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Recommendations for conducting invasive urodynamics for men with lower urinary tract symptoms: Qualitative interview findings from a large randomized controlled trial (UPSTREAM)

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Aims: To capture in-depth qualitative evidence regarding attitudes to and experiences of urodynamic testing among men with lower urinary tract symptoms (LUTS) at each end of the clinical pathway.

Methods: Semi-structured interview study conducted within the Urodynamics for Prostate Surgery: Randomized Evaluation of Assessment Methods (UPSTREAM) trial, which randomized men to a care pathway including urodynamics or routine non-invasive tests from 26 secondary care urology sites across England. Men were interviewed after assessments but prior to treatment, or after surgery for LUTS. Men were purposively sampled to include those who had urodynamics and those who did not, and diversity in demographic characteristics and symptom burden. Interviews were analyzed using inductive thematic analysis.

Results: Forty-one men participated (25 pre-treatment, 16 post-surgery), ages 52-89. The 16 men who had not previously experienced urodynamics said they would accept the test in their assessment, but some were apprehensive or wanted more information. The 25 men who had experienced urodynamics all found it acceptable, though some reported pain, infection, or embarrassment. Embarrassment was minimized by informing patients what the procedure would be like, and ensuring privacy. Urodynamics was valued for its perceived diagnostic insight. Information deficits were reported before, during, and after the test. How and when results were explained and the adequacy of explanations varied.

Conclusions: Urodynamics is acceptable to men with LUTS and generally well-tolerated. To ensure patients are prepared and informed, good communication before and during the procedure is essential. Privacy should be prioritized, and test results discussed promptly and in sufficient detail. Staff require training and guidance in these areas.

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INTRODUCTION

Ninety percent of men aged 50-80 years live with one or more lower urinary tract symptoms (LUTS), which can negatively impact quality of life. LUTS prevalence and severity increase with age, and with demographic aging the management of LUTS is an increasing priority.

Optimal LUTS treatment depends on identifying causal mechanisms. Urodynamic testing is well established in functional urological assessment for men with LUTS, to determine underlying pathologic lower urinary tract conditions. Urodynamics with invasive multichannel cystometry involves inserting small catheters in the bladder and rectum to measure bladder function and capacity. In current pathways, multi-channel urodynamics is for men who remain bothered by voiding LUTS despite initial pharmacological treatment, and are therefore considering interventional care. It aims to help determine whether an individual would realistically benefit from relief of bladder outlet obstruction (BOO) and whether there are any risk factors for adverse outcomes.

However, there is variation in urodynamic practice in most countries, including the UK, reflecting ongoing debate about the extent to which urodynamics should be used. Some clinicians advocate routine use of urodynamics to determine which men have BOO and will therefore benefit from surgery, and to prevent intervention in men who do not have BOO and will be at risk of adverse effects of unnecessary surgery (e.g., retrograde ejaculation because of transurethral resection of the prostate). Others advocate restricted use of urodynamics due to possible complication rates, perceived unpleasant experience, lack of evidence of better outcomes, and associated cost. Systematic reviews examining the outcomes of urodynamics are inconclusive, and current guidelines consequently make only limited recommendations for testing.

The need for an evidence-based understanding of urodynamics is recognized by the UK National Institute of Health Research (NIHR), which funded the Urodynamics for Prostate Surgery: Randomized Evaluation of Assessment Methods (UPSTREAM) randomized controlled trial. By randomizing 820 men in 26 UK hospitals to either urodynamic tests with invasive multichannel cystometry or a care pathway based on non-invasive routine tests, UPSTREAM aims to determine the effect of urodynamics on symptoms and rates of BOO surgery in men with bothersome LUTS seeking further treatment. Central to this, qualitative evidence regarding the acceptability and tolerance of urodynamics is critical to inform the implementation of trial findings (to be reported late 2018) and use of urodynamics in practice.

Existing evidence regarding the acceptability of urodynamics is largely from questionnaire-based studies and suggests that urodynamics is well-tolerated, but can also be uncomfortable and might cause complications, though the extent of these is unclear. A survey by Scarpero et al found that urodynamics was associated with minimal to moderate levels of discomfort, anxiety, and embarrassment; the authors concluded that a suspected lack of tolerance of urodynamics should not be a barrier to conducting the test. Other quantitative studies suggest that the pain experienced during urodynamics is higher in men and younger patients. However, there is very little in-depth qualitative research exploring the experiences and views of men receiving urodynamics. In 2000, Shaw et al published a qualitative study exploring satisfaction with urodynamics among 17 female and 4 male patients. They found patients were anxious because of fear of the unknown, and were embarrassed at the intimate nature of the procedure and lack of privacy. However, this study was not designed to explore the experiences of men in detail, who are likely to have different experiences of and attitudes towards urodynamics than women.

