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ARTICLE

Percutaneous tibial nerve stimulation for idiopathic and neurogenic overactive bladder dysfunction: a four-year follow-up single-centre experience

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ABSTRACT

Objective: Overactive bladder (OAB) affects hundreds of millions of people worldwide and has significant detrimental effects on quality-of-life. Percutaneous tibial nerve stimulation (PTNS) is endorsed in the European guidelines of Urology as second-line therapy – on par with pharmacological treatment for women with OAB.

Methods: This prospective cohort study describes our clinical experience with PTNS in a daily outpatient clinic, on a consecutive cohort. The cohort of 116 patients was mixed; including both men and women with idiopathic (iOAB) and neurogenic (nOAB) overactive bladder. Patients were treated with a 12-week course of PTNS followed by monthly maintenance treatment. Data were collected during 4 years.

Results: The most common indication for PTNS was OAB with urge incontinence (53%) followed by OAB-dry and nocturia (both 16%). One hundred and ten (95%) patients completed follow-up and 68 patients (62%) continued to maintenance treatment. A total of 68 patients reported an effect on PROM, BD and ICIQ-OAB, which is the same 62% that continue in maintenance PTNS. A significant decline was seen in overall ICIQ-OAB score, with a median drop from 87 to 54, a significant decline in overall frequency and nocturia on bladder diary and a shift in pad test group in 19% of the incontinence patients.

Conclusion: PTNS shows an equally significant effect on men as well as women both in the iOAB and nOAB subgroups in a daily outpatient clinic. In our opinion, PTNS should be a standard treatment option available at urological departments, where both men and women in both sub-groups could benefit from treatment. Further randomized studies focusing on men with iOAB are needed.

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OAB; PTNS; urinary incontinence; PROM

Introduction

Overactive bladder (OAB) affects hundreds of millions of people worldwide and has significant detrimental effects on quality-of-life. The prevalence of OAB increases with age, comorbidity (diabetes, neurological diseases), cognitive and functional deficits, alcohol intake, obesity, lower urinary tract diseases (LUTD) and urinary tract infection [1,2]. The prevalence of urinary incontinence (UI) in women increases with age and up to 39% of women aged above 60 years experience daily urgency UI. Men have lower prevalence, with as much as 11% of men older than 65 years experience daily urgency UI episodes [1,2].

Recommended first-line treatment for OAB includes behavioural therapy, bladder training and pelvic floor muscle training combined with pharmacological therapy to minimize symptoms and improve quality-of-life. Percutaneous tibial nerve stimulation (PTNS) is endorsed in the European guidelines of Urology (EAU) as second-line therapy for women with iOAB before third-line treatment options including intravesical onabotulinumtoxinA injections (Onabot) and sacral neuromodulation (SNM) [3]. The American Urological Association (AUA) does not distinguish between men and women with iOAB and the guidelines recommend PTNS as a third-line treatment on par with Onabot and SNM [4,5].

In the last 15 years, percutaneous tibial nerve stimulation (PTNS) has been shown to be a safe and effective treatment for OAB. PTNS has demonstrated efficacy in the treatment of idiopathic OAB in sham-controlled studies [6]. In women, the effect of PTNS is compatible with the effect of antimuscarinic treatment, but with a superior side-effect profile [3,7]. In men, there is insufficient evidence to conclude efficacy [3]. Patients with a neurological disease have shown a favourable response on the same parameters as idiopathic OAB patients, such as a reduction in daytime frequency, nocturia, number of incontinence episodes, suppressed detrusor overactivity, as well as treatment satisfaction and QoL [8–11].

PTNS was approved for the treatment of OAB in 2000. Electric impulses stimulate the sacral micturition centre via afferent fibres of the tibial nerve (S2–S4). It is a less invasive form of neuromodulation therapy than SNM. It requires a motivated patient to return weekly for 12 weeks and every 3–4 weeks in the following months to years [7,12].

This study aims to describe the clinical experience with PTNS in a daily outpatient clinic, on a consecutive cohort.

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The cohort represents the general patients we meet every day. The cohort is composed of mixed general urology patients. Men and women older than 12 years with idiopathic or neurogenic bladder dysfunction are included in this Danish cohort.

