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Editor's Choice

Nocturia is often inadequately assessed, diagnosed and treated by physicians: results of an observational, real-life practice database containing 8659 European and US-American patients

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Summary

Aims: The aim of this study was to investigate the quality and timing of the diagnosis and treatment of nocturia in real-life practice in European and US-American patients to obtain better insights into the management of nocturia in different Western healthcare systems.

Methods: Data were drawn from the "LUTS Disease Specific Programme," a real-life survey of physicians and patients in France, Germany, Spain, UK and the USA. Physicians completed a patient record form for lower urinary tract symptoms (LUTS) patients. Patients filled out a self-completion form, indicating – among other items – information on the mean number of day- and night-time voids during the last 7 days, and questions on the management of LUTS in daily practice.

Results: In total, 8659 patients were analysed. The majority of patients initially consulted a physician because of worsening of LUTS frequency (43%–58%) or severity (44%–55%). Only 37% of all LUTS diagnoses, regardless of the appearance or severity of nocturia, were based on bladder diaries. Patients took approximately 1 year to consult a medical professional following the onset of LUTS. At the initial visit, most patients received advice on behavioural strategies. Regardless the type of LUTS and physician, 59% of men received α-blockers and 76% of women antimuscarinics.

Conclusions: Data show that patients with nocturia and LUTS accept their symptoms for a considerable period before they seek help or ultimately receive treatment. They may therefore be enduring significant negative impact on their quality-of-life which could be avoided. Physicians rarely use bladder diaries and primarily use antimuscarinics (women) or α-blockers (men). Improved awareness of nocturia among patients and physicians could improve the management of nocturia.

1 | BACKGROUND AND OBJECTIVES

Lower urinary tract symptoms (LUTS) affect a large proportion of the adult female and male population worldwide but are often underreported due to embarrassment, acceptance of LUTS as an inevitable part of ageing, or lack of knowledge about the condition.[1–4] LUTS are unspecific for age and gender and have a multifactorial aetiology.[5,6] Early attempts to classify symptoms based around concepts of "prostatism" or benign prostatic hyperplasia (BPH) in men and overactive bladder (OAB) in women have long been recognised to be inadequate.[7–9] Neither OAB nor BPH produces a consistent set of symptoms in all patients.[10] As LUTS can be highly bothersome and patients seek help for fast symptom relief,[11,12] it is imperative that patients are assessed, labelled and treated correctly at the physician office.

One symptom in particular, nocturia, seems to be consistently overlooked in clinical practice with regard to its specific aetiology, impact on

quality-of-life and treatment, despite its high prevalence.[13] The analysis of 43 trials of community-dwelling people demonstrated that 20.4%–43.9% of women and 11.0%–35.2% of men aged 20–40 years have nocturia ≥1 times per night and 4.4%–18% of women and 2.0%–16.6% of men report about nocturia ≥2 times per night.[14] The prevalence of nocturia rises dramatically with ageing. Women or men aged >70 years have nocturia ≥1 time per night in 74.1%–77.1% and 68.9%–93.0%, respectively, and ≥2 times per night in 28.3%–61.5% and 29.0%–59.3%, respectively. In a German epidemiological study investigating 5504 men aged 50–80 years, 40.5% of participants had clinically important –voiding and/or storage LUTS.[15] Of all individual symptoms, nocturia had the highest symptom bother and was the only symptom significantly associated with physician consultations during the previous 2 years.[16]

Key instruments for diagnosing, quantifying and discriminating LUTS, with or without urinary incontinence, are patient history, symptom questionnaires and bladder diaries.[17,18] However, only bladder diaries can objectively quantify the number of voids during day- and night-time as well as document drinking and micturition volumes. Bladder diaries should be taken for 2–7 days and are recommended by international guidelines in patients with bladder storage symptoms or nocturia.[19–21] Without a bladder diary, it may be difficult to ascertain the correct diagnosis and, hence, the best possible treatment option(s).

Despite the recognition of nocturia by the International Continence Society and publication of a standardisation report, nocturia may be different and independent from other LUTS.[22] During the last decade, nocturia has gained increasing interest in the literature but it remains to be determined whether this has also translated into a greater focus in clinical practice with regard to earlier diagnosis or specific treatment. The aim of this study was to investigate the quality and timing of the diagnosis and treatment of nocturia by means of a large database analysis of European and US-American patients to obtain better insights into the management of nocturia in different Western healthcare systems.