In a large qualitative study nested within the UPSTREAM trial, we explored men’s attitudes to and experiences of urodynamics, to provide in-depth qualitative evidence to inform clinical practice.

MATERIALS AND METHODS

2.1 Study design

In-depth semi-structured interviews were conducted with patients enrolled in the UPSTREAM trial, at 26 secondary care urology sites across England. The value of combining qualitative and controlled trial methods has long been recognized and recommended. Qualitative methods are the most appropriate means to understand trial participants’ experiences of key medical events and trial conduct, and we adhere to international guidelines in study conduct and reporting.

Trial inclusion criteria were: men with bothersome LUTS seeking further treatment for their symptoms, which may
include surgery. Exclusion criteria included inability to pass urine without a catheter; relevant neurological disease; undergoing active treatment, or on active surveillance, for prostate or bladder cancer; previous prostate surgery; not medically fit for surgery; or unable to complete outcome assessments.  

### 2.2 Sampling and recruitment

Purposive sampling captured a maximum variation sample in terms of trial arm, trial site, and socio-demographic and clinical variables: age, ethnicity, socio-economic status, and baseline total International Prostate Symptom Score (IPSS). Socio-economic status was estimated using the Index of multiple deprivation decile, which ranks areas in England from most deprived (score of 1) to least deprived (score of 10); we sampled across three categories (high 1-4, medium 5-7, low 8-10). The IPSS assesses seven symptoms, scored 0 (best)—5 (worst): incomplete emptying, frequency, intermittency, urgency, weak stream, straining, and nocturia. Total IPSS score at baseline was categorized as high or low using the American Urological Association (AUA) Symptom Index classification: ≥20 = high symptom burden (severe symptoms) and ≤19 = low symptom burden (mild or moderate symptoms).  

Patients were recruited for interview at two time-points: either 1-8 weeks after the consultation in which their treatment had been decided and recorded, or 6 weeks to 4 months after receiving surgery for LUTS. This was to capture variation along the treatment pathway and in treatment types (surgery vs non-invasive treatment) to investigate if these factors impacted on perceptions of urodynamics. Informed consent (written for face-to-face interviews, verbal for phone interviews) was granted by all participants prior to interview. Patients participating in the interviews did not receive any incentives.

### 2.3 Data collection

Interviews were conducted face-to-face or by telephone by CAO or LES, both experienced and trained qualitative researchers with a background in health services research. Neither researcher works clinically in urology, nor was previously known to participants, facilitating open, and candid communication. Topic guides (Box 1) for the interviews were developed by the research team (both the clinical and the patient-involvement investigators) based on the study aims and the literature. Each topic guide was piloted with two men with LUTS (data not included in analysis) and refined prior to use. Topic guides were modified as necessary throughout the course of the study to ensure that issues emerging from the analysis were explored in future interviews. Interviews were digitally audio-recorded and transcribed verbatim prior to analysis. The interviews lasted between 29 min to 1 h 42 min, mean 50 min.

**Box 1 Summary of interview topic guide**

**Background**
- Age, family situation, accommodation and work circumstances, general health

**Lower Urinary Tract Symptoms (LUTS) experience**
- Help-seeking triggers for LUTS
- Symptoms experienced, bother and impact, primary concerns
- Understanding and management of symptoms
- Information received and needed in relation to LUTS

**LUTS assessment/consultation/treatments**
- Patient pathway to hospital, referral process
- Experiences at the hospital
- Assessments and tests received for LUTS including urodynamic testing: experiences, understanding of the assessments’ purpose, expectations of assessments, and information/support
- Explanation of assessment results: format, adequacy, understanding the results

**Decision-making**
- Treatment decision making process and outcome
- Patient and clinician involvement and role in decision-making
- Patient preferences re-treatment
- Impact of assessments on treatment decision-making
- Views of surgery for LUTS

**UPSTREAM**
- Motivations for taking part in UPSTREAM, experiences of trial participation
- Understanding of randomization and equipoise, preferences re-trial arm allocation
2.4 | Analysis