Materials and methods

This is a prospective observational cohort study of patients treated with a 12-week course of PTNS followed by monthly maintenance treatment. Data were collected at our institution over 4 years between 2016 and 2020.

Inclusion criteria

Patients referred to the Department of Urology with LUTD were investigated according to standard LUTD guidelines. If symptoms were predominantly OAB they were offered PTNS treatment as a second-line treatment after or instead of antimuscarinics or Mirabegron. Patients over 12 years were included, of both sexes and with both idiopathic OAB (iOAB) and neurogenic OAB (nOAB). We included more broadly than the guidelines recommend as several studies have shown a good effect on patient groups other than iOAB.

Exclusion criteria

Pregnancy, breastfeeding, implanted pacemakers and brain stimulators.

Evaluation

History of prior treatment was recorded at study inclusion. OAB symptoms were assessed at baseline, 6 weeks after treatment and after the induction course of PTNS (12 weeks) using a 3-day bladder diary (BD) and The International Consultation on Incontinence Questionnaire on OAB (ICIQ-OAB), a validated four-item questionnaire used to assess OAB symptoms. Patients' use of medicine and prior medical history was recorded. For assessment of patient overall treatment satisfaction, we used patient-reported outcome measure (PROM) using a 4-point reporting scale from 1 = 'worsening', 2 = 'no effect', 3 = 'improvement' to 4 = 'significant improvement'.

Patients who had subjective success, defined as a PROM responders score of 3 or 4 (improvement and significant improvement) and showed an effect on bladder diary, defined as a decline in day frequency and nocturia and effect on ICIQ-OAB (symptom score decline), were offered continued maintenance treatment every 4–6 weeks.

Patients not experiencing improvement after 12 weeks or who discontinued the maintenance treatment were offered alternative treatment for managing the OAB symptoms.

In the maintenance group, we recorded treatment intervals, the reason for drop-out and the need for burst treatment because of a waning effect.

PTNS methods

PTNS was applied according to Govier et al. [13]. The tibial nerve is located just anterior to the Achilles tendon cephalad to the medial malleolus [14]. PTNS is performed by placing a 34-G needle 3–5 cm cephalad to the medial malleolus and posterior to the tibia, at 60° [15]. A grounding pad is placed on the bottom of the foot, after which a low-voltage stimulator is attached to the needle. Correct needle placement is confirmed by observing dorsiflexion of the big toe or fanning of the toes, as well as a patient-reported sensation on the bottom of the foot. Stimulation is performed at 0.5–9.0 mA amplitude at a fixed frequency of 20 Hz and a set pulse width of 200 μs, based on patient sensation, motor response, and comfort [7,15]. The induction treatment course consists of 12 consecutive weekly sessions, for 30 minutes per session.

Data analysis

The bladder diary (BD) scores and pad test values were calculated as mean values over 3 days. Treatment response was calculated as the difference in scores between week 12, week 6 and baseline (week 0) for all patients, with patient divided into sub-groups and regarding different sub-scores.

Statistic

Patient data was stored in SharePoint 2019. Statistical analysis was performed using R statistical software v.4.1.0 (R Foundation for Statistical Computing, Vienna, Austria). Wilcoxon rank-sum test was used for comparing two groups and the Kruskal-Wallis test for comparison of multiple groups. p values < 0.05 were considered statistically significant. Continuous variables are reported as median and interquartile range (IQR).

Results

A total of 116 patients were included over the 4 years. The group included 45 men and 71 women. Baseline characteristics for different subgroups are listed in Tables 1 and 2. The most common indication for PTNS was OAB with urgency UI (OAB-wet 53%) followed by OAB-dry and nocturia (both 16%).

Prior to PTNS treatment one or more of the following first-line treatments had been attempted; behavioural modification, anticholinergics 87% (previously used by 75%, 12% still using), mirabegron by 95% (previously used by 73%, 22% still using), specialized pelvic floor physical therapy (35%) and local estrogen vagitoria (55% of women). Three women were primarily diagnosed with mixed incontinence. The stress incontinence in this three women was less pronounced than the urge component. They were all treated with vaginal estrogen and pelvic floor therapy during PTNS, with satisfactory follow-up.

Ninety patients (78%) had a urodynamic examination before the start of PTNS. Urodynamics was not a requirement

Table 1. Characteristics grouped by diagnosis.

