Moving beyond the bladder diary: does new technology now allow us to take investigation of LUTS into the community?
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Abstract

Context: Lower Urinary Tract Symptoms (LUTS) are defined by their distressing effect on patients' day-to-day life. Given the pressures on secondary care resources, LUTS may be overlooked or inadequately assessed and therefore patients may be burdened for an extended period before treatment.

Methods: In a debate held at the International Consultation on Incontinence Research Society (ICI-RS) meeting in Bristol in June 2024, we considered how new technologies might contribute to an expedited, dignified and effective investigation of LUTS.

Results: We describe three broad areas where technology has a role to play: streamlining of existing investigations through mobile and miniaturised technology; entirely new investigations made possible by the technology; and advanced analytics to provide better insights from the data available.

Conclusion: We describe key research questions that will signpost us towards answering the question raised in the title.

Introduction

Lower Urinary Tract Symptoms (LUTS) can necessitate lifestyle change and be a source of anxiety, fear, and discomfort. The bother and foreboding reported by patients with LUTS is a real issue that can have a profound impact on a patient's daily activities, quality of life and mental health. Despite this, most conditions causing LUTS are seldom life-threatening. Frequency, urgency and incontinence are all defined by behaviour change that is usually distressing for the individual because it interferes with their life or is not acceptable in a work or social situation. Once serious pathology has been ruled out, further investigation in secondary care may not be prioritised, and patients may be burdened with significant symptoms for extended periods prior to treatment.

With the emergence of new technologies, it may be possible for the initial investigation and management of LUTS to be carried out in primary care. This could potentially lead to more efficient initial management of these patients, avoiding significant delays associated with specialist referral.

This important clinical question was discussed and debated at the ICI-RS meeting in Bristol, held in June 2024. In this paper we report those discussions with consideration as to how new technology might make the assessment of LUTS quicker, more dignified, and bring it closer to home.

Streamlining of existing investigations

For many years and despite advances in technology, the investigation of LUTS has not changed [1]. Conventional wisdom suggests that bladder diary and uroflowmetry are not diagnostic for the cause(s) of the patient's LUTS. Therefore, conclusive diagnosis often requires a urodynamic study (UDS) which comprises filling cystometry and pressure-flow studies (PFS) of voiding coupled with an estimation of post-void residual volume (PVR) by ultrasound. UDS might also involve more complex techniques such as urethral pressure profilometry or video urodynamics to give further insight into the structure and functional performance of the bladder and lower urinary tract.

Historically, UDS has been a secondary care investigation. However, technological advances mean some of the investigations could be performed with guidance in primary care or community settings. Examples include PVR estimation using ultrasound or measurement of urine flow rate via home uroflowmeters, which would also provide an electronic frequency-volume chart. Nonetheless, European guidelines on male LUTS have shifted towards the importance of looking beyond the prostate when trying to assess the underlying functional basis of a patient's symptoms [2 3]. Perhaps the most obvious forward-looking strategy is to streamline the existing assessments that lend themselves to being carried out in the community.

The bladder diary

Symptoms are recorded by a validated patient-completed symptom questionnaire such as the ICIQ-MLUTS [4] in men or ICIQ-FLUTS [5] in women, and a bladder diary [6] to record fluid intake and urine output for a period of typically 3 days. These are the primary means for assessing the severity and impact of LUTS on the day-to-day activities of the patient. The LUTS questionnaire records the presence, severity and bother of each storage and voiding symptom. The bladder diary adds information on the quantity, timing and type of drinks, and on the time, frequency and volumes with which the patient feels obliged to pass urine due to urgency due to the threat of incontinence. Voiding parameters and the patient's sensation define frequency, urgency and nocturia. Volume and type of liquid intake, and urine volume may give insight into causative factors for the symptoms and indicate lifestyle modifications that would be helpful in conservative management [7].