Data were analyzed using an inductive thematic approach. Analysis was conducted in parallel to data collection, with findings from early analysis informing later data collection in an iterative process, until analysis indicated data saturation—such that no new themes were emerging from the data analysis by the end of data collection. The researchers (CAO for pre-treatment interviews, LES for post-surgery interviews) used line-by-line coding to construct draft coding frames, each based on three transcripts. A combination of deductive coding, based on the aims of the study and the topic guide, and inductive coding, identifying themes within the data, was used. To enhance analysis, team members (LES, JH, and CAO) independently coded transcripts to achieve coding consensus and maximize rigor. CAO/LES then applied the refined coding frame to all the transcripts, with regular meetings with JH to discuss emerging findings. Finally, LES used charting to identify patterns in the data and drafted a narrative based on the analysis, with input from CAO and JH. Transcripts from the pre-treatment and post-surgery interviews were analyzed separately and findings then compared. Data were analyzed using NVivo V10 (QSR International Pty Ltd., 2012) and Excel. Data extracts are tagged with a unique participant ID: the prefix “PT” denotes patients interviewed after their treatment decision but prior to any planned surgery; “PS” denotes patients interviewed post-surgery.

3 | RESULTS

Forty-one male patients from diverse locations in England were interviewed (25 pre-treatment, 16 post-surgery), age range 52-89 (Table 1). Fifteen patients had a high symptom burden at baseline. Twenty-five had experienced urodynamic testing. Four themes were identified: acceptability of urodynamics, experience of urodynamics, perceived value of urodynamics, and information deficits.

3.1 | Acceptability of urodynamics

All of the 25 men who underwent urodynamic testing reported that it was acceptable, despite any discomfort or other issues they might have experienced. Of the 16 men who had not had urodynamics previously, 10 said they would have been happy to have it if needed:

I’m used to being prodded and god knows what else. I don’t take any notice of that. . . The more tests the better I always say. . . you know exactly what’s going on then. MrPS5, age 60

Of the remaining six, four said they would have had it if needed, but would have been apprehensive due to its invasive nature and were glad it had not been required. Two men said they would want more information about the test and its purpose. One man had declined to have urodynamics because a prior cystoscopy had found a narrow constriction and he did not want to risk any damage which might delay his planned surgery.

The main reason for wanting urodynamics was the perceived accuracy of the test and the desire to have maximum information to inform the treatment decision:

I like answers . . . and we got the answers. So if I hadn’t had the test done, then we’re just left with a load of symptoms which could be caused by this or that. Erm, so I mean in terms of erm the invasion of the test, it’s . . . not a problem . . . totally acceptable. MrPT20, age 69

We did not find any evidence of associations between age or symptom severity and the acceptability of urodynamics.

3.2 | Experience of urodynamics

3.2.1 | Pain, discomfort, and infection

In general, urodynamics was well-tolerated by the 25 participants who had experienced it. However, there was variation in how uncomfortable men found the procedure. Seven reported that it was at least a little painful, with some experiencing severe pain, but they nevertheless thought urodynamics was acceptable:

MrPT6 (age 57): Having a tube stuck inside me and afterwards was 10 out of 10 pain . . . It was awful. But the people I dealt with were very good.

Interviewer: Okay, and how acceptable was the test for you?

MrPT6: Yes, no problem. Obviously embarrassing, uncomfortable, not very pleasant. Erm—well, I mean, I had the choice of having the test done or not, so, you know, I read about it, it sounded horrible, but, erm—I am quite a positive person. I want to live the best. I’ve got a family to look after, so . . .

Five men reported that the procedure was pain-free:
I was quite surprised, actually. Especially at the, at the rear end, I thought, “Oh, there might be a pain involved here.” But there wasn’t. I had no pain at all. I just—it was, it was better than what I thought it was going to be. MrPT11, age 75

Urodynamics was sometimes perceived as easier and less uncomfortable than uroflowmetry, because urodynamics does not involve having to wait with a full bladder:

When they put liquids into you, [it] was more uncomfortable... easier... It's able to fill your bladder through your penis, so that they can measure the flow... That was a bit embarrassing, but like I said, I found it better because I didn't have to retain anything. So to me... although embarrassing, [urodynamics] is a better system [than flowmetry]. MrPT4, age 67

Eight participants reported short-lived negative after-effects of urodynamics: stinging when urinating, a small amount of bleeding, a urinary tract infection (UTI) or disrupted flow/urgency. However, despite these issues the men said they would willingly have the test again if needed.

