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Ambulatory urodynamic monitoring: state of the art and future directions

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Abstract

Urodynamic studies are a key component of the clinical evaluation of lower urinary tract dysfunction and include filling cystometry, pressure-flow studies, uroflowmetry, urethral function tests and electromyography. However, pitfalls of traditional urodynamics include physical and emotional discomfort, artificial test conditions with catheters and rapid retrograde filling of the bladder, which result in variable diagnostic accuracy. Ambulatory urodynamic monitoring (AUM) uses physiological anterograde filling and, therefore, offers a longer and more physiologically relevant evaluation. However, AUM methods rely on traditional catheters and pressure transducers and do not measure volume continuously, which is required to provide context for pressure changes. Novel telemetric AUM (TAUM) methods that use wireless, catheter-free, battery-powered devices to monitor bladder pressure and volume while patients carry out their daily activities are currently being investigated. TAUM devices under current development are innovating in the areas of remote monitoring, rechargeable energy sources, device deployment and retrieval and materials engineering to provide increased diagnostic accuracy and improved comfort

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Author contributions

Competing interests

S.M. and M.S.D. are co-inventors on a patent titled 'Implantable Pressure Sensor' (US 10,143,391 B2), which might be perceived as a competitive technology to those described in this paper. This patent is assigned jointly to the Cleveland Clinic, Case Western Reserve University and the US Department of Veterans Affairs. It has not been licensed or optioned by a company. Additional related intellectual property with S.M. and M.S.D. as co-inventors include 'Intravesicular Device' (International Patent Application WO2005/115245 A1), 'Bladder Event Detection for Diagnosis of Urinary Incontinence or Treatment of Lower Urinary Tract Dysfunction' (US 15/142,704), 'Systems and Methods for Estimating a Volume of a Hollow Organ' (US 16/074,149; International Patent Application WO2017/136212) and 'Non-Surgical Mechanisms for Ambulatory Urodynamics' (US Provisional Patent filed 25 May 2018). None of this additional intellectual property has been licensed. These technologies are examples of the telemetric ambulatory urodynamic monitoring devices referred to in the manuscript. The other authors declare no competing interests.

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for patients with incontinence or voiding dysfunction. These devices hold promise for improving the diagnosis and management of patients with lower urinary tract disorders.

Urodynamic studies (UDS; also referred to as urodynamics) collect physiological data on lower urinary tract function during bladder filling and emptying¹ and are used to supplement clinical history, physical examination findings, laboratory results and radiological studies as health-care providers diagnose and manage lower urinary tract dysfunction (LUTD). Traditionally, UDS include filling cystometry, pressure-flow studies, uroflowmetry and electromyography².

Mosso and Pellacani³ first described human cystometry in 1882, a technique that was modified in 1927 by Rose⁴ for clinical diagnostic use. In 1933, Denny-Brown and Robertson⁵ were the first to assess the activity of the urethra and bladder neck, which was followed by the development of uroflowmetry by William Drake Jr⁶ in the late 1940s; these advances laid the groundwork for Von Garrelt's⁷ description of the use of these technologies in combination in 1957. Davis⁸ first coined the term 'urodynamics' in 1954 and later defined the methods used to evaluate vesical, abdominal and detrusor pressures and drainage of the renal pelvis⁶. On 12 May 1969, the Urodynamics Society, now known as the Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU), convened for the first time during the proceedings of the American Urological Association (AUA) annual meeting⁹. Thus, since the 1960s, UDS have enabled physicians to evaluate the filling and emptying of the bladder to identify and treat a variety of LUTDs such as overactive bladder (OAB), stress urinary incontinence (SUI), bladder outlet obstruction and neurogenic bladder. By the 1980s, urodynamics had helped to advance urology from its classical anatomical orientation to a functionally oriented surgical specialty⁹.

Although battery-powered and wireless technologies have transformed medical devices used in cardiac monitoring, gastrointestinal endoscopy and neuromodulation, modern urodynamics is largely based on the same technology prototyped by Gleason and Lattimer >50 years ago¹⁰. To address the nonphysiological nature of UDS, ambulatory urodynamic monitoring (AUM) has been developed and is being used at several centres worldwide¹¹. However, AUM also involves the use of catheters, which can potentially result in patient discomfort, lower urinary tract irritability and artefactual results. Moreover, AUM has not demonstrated increased diagnostic specificity compared with UDS¹². However, with advances in microelectronics, wireless communication and biocompatible packaging in the past decade, several investigators have made substantial progress in developing wireless, catheter-free AUM devices, which we refer to as telemetric AUM (TAUM) to differentiate this technology from catheter-based AUM.

In this Review, we evaluate the current trends in clinical urodynamics, outline the shortcomings of traditional office-based UDS and highlight the role of AUM in the diagnosis and treatment of LUTD. In addition, we also identify areas of future research in which collaboration between engineers and medical researchers can push the boundaries of wireless medical technology to develop TAUM devices.

