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Long term safety, continuation rates and subjective and objective success of Posterior Tibial Nerve Stimulation for Overactive Bladder

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ABSTRACT

Introduction: Posterior tibial nerve stimulation (PTNS) is currently offered to patients with refractory overactive bladder (OAB). We aim to evaluate the efficacy, safety and long-term continuation of PTNS over 11 years.

Methods: We conducted a retrospective cohort study on all patients who underwent PTNS from 2012 to 2023. The primary outcomes were change in urinary frequency over 24 hours, maximum voided volume (MVV), number of episodes of urgency urinary incontinence (UUI) and patient perception of intensity of urgency scale (PPIUS).

Results: We identified 81 patients. 83% of patients completed 12 treatments of PTNS, and 54% of those that did not complete their full course of treatment stated that this was due to inefficacy. 33% of patients underwent PTNS 'top ups' as needed. Only 1 patient reported an adverse effect of musculoskeletal leg pain.

28% of patients reported a subjective improvement of their symptoms by 50% or more. There was an average reduction in daytime frequency by 0.6 episodes ($p = 0.033$), an increase in MVV by 13mls ($p = 0.927$), a reduction in UUI episodes each day by 0.7 ($p = 0.008$) and a reduction in average PPIUS by 0.4 ($p = 0.024$).

Conclusion: PTNS remains a safe treatment option for patients with refractory OAB with evidence of both subjective and objective improvement to most symptoms. The majority of our patients completed a 12-week cycle but only 1 in 3 chose to have further PTNS 'top ups' and only 1 in 5 are continuing with PTNS for long term management of their OAB.

1. Introduction

Overactive bladder (OAB) is defined by the International Continence Society as urinary urgency, with or without urgency urinary incontinence (UUI), usually with increased daytime frequency and nocturia, in the absence of infection or other obvious pathology [1]. The pathophysiology of urinary urgency and development of OAB is yet to be fully understood [2,3]. In 44%–69% of patients with OAB symptoms, detrusor overactivity (DO) can be identified on urodynamic studies (UDS) [3]. OAB is estimated to affect 546 million individuals worldwide and can have a profound effect on a woman's physical, financial, and psychosocial wellbeing [4–6].

Initial conservative treatment of OAB includes weight loss in those with a raised BMI, modification of fluid and caffeine intake, bladder retraining (BRT) and pelvic floor muscle training (PFMT) [7]. Subsequent pharmacological treatment includes the use of anticholinergics [7]. In those whom anticholinergic use is contraindicated, poorly tolerated, or ineffective, a beta-3-adrenoreceptor agonist such as mirabegron can be used [8–10]. Medical therapy of OAB has high discontinuation rates of almost 80% at 12 months, due to side effects and inefficacy, as well as concerns regarding cognitive impairment [11,12]. Women who suffer from genitourinary symptoms of the menopause (GSM) and OAB symptoms may also benefit from the use of vaginal oestrogens, due to the impact of oestrogen deficiency on the lower urinary tract [13,14].

The use of posterior tibial nerve stimulation (PTNS) varies across different guidelines and treatment algorithms. Current National Institute for Health and Clinical Excellence (NICE) guidance suggests that in women whom non-surgical management has had inadequate effect and who decline treatment with intravesical botulinum toxin A injections or sacral nerve stimulation (SNS), PTNS should be offered after local multidisciplinary team (MDT) review [15]. PTNS is also part of the treatment algorithm for OAB in the European Association of Urology (EAU) guidance, as well as the American Urological Association (AUA) guidance [16,17]. Women may decline treatment with either Botox injections or SNS due to their more invasive nature, including the risks of recurrent UTI or self-catheterisation with Botox or implant revision with SNS [18,19].

PTNS involves stimulation of the afferent fibres of the posterior tibial nerve (L4-S3) which can be accessed by inserting a 34-gauge