### 3.3 Embarrassment

A minority of participants (7/25) reported that having urodynamics was embarrassing, either due to its intimate nature or not being prepared for its effects:

The final pee that I was having was with a catheter up my urethra. Now, how you’re supposed to pee into a jug when you’ve got a catheter up you, I do not know. But it went all over the wall and the floor, er, which embarrassed me. If they’d said, “Look, this is what’s going to happen, don’t worry about it”... One of the nurses had to clean it all up when she came back in. MrPT10, age 63

One patient reported that he found urodynamics less embarrassing than a rectal exam (“it’s not very nice for them anyway, and certainly not nice for you either” MrPT4).

The degree to which urodynamic assessments (and other tests for LUTS) were perceived as embarrassing depended in part on the level of privacy available, including the number of people in the room during the test, room location and size (a larger room near a corridor was more socially awkward). Patients preferred as few people present in the examination room as possible during the test, that staff were introduced to them, and they knew their roles:

<table>
<thead>
<tr>
<th>TABLE 1 Participant characteristics</th>
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<td><strong>Pre-treatment patients</strong></td>
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<td><strong>Age group</strong></td>
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<td>No</td>
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<td><strong>Treatment decision</strong></td>
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<td>Medium (5-7)</td>
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<td>Low (8-10)</td>
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<tr>
<td><strong>IPSS symptom burden (baseline)</strong></td>
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<td>Low (≤19)</td>
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<tr>
<td>Ethnicity (self-reported)</td>
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<td>Asian/British Asian</td>
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<td>White American</td>
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<td>Iranian</td>
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<td>Afro-Caribbean</td>
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<td>Not given</td>
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IPSS = International prostate symptom score.
MrPS11 (age 59): It was all right. Embarrassing [laughs]! Stood there in front of all the people!... There were a couple of students! [Laughs] A couple of nurses! [Laughs]

Interviewer: Were you asked about whether you minded them being there, or...?

Mr PS11: Yeah, yeah, [the doctor] asked me if I minded if they'd be there... I didn’t mind. Yeah, a little bit embarrassing, but I didn’t mind too much.

Another man reported a nurse coming in without knocking during the procedure and being reprimanded by a more senior nurse.

Who performed the urodynamic test could also be a concern and a cause of embarrassment. Two men mentioned the gender of the person performing the test in relation to their embarrassment. One would have preferred a woman to have carried out the test:

MrPT4, age 67: Well, it's not very nice for another man to play with your... Well, not play with you but actually touch you, they’re doing things. Then to stand in front of women as well...

Interviewer: Oh, there were women in the room?

MrPT4: Yeah, well, I was asked about... One was a trainee nurse and one was a senior nurse. So to be quite honest, to me, it's easier for me to be naked in front of a woman than what it is a man.

Another said that his test had been performed by a female nurse and initially he thought he would have preferred a man. However, by the end of the test he thought it was better to have it performed by a woman. Despite any embarrassment, men still found urodynamics acceptable.

3.4 | Perceived value of urodynamics

As previous results suggest, urodynamics was primarily valued by participants for the additional insight it gave them and their clinicians into their LUTS:

I was glad that it was clear result in itself... it was effective in actually showing, illustrating the problem and the extent of the problem... it was effective in actually getting something sorted. MrPT22, age 64

Urodynamics was often the last in a series of assessments participants had received for their LUTS. Many patients felt that having urodynamics meant they had received all the investigative tests available and therefore had all possible facts regarding their condition. There was satisfaction in this:

You’re having a test that was different from what erm, you’d experienced before... there was a sort of finality about that, you know. You felt that, you know, okay (−) there’s nowhere else to go, you know. MrPT1, age 67

Three patients reported that they found invasive urodynamic testing interesting or engaging as they learnt about the cause of their LUTS. Urodynamics was perceived as more informative than other tests, providing a more accurate account of the cause of LUTS:

I done the flow rate thing, the urodynamics was I think far more accurate... I thought it was a very clever test... You know, I think it showed a lot more... that other test was probably one of my bad days, because the growth of a prostate outside the bladder acts like a ball-valve so it shuts my flow off... Yeah, I think it was a good test. Mr PT15, 52

For some patients, the results of urodynamics played an important role in their treatment-decision-making:

Interviewer: Do you think the results of the assessments that you did helped make the decision for which treatment you’d get?

MrPT16 (age 68): Oh, yes, yes, yes... For both [clinician and patient], I think, because, I mean, although they weren’t pleasant, you feel as though at least everybody’s had a go, and they’ve done as much as they can. And I think when [consultant] sort of turned round and sort of said, “Well, that confirms everything”... and he’s not made any secrets of what he thought, so you knew what he was talking about.

