique aspect of the UM is that it relies on vesical pressure data alone without concomitant rectal or vaginal catheters to estimate intra-abdominal pressure. Our group has previously developed a context aware thresholding algorithm to identify bladder contractions and distinguish these from abdominal pressure events using signal processing methods in the absence of simultaneous abdominal pressure measurement from rectal or vaginal catheters.[12,13] Although this algorithm was not used in the current study, in a prior retrospective study using UDS data, this novel adaptive model detected 97% of bladder contractions within 1 second of onset without a significant false-positive rate, enabling real-time detection of bladder events.[12,13] Ongoing research is aimed at expanding the context aware thresholding algorithm to estimate detrusor pressure.

In this study, we demonstrated that the UM provided a safe and clinically feasible approach for TAUM with no associated peri-procedural complications. Feasibility was also demonstrated by the relative ease of both transurethral insertion and removal via techniques that are already familiar to urologists (ie, catheter insertion and double-J ureteral stent removal). Importantly, the UM did not significantly alter urinary storage or emptying ability. The device was well tolerated, with the most painful portions of the procedure involving device insertion and flexible cystoscopy. In contrast, when only the UM was in place and during device removal, pain and distress were minimal.

We analyzed simultaneous UM and UDS data to assess if the UM could be used to identify clinically relevant bladder pressure events. The UM performed exceedingly well, capturing 98% of urodynamic events. Missed events occurred due to radio reception errors in the prototype data collection system, which were corrected in the course of the study. Overall, UM-measured pressure tracings aligned closely with those from UDS, making visual interpretation and comparison straightforward.

Mean differences between simultaneous UM- and UDS-measured pressures were all near 0 (within 1 cm H_2O). While the range of SDs was 2.6 to 15.8 cm H_2O, these data are skewed by the first 3 subjects prior to technical improvements to the UM. In the final 6 subjects, 1 SD of the differences were all within 5 cm H_2O. Similarly, UM-measured pressures demonstrated moderate correlation with UDS recorded pressure data on linear regression analysis but improved over the course of the study with ongoing technical improvements to electronics and programming of the UM system.

The present study was not designed or powered to demonstrate superiority of the UM over UDS in terms of diagnostic capability. Nonetheless, there were no urodynamic findings identified by the UM that were not demonstrated on baseline UDS, suggesting comparability of the measurements. There was a 71% reduction in DO episodes during the catheter-free ambulatory UM monitoring phase compared to baseline UDS, despite the longer monitoring period, suggesting that the absence of a transurethral catheter may decrease the frequency of DO and more accurately reproduce bladder function. This is consistent with prior findings that placement of a urethral catheter can irritate the LUT.[19]

To our knowledge, catheter-free wireless bladder pressure data during ambulation and voiding have never before been reported in human subjects. Future studies with longer monitoring time and more subjects could be done to compare catheter-free voiding data to voiding data from conventional UDS to elucidate if catheter-free voids display consistent, unique differences from conventional UDS parameters. Ongoing studies test the use of the UM in a cohort of women with neurogenic LUT dysfunction, in whom longitudinal bladder pressure monitoring is critical to detect changes which could place the upper urinary tract at risk.

Demonstration of feasibility and safety with this study enables the use of the UM for further TAUM applications. By combining the UM with other noninvasive methods, including voiding diaries, novel telemetric incontinence pads, or at-home uroflow devices,

urologists may be able to more adequately capture a patient's true voiding behaviors and defer invasive UDS in select patients.[20-23] In addition, the UM could be used as a modality for objectively assessing responses to both second- and third-line therapies for overactive bladder, similar to how ambulatory urodynamics was employed by Drossaerts et al.[24] Furthermore, the UM could be used in conjunction with neuromodulation, providing real-time bladder pressure data, enabling conditional or triggered stimulation, potentially improving efficacy of the treatment and prolonging stimulator battery life.[10,14,25]

This was a proof-of concept, pilot study of a homogenous population, limiting the generalizability of these results. An insertion tool to enable UM testing in males is currently in development. Obese subjects were excluded at this stage, but future changes to the data transmission system could enable use of the UM in obese patients.