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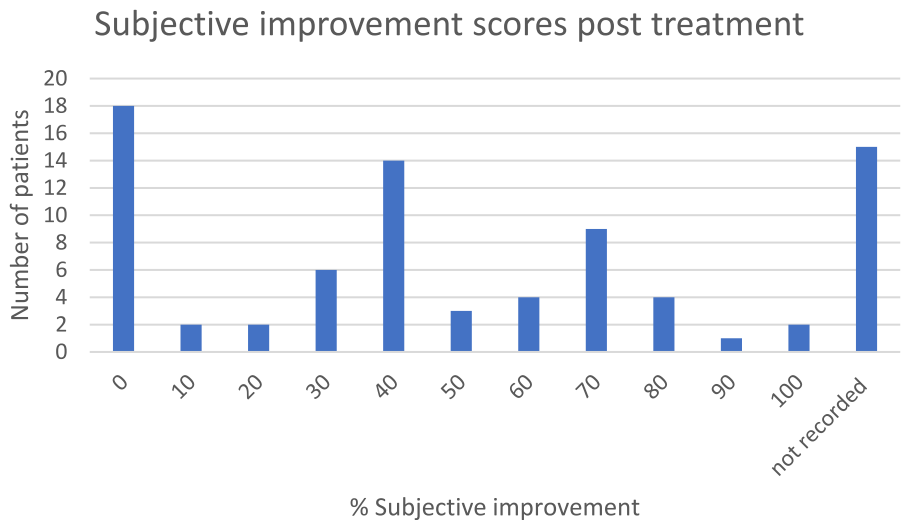

Fig. 1. Subjective improvement of symptoms post treatment.

needle 3–5 cm proximal to the medial malleolus. The method of action is thought to be secondary to neuromodulation of the sacral nerve plexus [20]. The use of PTNS has been established in the United Kingdom since 2010 with a low side effect profile [20]. Absolute contraindications for PTNS treatment are those that already have an implantable defibrillator or pacemakers, pregnancy or those planning a pregnancy and patients with coagulopathy. There is a lack of long-term data regarding continuation rates and the safety or efficacy of 'top ups' [15].

We aimed to evaluate the efficacy, safety, and long-term continuation rates of PTNS in our tertiary hospital over an 11-year period.

2. Methods

We conducted a retrospective cohort study of all women who underwent PTNS at our tertiary referral centre for urogynaecology from 2012 to 2023.

Patient medical records were reviewed to determine age, conservative management including BRT with our specialist urogynaecology nurses, physiotherapy as well as prior medical management. In our unit, all patients presenting with OAB symptoms have UDS, which includes uroflowmetry, subtracted multichannel cystometry and pressure-flow studies. Pre-PTNS UDS results including the presence of detrusor overactivity, bladder capacity and highest detrusor contraction were extracted. Bladder diaries and patient reported outcome measures including the King's Health Questionnaire (KHQ), a validated tool assessing the impact of urinary incontinence on quality of life [21], were obtained pre and post treatment. Total number of PTNS treatments including top-ups as well as any referral for alternative management of OAB were also noted.

The primary outcomes were (i) change in urinary frequency over 24 h, (ii) change in maximum voided volume (MVV), (iii) episodes of urgency urinary incontinence (UUI) and (iv) patient perception of intensity of urgency scale (PPIUS). The PPIUS is a validated scale measuring the severity of urgency during patient completion of a bladder diary, as demonstrated in Table 1 [22]. Secondary outcomes were quality of life scores, subjective success rates and adverse events.

In our unit, all patients with refractory DO who are suitable for second line treatment are offered PTNS or intravesical botulinum toxin A. The device we use is Urgent PC by Laborie. PTNS is administered by urogynaecology specialist nurses. Patients have a weekly 30-min session for 12 weeks, and then attend for tops ups as needed, at a maximum frequency of one top up every two months.

Statistical analysis was performed using the IBM SPSS® v28 software. Descriptive statistics were used for the parametric data. Due to the non-parametric nature of the pre and post intervention bladder diaries and KHQs, the Wilcoxon Signed Rank Test was used for analysis.

3. Results

We identified 95 patients, of whom 81 had available medical records. The mean age was 59 (SD = 12.80). The median length of follow up was 26 months (range 1–138).

Pre-PTNS Urodynamic findings

95% (n = 77) of patients had detrusor overactivity (DO) diagnosed on urodynamics. The median bladder capacity was 400 mls (range 100–600 mls). 19% (n = 15) also had a reduced bladder capacity (maximum cystometric capacity <350 mL) and 11% (n = 9) had low bladder compliance (an increase of 3 cm H20 per 100 mL of bladder filling) [23]. The median value of the highest recorded detrusor contraction was 35 cm H20 (range 9–146 cm H20) with 27% (n = 22) having 'high pressure DO' diagnosed as a detrusor contraction measuring greater than or equal to 40 cm H20.

