

Qualitative assessment of the conservative management of nocturia with standardised written materials for Lower Urinary Tract Symptoms in men treated in primary care

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Abstract

Context, Many men prefer conservative treatment of lower urinary tract symptoms (LUTS), but education and self-help guidance is limited in primary care

Objective, To report qualitative interview findings for men reporting nocturia in a primary care presentation for LUTS

Evidence Acquisition, TRIUMPH is a cluster randomised trial of standardised/ manualised care (a healthcare professional delivered booklet) vs. usual care for prevalent LUTS in primary care. The qualitative component included 58 early-stage and 33 late-stage participant interviews, assessing experience of LUTS and conservative treatment in primary care.

Evidence Synthesis, Nocturia is a common driver for seeking healthcare, perceived by men as relatively acceptable to discuss. Information and self-help guidance were largely absent from descriptions of GP consultations, other than reducing evening caffeine/ fluid intake. The TRIUMPH LUTS intervention booklet offered explanations and self-management guidance. Men with long-term disruptive symptoms, perceptions the booklet content was novel/ worthwhile, and belief that self-management might help were more receptive. In follow-up, improved nocturia was related to successful implementation of several aspects of the guidance. Most men were willing to do a bladder diary, but some found it inconvenient, especially men in employment.

Conclusion, Reassuring men that nocturia is part of ageing, without offering information and support, risks reinforcing tendencies to discount problematic LUTS. The trial booklet and healthcare professional training supports nocturia self-management guidance, which is most effective for men receptive to this approach. However, the nature of the trial population means the findings may not apply to all men.

Patient Summary, Men are more comfortable discussing waking at night to urinate than other urinary symptoms with their GP. This problem should lead to detailed discussion of all urinary symptoms, rather than being thought of as a sign of ageing. The study information booklet and nurse consultation helped many men to improve this problem.

Introduction

Lower urinary tract symptoms (LUTS) can be problematic for patients, and are commonly described as “bothersome” according to the impact on quality of life, work and other activities (1). Disease-specific, health-related quality of life measure findings are significantly worse in men with higher symptom severity and bother ratings in population-based studies (2). Men often present in primary and secondary care with a range of LUTS, very commonly including nocturia (3-5), which is recognised as a particularly high impact LUTS (6-9).

The assessment of LUTS should include several measures aimed at identifying underlying causes and cataloguing the severity and bother associated with the individual LUTS (10, 11). Due to the potential importance of nocturnal polyuria in nocturia (12, 13), this assessment requires completion of a bladder diary (14). A full assessment thereby enables a logical and informed approach to therapy (15, 16).

Men have been found to consistently prefer less invasive treatment options for LUTS, with a low risk of adverse events (17). An NHS Evidence Update indicated that self-management may have a role in the treatment of LUTS (18), citing a post-hoc analysis (19) of a single centre study (20) of 140 men with LUTS assigned to standard care plus a self-management programme, or standard care alone. Men assigned to the self-management programme reported reduced nocturia and daytime frequency, and better voided volumes. Conservative management is supported by key guidelines for male LUTS (15, 21).

The TRIUMPH (Treating Urinary Symptoms in Men in Primary Healthcare) randomised controlled trial (ISRCTN11669964) evaluated whether a standardised and manualised care intervention achieves superior symptomatic outcome compared with usual care for male LUTS (22). The study was primarily designed to establish whether this approach achieved sustained improvement of symptomatic outcomes compared to usual care. It included extensive qualitative research into experience of LUTS and conservative treatment in primary care. In the current report, we describe the qualitative findings in relation to men reporting nocturia.