	Idiopathic ($n = 59$)	Neurogen ($n = 57$)
Age (years)		
median (IQR)	65.88 (48.08–76.43)	61.12 (49.47–68.38)
min	14	19
max	91	82
Sex *n* (%)		
Female	35 (59.32%)	36 (63.16%)
Male	24 (40.68%)	21 (36.84%)
Primary symptom		
Urge (OAB-Wet)	23 (38.98%)	39 (68.42%)
Urge + frequency (OAB-dry)	13 (22.03%)	6 (10.53%)
Nocturia	12 (20.34%)	6 (10.53%)
Frequency	4 (6.78%)	2 (3.51%)
Urgency	2 (3.39%)	2 (3.51%)
Mixed incontinence (stress + urge)	2 (3.39%)	1 (1.75%)
Bladder pain syndrome	3 (5.08%)	0 (0.00%)
Dysuria	0 (0.00%)	1 (1.75%)
PROM		
Worsening	0 (0.00%)	1 (1.75%)
No effect	22 (37.29%)	23 (40.35%)
Improvement	13 (22.03%)	7 (12.28%)
Significant improvement	22 (37.29%)	25 (43.86%)
Did not complete treatment	2 (3.39%)	1 (1.75%)

Table 2. Characteristics grouped by gender.

	Female - Idiopathic ($n = 35$)	Male - Idiopathic ($n = 24$)	Female - Neurogenic ($n = 36$)	Male - Neurogenic ($n = 21$)
Age (years)				
Median (IQR)	58.48 (44.37–74.09)	74.27 (50.83–78.73)	56.27 (44.37–64.31)	67.77 (61.12–72.76)
Min	14	19	19	52
Max	91	88	77	82
Primary symptom				
Urge incontinence (OAB-wet)	13 (37.14%)	10 (41.67%)	24 (66.67%)	15 (71.43%)
Urge + frequency (OAB-dry)	7 (20.00%)	6 (25.00%)	5 (13.89%)	1 (4.76%)
Nocturia	8 (22.86%)	4 (16.67%)	4 (11.11%)	2 (9.52%)
Frequency	2 (5.71%)	2 (8.33%)	1 (2.78%)	1 (4.76%)
Urgency	0 (0.00%)	2 (8.33%)	0 (0.00%)	2 (9.52%)
Mixed incontinence (stress + urge)	2 (5.71%)	0 (0.00%)	1 (2.78%)	0 (0.00%)
Bladder pain syndrome	3 (8.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)
Subjective treatment effect				
Worsening	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)
No effect	16 (45.71%)	6 (25.00%)	14 (38.88%)	9 (42.86%)
Improvement	8 (22.86%)	5 (20.83%)	4 (11.11%)	3 (14.29%)
Significant improvement	10 (28.57%)	12 (50.00%)	17 (47.22%)	8 (38.10%)
Did not complete treatment	1 (2.86%)	1 (4.17%)	0 (0.00%)	1 (4.76%)

before instigating PTNS. However, urodynamic testing is often used as a guide when counselling patients and for matching patient expectations.

Three patients did not complete 12 weeks of treatment – two stated logistic reasons and one experienced mental challenges. Of the 113 patients, 110 patients (97%) completed follow-up. Sixty-eight continued treatment (maintenance), which is 62% overall.

From PROM the overall effect was 61%, 67 of the 110 patients stated 'improvement' or 'significant improvement' for subjective success. Data are shown in Tables 1 and 2. One patient reported 'no effect' in PROM but an effect in BD and ICIQ-OAB (decline in frequency and symptom score) and for that reason continued in maintenance with good response in the observation period. A total of 68 (67 + 1) patients reported an effect on PROM, BD and ICIQ-OAB, which is the same 62% that continue in maintenance PTNS.

Comparison of ICIQ-OAB score at baseline, 6 weeks and 12 weeks treatment shows an effect with a significant decline in symptom score from 87 (IQR = 64–114), 64 (IQR = 42–90) and 54 (IQR = 28–82), respectively ($p = 3.81e\text{-}10$) (Table 3). Figure 1 shows the difference when the group is divided by gender and OAB subtype (iOAB and nOAB). All groups demonstrated a significant decline in symptom score, with the greatest effect in the female nOAB group. The effect was significant in all ICIQ-OAB sub-scores – daytime frequency, night-time (nocturia), urgency and incontinence (Figure 2).