What's known

- Lower urinary tract symptoms (LUTS) and nocturia are highly prevalent in adult men and women in Western Societies.
- Lower urinary tract symptoms are disease- and gender-unspecific and highly bothersome, decrease quality-of-life and are responsible for morbidity/mortality.
- Bladder diaries can assess and quantify LUTS, can differentiate between the various causes, and are recommended by guidelines.
- Drug treatment should target the underlying pathophysiology of LUTS and nocturia.

What's new

- Clarifies the amount of patients seeking help for LUTS and/or nocturia in five Western countries.
- Describes the time between symptom onset and first consultation, diagnosis and treatment.
- Determines the reasons for physician consultations.
- Evaluates assessment tools and the use of bladder diaries.
- Describes the treatment pattern according to the type of LUTS.
- Quantifies conservative and medical treatment of LUTS and/or nocturia.

2 | MATERIAL AND METHODS

Data were drawn from the "Lower Urinary Tract Symptoms Disease Specific Programme" (LUTS-DSP), an observational, cross-sectional, real world, multinational survey of physicians and their consulting patients in France, Germany, Spain, the UK and the USA. The survey was conducted by Adelphi Real World between February and May 2013. Participating physicians were identified by local fieldwork teams from public lists according to predefined selection criteria. Primary care physicians (PCPs) and urologists had to have a minimum of four patients diagnosed with BPH and a minimum of three patients diagnosed with OAB consulting each week. Gynaecologists had to have a minimum of six patients diagnosed with OAB consulting each week. Physicians completed a patient record form (PRF) for the next 14 prospective patients whose diagnosis included "BPH" (PCPs/urologists only), "OAB" and/or "nocturia/nocturnal polyuria." Patients could have a single diagnosis or more than one, and the diagnoses were based on each physician's subjective assessment after his/her normal diagnostic procedure. Patients had to be aged between 18 and 89 years, currently being managed for LUTS (but could be consulting for the first time), consulting as an outpatient, not pregnant and not suffering from LUTS as the result of a urinary tract infection.

Physicians completed the PRF as soon as possible after the consultation providing relevant information gleaned during the consultation through observation of and/or discussion with the patient. Questions included information available from medical records such as time since first symptoms, time since diagnosis and time since first treatment for LUTS. Immediately after the consultation, each patient was invited to complete a patient self-completion (PSC) form independently of the physician. It also included a predefined list of reasons for initially consulting over LUTS. The overall aim of the PSC was to assess the degree of bother associated with LUTS, including waking to void. In addition, the study evaluated the previous use of bladder diaries during the normal diagnostic work-up of patients at the physician office and, furthermore, each patient was requested to provide an estimate of the mean number of voids during the waking and sleeping hours over the past 7 days.

The LUTS-DSP was conducted in accordance with the European Pharmaceutical Market Research association 2012 code of conduct for international healthcare market research and the US Health Insurance Portability and Accountability Act 1996[23] and as such ethical approval was not required. Informed consent was obtained after physicians explained the study and patients reviewed the collection forms. Data were collected by local fieldwork partners and were fully anonymised. Physicians were reimbursed for their participation in the study by the

TABLE 1 Patient demographics and number of day- and night-time voids reported by physicians or patients; numbers are provided as mean±SD or in %, range in parentheses

		Men			Women		
	All patients (N=8659)	Nocturia only (n=256)	BPH or OAB only (n=3849)	Nocturia+BPH/OAB (n=1060)	Nocturia only (n=320)	OAB only (n=2566)	Nocturia+OAB (n=608)
Age (years)*	64±12 (17–90)	64±14 (19–90)	67±10 (18–90)	68±10 (17–90)	59±14 (18–88)	59±13 (18–90)	61±13 (18–90)
BMI (kg/m^2)*	27.4±4.7 (14.2–72.7)	27.7±4.9 (19.0–55.8)	27.4±4.0 (14.8–63.4)	28.0±4.1 (14.9–50.2)	27.3±5.2 (16.2–53.8)	27.1±5.7 (14.2–72.7)	27.6±5.1 (15.1–50.4)
Live with partner*	71	71	74	72	63	69	67
Employed*	32	34	29	29	37	40	28
Retired*	54	62	67	67	34	32	41
Comorbidities							
Arterial hypertension	46	50	52	61	32	32	42
Hyperlipidaemia	26	32	28	39	18	18	24
Diabetes mellitus	19	22	19	29	21	14	23
Obesity	14	16	12	17	15	15	22
Anxiety	14	11	10	13	17	18	22
Arthritis	13	12	12	16	14	11	17
Depression	12	11	6	10	17	18	22
Sleep disorder	8	14	6	12	14	7	19
Dyspepsia	8	5	8	9	5	6	10
None	15	13	14	9	13	20	11
Number of daytime voids reported by physician (PRF)*	6.6±3.2 (0–104)	5.2±1.9 (1–10)	6.4±3.0 (0–100)	6.3±2.5 (0–20)	5.2±2.1 (0–13)	7.3±3.7 (0–104)	7.0±3.6 (1–52)
Number of daytime voids reported by patient (PSC)*	7.5±4.1 (0–120)	6.1±2.5 (0–15)	7.2±3.3 (0–75)	7.4±3.4 (0–28)	6.6±4.0 (0–46)	8.0±5.0 (0–120)	7.9±4.6 (0–60)
Number of nocturnal voids reported by physician (PRF)*	2.4±1.8 (0–40)	3.6±1.5 (0–8)	2.3±1.6 (0–21)	3.2±1.6 (0–12)	3.6±1.8 (0–12)	1.9±1.7 (0–30)	3.3±2.2 (0–40)
Number of nocturnal voids reported by patient (PSC)*	2.5±1.8 (0–23)	3.6±1.7 (0–9)	2.4±1.7 (0–23)	3.3±2.0 (0–22)	3.8±1.8 (0–10)	2.0±1.6 (0–20)	3.3±1.8 (0–15)