Bladder diary burden is a significant problem; in one study 40% of the participants had missing bladder diary data, and 20% did not return a useable diary; 'diary fatigue' and 'diary despair' have entered the lexicon [8]. This also affects interpretation for the clinician [9], where there are real challenges in transcribing a diary.

From anecdotal experience with the authors' PRIMUS study [10], there is no such thing as a 'typical' diary. Patients ignore instructions, or sometimes devise their own. If legible, a diary will take up to 30 minutes to transcribe, and the transcription will have 6 errors. Often therefore, the diary receives only superficial scrutiny. There have been attempts to digitise the bladder diary [11] that bring obvious benefits to the healthcare system, though not necessarily to the patient who may be more comfortable with a paper format.

RESEARCH QUESTION

How do we deal with diary burden for patients and healthcare professionals, yet obtain clinically meaningful diary data?

Uroflowmetry

Uroflowmetry, the measurement of urine flow rate and volume, is a simple and reasonably objective test that requires little specialist expertise. New devices allow for home or portable flow rate assessment in a community or public toilet setting [12 13]. These devices collect time-stamped records for up to two weeks to incorporate functions of uroflowmeter and frequency/volume diary. Unlike a paper bladder diary they typically do not measure fluid intake or sensation, though urine output may be more useful in advising people on their water intake [7]. These devices are useful in paediatric and elderly populations and may provide more reliable and comprehensive voiding data than hospital flow studies, with repeated measurements under familiar and representative test conditions [14].

Complex examinations in primary care

So-called non-invasive urodynamic tests - for example the penile compression/release manoeuvre [15], the condom catheter [16] or the cuff test [17] - offer some benefits of catheter urodynamics in a simpler package. Specifically, the tests make an estimate of bladder pressure to go alongside the urine flow

rate, but without requiring that the patient be catheterised for bladder and rectal pressure measurements. Given the anatomical differences, non-invasive tests are much better suited to men than to women, though a comparable test for women has been reported [18]. Despite evidence that these tests add value to uroflowmetry, the uptake in secondary care has been poor but it is not clear why; perhaps because conventional UDS are well-established, and it is felt easier to offer this standard method. Once a patient is attending secondary care, the resource saving from a simpler test may only be marginal.

Whether a non-invasive cuff test, for example, has a place in primary care is an unanswered question. There is a lack of basic continence knowledge among non-specialist healthcare professionals and therefore there are challenges in understanding when investigations are abnormal and how to act on the findings. This may be addressed through a combination of education [19] and advanced analytics; healthcare staff with high-quality and specific training can even offer urodynamics in a community setting [20].

RESEARCH QUESTION

Why have non-invasive and other reduced investigations seen poor uptake in secondary care?

Do these nevertheless have a role in primary care?

New directions for 'low-burden' tests of LUT function

Where simple tests such as bladder diary and uroflowmetry are not sufficient, some researchers have sought to reduce the complexity of further investigation by exploring alternative low-burden measures. Here we report on some of the key ideas.

Long-term bladder volume monitoring holds potential in the investigation and monitoring of LUTS. For example: monitoring patients with detrusor underactivity (DU) or bladder outlet obstruction (BOO) to assess voiding efficiency via voided volume and post-void residual (PVR) volume measurement; to prevent complications from high volume urinary retention in the post-operative setting; or for bladder management in women around peripartum.

In addition, bladder volume monitoring may assist in bladder training by providing real-time feedback in the management of overactive bladder (OAB), enuresis and dysfunctional voiding. There may also be a role for bladder volume monitoring to prevent over-distension in patients with reduced or absent bladder sensation, low compliance, or those using clean intermittent self-catheterization (CISC), by indicating that the person should empty their bladder.

Technologies reported regularly [21] include Ultrasound (43% of citations); Implantable Sensors (22%); Bioimpedance (13%); and Near-Infrared Spectroscopy (11%).