Table 3. Overall change in ICIQ-OAB scores.

Time	ICIQ (median)	25 percentile	75 percentile
Baseline	87	64	114
6 weeks	64	42	90
12 weeks	54	28	82

Overall ICIQ-OAB *p*-value for three different groups.
Kruskal-Wallis test. *p*-value = 3.8e-10.

Our cohort is heterogeneous with several subgroups. The patient population included three women under 18 years at the time of initiation of PTNS. All with urge incontinence. One with a neurological cause in the form of cerebral palsy, one with enuresis and one with a psychiatric history. All

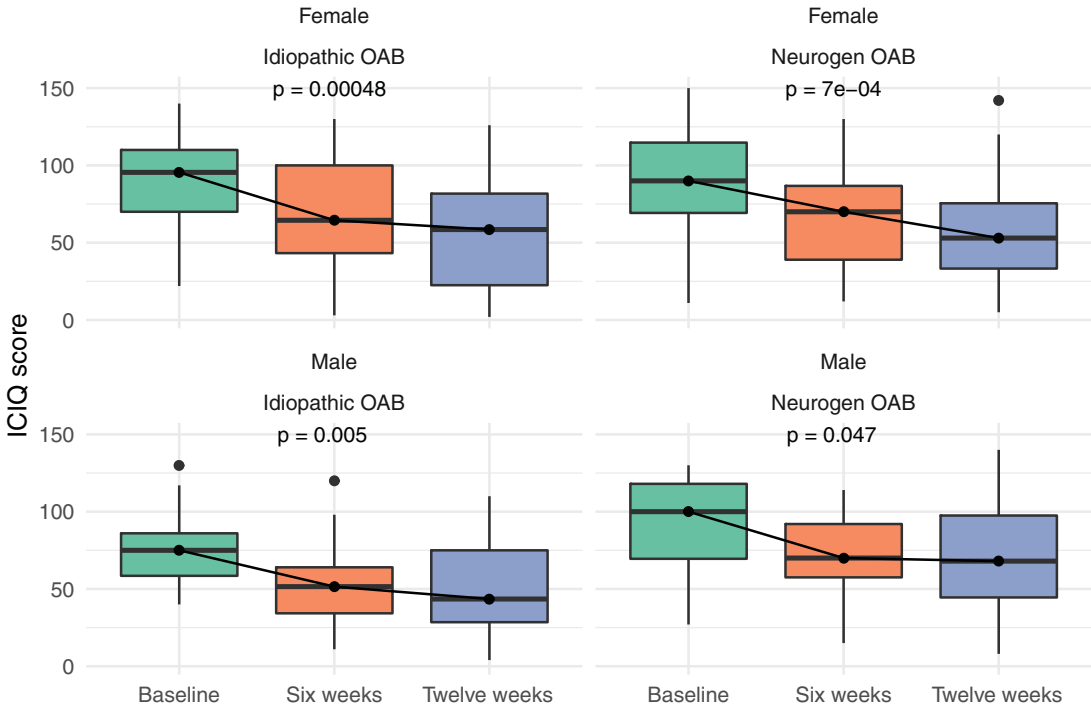

Figure 1. International Consultation on Incontinence Questionnaire (ICIQ) score at different time intervals. Grouped by gender and primary diagnosis. *p*-values Kruskal-Wallis test.