Current trends in urodynamics

UDS refers broadly to the physiological evaluation of bladder filling and/or emptying and typically includes four components — cystometry, uroflowmetry, urethral pressure measurements and electromyography¹³; when combined with fluoroscopy, the investigation is called ‘video urodynamics’. UDS is used in a variety of lower urinary tract conditions to characterize the pathophysiology and inform treatment. The AUA–SUFU urodynamics guidelines¹⁴ indicate a role for UDS in adults with SUI and/or pelvic organ prolapse, OAB and/or urge urinary incontinence (UI), neurogenic bladder or lower urinary tract symptoms. A review of the AUA–SUFU clinical guidelines described five scenarios in which physicians use UDS, including to identify factors contributing to LUTD and assess their relevance; to predict the consequences of LUTD on the upper urinary tract; to predict the consequences and outcomes of therapeutic interventions; to confirm and/or understand treatment effects of interventions; and to investigate reasons for treatment failure¹⁵. Importantly, the International Continence Society (ICS) describes the aim of clinical UDS as the reproduction of symptoms while making precise measurements in order to identify the underlying causes of these symptoms². A unifying characteristic of the ICS, AUA and International Children’s Continence Society (ICCS) guidelines is that they recommend limiting invasive studies to when traditional noninvasive evaluations (such as voiding diaries and uroflowmetry) are nondiagnostic or when the results of cystometry could guide treatment^{1,15,16}.

UDS is also used in certain paediatric urology scenarios, particularly in monitoring risk of renal deterioration in patients with neurogenic LUTD¹⁷. In 2015, the ICCS published guidelines for the use of UDS in children¹⁶. This document provides indications for invasive UDS in non-neurogenic conditions as voiding frequency of three times per day, straining or manual expression during voiding, a weak urinary stream, urge incontinence that is unresponsive to proper elimination habits or pharmacotherapy, pronounced apparent stress incontinence or new or worsening dilating vesicoureteral reflux¹⁶.

The potential for overuse of UDS is a subject of continued debate¹⁸, which is reflected in the AUA guideline recommendations against the use of routine UDS in most patients with SUI or UI^{13–15}. Nonetheless, UDS remains a central element of the urologist’s toolkit¹³.

Limitations of traditional urodynamics

The limitations of traditional UDS can be grouped into four broad categories — adverse effects or complications of the procedure, diagnostic failures, issues with data reproducibility and protocol standardization and financial cost.

Adverse effects and complications

Cystometry requires the placement of catheters to measure intravesical and intra-abdominal pressures during bladder filling, which is often done artificially with retrograde bladder filling². Concurrent electromyography or fluoroscopy can also be used to garner additional information related to muscle tone and anatomical factors, respectively. A survey of 78 men and 88 women undergoing UDS for the first time revealed that >50% of these patients had

moderate or severe anxiety in anticipation of UDS¹⁹. Another study demonstrated that ~50% of patients undergoing UDS reported feeling physically or emotionally uncomfortable, particularly during urethral catheterization²⁰. Both studies showed that younger patients (adults under age 40 years) typically experienced more physical and/or emotional discomfort during UDS. Yiou et al.²¹ identified an age of <54 years as a risk factor for pain and embarrassment among 170 consecutive patients undergoing UDS.

In addition to the possibility of physical and emotional discomfort, UDS, similar to any diagnostic procedure, also confers a small risk of complications. Klinger et al.²² reported a complication rate (defined as urinary retention, gross haematuria, urinary tract infection (UTI) or fever) of 19% among men ($n = 63$) and 1.8% among women ($n = 65$) undergoing UDS. The higher complication rate in men is probably explained by the need to catheterize men with prostatic enlargement.

Thus, UDS, although clinically useful, is an embarrassing and uncomfortable examination that has a risk, albeit low, of serious complications.

Diagnostic failure

Nondiagnostic testing can occur as a result of several factors. First, studies have described a failure to reproduce symptoms in up to 46% of patients during UDS^{12,23,24}. Second, nonphysiological retrograde bladder filling using a urethral catheter can trigger symptoms²⁵, leading to false-positive results with UDS²⁶. Third, the false-negative rate for diagnosing detrusor overactivity can be very high (up to 50%), probably owing to a rapid rate of filling that might subdue the expression of detrusor overactivity¹², but does not influence therapeutic success with antimuscarinic agents in patients with OAB²⁷. Last, considerable embarrassment and a lack of privacy (due to continual observation by clinicians, nurses and technicians) leads to many individuals being unable to void during UDS, which greatly limits the diagnostic information obtained from the study. Together, these shortcomings result in 19–44% of UDS being nondiagnostic²⁸.

Reproducibility and standardization

Overall, the clinical utility of UDS relies on the production of high-quality data that can be reproducibly interpreted between investigators. A 2017 study found weak inter-rater reliability in identifying detrusor overactivity and electromyographic synergy in children¹⁷. This finding echoes concerns regarding inter-rater reliability and protocol consistency in the ICS's Good Urodynamic Practice guideline², which notes that this issue is not an inherent problem of the measurement itself but is rather a result of the current limitations of UDS equipment and the lack of a consensus on the precise method of measurement, signal processing, quantification, documentation and interpretation. The same barriers in standardization and protocol development also remain a challenge in AUM²⁹.

Financial cost

The 2014 Centers for Medicare and Medicaid Services (CMS) reimbursement rates per patient for UDS are approximately US\$350 (REF.²⁹), an expenditure that can be justified

only if UDS results in effective treatment that improves the patient's quality of life. Furthermore, this study demonstrated that \$13–33 million could be saved annually in the USA if women with uncomplicated SUI did not undergo preoperative urodynamics²⁹. Reassuringly, after the Value of Urodynamic Evaluation (ValUE) study³⁰ demonstrated that preoperative urodynamics were unnecessary in this patient population, clinicians in the USA appropriately adjusted their practice patterns¹⁸.