Ultrasound

Wearable ultrasound gives a continuous measurement of bladder dimensions to determine bladder volume. There are many challenges with the cost & accuracy of wearable devices. Most studies are in the paediatric population with voiding difficulties or in spinal cord injury patients and give only a qualitative assessment of bladder volume studies [22] [23] [24] [25]. Notably, no studies used wearable ultrasound to assess post-void residual.

Near infra-red spectroscopy

Near infrared spectrometry (NIRS) is the measurement of light absorption which is proportional to the fullness of the bladder. NIRS has been used in the assessment of bladder urine volume in patients with symptoms of bladder outflow obstruction, overactive bladder and underactive bladder. Studies are limited by small sample sizes without matched controls, and there are issues with reproducibility and motion artefact. Again, no studies specifically consider post void residual [26] [27] [28].

Bioimpedance

Since urine contains electrolytes that conduct electricity well, the impedance of the bladder and therefore the abdomen decreases as the bladder fills. This is the premise of electrical impedance tomography; simple wearable systems can give an indication of bladder volume. For example, one group developed a battery-operated wearable wireless system for long-term monitoring [29] with good accuracy on the binary task of full versus empty bladder. However there remain issues with random noise, artefact, reliability and small numbers in clinical trials.

Audio assessment of flow rate

The microphone on a smart watch has been used to extract waveforms from urination sounds to measure volumes voided [30]. The authors conclude it has "potential.• .to.deliver.more.personalized. and.effective.health.care.at.home.with.less.waste.of.time.and.resources."

Implantable bladder pressure monitoring

The holy grail of community diagnosis may be implantable bladder pressure monitoring using a wireless sensor; in essence, a long-term urodynamic pressure-flow study. This idea has reached the point of feasibility in a research setting, with candidate systems reported in the literature [31] [32]. The technical and practical challenges are not insignificant: obtaining a stable atmospheric pressure reference; accounting for abdominal pressure measurement and changes; long-term power supply and data telemetry; and recovering the sensor after use.

Indeed there is no sense in which these current proposed solutions are simpler, quicker, lower-cost or less invasive than a catheter urodynamic study. Therefore, one might speculate that this would be useful for the few cases where office or ambulatory urodynamics don't give a clear diagnosis. Or perhaps long-term wireless monitoring of bladder pressure will prove helpful as a research tool in improving our understanding of bladder physiology.

While these new technologies have some supporting evidence and may have a place in urodiagnostics and monitoring, all have fundamental issues with reliability, artefact, usability and the populations and situations in which they have been assessed [21]. For example, there is ongoing debate regarding reference ranges. To consider PVR volume, decision-making thresholds come from evidence gathered in a clinical setting and it is unclear whether those reference ranges can be applied directly to a home setting. Likewise in long-term pressure measurement, experience from ambulatory urodynamics suggests some hidden surprises; for example, we may have to revisit our definition of 'abnormal' given that many asymptomatic subjects have been shown to have detrusor overactivity by the ICS definition, if one measures for long enough [33].

RESEARCH QUESTION

How does new technology build the evidence to disrupt the inertia of established tools with over 50 years of experience behind them?

Advanced analytics

Primary care-based assessments are only a part-resolution to the wider problem. From a health systems perspective they shift a burden from secondary care to primary care. In order to change a clinical pathway for patients with LUTS, we must ensure sufficient education for primary care physicians regarding urological conditions and provide user-friendly tools for the non-specialist.

Re-thinking the simple tests

Simple index tests from questionnaires, bladder diary, uroflowmetry, and post-void residual volume described earlier have some predictive value for urodynamic diagnosis. No single index test gives a

secure urodynamic diagnosis but if these tests convey somewhat independent information, then combining the tests 'ought to' improve the diagnostic value. This was the premise of the PRImary.care. Management.of.lower.Urinary.tract.Symptoms (PRIMUS) study, a recent UK multi-centre trial to assess the diagnostic accuracy of simple tests for common conditions causing male LUTS. The simple tests were built into a logistic regression model to predict Bladder Outlet Obstruction, Detrusor Overactivity and Detrusor Underactivity. Despite not all men being diagnosed accurately, diagnostic performance [20] was comparable to other predictive tools used in primary care such as Q-risk [34] which is used to predict the future risk of cardiovascular disease.

