

# Qualitative exploration of the patient experience of underactive bladder

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## Abstract

### Background

Underactive bladder (UAB) is considered the symptom complex associated with the urodynamic diagnosis of detrusor underactivity (DU).

### Objective

The aim of this research was to investigate the patient reported experience of the symptoms, signs and impact of underactive bladder (UAB). This research is also part of the initial qualitative phase for the development of a new patient reported outcome (PRO) measure for the assessment of UAB.

### Design, Setting and Participants

Qualitative methods were used to understand the experience of UAB from a patient perspective, in a purposive sample of male (n=29) and female (n=15) patients aged 27-88 years (mean: 64 years), diagnosed with a primary diagnosis of DU, with or without co-existing urological conditions. Semi-structured interviews were conducted in Bristol, UK.

### Results

Male and female patients reported a variety of lower urinary tract symptoms and associated impact on quality of life. Storage symptoms of nocturia, increased daytime frequency and urgency, and the voiding symptoms of slow stream, hesitancy and straining were reported by over half of the patients. A sensation of incomplete emptying and post-micturition dribble were also frequently described. Most had a post void residual >30ml (n=34, 77%, median: 199ml) with many reporting urinary tract infections, a history of self-catheterisation and some experiencing occasional acute retention episodes. These symptoms and signs can have a broad impact on quality of life including having to plan their daily activities around the location of toilets, disruption to sleep, social life and associated effect on family and friends.

### Conclusions

Knowledge of the lived experience of UAB obtained in the current study will be used for the development of a new PRO measure and help inform the current working definition of UAB.

**Patient summary**

The symptoms, signs and impact on quality of life of underactive bladder are described by patients with the condition.

## 1. Introduction

Underactive bladder (UAB), which is considered to be the symptom complex of urodynamically diagnosed detrusor underactivity (DU), is a condition that is relatively under-researched. The current working definition describes UAB as “characterised by prolonged urination time with or without sensation of incomplete bladder emptying, usually with hesitancy, reduced sensation on filling, and a slow stream” [1].

In men and women presenting with lower urinary tract symptoms (LUTS) and referred to urodynamic studies, the prevalence of DU has been shown to be up to 40% in men and 13% in women [2] and as much as 48% in particular groups such as male patients over 70 years of age [3]. In men, DU has been reported alongside co-existing bladder outlet obstruction (BOO) or detrusor overactivity (DO) in 47% of subjects, and with co-existing DO or urodynamic stress urinary incontinence (SUI) in 73% of female subjects [2]. It is recognised that there is an overlap of LUTS associated with these conditions and UAB, such as slow flow, nocturia, increased urinary frequency and incontinence [1,4,5]. The symptomatic burden of LUTS associated with DU [5-7] and known impact of LUTS on quality of life [8,9] highlight the requirement to understand how the patient with UAB feels and functions for clinical outcome assessment purposes.

Currently, no fully validated patient reported outcome (PRO) measures exist for the assessment of UAB. In order for a PRO instrument to be used in patient management, exploration of the reported symptoms, signs or other functional aspects should be carried out in a sample of patients known to have the condition, using accepted qualitative methodology. In this type of study an exact representative sample is not required, but a good spread of participant characteristics is advantageous in order to capture all relevant backgrounds and experiences of the condition [10]. There is no definitive sample size for a study such as this but thirty or forty interviews are typical [9,11,12]. To our knowledge, this is the first qualitative research study which focuses on elucidating the patient reported experience of UAB. This study also aims to contribute essential evidence of content validity for a new PRO measure [13,14], for the assessment of the symptoms, signs and impact of UAB in research and clinical practice.

## 2. Material and Methods

Qualitative methods were employed in order to understand the experience of UAB from a patient perspective. Semi-structured interviews were conducted with a purposive sample of male and female patients with a primary diagnosis of DU. Patients with DU alone and in combination with other common co-existing urological conditions, were interviewed to ensure the relevance of the PRO instrument to all patients with the condition. The primary objective to the interviews was to elicit the symptoms, signs and impact of UAB, with an emphasis on capturing key idiomatic expressions and language used to describe their symptoms.