Medical management

88% (n = 84) of patients had PFMT and 91% (n = 86) had BRT. All patients had failed on medical therapy, with a median number of different medications trialled being four (range 1–6). 86% (n = 82) of patients proceeded with PTNS due to inefficacy of medical therapy, i.e., minimal or no change to symptoms reported at follow up, and 14% (n = 13) due to intolerability.

Baseline bladder diary/KHQ scores

At baseline, patients reported a median of 8 daytime voids, 1 night-time void, 2 daily episodes of UUI and a PPIUS of 3.

PTNS treatment

83% of patients completed 12 treatments of PTNS. For the 17% of patients who did not complete their 12 treatments, 54% (n = 9) stated that this was due to inefficacy, 24% (n = 4) felt unwell due to unrelated reasons and 24% (n = 4) did not attend their appointment.

Subjective improvement

28% of patients (n = 23) reported a subjective improvement of their symptoms at the end of their treatment by 50% or more. The median subjective improvement was by 40%, with a range of 0%–100%. The frequency of subjective improvement scores are illustrated in Fig. 1.

Objective improvement

54 patients had completed bladder diaries and KHQs pre and post treatment.

A 'responder' to treatment for OAB has varying definitions in the literature [24,25]. Based on previous ICS discussions, we have calculated the success of treatment based on the following classifications, as documented below and illustrated in Fig. 2.

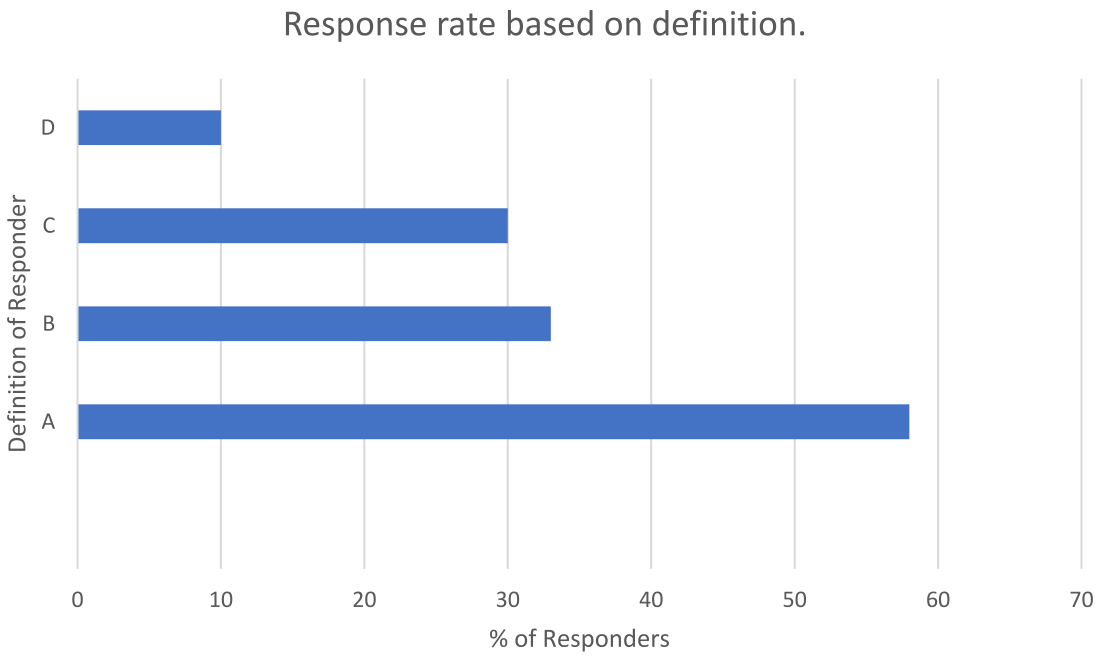

Fig. 2. Response rate based on definition.

Table 1
PPIUS definitions.

PPIUS score	Definition
0	No urgency: I felt no need to empty my bladder but did so for other reasons.
1	Mild urgency: I could postpone voiding for as long as necessary without fear of wetting myself.
2	Moderate urgency: I could postpone voiding for a short while without fear of wetting myself.
3	Severe urgency: I could not postpone voiding but had to rush to the toilet in order not to wet myself.
4	Urgency incontinence: I leaked before arriving at the toilet.

Table 2
Changes in voiding pre and post PTNS treatment.