Bladder modelling

The origins of bladder modelling are to be found in the crossover between physics and basic physiology, with seminal work from Derek Griffiths [35], and others that became the computer model from the VBN group. The VBN model [36] is useful for the modelling of urodynamic function, as opposed to the analysis of a single unique void. Its main application is to obtain a coherent interpretation of a set of several PFS in a patient, either during the same session or with follow-up visits. This tool has been used to test objectively the effects of drug therapy, other techniques and surgical intervention. Their D-index can be obtained from a free uroflow and appears a valuable alternative to catheter urodynamic investigations when the diagnosis of bladder outlet obstruction needs to be more solidly established before a treatment decision, or in men suspected of benign prostatic obstruction who elect for watchful waiting.

Machine Learning & Artificial Intelligence

At a previous ICI-RS meeting [37], the group considered machine learning and artificial intelligence in the interpretation of simple urodynamic index tests; symptoms questionnaires; uroflowmetry; bladder diary; etc. While we will not repeat the findings of that paper, some observations are appropriate.

Many approaches to machine learning are formed in the image of their creators; the features built into the diagnostic model are those we human masters believe to be important. In a patient with LUTS that might include voided volume, flow rate, 24h urine volume, symptom score, etc. The models lack the wider context a urologist would take from a patient's history and presentation. It would perhaps be a surprise if these models were better than humans at making a urodynamic diagnosis.

An important distinction with new ML techniques (deep learning, large language models such as chat-GPT, etc) is that the model has no preconception of how to do its job. It can find features and relationships that have never been tested or even imagined. This leads to recent and poorly-understood findings that (for example) the ethnicity of a patient can be determined reliably from a small and de-focussed section of an X-ray image [38]. Appropriately used, these methods might lead to better diagnostic models in urology.

RESEARCH QUESTION

What latent information in a patient's history or investigations might shed new light on lower urinary tract symptoms?

Fitting into the clinical pathway

Few studies assess the feasibility of these new technologies in practice and the potential impact that they have on patient pathways in terms of diagnosis, treatment outcomes, cost effectiveness and overall patient satisfaction. Key issues will include:

Patient factors

Some patients find investigations such as flow rate testing in the clinic setting difficult, as they may be self-conscious or anxious, which influences their urinary tract behaviour. This is an argument to support the development of home flow rate testing, where such psychological factors are less likely to affect test results [39].

In LUTS, the common diagnoses and therefore the relevant investigations have a partial overlap between men and women. Even for investigations that superficially appear to be shared between genders, there may be challenges in the practical implementation. For example, home uroflowmetry is a far simple technical challenge for a men's device than for a women's device.

Age, mental capacity and morphological factors such as height, Body Mass Index (BMI) and other indices of general wellbeing eg. Cardiometabolic Index (CMI); Weight-adjusted Waist Index, (WWI) affect the patient's ability to comply with the investigation. To this end, medical device regulations place increasing importance on co-design with patients and usability engineering.

Devices should have an intuitive design with a clear patient-centred interface. Wearables must be easy to wear and integrate into daily life without discomfort; be appropriately sized, lightweight, and comfortable for extended use. Invasive devices are possible but raise their own challenges.

Device factors

There are particular challenges to medical devices for unattended or long-term monitoring. These include: battery life; and maintaining measurement accuracy in the face of postural change, sensor drift and other artefacts that affect office urodynamic measurements.

Health services factors

Digital methods offer continuous and real-time data transmission, for immediate analysis and reporting of data. This facilitates large-scale data collection and analysis for 'Big Data' research and subsequent personalized treatment. Security of data is paramount, especially in technology that logs and transmits real-time information.