Interviews were conducted by trained qualitative researchers either in-person at the patient's home, *in situ* at the hospital, or over the phone. Informed written consent was obtained to participate and audio record the interviews, which were then transcribed verbatim and organised using qualitative research software package NVivo v10. Following the first exploratory interviews, an inductive approach [15] to analysis of the transcripts revealed concepts that contributed to the ongoing development of a coding framework. Concepts identified early on in the coding process were followed-up in subsequent interviews through iterative revisions of an interview schedule. Data collection and analysis continued concurrently, using a reflexive and constant comparison approach [16]. Concepts relating to symptom or impacts which were spontaneously reported in the interview (without prompting by the interviewer) were given particular attention. Towards the end of data collection, concepts were coded by urologic defined symptoms (e.g. 'hesitancy', 'increased urinary frequency', 'urgency') which categorized the data within the current urological and theoretical context [17,18]. Discussion meetings between researchers evaluated discrepant codes to achieve consensus and consistent coding across transcripts. Interviews continued until the dataset was considered saturated, that is, when it was considered that no further concepts relevant to DU were likely to be found by conducting further interviews. Ethics approval was granted as a substantial amendment of an existing project: Reference 087/99.

### ***Sample inclusion criteria***

Male and female subjects of 18 years of age or over with a slow stream associated with a weak bladder contraction, were selected by retrospective review of the urodynamic reports of patients referred for pressure flow studies (PFS). Table 1 shows the urodynamic criteria used to select subjects with a primary diagnosis of DU. The patients were grouped by the presence or absence of co-existing urological conditions.

### 3. Results

A total of 44 semi-structured interviews were conducted in Bristol, UK, from Jan - Dec 2014. Table 2 summarises the demographic and clinical characteristics of the sample. All patients were Caucasian, and came from a variety of educational backgrounds (ranging from school leaver at 16 or younger, to college or university educated) and occupations (manual, service and professional).

It was confirmed that saturation had been achieved by the first 12 (out of 19) interviews in patients with DU (without co-existing urological conditions). Further exploration was required in the diagnostic groups that included co-existing urological conditions as isolated minor concepts were still being elicited. Ultimately, these were all considered to be sub-concepts of already elicited symptoms or unlikely to be related to DU.

The content analysis revealed that patients reported a range of LUTS that could have an associated impact on quality of life. More than 20 storage, voiding and other urological signs and symptoms were described by the patients, as illustrated in figure 1, along with the indication of relative prevalence. The following summarises the main findings and the supplementary material online provides further detail including additional representative quotes from the patient's accounts.

#### **Storage symptoms**

The storage symptoms reported by over half of the patients included nocturia, increased daytime frequency and urgency. These were reported by both sexes, often spontaneously (without prompting) and frequently associated with a high degree of bother. Nocturia and/or nocturnal voids was the most commonly reported overall symptom (n=34, 77%), as most patients described having to get out of bed at least once in the night to urinate. Patients reported a frequency of micturition from once or twice to over 12 urinations per day. This was often associated with urgency, the need to immediately re-void or 'clustering' of voids at certain times of day. Urinary incontinence occurred in all diagnostic groups and was very bothersome, but was mainly associated with patients who demonstrated DU and co-existing conditions (DO and SUI) during PFS. The reduced sensation of the ability to detect the fullness of the bladder was described by a minority of patients (n=5, 11%).

*P36: "I'm getting up every night two or three times, average twice a night and not getting very good sleep"*

*P34: "Just constantly going back and to and from the toilet"*

*P22: "I can feel it coming on and then all of a sudden I think gosh I've got to go"*

#### **Voiding symptoms**

The voiding symptoms described by the majority of patients (>50%) included a slow stream, hesitancy and straining. These were often spontaneously reported by either gender with high degree of associated bother. The combination of these symptoms in individual patients could result in extended voiding time and lengthy stays in the bathroom. The strength of the urinary stream was described as 'slow' or 'weak', and could be unpredictable or variable. Patients described 'having to wait' or 'concentrate' before the urine flow would begin, usually for a few seconds but was up to 20 minutes in one male patient. Straining could be described as 'pushing' or 'squeezing' and was used

to initiate or maintain the flow, or to try and make sure the bladder was empty at the end of micturition. An intermittent stream, spraying of the flow (in men) and urinations of small volume per void were also reported.