Ambulatory urodynamic monitoring

AUM refers to the continuous catheter-based monitoring of bladder pressure during physiological filling and voiding while the patient is fully ambulant and can, therefore, reflect physiological bladder behaviour while they carry out their usual daily activities (FIG. 1). AUM can be done over a longer period of time than routine UDS and was developed, in part, to address the aforementioned diagnostic limitations of traditional UDS. Because AUM does not measure or independently control bladder volume, it can be supplemented with noninvasive methods to provide a snapshot measurement of bladder volume; AUM is currently supplemented with ultrasonography-based systems³¹ such as using the BladderScan or Noviomini devices (FIG. 1).

Initial investigations into AUM used standard urethral and rectal catheters from conventional UDS but replaced the office monitoring system with a small portable recording device and replaced retrograde bladder filling with physiological diuresis and the storage of urine¹¹. Subsequent technological improvements included the development of a urine-loss diaper to facilitate recording leaks as well as an event button for the patient to electronically identify symptomatic events such as urinary urgency³².

Initial studies of the clinical utility of AUM focused on patients who had previously undergone conventional UDS that were nondiagnostic. One would expect that transient symptoms in patients with intermittent claudication represent an excellent example of a time during which a short office study might be negative whereas a longer physiological study could identify pathology. In patients with nondiagnostic conventional UDS, one study reported that AUM improved the detection of OAB compared with conventional UDS²⁸. In a prospective study of 106 women with UI, involuntary detrusor activity was identified in 32 patients using conventional UDS and in 70 patients using AUM (patients underwent both procedures in a randomized crossover design)¹². Other studies determined that AUM offered no substantial benefits over UDS in terms of sensitivity and specificity of identifying detrusor overactivity in patients with spinal cord injury^{33,34}. In a study of 50 children with voiding symptoms, greater diversity of voiding patterns was observed with AUM than UDS, and UDS had a lower sensitivity, potentially owing to the children's inhibition to void in front of health-care providers³⁵.

An initial obstacle that was identified while interpreting first-generation AUM data was in differentiating physiological bladder contractions from abnormal detrusor contractions, which can result in false-positive results³⁶. Since this issue was recognized, the rigour of testing and interpretation protocols have improved. In a study of 26 healthy female control individuals using a rigorous protocol, stable bladder physiology was demonstrated in ~90%

of women³⁶, suggesting that the rate of false positives was reduced to 10%. Another early pitfall of AUM was technical failure, which occurred in up to 25% of patients in some series and resulted from issues such as catheter displacement, power loss or device failure; these problems also occur in the clinic with conventional UDS but can be remedied by clinicians before the test is completed²³.

Overall, a generalization regarding the utility of UDS compared with AUM is that the former is less sensitive and more specific whereas the latter is more sensitive and less specific; thus, both approaches have limitations. Given the high false-negative rate of standard cystometry²⁴, studies evaluating the efficacy of interventions for the treatment of detrusor overactivity require a large number of participants for adequate statistical power. AUM, with its higher sensitivity than standard cystometry, can be utilized for such research by using a randomized placebo-controlled crossover design, with which the poor specificity of AUM would not pose as great a problem. In a small preliminary crossover study of patients with detrusor instability, Rosario et al.³⁷ showed that patients who reported symptomatic improvement with the antimuscarinic agent darifenacin ($n = 3$) demonstrated a response in AUM and that those who did not report improvement ($n = 2$) showed little or no change in AUM outcomes. A similar study comparing the effects of behavioural interventions on outcomes in UDS and AUM in 50 active-duty female soldiers with exercise-induced urinary incontinence also showed greater sensitivity with AUM³⁸.

Although these studies suggest an increased diagnostic capability of AUM compared with UDS, at least for detrusor overactivity, AUM technology has not been adopted in routine clinical practice. Several reasons probably explain this lack of widespread acceptance, including the complexity, time demand, technical failure rate and inadequate financial reimbursement associated with AUM. Clinicians must consider whether the expanded diagnostic capabilities of AUM outweigh its pitfalls.

Development of TAUM

Technology from other medical fields has become smaller, remotely operated, interactive and rechargeable over time; thus, a notable opportunity exists to similarly redefine AUM. At present, various wireless, catheter-free, battery-powered TAUM devices are under development with the goal of addressing the challenges limiting first-generation AUM devices. Most devices for TAUM mimic the basic functionality of traditional AUM systems — measuring intravesical and/or intra-abdominal pressure — without the use of indwelling bothersome catheters that can produce artefacts. Some TAUM devices aim to extend the capabilities of AUM by including bladder volume measurement. Several TAUM devices have reached a developmental stage involving in vitro bench testing or in vivo trials in humans or animals.

Pressure monitoring

From 2002 to present, 15 unique wireless catheter-free pressure sensors have been evaluated and demonstrated pressure monitoring functionality either in vitro or in vivo (TABLE 1).

The devices assess intraluminal bladder pressure using one of three approaches — intravesical, intradetrusor or transdetrusor device placement (FIG. 2).

Intravesical devices.