Bladder diary variable	Pre-treatment median (IQR range)	Post-treatment median (IQR range)	P value (Wilcoxon Signed Rank Test)
Daytime urinary frequency	8 (5.5–9.5)	7 (6–9)	**0.033**
Night-time urinary frequency	1 (0–2)	1 (0–2)	0.837
Maximum functional capacity (mls)	300 (252.5–400)	340 (250–400)	0.927
UUI episodes each day	2 (0.475–3)	1 (0–3)	**0.008**
PPIUS	3 (2–3)	2 (2–3)	**0.024**

A. Those with a reduction of 50% or more in their number of voids over eight in a 24 h period = 58%.
B. Those that have 'top ups' following their course of treatment = 33%.
C. Those with a reduction of 50% or more in their episodes of UUI = 30%.
D. Those with a reduction of 50% or more in their episodes of daytime urinary frequency = 10%.

There was a statistically significant reduction in daytime frequency by 1 episode (p = 0.033), no change to night-time urinary frequency (p = 0.837), an non-statistically significant increase in MVV by 40 mls (p = 0.927), a statistically significant reduction in UUI episodes each day by 1 (p = 0.008) and a statistically significant reduction in average PPIUS by 1 (p = 0.024) (Table 2).

The mean reduction in total KHQ scores following treatment was by 5.42 points (p = 0.03). There was a significant reduction in scores post treatment for the following domains: general health perception, incontinence impact, role limitations, personal relationships, emotions, sleep and total KHQ scores (Table 3).

The minimally clinically important difference (MCID) for the KHQ has been described as a reduction in 5–10 points in each domain [26]. This was most frequently observed in the incontinence severity domain, by a total of 13 patients (24%). The changes across the other KHQ domains are documented in Table 4.

Adverse events

Only one patient (1%) reported an adverse effect of musculoskeletal leg pain.

Follow up

33% of patients underwent PTNS 'top ups' as needed, after completing their course of initial treatment, with the median number of top ups being 3 (range 1–45).

22% of patients (n = 18) are continuing with ongoing PTNS. 22% of patients (n = 18) were referred for alternative management options for refractory OAB, including SNS and intravesical Botulinum Toxin, and 14% (n = 11) reverted to medical therapy. 42% (n = 34) were lost to follow up.

4. Discussion

This study found that after a 12-week course of treatment with PTNS, 28% of patients reported subjective success rates of 50% or more. There was also a significant reduction in daytime urinary frequency episodes, UUI episodes and PPIUS from baseline to 12 week follow up.

Table 3
Changes in KHQ scores pre and post PTNS treatment.

KHQ domain	Pre-treatment median (IQR range)	Post-treatment median (IQR range)	P value, z value (Wilcoxon Signed Rank Test)
General health perception	3.00 (2.00–3.00)	3.00 (2.0-0-3.00)	**0.041, −2.045**
Incontinence impact	4.00 (3.00–4.00)	3.00 (3.00–4.00)	**0.01, −3.288**
Role Limitations	6.00 (4.00–8.00)	6.00 (4.00–7.00)	**0.011, −2.532**
Physical limitations	13.00 (8.50–16.0)	11.00 (8.75–15.00)	0.534, −0.621
Social life	6.00 (2.00–10.00)	4.00 (2.00–9.00)	0.524, −0.636
Personal Relationships	10.00 (8.00–12.00)	8.00 (5.00–12.00)	**0.04, −2.864**
Emotions	6.00 (4.00–8.00)	6.00 (4.00–8.00)	**0.046, 1.995**
Sleep	13.00 (10.00–15.00)	12.00 (10.00–15.00)	**0.048, −1.978**
Incontinence severity	14.00 (10.00–17.50)	13.00 (8.50–18.00)	0.71, −1.807
Total score	73.00 (60.00–85.50)	67.50 (50.75)	**0.03, −2.976**

Table 4
MCID across KHQ domains post treatment.

KHQ domain	MCIDs observed, n (%)
General health perception	0 (0)
Incontinence impact	0 (0)
Role Limitations	0 (0)
Physical limitations	4 (7)
Social life	6 (11)
Personal Relationships	3 (6)
Emotions	1 (2)
Sleep	2 (4)
Incontinence severity	12 (24)

There was no difference in MVV or nocturia episodes but there was improvement in the majority of the KHQ domains.