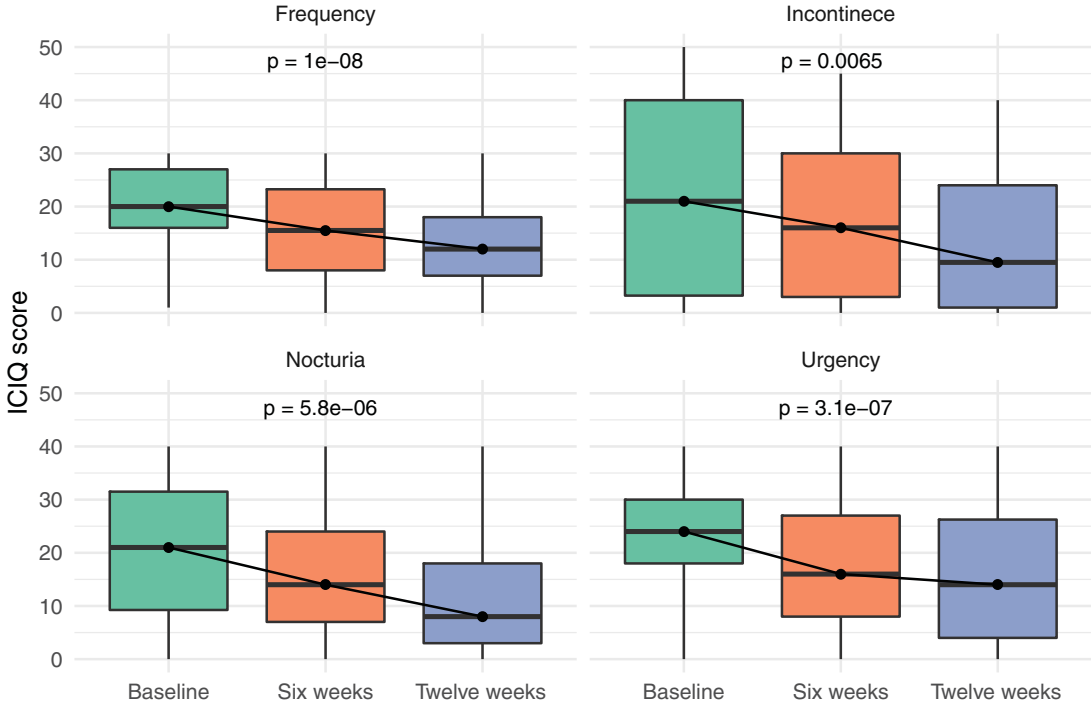

Figure 2. International Consultation on Incontinence Questionnaire (ICIQ) score at different time intervals. Different subscore daytime, nighttime, urge and incontinence. *p*-value Kruskal-Wallis test.

indicate clear improvement after 12 weeks of PTNS and they all have a decrease in symptom ICIQ-OAB score from 88 to 30. Three women were included with primary Bladder Pain Syndrome (BPS). One indicated significant improvement on the urge symptoms and thus also less pain in the bladder. The other two noticed no difference.

The neurogenic OAB subgroup is also very heterogeneous. Out of 57 patients classified with a neurogenic cause of OAB, there are 23 patients (40%) with MS and nine (16%) with Parkinson's disease. The remainder included patients had late effects after lumbar spine surgery, pelvic trauma, syringomyelia, cerebral palsy, late effects after spinal cord infections, Myasthenia gravis, developmental abnormalities in the genitalia, etc. The largest and most homogeneous group was the MS subgroup. Of these, 17 (74%) report a sufficiently satisfactory effect on symptom score and in PROM that they