Intravesical devices are placed in the bladder either transurethral (under direct vision via cystoscope or manually with an insertion device) or surgically through a cystotomy (FIG. 2a). Most intravesical devices are designed to remain unanchored within the bladder lumen^{39–45} with efforts to engineer the shape of the device to promote retention in the bladder without migration into the bladder neck (which would cause urethral occlusion). All modern examples of intravesical devices measure lumen pressure directly using silicon-based absolute pressure sensors fabricated by micromachining and thin-film deposition. The fundamental structure of these pressure sensors involves the suspension of a very thin silicon membrane above a vacuum-sealed reference chamber; pressures greater than vacuum cause the membrane to deflect in measurable ranges. These miniaturized pressure sensors typically have sizes $<10\text{ mm}^3$ (REFS^{5–9}) and transmit the bladder pressure wirelessly to a receiver outside of the body and/or store the data onboard the intravesical device for downloading after retrieval.

One device (probably intended for surgical implantation) includes an anchor with a metal coil that ‘screws’ into the detrusor and protrudes into the bladder lumen, therefore remaining anchored in place to enable its intravesical component to transduce intravesical pressure. Although this device is anchored to the detrusor, it is still functionally an intravesical sensor because the rest of the device is exposed to the lumen. However, no in vivo applications of the device have been described⁴⁶. The ultimate goal for all intravesical devices under development is for their use in patients, but not all of the devices are small enough for transurethral insertion.

Intravesical devices ranging in diameter from 15 to 21 Fr (REFS^{40,41,47,48}) are suitable for urethral insertion, and some prototypes have been transurethral placed in urological training mannequins⁴¹ and into the bladders of large animals (calves, swine and minipigs)^{47,48}. Other devices proposed for intravesical use are much larger than urological cystoscopes or drainage catheters, ranging from 27 to 48 Fr in diameter^{42–46}, and are, therefore, not amenable for transurethral insertion. However, a 27 Fr device was successfully placed in the bladder of a female patient and was retained intravesically for 5 minutes⁴². Most other large devices (defined as >24 Fr, the largest routinely used urethral catheter) have been tested only in vitro or using invasive nonsurvival studies in which a cystotomy was made to insert the device in animals^{42–46}.

Intradetrusor devices.

Intradetrusor devices are intended to measure intravesical pressure without contacting urine, which avoids corrosion of the device and stone formation. One assumption behind the location of this implant is that a thin layer of tissue is sufficient to separate the device from the lumen but does not preclude measurement of lumen pressure. Similar to intravesical devices, pressure transduction in intradetrusor devices uses miniaturized silicon-based pressure sensors. Intradetrusor devices are placed either deep within the muscle layers of the

muscularis propria (detrusor muscle) or abutting the superficial muscle fibres of the muscularis propria at the interface of the lamina propria⁴⁹. Intradetrusor devices can be implanted either surgically via skin incision by creating a pocket within the detrusor from the serosal surface of the bladder^{49,50} or cystoscopically by raising a flap of urothelium and lamina propria, which is a less invasive procedure^{47,48} (FIG. 2b). Such invasive methods are clearly excessive in the diagnostic setting but might be relevant for long-term applications. Intradetrusor sensors surgically implanted from the serosal side can be wired to the location of a transmitter, recorder or other interface device^{49,50}. By contrast, cystoscopically implanted intradetrusor sensors must be small enough to fit through a cystoscope (<26 Fr in diameter) and need to be fully wireless and free of elements that protrude into the bladder lumen or through the detrusor muscle^{47,48}. Cystoscopic implantation is minimally invasive and could be performed at the time of other endoscopic procedures, but all of the intradetrusor devices tested to date have eroded or migrated into the bladder, with large animal models demonstrating that no devices remained at the implant location for >4 weeks^{47–50}. However, these small wireless devices remained implanted within the detrusor for at least 2 weeks in large animals^{47,48}, a duration that should be sufficient to enable AUM over considerably longer time periods than those achieved with catheters. However, device retrieval must be considered to avoid potential urethral obstruction from a device that has migrated into the bladder lumen.

Transdetrusor devices.

Transdetrusor devices consist of a miniaturized silicon pressure sensor at the end of a catheter-like wire, which is placed through the detrusor and into the lumen; the other end of the wire is connected to an implanted or external data recording or transmitting unit worn on the patient's waist. As the sensor-equipped end of the catheter is in the lumen, vesical pressure is measured directly (similar to intravesical devices). Transdetrusor devices can be implanted surgically through the bladder^{51,52} (FIG. 2c) or with a percutaneous approach (FIG. 2d) using ultrasonography guidance for pressure sensor placement⁵². In the percutaneous method, placement of an abdominal sensor is also completed under ultrasonography guidance and the wires from both transducers of the pressure sensor and abdominal sensor can then be externalized through the skin for connection to recording or transmitting devices.

The transdetrusor approach has the advantage of separating the pressure sensor element from the larger power supply and data processing unit^{51,52}. Thus, the element protruding into the bladder lumen is only 4–14 Fr in diameter. These systems have been successfully maintained in the detrusor for 17 hours⁵¹ in humans and for 2–4 days in animal models⁵². The long-term stability of the transdetrusor approach remains unknown but, similar to that observed with intradetrusor devices, might be limited by tissue erosion, albeit with a theoretically greater risk of detrusor perforation due to the extravesical origin of the sensor entering the bladder and wires extending from the bladder wall.

Limitations and considerations.