3.5 | Information provision

Although overall men's experiences of care were positive, there were instances along the diagnostic pathway when participants reported they had been inadequately informed. Four patients felt that they had not been fully informed about the process of urodynamics in advance, such as what it would
involve, the need to urinate and possibly spray, or the risk of developing a UTI afterwards:

They put a catheter in, and I told them, the nurse how a sd o i n gi t ... When you put that catheter in, I know for a fact, by at least tomorrow, I’m going to have an infection.” —“No, everything’s sterilized. You won’t have an infection.”

True enough, I had an infection, and it was a Saturday the next day. My doctor was closed. MrPT11, age 75

While most participants reported being given leaflets about the test prior to having it, one patient did not know he was having urodynamics until he arrived at the hospital on the day of the test. One participant described the importance of patients feeling fully informed while awaiting their tests:

Very clear information is very important. You’ll be sitting here; you’ll be sitting here for an hour. It’ll be that length of time before we will call you, or this will take, given the number of people we’ve got, I expect it’ll be this. If it’s wrong, it’s wrong, it doesn’t matter, but actually giving clear and confident messages allows people to feel that they’re not completely out of control... they haven’t been forgotten in the corner. MrPT22, age 64

There was variability in participants’ reports of how and when their test results were explained to them and the adequacies of the explanations they received. Men had the results of urodynamics explained to them during the test by the technician or nurse undertaking it, from a doctor straight after receiving the test, or at a separate appointment with a doctor a short time later. When test results were available and discussed with a clinician immediately after the test this was appreciated:

I had an instant diagnosis, saying that I needed an operation... I wasn’t expecting that. I was expecting to have a letter a week later saying, “We think this, that and the other.” MrPT4, age 67

[Getting] the information on the day, obviously that’s better for everybody, you know. I think it takes the angst out of it really. MrPT1, age 66

Most men were satisfied with the explanation of test results, reporting that the explanations received were excellent or adequate:

So I could understand, you know, what results they were looking for and they actually showed me the graph results. So erm, that was quite interesting. That was explained. MrPT13, age 75

Interviewer: Having done the different tests, how were the results explained to you?

MrPT6 (age 57): Yes, very well... The nurse explained it to me as well, and then I came back to the doctor and he went through it with me.

Two men reported poor explanations of urodynamics results. One reported particular problems with the results of the urodynamics being explained rapidly straight after the test:

The consultant was in a hurry, so he started trying to explain the readings off the test on the computer to me while I was still standing there in a gown with a catheter in. And I said, “I’m sorry. I can’t take this in now. Can you wait until I’ve got dressed?”... The only thing he [doctor] said to me was this thing about, “There’s an awful lot of pressure going in, and not a lot of urine coming out.” Erm, so I saw, you know, the computer monitor and one or two printouts, but I didn’t ask. I wasn’t shown those. MrPT10, age 63

4 | DISCUSSION

This is the first in-depth study of men’s attitudes to and experiences of invasive urodynamic testing for LUTS using formal qualitative research methodology. We found that urodynamics testing was acceptable, despite a minority of participants experiencing pain, UTI, or embarrassment. Urodynamics was valued for its perceived accuracy and the information it provided about symptom aetiology, and thought to give more insight into LUTS than other tests. Reflecting clinical guidelines, urodynamics was carried out after other assessments such as uroflowmetry and completion of bladder diaries, and was therefore perceived as completing the possible assessments comprehensively. For some men, the results of urodynamics played an important role in treatment-decision-making; this will be explored further from clinician and patient perspectives in a separate publication.

Levels of discomfort and embarrassment experienced during the test varied, but all the men were prepared to have the test again if needed, despite any negative experiences. Embarrassment related to the intimate nature of the test and a lack of awareness or preparation for its effects. Key to minimizing embarrassment were good communication and
privacy: ensuring men knew what to expect, limiting the staff present, introducing staff, and explaining their role. For some men, the gender of the person performing the test was important, with a female clinician preferred. Information deficits were reported before, during, and after the test, and there was variability in how and when results were explained and the adequacy of explanations.

Our findings support those of Scarpero et al., who found that urodynamics was well-tolerated, with patients experiencing minimal to moderate discomfort and embarrassment. As in Shaw et al.'s mixed-sex (female-predominant) qualitative study, embarrassment was related to the intimacy of the procedure and privacy was therefore important. Previous research has suggested that urodynamics might be less acceptable to younger patients. This was not evidenced among our participants, but this could be due to the older age group of men with LUTS, reflected in our study sample (age range 52-89); Yiou et al. found being <54 years’ old was associated with painful sensation in a cohort of 68 men and 103 women.