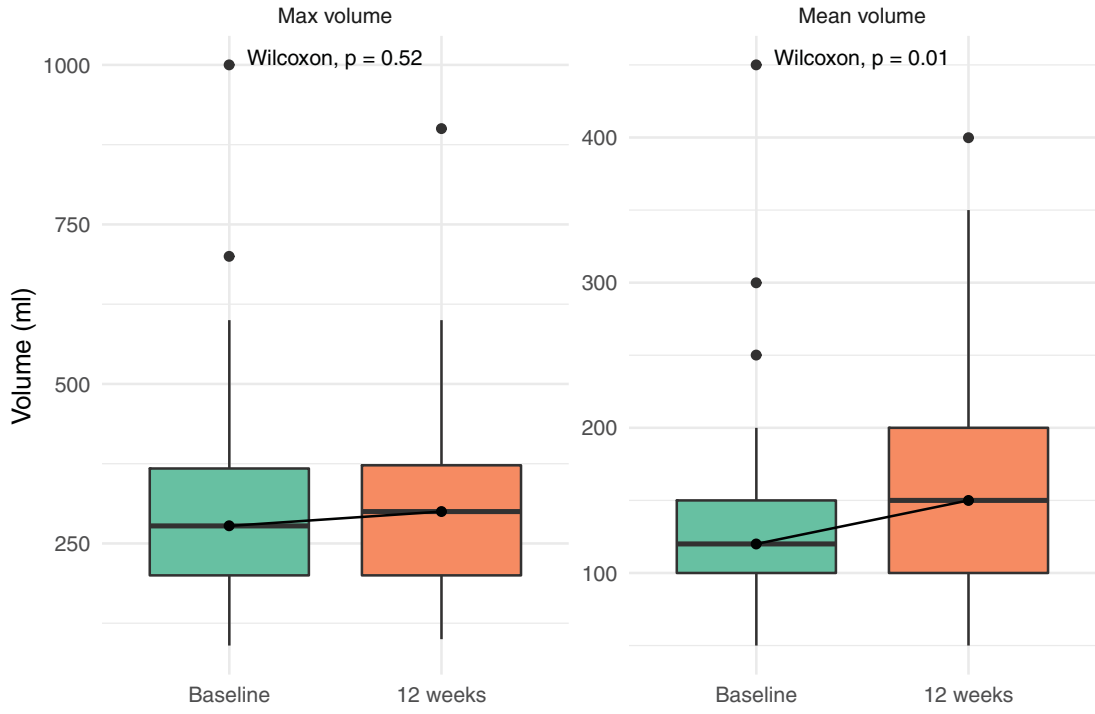

Figure 3. Mean and maximum voiding volume at baseline and treatment completion.

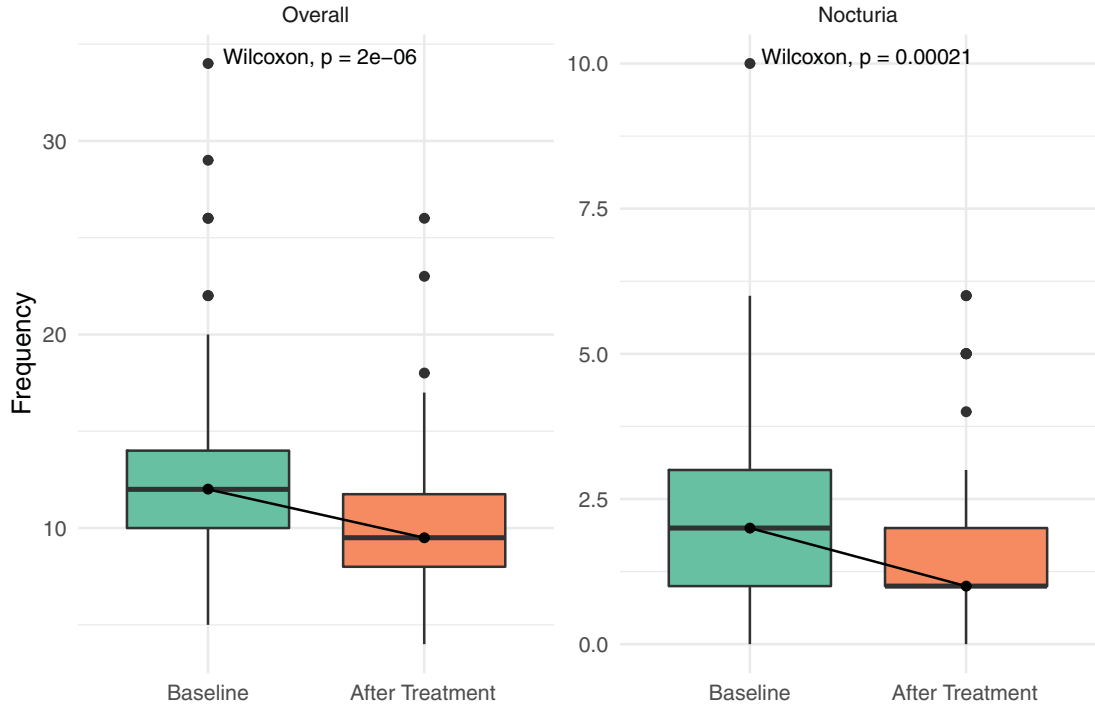

Figure 4. Voiding diary frequency.

continue PTNS maintenance treatment. Thirty-six patients used either antimuscarinics or Mirabegron therapy at the onset of PTNS. Twenty-four (67%) of the 36 continued in maintenance PTNS as an expression of the good effect of the combination treatment. We do not have data on how many patients have stopped the medical treatment due to the effect of PTNS.