Finally, investigations must be cost-effective for widespread clinical use. The case for new technologies is difficult to establish, more so for diagnostics. Even where a technology is effective, it is challenging to show how it affects management and outcomes, and whether the benefit to the population outweighs the increased cost.

The future for new technologies

Even for technologies that demonstrate clinical utility, the path to adoption is long; 90% of med-tech start-ups fail. After the regulatory pathway, demonstrating health-economic value is an entirely different question requiring different evidence that typically takes years to collect. The reality is that most new technologies, even the good ones, never make it far enough to succeed.

RESEARCH QUESTION

How can we expedite promising new technologies into the clinical pathway by demonstrating efficacy and cost-effectiveness?

Discussion

LUTS pathways include behavioural therapies, medications and surgery. The use of flow rate has a role in secondary care for decision-making on treatment: this is not established in primary care. Furthermore, it is common for initiation of management to be supported with only limited test results. For example, a drug can be started without test results, since it can easily be discontinued based on symptom outcome. Hence, the introduction of new technology to support primary care testing needs justification based on improvement in clinical pathways, and in particular symptom outcome. This justification might be offered once the results of the PRIMUS study are available. For other populations, notably women, older people and paediatric age groups, there is little indication that adoption of this technology into primary care will achieve improved outcomes. An important challenge will be the recognition that bladder volume measurement is necessary for clinical interpretation in most contexts. The voided volume is easy to assess, but measurement of post void residual requires technology that greatly increases the practical complexity of flow rate testing.

Recommended pathways for patient care and the diagnostic process have been developed to promote good standard practice and to aid the new practitioner [40]. New technology may allow improvements to these pathways, but until the whole pathway is revised it may be hard for these novel approaches to become incorporated into clinical use. Such factors may be a reason why some promising new techniques have taken significant time to enter the clinical mainstream, if at all.

In the context of this ICI-RS meeting, we considered how such limitations and their mitigations could apply to home or community measurement of urine output. It was acknowledged that besides the issue of a change to current practice, challenges also exist of carrying out good health economic analysis, protection of patient data and assuring effective use of technology away from trained healthcare staff. One study tried during the COVID outbreak to use a novel home-based urine volume recorder without uroflowmetry (Diary Pod, Minze, Antwerp, Belgium) to alleviate pressure on face-to-face uroflowmetry clinics. While clear advantages of this technology could be seen if used by a subset of the clinic's patients, the health economic case failed to convince management and a quick response to the need was not possible. Since that time, however, the device has been incorporated into a clinical trial and once the patient data protection has been assured, some devices will be used in an evaluation during standard clinics. Had the incorporation into practice been possible quicker, we would potentially have seen advantages to patients and savings to the health service during the COVID emergency itself.

A solution could be to make the process of health technology assessment (HTA) more accessible. For the topic considered in this proposal, it was envisaged that a mathematical model of a service could include the indications for and sensitivity of a test or device, the prevalence of the conditions, the capital, operating and staff costs, and the possible outcomes for the patient. Having this HTA model available would, if it was made adjustable for the local host or national context, enable faster uptake of new technology in a wide variety of settings. In fact, the same would also be true for a number of non-catheter urodynamic tests that have been developed, that may not need to rely on hospital-based services to be carried out.

Take up of home flow rate testing might be accepted by hospital management on the basis of a business case demonstrating reduced cost, reduced hospital appointments, better use of limited resources (especially staff time) or improved patient satisfaction. Such business cases will need adjustment for each country's costing environment. Possibly by providing a template to make this quicker, one might envisage a system-wide adoption of technology by this route. Furthermore, the business case might be developed in secondary care, where there are sufficient cases and healthcare professionals with a particular interest in treating LUTS. In primary care, some practices may have a doctor with a specialist interest, but most do not. All practices have a large number of substantial healthcare challenges which will be perceived to have higher priority than LUTS assessment. Hence,

justification of community-based flow testing will have to be driven from secondary care. This is likely to rely on demonstrated improvement of outcomes, leading to more accurate prediction of therapy outcome. Potentially the possibility of additional charging for supplementary testing could support introduction in some health systems.