All pressure monitoring devices are intended for clinical translation and use in humans. However, some designs possess substantial shortcomings that limit their clinical utility. For

instance, not all of these devices were intended for AUM given that some require invasive surgery, but such devices could be suitable for long-term monitoring of bladder function or for measuring physiological data for feedback to neuroprostheses that provide bladder control.

An assumption underlying the clinical utility of all but one of these catheter-free pressure monitoring devices is that intravesical pressure alone is sufficient to characterize bladder function. The only device to also measure abdominal pressure was a transdetrusor device that used sensors tunnelled into the bladder and peritoneal cavity⁵¹. This approach closely mimics the functionality of catheter-based AUM, but it poses an increased risk of complications (such as infections) owing to the need for two transcutaneous wires and peritoneal access.

As the majority of pressure monitoring devices are solely focused on single-channel, intravesical measurement, ascertaining clinically useful urodynamic information from such recordings is probably feasible. However, limitations might include artefact from patient movement, unexplained pressure changes if abdominal pressure is not monitored and slow filling rate. Using mathematical algorithms, the influence of abdominal pressure artefacts on vesical pressure measurements has been sufficiently reduced to produce data comparable to that of catheter-based UDS⁵³. This approach can also be used to automatically detect bladder contractions with high accuracy⁵³ and is, therefore, promising for the development of next-generation AUM devices. If intravesical pressure measurements alone are unreliable, an abdominal pressure catheter could be combined with a catheter-free intravesical pressure sensor to obtain the required information and avoid the use of a urethral catheter.

Intravesical capsule-shaped devices <30 Fr in size are probably the most likely platform to deliver clinical utility as they can be used without catheters, invasive surgery or percutaneous leads^{39–45,47,48}. All devices with this design demonstrate pressure accuracy that is sufficient for AUM (resolution >5 cm H₂O), with the exception of one device that intentionally limits pressure sensitivity to limit artefact³⁹. Several differences remain between these devices that might limit their clinical utility and must be considered, including power source, real-time data transmission versus passive recording method and pressure sampling rate.

To date, battery-powered devices have used non-rechargeable^{39,41–43} or wirelessly rechargeable^{47,48} batteries to achieve a minimum recording time of 24 hours. Battery-powered devices can gather data autonomously without the need for bulky external instrumentation, but only over a finite time period (24–336 hours)^{39,41–43,47,48}. Battery-powered devices also have longer operational ranges over which data can be wirelessly transmitted (20–1,000 cm)^{42,43,47,48} than wirelessly powered devices. Alternatively, wirelessly powered devices have used radio frequency energy^{40,45} or audible acoustic energy to wirelessly power the internal devices at moderate ranges⁴⁴. These wirelessly powered devices could potentially function in vivo for longer time periods with a theoretically unlimited external power source, but their successful use requires substantial external instrumentation and precise alignment of the power source, which would probably limit their ease of use^{40,45}. Most importantly, externally powered devices have functional distances of

2–12 cm from the power source at the skin surface, which greatly limits their use in the general population given that central obesity rates are increasing^{40,45,46}.

All of the aforementioned pressure monitoring devices manage pressure data using one of two methods. The devices specifically designed for AUM and transurethral insertion are built to store data in their internal onboard flash memory for later download from the device after extraction from the bladder^{39,41,51}. By contrast, other devices intended for either AUM or long-term applications^{47–50} transmit data in real time over a wired or wireless connection. Real-time data transmission is advantageous for research but requires external instrumentation and antennas in close proximity to the implanted device (which is often on the skin surface) to detect the radio signal. Although external radio devices could be miniaturized to resemble consumer electronics, real-time data broadcasting imparts a higher risk of data corruption or loss than devices with onboard memory if a component of the system malfunctions. Thus, for AUM, pressure recording devices with onboard memory might be more infallible for clinical use; however, devices transmitting data in real time would facilitate time-stamping and synchronization with other systems such as electronic voiding diaries and uroflowmetry.

A final consideration is the resolution at which data are acquired — the pressure sampling rate. The choice of pressure sampling rate is widely divergent among devices suitable for AUM. Some devices use very low sample rates ranging from 0.5 Hz (one measurement every other second)⁴⁵ to 0.003 Hz (a single measurement every 5 minutes)⁴², possibly in an attempt to conserve power⁴³. The intended use for devices with these low sample rates is unclear, but, in general, pressure sampling rates <1 Hz are probably unsuitable for AUM, particularly considering the duration of relevant events such as coughing or sneezing. Accordingly, a number of the devices currently under development sample at rates >1 Hz (REFS^{39–42,46–52,54,55}) to identify the onset of detrusor contraction, although evidence suggests that rates >20 Hz increase the accuracy of contraction onset detection^{47–50}.

Volume monitoring

Clinical determinations of bladder volume generally rely on bedside bladder ultrasonography, which quickly and grossly estimates the fluid volume⁵⁶. However, straight catheterization provides a gold-standard measurement of bladder contents. Thus, in clinical UDS, fluid is infused at a known rate into an emptied bladder, providing a real-time value of bladder volume based on the duration of infusion; however, renal diuresis will confound this measurement⁵⁷. Furthermore, voided volume is measured over time by uroflowmetry, providing information on urine flow in addition to quantity. The measurement of voided volume in AUM is crucial given that bladder filling relies on physiological urine production, which occurs at a variable rate on the basis of fluid intake and diuresis.