BMI, body-mass index; PRF, patient record form; PSC, patient self-completion (form). *P<.0001 across all groups; percentages were calculated excl. missing responses.

local fieldwork partners at fair market rates and the fieldwork teams adhered to national data collection regulations. A full description of the methodology has been published previously.[24]

Based on the clinical diagnoses of the physicians, patients were divided into one of the six groups:

- men with nocturia only
- men with BPH or OAB only
- men with nocturia+BPH or OAB
- women with nocturia only
- women with OAB only
- women with nocturia+OAB.

Demographic data, patient- and physician-reported number of voids (during day and night), reasons for consulting a medical professional, type of medical physician visited, use of a bladder diary, time to consultation, diagnosis and treatment and type of treatment were recorded and evaluated in this study.

3 | RESULTS

3.1 | Patient demographics and number of voids

A total of 627 physicians [261 PCPs (41.6%) and 366 urologists or gynaecologists (58.4%)] completed records for 8738 patients, of whom 5335 (61.1%) completed the PSC. A diagnosis was reported by physicians in 8659 cases (99.1%). Of the total patient population with a diagnosis label, the mean age was 64.0 years and 5165 participants (59.6%) were men (Table 1 and Fig. 1). The "average" patient was slightly overweight. The majority of patients (71%) lived with a partner and was not employed (68%), with the majority of these being retired. Eighty-five per cent of patients had comorbid conditions of which arterial hypertension (46%), hyperlipidaemia (26%) and diabetes mellitus (19%) were most frequently reported (Table 1).

Patients reported a mean of 7.5 daytime and 2.5 night-time voids. Physicians appeared to under-record the number of daytime voids compared with patient reports in all male and female patient subgroups but were more likely to agree with the patient on the number of nocturnal voids. A total of 2244 patients (25.9%) had a confirmed diagnosis of nocturia (nocturia or nocturnal polyuria; Table 1 and Fig. 1), as recorded by the physician in the PRF. Although all patient groups had symptoms of nocturia, physicians indicated nocturia as part of the diagnosis in only 1316 men (25.5% of the male study population) and 928 women (26.6% of the female study population). Nocturia as part of the diagnosis was more likely when patients had a higher nocturia frequency (3.3–3.8 voids per night according to the PSC form in subjects with vs 2.0–2.4 voids/night for those without nocturia in their diagnosis).

3.2 | Reasons for consulting medical professionals

The majority of patients (69%) first consulted a PCP, of whom 48% were later referred to a specialist who made the diagnosis and initiated treatment. Patient-reported reasons for seeking initial professional help were similar for men and women. Most patients initially consulted a physician because of worsening of LUTS frequency (43%–58%) or deterioration of LUTS severity (44%–55%; Fig. 2). Women with OAB were most likely to have first consulted a physician because of urinary incontinence. Tiredness due to sleep disturbance was also an important indicator for seeking help with up to 25% (women with nocturia+OAB) of patients diagnosed with nocturia consulting because of sleep loss. Other reasons for consulting a medical professional were fear of other diseases (19%–25% of men vs 16%–19% of women) or suggestion of a friend or relative (12%–16% in men vs 11%–15% in women). There was a tendency towards higher patient numbers with increasing LUTS severity [nocturia only → (BPH)/OAB only → nocturia+(BPH)/OAB].