Strengths of the current study include our focus on an in-depth understanding of men’s perspectives and experiences, the recruitment of a large and diverse sample in terms of age, symptom burden, and treatment decision, and the attainment of data saturation. Not all the men we included had urodynamic testing, as the views and attitudes of those who have not had the test are also important in considering acceptability in the target population. Although for the post-surgery participants several months had passed since they had urodynamic testing, participants were able to talk at length about the procedure, demonstrating that this was a key medical event for them. The inclusion of these accounts adds value in capturing the long-lasting perceptions and attitudes to the procedure and understanding how urodynamic testing is viewed in relation to the eventual outcome of the treatment decision and surgery. Analysis demonstrated a high degree of similarity between pre-treatment and post-surgery interviews, with both containing positive and negative views and experiences of urodynamic testing not dependent on treatment decisions or surgery outcome. Although we achieved representation across England, more men from south England were interviewed. Practice, staff expertise, and patient perspectives might vary in other settings, so specific aspects of the current findings may vary elsewhere. Finally, men in this qualitative study had consented to a trial in which there was a 50% chance of randomization to receive urodynamics, so those totally opposed to it might not have consented to the trial; this should be taken into account in interpreting our findings.

This study has clear clinical implications. It is essential that clinicians inform patients in advance about what to expect during and after the test, including the risk and treatment of UTIs. Patients should be informed that passing urine during the test can be associated with spraying, and that this will easily be dealt with afterwards. During urodynamic practice, efforts should be made to limit the number of staff present in the assessment room and ensure maximum possible privacy is maintained. Patients should be introduced to the clinicians present and informed of their role, with agreement sought for the involvement of trainees in the procedure. After the test, patients should be allowed to get dressed in their normal clothes before the concluding discussions. Clinicians should discuss side-effects with patients and what to do if they experience any problems. Clinicians and patients will ideally discuss the results of urodynamic testing on the same day as the test or shortly after, with the detail and depth of the explanation in line with patients’ preference.

Our finding of variability in the degree of privacy, dignity, discomfort, and information provision experienced by patients undergoing urodynamic testing indicate that staff require training and guidance in these areas. Current urodynamic guidelines omit guidance on how to ensure urological assessment is patient-centered, yet this is crucial to ensure positive experiences among patients. Inadequacies in UK training in the conduct of urodynamic investigations have been reported previously; our findings suggest that such training needs to include the sensitive conduct of invasive urodynamic testing and associated information provision.

Further research is needed to determine best practice in the content and timing of information: previous research has found that information given prior to urodynamics can increase expectations of pain and there have been mixed results regarding its effect on patient anxiety.

5 | CONCLUSIONS

Our findings suggest that, in the opinion of patients who have experienced urodynamic testing, the perceived accuracy of urodynamic findings and the benefits of deriving maximal clinical information over-ride short-term negative after-effects. To ensure patients are prepared and informed, good communication before and during urodynamics is essential. Privacy should be prioritized, and test results discussed promptly once the patient is dressed in his normal clothes. Variability in patients’ experiences suggest that staff require training and guidance in these areas.

7 | ACKNOWLEDGMENTS

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designed and delivered in collaboration with the Bristol Randomised Trials Collaboration (BRTC), a UKCRC registered clinical trials unit which, as part of the Bristol Trials Centre, is in receipt of National Institute for Health Research CTU support funding. The views and opinions expressed are those of the authors and not necessarily those of the HTA program, NIHR, NHS, or the Department of Health and Social Care. The UPSTREAM trial is sponsored by North Bristol NHS Trust (NBT). Trial registration: Controlled-trials.com—ISRCTN56164274 (confirmed registration: 8 April 2014).

AUTHORS’ CONTRIBUTIONS

MJD, JH, and LES were responsible for developing the research questions and study design; LES and JH for study management; CAO and LES for data collection and CAO, LES, and JH for data analysis. ALL managed the UPSTREAM trial and contributed to data retrieval and trial design. LS led writing of the manuscript, with input from CAO, JH, ALL, and MJD. All authors approved the final version of this manuscript.

CONFLICTS OF INTEREST

The authors declare that there is no conflict of interests.

ETHICAL APPROVALS

Ethical approval was obtained from NHS Health Research Authority NRES Committee South Central—Oxford B (14/SC/0237).

DISCLOSURE STATEMENT

None of the authors have any competing interests in the manuscript.

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