*P21: "Stopping and starting with a very weak flow, then I could stand in front of the loo for at least three or four minutes and nothing happens"*

*P39 "It's a combination of sort of mental and physical cajoling to make it start."*

*P12: "There would be very little natural flow and the majority of the flow would be as a result of having to strain"*

### **Post-micturition symptoms**

A sensation of incomplete emptying of the bladder (n=19, 43%), often resulting in the need to re-void within a short period of time was frequently described by patients in all diagnostic groups. A post-micturition dribble was reported almost exclusively by men in this sample (n=17, 39%). Lower urinary tract pain was reported by 25% of patients (n=11) but the accounts were variable with regard to the type, source and severity of pain experienced.

*P12: "I know I need to do more and I can't. That seems to be the biggest annoyance because I'll have to go again in a short period of time rather than a proper emptying of the bladder"*

*P6: "Usually when I have put myself together again after I've urinated I do a little bit again"*

### **Other signs or symptoms**

Many of the patients were either currently or had historically been performing self-catheterisation (n=23, 52%), and had experienced recurrent urinary tract infections for which they had sought treatment in the past (n=17, 39%). Four patients from the DU diagnostic group described occasional episodes where they were unable to perform a volitional void, and they would return to pass urine successfully a short time after. In isolated incidents, six patients had acute retention episodes that required hospital admission for catheterisation. A minority of patients (n=8, 18%) had bowel issues (e.g. constipation) and two female patients noticed an association of these with the reported severity of their lower urinary tract symptoms.

*P14: "My biggest concern quite honestly is the catheter one way and another, what with infections and so on"*

*P21: "Now and again which is very rare I just cannot go. I can actually go to the loo about four or five times and I just cannot perform at all"*

### **Impact**

The impact of their symptoms on quality of life was highly variable among different individuals. Some described the negative consequences on their lives, whilst others reported relatively little inconvenience saying they had become 'used to it' due to the chronic nature of their condition (n=12, 27%). In particular, the symptoms of high urinary frequency, nocturnal voids and urgency caused a reliance on planning their daily activities around the location of toilets (n=27, 61%) and

daytime somnolence as a result of interrupted sleep (n=14, 32%). The ensuing disruption to social, work-life or physical activities could be very bothersome. The consequence was an impact on self-image or confidence, feelings of embarrassment in certain situations, and impact on relationships with family and friends, including sex-life for a minority of patients. The control of fluid intake was one way patients often sought to manage their symptoms (n=15, 34%).

*P1: "It makes life uncomfortable, I'm always looking to be somewhere near the loo so I can go if I need to"*

*P12: I couldn't start the urine flow very easily and I became a bit embarrassed by that situation because I was just stood there doing nothing"*

*P22: "It does interfere with my social life, and sleep as well"*

#### 4. Discussion

To our knowledge, this is the first study to explore and document the patient reported experience of UAB, elicited from a purposive sample of male and female patients with a primary diagnosis of DU. The result is a comprehensive patient-centered description of the symptoms, signs and impact of UAB, revealing the condition to be a myriad of storage and voiding LUTS.

The storage symptoms of nocturia, high urinary frequency, urgency and incontinence and voiding symptoms of slow stream, hesitancy and straining were most commonly reported by both male and female patients. Straining (to initiate, maintain or finish urination) is of particular note as it was well represented in the DU diagnostic group and is not currently included in the 2015 UAB symptomatic definition [1]. These classic LUTS are consistent with a weak bladder contraction and are in accordance with symptoms associated with DU in the literature [5-7]. The current study also corroborated recent findings by Gammie et al [19] which associated a feeling of incomplete emptying, absent or reduced sensation and a variety of bowel issues to DU patients. A PVR of >30mls (median: 199ml) was present in the majority of participants, and a large proportion of patients were currently or had historically self-catheterised and/or had urinary tract infections, as well as some who had experienced acute retention episodes.