Comparing the voiding chart at baseline and treatment completion (12 weeks), we saw a significant change in mean volume, but no significant change in maximal volume (Figure 3). In frequency, the data in Figure 4 shows a significant decline in both overall frequencies and nighttime (nocturia).

In Table 4 and Figures 5 and 6 data from the pad weight test is shown. At the end of treatment, nine patients were dry, shifting from the group less than 20 g/day to completely dry. Overall 21 patients (19%) shifted one or two groups down regarding pad weight test before and after treatment.

Table 4. Leakage amount = 19% shift one or two groups down regarding pad weight test before and after treatment.

Change in pad-test	*n*
< 20 g to 0 g	9
20–100 g to < 20 g	8
> 100 g to 20–100 g	3
> 100 g to < 20 g	1

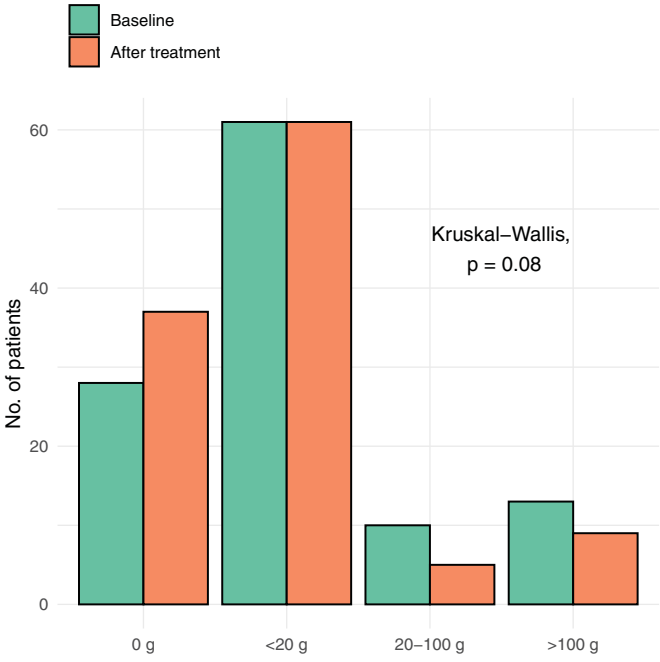

Figure 5. Average leakage amount at baseline and treatment completion.

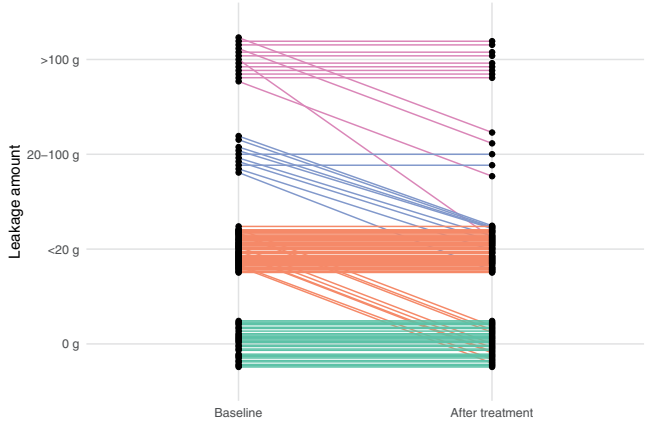

Figure 6. Average leakage amount at baseline and treatment completion.

Table 5. Reason given for ending treatment.

Reason	*n*
A decline in efficiency – shift to OnaBot treatment	15
Satisfied and attempting treatment break	3
Logistics or relocation	2

One adverse event was reported: The patient complained of ongoing pain in the arch. Further investigations showed no muscular or neurological damage. No other adverse events were observed during the 4 years.

At the end of the observation period, 74% ($n = 50$) of the 68 patients who continued treatment (maintenance) were still undergoing monthly PTNS treatment; 58% ($n = 29$) of patients have received treatment for more than 1 year, and 16% ($n = 8$) have continued treatment for more than 2 years. Twenty patients discontinued their maintenance treatment within the first year. The reasons are listed in Table 5.