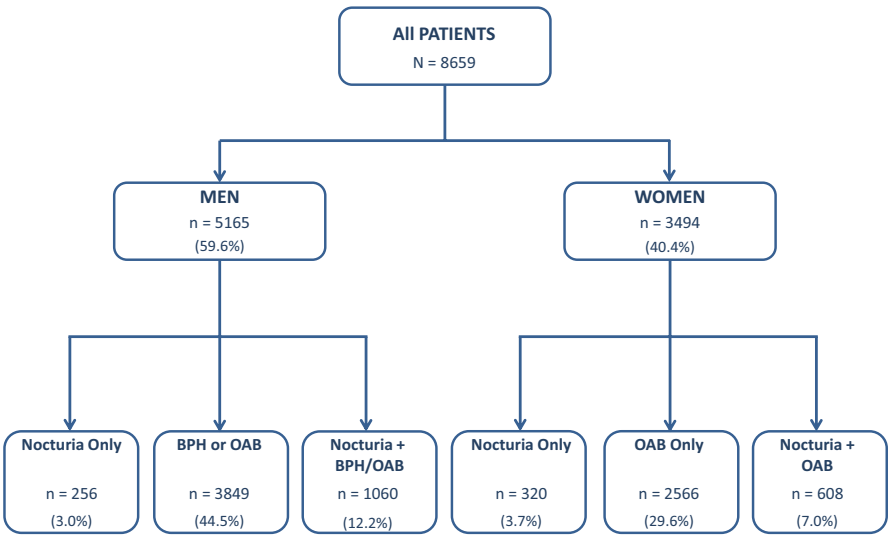

FIGURE 1 Distribution of patients of this observational study. All percentages refer to the analysis sample with a reported diagnosis

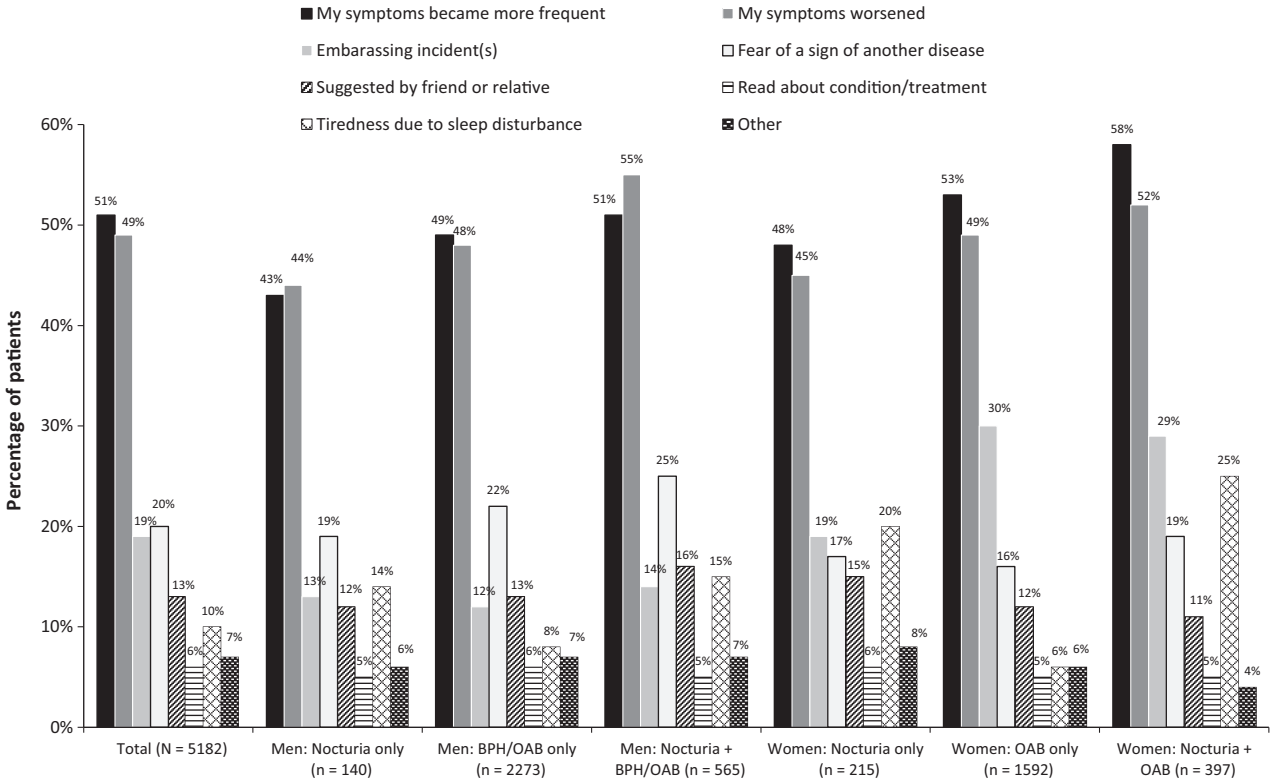

FIGURE 2 Reasons for consultation of a medical professional (more than one answer allowed). Percentages were calculated excluding missing responses