Several modalities exist for estimating bladder volume in real time that could be combined with pressure monitoring devices to enhance AUM. These modalities include noninvasive techniques such as ultrasonography⁵⁸, near-infrared spectroscopy^{59,60} and bioimpedance^{61,62}, as well as minimally invasive techniques such as urine-volume conductance measurement⁶³. Of the noninvasive methods, ultrasonography has been

demonstrated to successfully detect changes in bladder volume^{64,65} with no risk of complications and high accuracy. However, ultrasonography remains a challenging modality to apply in ambulatory patients given its high power consumption and, therefore, its need for a non-mobile energy source.

Ultrasonography.

Technological improvements in ultrasound transducers and low-power image processing have rapidly driven the miniaturization of ultrasound-based bladder imaging devices. In 2018, a new, low-power wearable ultrasonic monitor for paediatric use, the Novioscan SENS-U bladder sensor, entered pilot clinical use in the Netherlands⁶⁶. In an initial study of 30 paediatric patients, the SENS-U device detected a full bladder in 27 of 30 patients when using a patient-specific detection threshold, with detectable bladder volumes from 30.1 to 159 ml. This study was performed only in a seated cystometric setting to maintain alignment of the bladder in the imager field of vision but is a demonstration of the promise of wearable ultrasonography⁶⁶.

Low-power ultrasonography might be more effective in the paediatric population than in adults owing to the shorter skin-to-bladder distance in children, but some modification of the technology, such as reductions in power consumption, could conceivably enable its use in adults. Nevertheless, the accuracy of wearable ultrasonography systems for measuring bladder volume remains unclear given that widely used clinical ultrasonography systems can have a volume measurement error of 14–22%^{56,67}. By contrast, infusion urodynamics systems provide accurate estimates of infused volume, assuming negligible urine production during the test period². Thus, volume-estimating sensors for AUM and TAUM with improved accuracy are needed.

Near-infrared spectroscopy and bioimpedance.

Near-infrared spectroscopy and bioimpedance techniques are similar in that they are nonspecific methods that do not rely on imaging the bladder relative to other pelvic organs. Thus, these methods might have more utility in AUM than traditional UDS given that bladder localization is unnecessary. Essentially, these methods assume that the optical and electrical properties of the pelvic organs are constant and that variations in measurements result from changing levels of urine in the bladder^{68,69}. Denniston and Baker⁶⁸ pioneered using noninvasive impedance-based technology in 1975 when they placed a band of electrodes around the abdomens of anaesthetized dogs to measure the relative ratio of urine to surrounding tissue. Since then, the sensitivity of the technique has improved and bioimpedance is now used in a device developed by Schlebusch⁶⁹ that actively measures bladder volume to advise patients who lack bladder sensation on appropriate self-catheterization frequency.

Near-infrared spectroscopy estimates the quantity of water in the abdomen by transmitting light at near-infrared wavelengths (for example, 950 nm (REF.⁶⁰)) from a light-emitting diode source into abdominal tissues. A photodetector sensitive to the same wavelength of light is placed elsewhere on the abdomen to measure the level of reflected light; increasing water content absorbs increased levels of the incident light and, therefore, total water content

in the region of interest is estimated⁶⁰. During voiding, the water content of the bladder and, therefore, abdomen, changes substantially and suddenly, such that near-infrared spectroscopy can differentiate between a full and empty bladder in humans⁶⁰. However, bioimpedance and near-infrared spectroscopy might be most suited to providing coarse estimations of bladder volume owing to the low specificity of these techniques.

Urine-volume conductance measurement.

In contrast to noninvasive methods, direct measurement of the electrical impedance of the bladder itself could be more specific given that it might be influenced to a lesser degree by changes in bowel content, overall hydration level and posture changes. One approach used 'stretch' sensors attached to the bladder wall for long-term monitoring of bladder volume^{70,71}. In another study, a multitude of electrodes attached to the serosal surface of the bladder were used to estimate bladder volume by measuring the change in electrical conductance caused by the urine contained within the bladder⁷². These technologies, although interesting, remain too invasive for AUM in their current form.

One promising technique currently under development that might be compatible with intravesical AUM and TAUM systems is based on measurement of the electrical conductance of the urine volume from within the bladder lumen⁶³. This technique, when studied using a benchtop bladder model consisting of a pig bladder in a physiological salt solution, had excellent volume detection accuracy at low bladder volumes, suggesting utility in measuring postvoid residual bladder volume. However, the same study found that sensor accuracy decreased at bladder volumes greater than ~20% of cystometric capacity and that the measurements are affected by changes in urine concentration (modelled as different concentrations of Tyrode's solution, from 0.12 to 4 times normal physiological concentration)⁶³. We posit that sensitivity to urine concentration influences the sensitivity and specificity of all methods that are based on urine conductance, including noninvasive bioimpedance measurements and near-infrared spectroscopy. Incorporating an electrical conductivity sensor⁶³ with an intravesical pressure monitor should permit compensation for changes in urine concentrations and, therefore, improve the accuracy of these techniques.