Previous research supports the findings that there can be a broad impact on patient's lives associated with LUTS [20,21]. The requirement to plan ahead around the location of toilets, disruption to sleep, embarrassment in certain situations, and consequent effect on social life, self-esteem and confidence are supported by other qualitative studies in male and female patients with LUTS [9,22,23]. Many of the patients with UAB experienced similar levels of impact but others felt they were able to manage their symptoms to minimise the impact on their lives.

The current study provides a robust evidence base on which to base the development of a PRO instrument to evaluate interventions for UAB. A number of symptoms, signs and areas of impact were identified that may provide sensitive indicators of improvement or deterioration in UAB following treatment. However, there are several challenges to the development of a specific UAB PRO measure. Some of the commonly reported symptoms may have multiple aetiologies, such as pain or nocturia, which may be a consequence of other health or behavioural factors unrelated to lower urinary tract dysfunction [24-26]. The overlap of the reported symptoms in patients with co-existing OAB or BOO is already recognised [5,7] and will be investigated further in later quantitative PRO measure validation studies.

A strength of this study is that all patients were clinically verified to have a primary diagnosis of DU by PFS. In addition, those with co-existing urological conditions were included to ensure the relevance of the PRO measure to the whole spectrum of DU patients. The study is not intended to produce representative epidemiological data but to elicit the overall patient experience of UAB. The further elucidation of symptom prevalence and bother will be possible later in the PRO measure development process. This study also cannot be used to link UAB to urodynamic DU. Further interviews with patients from the United States and Japan are scheduled in order to explore potential differences in how patients from other cultures and ethnicities describe UAB symptoms.



## **5. Conclusions**

The current study describes the progress in our understanding of how the clinical diagnosis of DU manifests as symptoms, by a thorough exploration of the lived experience of patients. This knowledge supports the development of a PRO measure for the outcome assessment of UAB for use in trials, research and clinical practice and is valuable to the further development of the definition of UAB.

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Figure 1. Prevalence of symptoms and signs reported in the total sample. The proportion reported by patients with DU, and by those with DU and co-existing urological conditions are shown.