3.3 | Use of bladder diaries

Only 37% of all LUTS diagnoses were based on previous bladder diaries. Among men diagnosed with "nocturia+BPH/OAB," only 35% had completed a diary before participating in the LUTS-DSP. A greater proportion of females with "nocturia+OAB" had previously completed a diary (55%). Men with "BPH or OAB only" were the least likely group to have been diagnosed with a bladder diary (27%). In the subgroup of patients with nocturia of any type (Table 2), PCPs were particularly unlikely to have employed a bladder diary to make the diagnosis of nocturia and differentiate the underlying pathophysiology (34%). Among specialists, urologists had employed a bladder diary to evaluate nocturia in 45% of patients, whereas gynaecologists were the most likely physician group to have used a bladder diary for diagnosis (60%).

In patient groups without nocturia as part of the diagnosis, 40% of the patients with at least one nocturnal void, who felt bothered by nocturnal voiding, were diagnosed using a bladder diary. This number was even lower in patients with ≥2 voids per night (37%). Even among patients diagnosed with nocturnal polyuria, 45% of the patients were diagnosed without a diary. Approximately half of the female patients with nocturia (48%) were not evaluated with a diary, while this proportion increased to 63% in men.

3.4 | Time to treatment

Overall, patients took approximately one year to consult a medical professional following the onset of LUTS (Table 3). Diagnosis was made approximately 12 weeks later, with small differences between the groups. It then took another 37 weeks until initiation of treatment, with a mean total of 106 weeks (i.e. over 2 years) between symptom onset and first treatment. Among patient subgroups, women diagnosed with "OAB only" experienced the longest time at every stage of the patient journey to treatment (mean total time to treatment 131.4 weeks), while men with "BPH or OAB" had the shortest total time to treatment (89.6 weeks; difference ~42 weeks). Men and women with a mixed nocturia diagnosis waited for a mean of 105 weeks from symptom onset to first treatment, while those with a "nocturia only" diagnosis had a slightly shorter time to treatment (mean for men 93 weeks vs women 92 weeks; difference ~12 weeks).

3.5 | Initial treatment

During the initial office visit to any type of medical professional, most patients were given advice on behavioural strategies, such as limitation of fluid intake, avoidance of alcohol or caffeine, and bladder training, but almost a quarter (23%) of patients were not currently receiving any lifestyle advice or behavioural modifications (Table 4). Women with nocturia, with or without OAB, were most likely to receive conservative treatments, most frequently pelvic floor muscle exercise or bladder training.

Most patients were on drug treatment (Fig. 3). In the "nocturia only" group, 19% of men and 22% of women were not receiving prescription drugs for their LUTS condition (although they may have received behavioural advice) at the time of the survey – the highest

TABLE 2 Proportion of patients with any type of nocturia previously completing a bladder diary

	Number of patients (with bladder diary data reported)	Bladder diary conducted (%)
Any nocturia diagnosis	2233	43
Consulting a primary care physician[a]	862	34
Consulting a urologist[a]	1032	45
Consulting a gynaecologist[a]	339	60
Male nocturia patients[a]	1309	37
Female nocturia patients[a]	924	52
All patients with ≥1 nocturnal void+bother (without a diagnosis of nocturia)	1212	40
All patients with ≥2 nocturnal voids (without a diagnosis of nocturia)	2433	37
First consulted due to tiredness (without a diagnosis of nocturia)	286	35
Diagnosis of nocturnal polyuria by physician	589	55

Percentages were calculated excluding missing responses. [a]For patients with a diagnosis of nocturia (nocturia or nocturnal polyuria).

proportion of any diagnosis group. In the group of men with "nocturia+BPH/OAB," only 6% were not receiving prescription drugs for their LUTS condition.

Regardless of the type of physician currently consulted and presence or absence of nocturia as part of the patients diagnosis, 59% of men received α-blockers and 76% of women received antimuscarinics. There was a clear treatment pattern, with almost half (46%) of the men with "nocturia+BPH/OAB" receiving the α-blocker tamsulosin and 37% of the females with "OAB only" receiving the antimuscarinic solifenacin. Among patients with "nocturia only," 18% of men and 15% of women used desmopressin (melt or tablet), while 63% of men and women received another drug in addition to desmopressin, most typically an OAB (antimuscarinic) or BPH (α-blocker) drug, although these conditions were not part of their diagnosis. Diuretics for the treatment of LUTS (e.g. furosemide, torasemide) were used in 20 patients (0.23% of the total study population) and only in those with "nocturia only" (5.5% of men and 1.9% of women of this subpopulation).