Methods

The TRIUMPH study is a multicentre, pragmatic, two-arm cluster randomised controlled trial of a care pathway based on a standardised and manualised care intervention (TRIUMPH intervention arm) and usual care arm for men with LUTS (22). The trial was conducted in thirty general practice (GP) sites in the UK, recruiting patients from June 2018 to August 2019. Sites were randomised to the intervention or usual care arm. In the intervention arm, delivery of a standardised booklet of LUTS information and advice was individualised by a healthcare professional (nurse or healthcare assistant), who reviewed the patient’s baseline urinary symptoms (IPSS, ICIQ-UI-SF and ICIQ bladder diary) and then directed the patient to the relevant sections of the booklet. In the usual care arm, sites were requested to follow their standard local practice for trial patients. Potential participants were identified from practice databases using a search for symptom or treatment codes related to LUTS (i.e. were not

recruited from incident cases of men newly presenting with LUTS during the trial recruitment window). There were 524 participants (mean age 69) in the intervention arm and 553 in the usual care arm (mean age 68).

All participants completed the International Prostate Symptom Score and International Consultation on Incontinence Questionnaire (ICIQ)-Urinary Incontinence-Short Form (ICIQ-UI-SF) at baseline. The mean (standard deviation) IPSS was 13.6 (5.8) and 14.6 (6.6) in the intervention and usual care arms respectively. The IPSS quality of life scores were 3.5 (1.2) and 3.6 (1.1), respectively. The scores for IPSS question 7 about nocturia severity were 2.6 (1.4) and 2.4 (1.3), respectively. Men in the intervention arm completed the ICIQ bladder diary (23) at baseline to help inform intervention delivery. This identified nocturia in 85% of participants, defined as waking up in the night to urinate at least once on both fully-completed nights OR waking up in the night to urinate twice or more on one night.

In the qualitative component of the study, 58 early-stage patient interviews were done (30 intervention arm, 15 usual care) and 33 late-stage interviews (22 intervention, 10 usual care). Early stage interviews typically took place 0-3 months after joining the study. Late-stage interviews took place from 3 to 9 months later, towards the end of the 12 month study participation. Purposive sampling aimed to provide a diverse sample for interviews and utilised;

- IPSS scores ranging from 3- 31, with a mean of 14.8 at baseline;
- a range of LUTS experiences, including men with more severe problems (higher scores, of 3 or more out of 5 for the respective IPSS or ICIQ-UI-SF item) relating specifically to: nocturia (25 men); an urgent need to urinate (23 men); urinary leakage (12 men); and a frequent need to urinate (31 men). 22 men experiencing post-micturition dribble were also interviewed.
- ages ranging from 40-84 years, with a mean age 65 years;
- a diverse range of GP sites.

The cohort included four men who identified as Black, Asian, or mixed-race, alongside 54 white men.

The qualitative sample suggested a predominance of apparently relatively affluent, married, retired men with largely healthy lifestyles, who were also fairly proactive in their health seeking behaviours. Nevertheless, there was a wide range of participants with differing characteristics (some men were much younger, full-time working in a wide range of occupations, unemployed or unable to do paid work due to ill health or caring responsibilities).

Results

Nocturia is a common driver for seeking primary care input

Men commonly presented with nocturia, and this was a precursor to seeking primary care support for a large proportion. Many men opened their account of LUTS onset with a description of the emergence of increasingly regular disturbance (most nights or every night) often waking more than once (indeed

many times) each night to urinate. A lot stated that this led to their first LUTS-related GP visit, or first 'in passing' LUTS-related question to a GP.

"...the main problem I have encountered is having to get up in and being disturbed repeatedly in the night to pee and it was sort of at least three times a night." Intervention Group man, age 69, IG2

Nocturia may be easier to talk about, but may mask other LUTS

Nocturia was considered a highly distressing symptom by many men, since sleep disturbance and tiredness can lead to low mood, poor concentration, difficulties with work and impacts on relationships. This was especially the case for working men waking more than 2 or 3 times a night. However, additional concerns were also expressed: 1) the experience of worsening nocturia often triggered concerns about prostate cancer; 2) on further discussion, men often reported a range of additional LUTS, which in many cases had not been reported to their GP, including leakage, urgency, dribble, hesitancy and slow flow. It appeared that some men felt that nocturia could more readily be described and discussed than other LUTS, and were more comfortable raising this symptom. In contrast, symptoms such as frequency and urgency, were less straightforward, representing a worse implication for self-esteem.