Discussion

This prospective observational cohort study was open for all patients with voiding symptoms, predominantly OAB, at a single-centre clinical urological department. PTNS demonstrate a significant favourable effect on the day- and night-time frequency and urgency following the findings of previous studies [8,13,15–19]. Furthermore, we recorded an improvement on incontinence level (pad weight) for 19% of the patients, which has a tremendous impact on the quality-of-life [20–23]. PTNS treatment is well tolerated and can be offered to a wide range of urology patients, including men and women of all ages with equally good effect, as shown in Table 2 and Figure 1. Both patients with idiopathic and neurogenic OAB have a significant effect on OAB symptoms, as shown in other studies [8,10,12,17,24]. Some small studies include nOAB men [8,11], but not many studies are focusing on the subgroup of iOAB-men [10,25] and the effect on their OAB symptoms. The current EAU recommendations describe insufficient evidence to conclude efficacy [3]. In this study, we have 116 participants, with men accounting for 39%. We find an equally significant effect in men as well as women, in both iOAB and nOAB subgroups. Still there is a need for randomized studies focusing on the subgroup of iOAB men. There are questions to be investigated for men, especially because of their different lower urinary tract anatomy and the confluence of infra-vesical obstruction. Nevertheless, this study indicates that the urologists must bear in mind the symptom-based treatment for men with predominantly OAB (reservoir) symptoms and consider PTNS.

The subjective success rate was 62% after the 12-week completion – 68 patients continued in maintenance treatment. This finding is comparable to existing trials and single-centre studies [12,15,16,19,25–27]. Our study shows the continuous effect of maintenance treatment for several years. Seventy-four per cent of the patients who continued in maintenance treatment are still receiving the treatment every 4–6 weeks (extended subjective success). Again, this is on par with other studies [11,12,15,28] including STEP-trial [26] and OrBit [29] with data for 3-year and 1-year maintenance, respectively. Longer therapy intervals after the initial 12 weekly treatments may contribute to long-term patient compliance and lessen the long-term economic impact on the healthcare system.

Compliance for both the 12 weeks – and maintenance treatment is much higher than compared to peroral treatment. Several studies have reported mean time to discontinue treatment after 60–130 days for antimuscarinics and 140–170 days for Mirabegron [7,30–32]. No side-effects from long-term treatment were observed – which equals other studies. We expect that better compliance is because of the effectiveness of the treatment, the close relation to the

Urological department and the positive side-effect profile. It outweighs the travel distance for maintenance treatment. It would be interesting to perform a trial where the treatment was performed by the patient at home. At present, this is not economically feasible, but we expect it to be the future way of treatment. Also, we expect to implement the continual tibial stimulators in the near future as well [33–35].

PTNS treatment is a good alternative treatment for a large group of patients with OAB. It should be offered right after or at the same time as peroral treatment – as a second-line treatment as recommended in the EAU guidelines. PTNS could be considered for refractory OAB before the more invasive Onabot or SNM treatment. Although PTNS is not as effective, it is durable, less invasive, reversible, safe and without side-effects [36]. Many patients with OAB are elderly, fragile or have multiple medical comorbidities that preclude the option of surgery. PTNS may be the only option for treatment and in our opinion a treatment option which should be available at urological departments.

The limitations of the study are primarily a lack of control group. A control group to limit the placebo effect could be in the form of placebo treatment on the ward or home treatment where the patient does not have regular contact with the treating nurse (limited nursing-effect).

Our cohort is very heterogenic and data would probably have been even better with a more homogeneous cohort. The choice of this heterogeneous group was made to reflect the daily life of a urological outpatient clinic, where patients do not necessarily fit clear diagnostic criteria. From the results section, the more specific data extracts for the individual subgroups can be used for guidance in the individual patient.

Due to the current COVID-19 situation some patients have had their maintenance treatment cycle interrupted. We manage to follow-up every single patient. Some patients have chosen to use the interruption to a longer treatment break. To kick-start the maintenance treatment we are using personally selected methods including 3–5-times boosting, prolonged break (extended subjective success) or restarts the 12 weeks of treatment-cycle. Results from these reinduction treatments are pending.

Conclusion

PTNS treatment is an effective and well-tolerated second-line treatment for OAB. This study shows an equally excellent significant effect on men as well as women, both in the iOAB and nOAB subgroup. In our opinion, PTNS should be a treatment option available at urological departments, where both men and women in both subgroups could benefit from the treatment. There is a need for randomized studies focusing on the subgroup of iOAB men.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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