Examples of technological developments that could make adoption easier were also considered. Devices that included analysis of collected urinary diary data would save hospital diagnostic time and patient attendance. In addition, developing an app (or even simple paper-based advice) on self-management of liquid intake could reduce the need for further diagnostic tests for patients whose symptoms are purely due to amount, timing or type of liquid consumed [41]. It was also proposed that flow rate measurement technology should be aligned to the capture of other basic LUTS evaluations, supporting communication by a single portal which is efficient and reliable, should be developed. A single invitation would be sent to the patient for completion of all the basic measures, the patient could have an easy 'one click' mechanism to return the measures once completed, and then generate a single report integrating all the various current LUTS questionnaires and measurements. This would reduce time, duplication of effort, errors of data loss, logistics of data entry and patient frustration.

Modern technology improvements in flow testing need to consider how results of home flow tests could be integrated into electronic health records (EHR) seamlessly and automatically, without the need for manual upload. This is a challenge, due to the existence of several EHR systems, with limited compatibility between different systems, certainly in the UK. Furthermore, personal data security and protection of EHR systems from data attacks restrict the willingness of information technology departments to accept automated solutions for integration of results into EHRs from third party technology.

Conclusions

The reported discussions from this think tank held at the ICI-RS meeting in Bristol, in June 2024 identified a clinical and health economic need to evaluate current patient pathways for lower urinary tract symptom investigation and management.

In most public health care systems the waiting times for patients presenting with urinary symptoms are significant and there was widespread recognition that critical evaluation of current care pathways was needed. With the increasingly widespread availability of new technologies, conventional tests such as urine flow rate measurement, bladder diary data acquisition and post void residual volume estimation may be offered within a primary care setting. With further education of non-specialist health care providers, the initial management of these patients could be undertaken prior to referral for specialist input, if indicated.

RESEARCH QUESTION	OBSERVATIONS ON APPROPRIATE DESIGN
How do we deal with diary burden for patients and healthcare professionals, yet obtain clinically meaningful diary data?	Comparative trials of diary implementation supported by dual outcomes; objective validity data and user-reported outcome measures.
Why have non-invasive and other reduced investigations seen poor uptake in secondary care?	Qualitative research with secondary care stakeholders (consultants; continence nurses) by interviews and focus groups.
Do non-invasive and other reduced investigations nevertheless have a role in primary care?	Qualitative research with primary care stakeholders (GPs; practice nurses). Subsequently, education and up-skilling as appropriate.

How does new technology build the evidence to disrupt the inertia of established tools with over 50 years of experience behind them?	Consolidation of evidence per.NICE evaluation guidelines (ie. systematic review, meta-analysis), to assess state of the art.
What latent information in a patient's history or investigations might shed new light on lower urinary tract symptoms?	Retrospective diagnostic accuracy studies applying new analytics to historic data, followed by prospective studies of promising directions.
How can we expedite promising new technologies into the clinical pathway by demonstrating efficacy and cost-effectiveness?	A wider problem that will have to be addressed by NICE and other evaluation bodies given the accelerating pace of new technologies, particularly analytics.

Table.7¡.Summary.of.research.questions.with.observations.on.appropriate.study.design¡

Some key research questions with observations on appropriate study design are summarised in Table 1. Further research is needed not only to evaluate the diagnostic accuracy of any community-based clinical pathway but to examine the views and experiences of both patients and primary care physicians resulting from any shift of care into the community.

Finally, and for public health care systems in particular, the health economic impact of any pathway change will also need a full evaluation in terms of cost effectiveness.

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