"I don't think I would have discussed the urgency problem... actually, thinking about it. No, it would have been around getting up in the night... [Interviewer: What stops you...?] I suppose embarrassment. It's to do with... self-esteem. You feel that you are diminished, in your own view, that I lack control... Therefore, I would feel embarrassed..." Intervention Group, age 78, IG6

Men take time to reach primary care

Men often discounted symptoms as just a part of normal aging, and were uncertain about when it might be appropriate to seek medical support.

"The night-time waking I just accept and I don't know if maybe having to rush to the toilet maybe I just think I hope it will go away some time. I wouldn't know whether medically anything can be done about that so I've just accepted it as it is." Control Group, age 81, CG4

Many men described a gradual worsening of symptoms, often over lengthy time periods, before seeing their GP. For some men the threshold for seeking primary care input seemed relatively low (for instance, waking once a night over a period of months) - and this 'low' threshold was often accompanied by concerns about the possibility of prostate cancer. However, for many men, the threshold was relatively high or very high (for instance waking 6 or 7 times a night for 20 years before seeking help or advice from primary care).

“It had become more often over a period of time but whereas you start from not having to go at all and just wake up in the morning and go to the toilet, you then find once during the night I’d get up and then a year or two later you’d notice it’s twice a night I’m getting up now, and then a year or two later I got up three times last night... It developed over probably five or 10 years and it’s when it reaches the point where it becomes three and maybe even four times a night that then you really feel isn’t there something we can do about this and that’s when I went off to see the GP.” Intervention Group, age 75, IG19

GP response

Men described GP responses that ranged from consultations that: a) offered reassurance (that LUTS is nothing to worry about, and common in older age); b) provided a fuller assessment and therapy guidance, particularly around liquid intake and caffeine; c) offered pharmacological medication; d) involved referral for urological investigation. In relation to nocturia, some men reported receiving advice to reduce caffeine and fluid intake in the evening. Nevertheless, comprehensive LUTS information and self-help guidance was largely absent from men’s descriptions of their GP consultations. Men generally remained ill-informed despite primary care engagement. Awareness of comprehensive self-management techniques was rare.

Men with severe nocturia were often offered medications, with varied outcomes, and follow up. Men were unsure of the appropriate symptom thresholds for requesting a review of their LUTS-related medication and often continued with medications, though uncertain of the benefits, for fear that symptoms might otherwise worsen.

[Interviewer: How many times are you waking up at the moment since taking the tablets?...] I would say the average is probably...three visits in the night...[Interviewer: ...any shift in that since starting the medication?] No, I think about the same... it’s probably kept it under control. If I stopped taking the medication, it might obviously possibly change things a little bit. Intervention Group, age 76, IG21

Experiences of the TRIUMPH intervention booklet and nurse consultation

For the most part, men were strongly positive about the booklet, in terms of accessible language, diagrams and images and content, including both explanation and self-management guidance. They also considered the focused sections structure effective, so that nocturia sat alongside the other LUTS they experienced. Men were most receptive who had;

- Symptoms that were disruptive, distressing or frustrating, and which they wished to remedy;
- Long-term experience of disruptive symptoms, reflecting reluctance to revisit/bother the GP and/or poor resolution of symptoms;
- Perception that the TRIUMPH booklet content was novel and worthwhile;
- Belief that self-management techniques might alleviate symptoms;

Some men were ambivalent, especially if symptoms were minor or severe ('too far down the line'). They were less engaged if they felt the guidance did not offer something new or was unlikely to be helpful, or if it appeared difficult to implement or overly disruptive to everyday life.