4 | DISCUSSION

This study included 8659 adult male and female patients who sought help for LUTS by a physician during a 4-month data collection period. This was a representative cross-sectional study in five Western countries, describing the assessment and treatment patterns of LUTS in general and of nocturia in particular. Only 5% of men and 9.2% of women sought help for nocturia as a single symptom, whereas nocturia concomitantly appeared with other storage and/or voiding LUTS in 20.5% of men and 17.4% of women. The majority of patients sought for professional help because of deterioration of LUTS frequency or severity. Patients with a diagnosis of nocturia, alone or in combination with BPH or OAB, were more likely to have first consulted a medical specialist because of tiredness due to lack of sleep compared with patients without a diagnosis of nocturia. Our study also demonstrated that all male and female patients, independent of any nocturia label as part of the diagnosis, had a considerable night-time voiding frequency; however, nocturia a part of the diagnosis was more likely when patients had a more severe nocturnal voiding frequency (2.0–2.4 voids per night in patients without vs 3.3–3.8 voids per night in patients with nocturia diagnosis), although the number of nocturnal voids was adequately captured by the physicians. Although 40% of patients with ≥1 void per night and 37% of patients with ≥2 voids per night were bothered by nocturia, they were not particularly labelled with the diagnosis "nocturia;" instead, nocturia in these patients was considered to be a part of the diagnosis "BPH" or "OAB."

Timing of first consultation after appearance of LUTS (nocturia) as well as evaluation of the time from the assessment to initiation of LUTS (nocturia) treatment has never been described before. Therefore, this observational study, for the first time, provides valuable information accordingly. The time from first symptom appearance to first physician consultation was almost 1 year for all patient subgroups but the time for patients with nocturia appeared to be slightly shorter, suggesting a clinically important increase in bother associated with this symptom. The time from the diagnosis to the initiation of first therapy, behavioural treatment and lifestyle advice included, was surprisingly long, ranging from 27 to 41 weeks. Furthermore, the total time from first symptom appearance to first prescribed treatment was approximately 2 years, which also seems surprisingly long and underlines that LUTS are often considered an unescapable part of ageing by patients and suggests that physicians may underestimate the symptom burden, bother and decrease in quality-of-life associated with LUTS.

Only 37% of the LUTS patients were diagnosed and their symptoms differentiated with a bladder dairy. Of these, 75% of patients (n=1401) had ≥2 voids per night, but were not specifically diagnosed with nocturia. Among the 63% of patients with LUTS who were diagnosed without a bladder diary, 70% of patients (n=2207) had ≥2 voids per night, yet were not labelled with the diagnosis "nocturia." It has to be kept in mind that several community-based studies determined a night-time frequency ≥2 voids to be associated with substantial symptom bother and decrease in health-specific quality-of life.[16,25] Furthermore, two longitudinal population studies demonstrated that a night-time frequency ≥2 voids is associated with a significantly

TABLE 3 Duration from symptom onset until first consultation, diagnosis and treatment

	All patients (N=8659)	Men			Women		
		Nocturia only (n=256)	BPH or OAB only (n=3849)	Nocturia+BPH/OAB (n=1060)	Nocturia only (n=320)	OAB only (n=2566)	Nocturia+OAB (n=608)
Time from symptom onset to first consultation, weeks	51.0±88.2 (0–2080)	48.7±70.5 (0–520)	42.1±68.4 (0–1300)	53.9±77.5 (0–1040)	43.7±60.0 (0–300)	62.7±111.5 (0–2080)	57.2±113.3 (0–1820)
Time from first consultation to diagnosis, weeks	11.8±36.8 (0–780)	13.6±33.9 (0–260)	9.4±24.0 (0–520)	9.5±21.4 (0–312)	12.8±43.2 (0–520)	16.3±52.3 (0–780)	12.5±44.3 (0–520)
Time from diagnosis to first prescribed treatment[a], weeks	36.8±115.1 (0–2080)	37.8±83.0 (0–416)	34.8±117.5 (0–1664)	40.5±107.4 (0–1144)	26.7±47.1 (0–208)	40.9±128.3 (0–2080)	28.8±75.9 (0–728)
Total, time from symptom onset to treatment, weeks	105.5±179.8 (0–2340)	93.0±142.6 (4–780)	89.6±149.5 (0–1688)	105.6±141.1 (0–1196)	92.2±120.5 (0–536)	131.4±236.3 (0–2340)	105.1±155.7 (0–1048)