Technical considerations

The development of most devices for TAUM has focused on sensor technology or microsystem design. However, for a TAUM system to be practical, several other variables remain crucial, because without context, the clinical interpretation of natural-filling TAUM might be difficult. First, patient sensations and experiences must be captured relative to the recorded pressure data, warranting consideration of an electronic diary or event recording system. If possible, patient movement could also be recorded using an accelerometer array in order to provide context and detect motion artefacts. The leakage of urine will also need to be detected and can be measured using sensors placed in undergarments⁴¹ or by patient reports in the diary system. Lastly, uroflowmetry equipment in the patient's home could help to determine voiding frequency and flow data. The aforementioned volume-measuring devices might be suitable for measuring voiding dynamics if they have adequate capture frequency to accurately document changes in urine flow.

Data analysis

Data management and the clinical interpretation of multisensor data recorded over the course of several days of monitoring present a new challenge to clinicians who are accustomed to reading studies done over a short period of time in the office. Thus, data fusion algorithms and automated systems capable of determining noteworthy bladder ‘events’ will be crucial to the clinical implementation of TAUM systems. For example, detection algorithms could flag bladder events to let the clinician focus only on important data rather than examining large data sets. In 2016, a wavelet-based algorithm for decomposition of vesical pressure was shown to separate abdominal artefacts from detrusor contractions, enabling the automatic identification of detrusor contractions with high sensitivity (97%)⁵³. In the future, such algorithms might conceivably provide objective numerical measures of bladder function to aid in a diagnosis using long-term, catheter-free TAUM.

Future directions for TAUM

TAUM has great potential not only as a diagnostic tool but also for research that aims to objectively assess therapeutic mechanisms of action (drug or device) or to determine medication regimens or dosing or as a component of a therapeutic intervention such as conditioned sacral nerve stimulation (SNS)⁷³. For example, the efficacy of pharmaceutical interventions is typically measured only on the basis of subjective patient-reported outcomes⁷⁴, whereas TAUM could provide objective evidence of therapeutic benefit in a home environment. Although current SNS programming is based on continuous stimulation, concerns regarding battery life and nerve habituation have motivated investigation into conditional stimulation, in which stimulation is turned on only at physiologically appropriate or necessary times⁷⁵. Such technology would require some element of ‘sensory’ input, raising the possibility of using continuous intravesical pressure monitoring to provide the feedback signal. Similarly, attempts at automating the bladder fill–empty cycle in patients with neurogenic bladder must rely on real-time, durable monitoring of a ‘full’ signal, which could be provided by a wireless pressure-monitoring or volume-monitoring device⁷⁶. The current state of technology has the potential to implement a neuroprosthetic or a device that can replace or supplement an injured or absent neural pathway with a wireless catheter-free device that augments the missing sensory signals, such as sensation of a full bladder⁷⁷.

Material design must have a major role in the development of any clinically translatable device, given the corrosive environment and dynamic conditions of urine and the urinary bladder. Durability is even more crucial in chronic neuroprosthetic systems as opposed to short-term diagnostic monitoring devices given that such devices would typically be permanent implants in patients with irreversible neurological diseases. In addition, any reliable and clinically feasible ambulatory urodynamics device must be easy to deploy and easy to remove. Technology that provides powerful results but requires surgery for implantation might not be acceptable for clinical implementation. Lastly, major effort in the past decade has been dedicated to standardizing the use, testing and interpretation protocols for traditional UDS. As with any new technology attempting to stand the test of time, TAUM

devices should arrive with established protocols that can then be validated against current techniques in relevant disease states.

Conclusions

Traditional UDS have a key role in the diagnosis and treatment of urological diseases but have important limitations, including adverse effects and patient discomfort, diagnostic inaccuracy, financial cost and poor standardization. AUM systems have addressed some of these challenges, particularly by improving diagnostic inaccuracy and limiting patient discomfort. TAUM devices are under current development to measure bladder dynamics in real time during physiological bladder filling in order to improve disease diagnosis and evaluate treatment effects and for integration with neuroprostheses. Regarding neuroprosthetic integration, implantable cardiac defibrillators exemplify the integration between continuous signal input (electrocardiogram) and real-time treatment (defibrillation)⁷⁸. Urology has similarly generated and nurtured new technologies such as robotic surgical systems, novel medical oncological treatments, neuromodulation, endoscopic equipment and implantable erectile dysfunction and incontinence devices^{79–82}. More than a century after cystometry was first described, ambulatory urodynamics is an area ripe for innovation with the potential to greatly benefit patients. The continued collaboration between engineers and urologists will push the boundaries of new technologies for AUM and TAUM to improve patient care.

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Key points

- Urodynamics is the current standard method for objectively diagnosing and differentiating lower urinary tract disorders, but it has major limitations, including adverse effects and complications, diagnostic failures and data reproducibility issues.
- Urodynamics is a snapshot examination in a clinical laboratory environment and involves catheterization, retrograde filling of the bladder (at faster-than-physiological rates) and observation of private bodily functions by clinical personnel.
- Ambulatory urodynamic monitoring (AUM) resolves some of the limitations of traditional urodynamic studies; nonetheless, AUM involves catheters and does not record bladder volumes other than residual urine and voided volume.
- Novel telemetric Aum (TAUM) systems using wireless, catheter-free, battery-powered devices for monitoring bladder pressure and volume during everyday activities in the privacy of a patient's home are under current development.
- To improve diagnostic accuracy and patient comfort, TAUM devices are innovating in the areas of remote monitoring, rechargeable energy sources, device deployment and retrieval and materials engineering.