The booklet was the focus of men's meeting with a trial or practice nurse who identified the appropriate sections relevant to the men's individual LUTS, one of which was a section that focused on nocturia. In practice, many men read and attempted to implement other aspects, along with the recommended nocturia section. Many men reported improved nocturia, but they often did not relate this to the relevant booklet section on "Reducing Sleep Disturbance". The information in that section was less novel for the participants, as a result of prior discussions with their GP, and/or through other sources of guidance on sleep improvement. Instead, they felt improved nocturia was because of their successful implementation of other aspects of the guidance. The section on "Fluid Intake and Diet", covering volume, timing and type of intake, including the reminder that many foods contain water (fruit, vegetables, pasta), was helpful to alleviate competing health concerns around fluid intake. Some men who managed to reduce or eliminate certain drinks/ foods/ salt, experienced considerable improvement of nocturia. "Controlling Bladder Leakage" (teaching pelvic floor exercises), "Controlling an Urgent Need to Pass Urine" (bladder training) and "Emptying your bladder as completely as possible" were also reported to be useful for nocturia. For instance, following a recommendation on 'taking your time' to urinate, men reported making the effort to stand or sit for longer than they might have done, and finding they woke once or twice less often as a consequence. Men undertaking pelvic floor exercises and bladder training to increase daytime control also noted improved night-time control, which was related to improved muscular strength.

Men who found nocturia symptom alleviation through lifestyle methods also described feeling better about their symptoms because they had better understanding of the nature of their condition and of a range of strategies to alleviate symptoms. They also reported feeling less anxious about the possibility of underlying conditions (particularly that nocturia might be a sign of prostate cancer).

*"...actually it was also quite empowering to be told that it is okay to make that value judgement... It's about understanding what your symptoms are, what makes things better, what makes things worse and then managing it realistically within your lifestyle."
Intervention Group, age 57, IG16*

"It's not going to go away so I'm going to have to do something and by doing these things I've got a certain amount of control over it." Feasibility Group, age 52, FG2

Issues with bladder diaries

Bladder diaries were not identified as routine in nocturia consultations. When asked to complete one for the study, many men made no complaint, and some described completing it as an interesting and informative experience in relation to their LUTS (and their desire to better understand any patterns or aggravating factors).

“The bladder diary was useful. It’s something I’ll probably do again at some point just to see if there has been a good change. It’s a good way to monitor.” Feasibility Group, age 56, FG5

However, some men said they found completion of the bladder diary somewhat irksome, especially men who were working (and needed to carry a measuring pot with them to work, for instance).

“I think the one tricky thing was doing the bladder diary at the start, my lifestyle doesn’t actually lend itself that easily, being able to find somewhere to go collecting urine, to measure urine really.” Intervention Group, age 53, IG3

A few men ultimately took part without completing their bladder diaries. Sometimes men were asked to describe their frequency and nocturia, perhaps supported by keeping stringent notes rather than a bladder diary.

Discussion

The potential benefit for improving diagnostic approaches to LUTS in primary care is known (24), but the current study identified that rigorous, structured and targeted self-management is not reliably covered in current primary care therapy for nocturia. Those men receiving the TRIUMPH trial intervention reported that their nocturia benefitted from several aspects of the booklet, beyond those typically offered to address nocturia itself. The guidance appeared to increase men’s self-efficacy and empowerment in relation to their health.

In general, there was a common tendency among men to downplay nocturia (and other LUTS) as ‘part of getting old’. Nonetheless, passing urine during the night both caused men distress, and seemed to be the LUTS which men felt most able to discuss with their GP, so nocturia is commonly the primary LUTS presentation. Since men appear willing to disclose nocturia more readily than other symptoms, disclosure of this symptom means that sensitive enquiry should follow to identify any other LUTS the man may be struggling with but which they are more reluctant to report spontaneously.