Numbers are provided as mean±SD (range in parentheses). [a]Including behavioural treatment.

increased mortality rate during the next 5 years.[26,27] This leads to the questions why so few physicians used bladder diaries and, when a bladder diary was used, why the physicians did not transfer the diary results to meaningful, pathophysiology-based treatments, especially considering that bladder diaries are recommended by several expert groups and guideline panels in case patients report about nocturia or bladder storage symptoms.[17,20,21] A bladder diary for 2–7 days is the diagnostic tool of first choice to detect the underlying pathophysiology of nocturia, where global polyuria (24-hour urine volume >40 mL/kg body weight), nocturnal polyuria (nocturnal urine volume >33% of the 24-hour urine volume) or reduced maximum voided volume (urinary frequency due to reduced anatomical or functional bladder capacity) can be discriminated.[22,28] The results of bladder diaries can be used to initiate treatment based on the pathophysiology of LUTS. The majority of physicians of this study obviously had not used bladder diaries or did not take the diagnostic and differential values of bladder diaries into consideration when determining the underlying causes of LUTS in general and nocturia in particular. Therefore, education and training of physicians with regard to the use and interpretation of bladder diaries could improve the assessment and, consequently, treatment of patients with LUTS in the future.

Bladder diaries were more likely to be used when the diagnosis "nocturnal polyuria" rather than "nocturia" was part of the symptom complex. However, even within the group of patients with a diagnosis of "nocturnal polyuria," the diagnosis was based on a bladder diary in only 55% of the cases. More reassuring was the finding that attempts to limit fluid intake and that a high number of night-time voids (≥3 voids per night at the time of diagnosis) increased the chances of using of bladder diary.

If targeted and effective management plans of nocturia are not applied early enough, subjects are of increased risk of falling, suffering of bone fractures, developing sleep disorders, diabetes mellitus or cardiovascular diseases, becoming disappointed or resigning to their condition, which all unnecessarily lower life expectancy and quality-of-life.[26,29–33]

Most patients were recommended behavioural advice by the physician. However, 59% of all male patients still received α-blockers and 76% of all females received antimuscarinics regardless of the diagnosis. The high level use of α-blockers and antimuscarinics might reflect their low price and a trial-and-error approach. Specific drugs for the treatment of nocturnal polyuria were only rarely prescribed (diuretics or antidiuretics), maybe reflecting the inadequate assessment of LUTS with bladder diaries, comorbidities, concomitant polypharmacy or the higher patient age. Diuretics for the treatment of nocturia (e.g. furosemide or torasemide in the afternoon) increase urine secretion during the evening and reduce nocturnal diuresis. Furosemide has shown to significantly reduce nocturnal voids and percentage of night-time voided volume in men[34] but, however, was rarely used in male (5.5%) or female (1.9%) participants of this study. Until recently it was not recommended to use the antidiuretic drug desmopressin in patients aged ≥65 years because of the risk of developing hyponatremia. However, a new formulation of desmopressin has recently been approved in the European Union and Canada which now allows treatment of idiopathic

TABLE 4 Current use of non-drug management strategies

		Men			Women		
	All patients (N=8659)	Nocturia only (n=256)	BPH or OAB only (n=3849)	Nocturia+BPH/OAB (n=1060)	Nocturia only (n=320)	OAB only (n=2256)	Nocturia+OAB (n=608)
Limiting of water/fluid intake	46	55	42	50	60	44	62
Avoid certain foods/alcohol/caffeine	38	42	36	42	43	37	48
None	23	24	33	22	14	13	8
Pelvic floor muscle exercises	22	9	6	7	31	45	46
Bladder training	21	14	11	14	26	36	38
Counselling/advice	14	12	12	16	18	15	23

Values are expressed as percentages. Percentages were calculated excluding missing responses.

nocturnal polyuria with this drug also in the elderly population but without the risk of hyponatremia. Combined with a low use of bladder diaries, and long-time interval from initial visit to the doctor to medical treatment of symptoms, it seems that treatment of LUTS patients can still be optimised.

5 | LIMITATIONS

Limitations of the observational research and real world data collection approach used in the LUTS-DSP include selection and diagnosis of patients. Although respondents are requested to collect data on a series of consecutive patients to avoid selection bias, in the absence of randomisation this is contingent upon the integrity of the participating respondent rather than formalised source verification procedures. Moreover, diagnosis in the target patient group is based primarily on the judgement and diagnostic skills of the respondent physician rather than on a formalised diagnostic checklist, although patients are managed in accordance with the same routine diagnostic procedures representative of that clinical practice setting. A further limitation of the DSPs is that being cross-sectional, they cannot be used to demonstrate cause and effect. To demonstrate this, an experimental study would be necessary – even analyses of large administrative databases do not allow for causal inferences to be made due to their design and the need for statistical control of confounding factors.