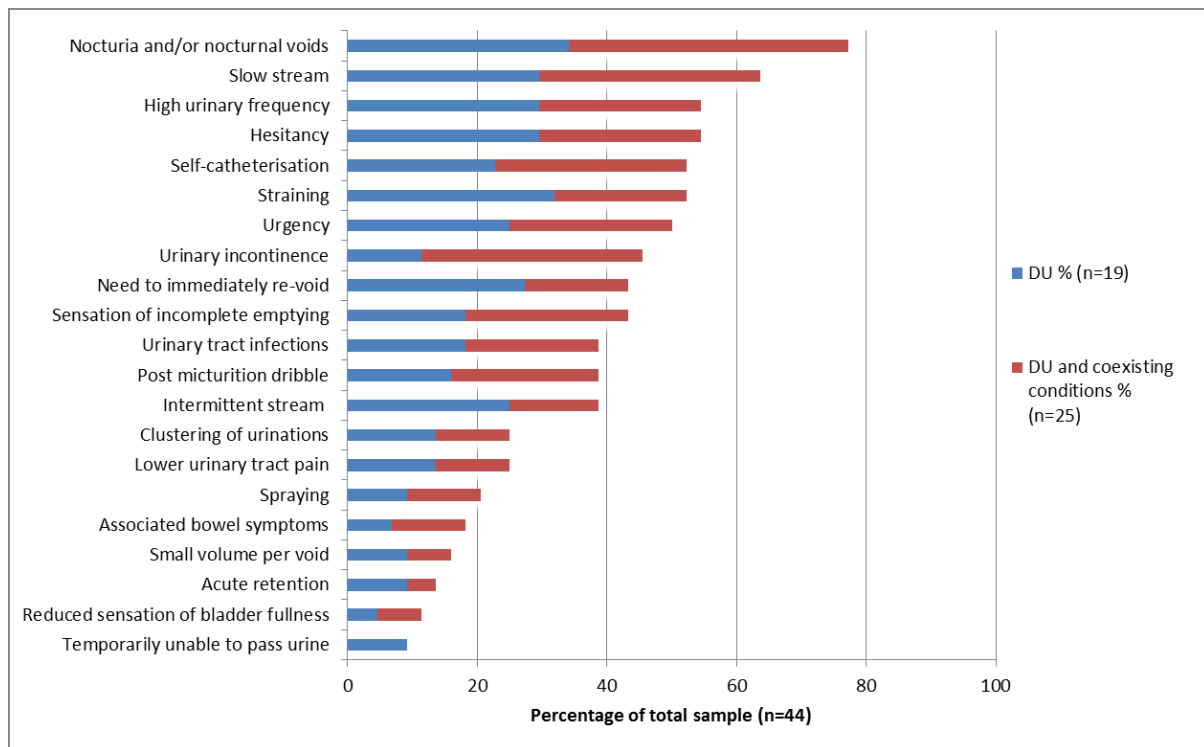


Table 1. Diagnosis group inclusion criteria and number of patients per diagnosis group.

<b>All DU patients included in the study (n=44)</b>			
Males: BCI <100 BOOI <20		Females: $p_{det}Q_{max} < 20 \text{ cmH}_2\text{O}$ $Q_{max} < 15 \text{ ml/s}$	
<b>DU without co-existing urological conditions (n=19)</b>			
<b>DU + co-existing urological conditions (n=25)</b>			
Mild SUI/USI (n=7)	Mild DO (n=8)	BOO-E (n=5) BOOI $\geq 20 - < 40$	BOO (n=5) BOOI $\geq 40$

Abbreviations: Detrusor pressure at maximum flow ( $p_{det}Q_{max}$ ), maximum flow rate ( $Q_{max}$ ), bladder contractility index (BCI) calculated by  $BCI = p_{det}Q_{max} + 5Q_{max}$ , Bladder Outlet Obstruction Index (BOOI) calculated by  $BOOI = p_{det}Q_{max} - 2Q_{max}$ .

Table 2. Sample demographic and clinical characteristics.

<b>Clinical or demographic characteristic</b>	<b>Total sample</b>	<b>DU</b>	<b>DU + co-existing urological conditions</b>
<i>n</i>	44	19	25
Mean age and range (years)	64 (27-88)	59 (27-88)	68 (38-87)
Gender, male <i>n</i> (%)	29 (66)	12 (63)	17 (68)
Intermittent self-catheterisation <i>n</i> (%) (Historical or current)	23 (52)	10 (53)	13 (52)
PVR >30ml* <i>n</i> (%)	34 (77)	14 (74)	20 (80)
PVR >30ml* (ml) (median and interquartile range)	199 (100-492)	335 (119-492)	170 (100-360)
BCI (median and interquartile range)	62 (49-79)	62 (48-82)	62 (50-77)
BOOI (median and interquartile range)**	18 (8-28)	15 (6-18)	25 (9-41)
$p_{det}Q_{max}$ (cmH20) (median and interquartile range)	25 (12-35)	24 (12-29)	26 (12-36)
$Q_{max}$ (ml/sec) (median and interquartile range)	8 (6-10)	8 (6-11)	6 (5-9)

\*In the absence of any evidence base for the lower limit of a 'significant' PVR we chose >30mls.

\*\*Males only

Abbreviations: Detrusor pressure at maximum flow ( $p_{det}Q_{max}$ ), maximum flow rate ( $Q_{max}$ ), bladder contractility index (BCI) calculated by  $BCI = p_{det}Q_{max} + 5Q_{max}$ , Bladder Outlet Obstruction Index (BOOI) calculated by  $BOOI = p_{det}Q_{max} - 2Q_{max}$ , Post Void Residual (PVR).