Nocturia in particular needs careful evaluation, since there can be medical issues underlying the symptom in some cases (25-27). While some men described GP encounters (and referrals to urology) involving detailed evaluation, for others, cursory reassurance summed up the entire encounter. In the latter case, men described feeling that the notion that LUTS was an inevitable part of aging and not a clinical concern, was reinforced (an issue that has been identified previously (24, 28)). Reassurance that nocturia is commonplace and nothing to worry about does allay underlying concerns about prostate cancer. However, it was also problematic. Firstly, it meant LUTS identification and symptom alleviation was incomplete, so that men often put up with increasingly severe symptoms without returning to their GP for many years. Secondly, it reinforced men’s doubts about the legitimacy of LUTS as a condition worthy of medical attention and reduced the likelihood they might seek further support or return to the GP as symptoms worsened. Hence men may become even more reluctant to

bother their GP. Since GPs often rely on patients to come forward once symptoms become sufficiently problematic, the situation risks leaving men struggling with increasingly severe LUTS. While men reported being satisfied with their LUTS-related GP consultations, this sometimes reflected low expectations from LUTS treatment, a belief that they should not bother their GP about LUTS, and positive regard for their GP.

Education and self-help guidance, or 'conservative care', are a recommended component of preliminary treatment (10, 16, 29, 30). However, the early-stage interviews found that men's awareness of LUTS self-management guidance appears limited, and men generally seemed poorly informed about their symptoms, in line with findings from other research (28, 31-33). Most men taking medication for LUTS remained unfamiliar with recommended self-management approaches, other than fluid/ caffeine reduction in the evening. Since participants were identified from database search, they had previously had GP contact in order to have been allocated a LUTS code, indicating that conservative care as currently practiced does not achieve an effective improvement in knowledge or self-care.

Since much has to be covered in GP consultations, scope for detailed education and initiation of conservative therapy is constrained. Availability of nurse- or healthcare assistant-led delivery of this material provides additional settings to encourage self-help take-up. The TRIUMPH intervention offers an efficient approach to enable GPs to offer a greater depth and diversity of self-management, and to better orient initial LUTS consultations around this material. Bringing men into contact with accessible background information mechanisms and self-help for LUTS supported men to better manage their nocturia.

As with all self-help, men needed to be sufficiently motivated to make changes. For some men involvement in the study was transformational in relation to symptom alleviation and quality of life. Men who made changes and found benefit were inspired to try other aspects of the booklet and became active investigators in relation to the impact of their lifestyle on their symptoms, ready to trial different approaches. Conversely, men who felt minimal interest and/or found little benefit in their initial attempts at modification were discouraged from making or trialling further aspects.

The bladder diary used in LUTS assessment was the ICIQ bladder diary (34), which is the only validated diary. The diary is needed for understanding the mechanism of increased voiding frequency, and nocturia in particular (35, 36). However, bladder diaries do seem to represent a barrier for many patients, in terms of the inconvenience of measuring voided volumes over three full days.

Strengths of the qualitative study included a relatively large sample of men with diverse LUTS experiences. On the other hand, the sample probably included men who were wanting help in relation to neglected symptoms (so were receptive), and those who had time (e.g. retired from work) and inclination to complete the study procedures and participate in a trial. Hence, there may have been proportionately fewer men with the most complex health needs, disabilities, caring responsibilities,

and full-time working or unemployed men. In particular, the study was taken up mostly by men who were white, and the qualitative sample as a result included the views and experiences of only four men out of 58 who were Black, Asian, or Mixed-race. Furthermore, the area-level deprivation of the study sites (based on practice postcode) had less representation from low-affluence areas. Additional focused work should target diverse UK cultural communities to address LUTS self-management and support LUTS primary care across UK communities.

Conclusions

Reassuring men that nocturia is 'just a normal part of getting old', without offering further information and support, risks reinforcing men's tendency to discount distressing LUTS experiences. Men reporting nocturia should be sensitively asked about other LUTS, and offered comprehensive lifestyle guidance. Embedding the study booklet, guidance and healthcare professional training in primary care, supports thorough nocturia self-management guidance. This is most effective for men receptive to this approach. However, the study population recruited means that the findings may not apply to all men.

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