These limitations need to be balanced against the methodological strengths that ensure the representative nature of the respondent sample within predefined parameters. Moreover, the methodology takes into account the potential differences in customs and practices for the management of target illnesses across different cultures and countries.

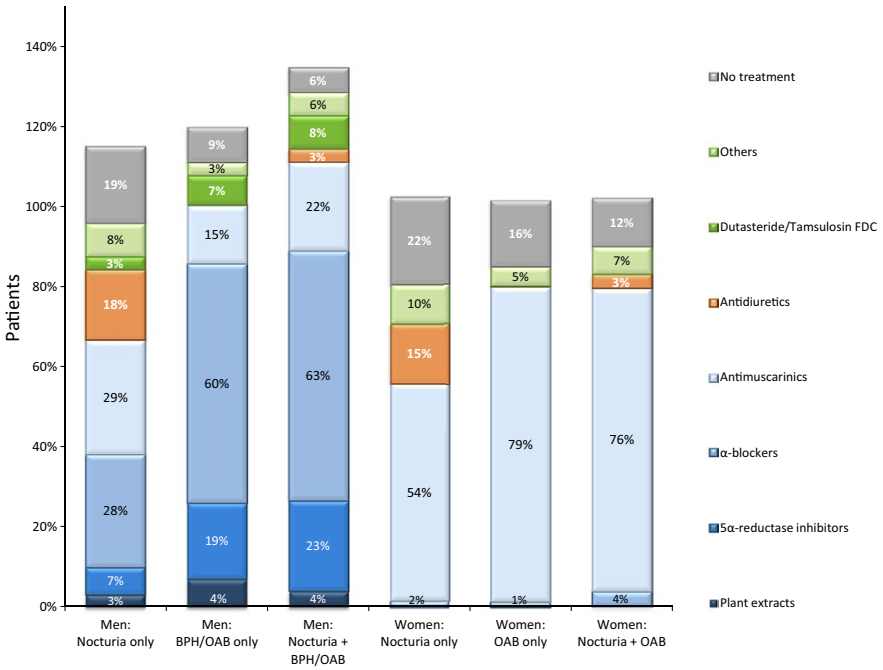

FIGURE 3 Drug prescriptions (drug classes) after making the LUTS diagnosis. Desmopressin was the only drug in the group of antidiuretics; all other drug classes included several drugs. FDC, fixed dose combination (dutasteride+tamsulosin=Duodart®, Combodart®)

6 | CONCLUSIONS

This analysis of real-life practice helps understanding the journey of LUTS patients. These observational studies are particularly useful for conditions, which may be embarrassing or where patients may unnecessarily resign themselves to accepting their symptoms as an unescapable part of ageing. Data from this study show that patients with LUTS (nocturia) wait for a considerable time before seeking help (approximately 1 year) or ultimately receiving treatment for their condition (approx. 2 years). Therefore, LUTS patients could shorten or avoid a negative impact on their quality-of-life when they would visit a medical professional for their symptoms earlier. The main reasons of LUTS (nocturia) patients for consulting medical professionals are worsening of symptom frequency and severity as well as the appearance of embarrassing incidents and sleep impairment. Although the majority of patients have nocturia, most physicians do not use bladder diaries to make the diagnosis or differentiate between the various causes, despite distinct recommendations in guidelines of various medical societies. Physicians primarily use antimuscarinics or α-blockers regardless the diagnosis even in patients with nocturia. Improved nocturia awareness among patients and physicians could help to improve the assessment, diagnosis and treatment.

DISCLOSURES

Matthias Oelke has been consultant, speaker and/or trial participant for Apogepha, Astellas, Bayer, Duchesnay, GlaxoSmithKline, Ferring, Lilly, Pfizer, and Recordati. Peter Anderson has been consulting for Ferring Pharmaceuticals A/S. Robert Wood has been consulting for Ferring Pharmaceuticals A/S. Tove Holm-Larsen has been consulting for Ferring Pharmaceuticals A/S.

AUTHOR CONTRIBUTIONS

M. Oelke: Data analysis, drafting, critical revision and approval of article. P. Anderson: Protocol/project development, data collection and management, critical revision and approval of article. R. Wood: Data analysis, critical revision and approval of article. T. Holm-Larsen: Protocol/project development, data analysis, drafting, critical revision and approval of article.

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