Qualitative analysis comparing UDS- and UM-obtained pressure data was performed by 2 non-blinded urologists, introducing a potential source of experimental bias. Two subjects were excluded from quantitative analysis due to radio interference encountered during the study, but data collection methods and device modifications were made throughout the study to resolve these issues. The static pressure accuracy of the UM at low volumes did not correlate well with UDS pressure likely due to specifics of device packaging. Research is ongoing to resolve this issue. As a result, our data analysis was limited to pressure events (eg, DO) which are clinically meaningful but not quantitatively interpreted. Another limitation of the UM is that it was not designed to provide data regarding bladder volume, limiting the ability to determine compliance and assess capacity. Additionally, voided volumes were not recorded during the UM-only phase, limiting comparison of bladder volumes during the UDS and ambulatory UM phases of the study. Our group has developed a conductance-based volume sensor which may enable the UM to provide a more comprehensive assessment of LUT function, which can be added to a later version of the UM.[26,27]

CONCLUSIONS

The UM is the first device to enable catheter-free telemetric ambulatory bladder pressure monitoring in humans. The UM appears safe, is well tolerated by patients, and does not impede LUT function. The UM enables ambulatory bladder pressure data collection without catheters or UDS equipment that may impede normal activity. Results of this study suggest the UM can reliably identify relevant bladder events; however, additional study of the device in human subjects is warranted to elucidate fully its diagnostic capability and clinical applicability.

ACKNOWLEDGMENTS

We thank Dr Sandip Vasavada for his work recruiting patients, and Therese Bahniuk, RN, and Tara Amero-Powell, BSN, RN, for their work performing urodynamics.

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EDITORIAL COMMENT

The term urodynamics (UDS) was adopted from "hydrodynamic" and first used by Davis in 1953 to allow clinicians to assess the dynamics of storage and passage of urine through the bladder. Its use was first reported in *The Journal of Urology*® in 1962 by Davis and Zimskind.[1] UDS aims to assess the interactions between the volume/flow and pressures in the bladder that lead to clinical "events" such as incontinence, frequency, urgency, pain, retention, etc. However, the fundamental limitation of UDS has been our inability to measure those interactions in real time and place when those clinical events occur. Because of our technical limitations, and over the past 60 years, we have accepted the limitation of UDS-generated data/artifacts and its application for clinical decision-making. However, we have always desired to have diagnostic tools by which we can assess the interactions between volume/flow, pressure, and hopefully sensation (afferent and efferent) of the bladder.[2,3]

In this article, Frainey et al present their first evidence for the feasibility and safety of use of an insertable device (UroMonitor [UM]) that is capable of measuring bladder pressure and communicating the values wirelessly to a PC.[4] This was the natural step of development of UM following their presentation of technical details of UM in other biomedical journals. The authors ought to be congratulated for their scientific persistence.

Despite UM's many technical (it only measures pressures and not volume or sensation) and clinical (narrow clinical cohort) limitations, availability of UM is undoubtedly a technical breakthrough for urology. First and foremost, it would allow us to measure the bladder events in real time and a location that is clinically more acceptable. Further, UM would allow the innovators to use UM in conjunction with other tools of assessment of lower urinary tract function (diaries, sensory measures, etc) so, hopefully, we will have a reliable tool(s) for assessment of the clinical situation for millions of individuals who suffer from lower urinary tract diseases. UM application must be tested for many more lower urinary tract disease cohorts.

The lingering question in my mind is whether, with a real-time assessment of bladder function, the role of UDS in clinical decision-making (surgical management of stress urinary incontinence, pelvic organ prolapse, bladder outlet obstruction) should be reevaluated.

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REPLY BY AUTHORS

We thank Dr Daneshgari for the positive comment. We agree that the UroMonitor "is undoubtedly a technical breakthrough for urology." In this initial patient cohort, we kept the risk low by testing in the clinic only and not sending patients home with the UroMonitor.[1] It now becomes possible to conduct a follow-on study that better replicates the expected clinical use of the UroMonitor, monitoring bladder function at home during activities of daily living. In addition to clinical studies conducted at home, ongoing and planned research in the laboratory includes addition of volume sensing to the UroMonitor, testing in men, and synchronization with both patient input regarding activities and sensation and data from other devices such as flowmeters.

It is worth noting that the first Holter monitor was introduced in 1961 and required carrying a 75-lb backpack containing a reel-to-reel tape recorder.[2] With this start, the Holter monitor came to revolutionize the state of cardiac care. As the technology progressed, remote telemetric cardiac monitors became smaller, more accurate, easier to use, and readily accessible to many patients. The indications for use and cardiac diagnoses available to clinicians have improved as the technology matured.[3] We expect similar maturation of functional lower urinary tract assessment and treatment as UroMonitor technology matures and data become available describing both normal and pathological bladder function and response to therapeutics at home. The answer to the question regarding the future of urodynamics will become readily evident with advancements in technology and further use of the UroMonitor.

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