Fig. 1 |. Ambulatory urodynamics monitoring.

No perfect test currently exists to monitor bladder function in ambulatory patients. Clinical ultrasonography-based systems (part **a**) capture bladder volume measurements at a single time point and do not provide information on bladder pressure⁶⁷. Ambulatory urodynamic monitoring equipment (part **b**) measures bladder pressure over longer periods of time but requires indwelling catheters (inserted into the bladder and rectum to measure bladder pressure and abdominal pressure, respectively)⁸³.

Fig. 2 |. Telemetric ambulatory urodynamic monitoring of bladder pressure.

Four major types of research devices for telemetric ambulatory urodynamic monitoring of bladder pressure have been proposed. These types include intravesical devices that are placed within the bladder lumen through the urethra and that float freely in the bladder lumen (part **a**)³⁹, devices with wireless sensors that are embedded within the detrusor wall through a minimally invasive cystoscopic procedure (part **b**)⁴⁸, implanted devices with a transdetrusor catheter (which is implanted invasively) (part **c**)⁵² and devices incorporating percutaneous leads tunnelled into the abdomen and across the bladder dome (part **d**)⁵¹. None of these devices is approved for clinical use. Part **a** is reproduced with permission from REF.³⁹, Elsevier. Part **b** is reproduced with permission from REF.⁴⁸, IEEE. Part **c** is reproduced from REF.⁵², Springer Nature Limited. Part **d** is reproduced with permission from REF.⁵¹, IEEE.

Table 1 |

Wireless catheter-free devices for bladder pressure monitoring

Dimensions	Implanted device volume (cm ³)	Urethral insertion diameter (Fr)	Battery lifespan (hours)	Data transmission	Pressure sample rate (Hz)	Testing status	Key advantage	Key disadvantage	Refs
Intradetrusor placement									
13.6 × 2 mm disc, wired	0.29 (intradetrusor element only)	NA	Wired	Wired	100	Acute in vivo (n = 7)	Pressure accuracy	Invasive implantation	49
7 × 3.5 × 15 mm	0.37 (submucosal element only)	NA	Wired	Wired	4,900	Acute (n = 2) and 7 days in vivo (n = 1)	Response speed	Invasive implantation	50
6.8 × 3.5 × 17 mm	0.40	21	48	Wireless, >20 cm range ^a	100	14–30 days in vivo (n = 6)	Urethral insertion	Pressure attenuation	47
7 × 3.5 × 15 mm	0.37	21	72	Wireless, >20 cm range ^a	100	30 days in vivo (n = 1)	Urethral insertion	Pressure attenuation	48
Intravesical placement									
40 × 5 mm cylinder	0.79	15	24	Memory storage only	2	24 hours in vitro ^a	Urethral insertion	Device must be disassembled to retrieve data	39
30 × 5 mm cylinder	0.59	15	Externally powered	Wireless, 12 cm range	>5	Acute in vivo (n = 6)	No onboard battery	Sensitive to alignment	40
45 × 5.5 mm cylinder	1.07	17	84	Memory storage only	4	Bench (in vitro) using phantom materials, 24 hours	Urethral insertion	Device must be disassembled to retrieve data	41
44 × 9 mm cylinder	2.80	27	115	Wireless, 30 cm range	Not stated	Human female (not stated)	Urethral insertion	Large device	42
25 × 10 mm spheroid	8.20	30	336	Wireless, 1,000 cm range	0.003	Bench (in vitro) using phantom materials, acute ^a	Large battery lifespan	Extremely low sample rate	43
40 × 8–9 mm cylinder	2.27	27	Externally powered	Wireless, 7 cm range	Not stated	Duration not stated, in vivo (n = 1)	No onboard battery	Short operational range	44
9 × 15 mm cylinder	0.95	27	Externally powered	Wireless, 2 cm range	0.5	Acute in vivo (n = 1)	No onboard battery	Short operational range	45
16 × 45 mm cylinder	36.19	48	24	Wireless, 5,000 cm range	10	Bench (in vitro) using phantom materials, duration not stated	Long wireless range	Large device	46
Suprapubic placement									
4 Fr suprapubic catheter, 50 × 100 × 30 mm logger	0.15 (suprapubic catheter only)	NA	Wired	Memory storage only	Not stated	Human (n = 1), 17 hours	Abdominal pressure reference	Percutaneous leads	51

Dimensions	Implanted device volume (cm ³)	Urethral insertion diameter (Fr)	Battery lifespan (hours)	Data transmission	Pressure sample rate (Hz)	Testing status	Key advantage	Key disadvantage	Refs
<i>Transdetrusor placement</i>									
12 Fr catheter and 30 × 10 × 75 mm implant ^a	22.5 (module) + 0.57 (catheter)	NA	107	Wireless, 6,000 cm range	1	2–4 days in vivo, number not stated	Long wireless range	Invasive implantation	52
14 Fr, 50 mm catheter, 23 × 5.4 mm coin battery ^a and 21 × 14 × 3 mm implant ^a	3.1 (module + battery) + 0.05 (transdetrusor element)	NA	816	Wireless, range not stated	0.3	Bench (in vitro) using phantom materials, duration not stated	Long battery lifespan	Invasive implantation	54

NA, not applicable.

^aSmallest implantable battery mentioned in article text.