When compared to existing literature, a prospective randomised controlled trial (RCT) in 2021 (n = 60 females) demonstrated that severity of incontinence, frequency, incontinence episodes, nocturia and quality of life were significantly improved in those who had PTNS with bladder retraining compared to those who had bladder retraining alone (P<0.0167) [27]. Another RCT in the United States of America who enrolled 220 patients with OAB to PTNS (n = 86 females) or a sham group (n = 88 females) showed that 54.5% patients who had PTNS had a marked or moderate improvement to their symptoms with no significant adverse effects, compared to 20.9% in the sham group [28]. Interestingly, 29 of these PTNS patients completed a three year follow up, and 77% of them maintained either a marked or moderate improvement in their symptoms [29]. The findings in our study show a similarly low rate of complications, however, we only assessed subjective and objective cure rates at 12 week follow up.

When comparing PTNS treatment to medical therapy, a multicentre study included 100 patients who were randomised to treatment with tolterodine or PTNS [30]. Those treated with PTNS had a statistically significant higher subjective improvement to their symptoms, although there was no demonstrable difference in objective outcomes such as frequency of voids, urgency scores of episodes of UUI. PTNS may also be an efficacious alternative in older populations, where anticholinergic burden is associated with an increased risk of cognitive impairment and all-cause mortality [31].

Although post treatment bladder diaries in our cohort showed a significant reduction in daytime urinary frequency episodes, UUI episodes and PPIUS, it is important to highlight that clinically, these represent a reduction in PPIUS by one as well as daytime frequency and UUI by one episode. It is important to consider whether these changes will correlate with a clinical significance to all patients.

There is also marked heterogeneity in the definition of treatment 'success' or 'response' in the literature. A systematic review performed in 2013 showed that the majority of studies use symptom-based definitions or patient-reported outcome measures (PROMs) [32]. The majority of symptom-based definitions of success were an improvement of 50%–100%, usually in episodes of UUI. Other treatments of success as discussed by Payne et al. are based on the ICS definition of OAB, and include the following definitions: (i) a reduction by half or more in all baseline symptoms; (ii) a reduction by half or more in urgency and at least one other symptom; or (iii) resolution of urgency episodes and at least one other symptoms. Improvement of symptoms based on these definitions of 'treatment success' are usually associated with improvements in KHQ quality of life scores [25]. Difficulties in unifying treatment success include the variations in OAB severity and level of bother, which means that different patients have different levels of urgency or UUI [24]. There is also a difference in the impact that these symptoms have on a patient's quality of life, which means that different patients may opt for different treatments based on the reduction of specific symptoms — this is not explored in the current literature.

Although the majority of our patients completed a 12-week cycle, only 1 in 3 chose to have further PTNS 'top ups' and only 1 in 5 are continuing with PTNS for long term management of their OAB. This is also reflected in the study by Dorsthorst et al. in which 57% of patients continued with treatment beyond their 12 week course [33]. Of those that discontinued their treatment, greater than 40% did so due to logistical grounds, including distance of travel and time commitment of weekly sessions. The adherence of treatment in older adults is particularly poor mainly due to reduced mobility, frailty and logistical burdens [34]. These difficulties may be the reason for the high number of patients lost to follow up in our cohort. It is also important to consider that in the early stages of PTNS implementation, the delivery of PTNS was based in a few tertiary hospitals in London, so patients may have been more willing to travel a further distance to receive treatment. Once the number of departments with an established PTNS service had increased, some of our patients may have moved to more local units to continue with their ongoing care, and this may have contributed to our attrition rates. It is also important to consider the mobile nature of the London population and the impact that this has on health service delivery.

In a retrospective cohort study by Rachaneni et al. 103 patients who underwent PTNS treatment were assessed for factors predicting those that continued with 'top ups' after completing their treatment course. There were no differences in baseline demographics of the two groups, bladder diary parameters or co-existing urogynaecological co-morbidities including prolapse and stress incontinence [35]. There was a non-significant higher prevalence of mental health disorders in the non-responder group. Salatzki et al. analysed a cohort of 73 patients who had PTNS treatment for OAB, and found that patients that returned for maintenance treatment were more likely to be those that reported a significant improvement in their nocturia symptoms and their International Consultation on Incontinence Questionnaire on lower urinary tract symptoms (LUTS) related quality of life (ICIQ-LUTSqol) scores [36]. There is therefore heterogeneity in the literature regarding the factors that predict positive or negative response to PTNS,

and this is likely to have been influenced by the variation in definitions of treatment success, as discussed previously.

The novel development of implantable PTNS devices, such as BlueWind ™ and eCoin ™ which can be implanted under local anaesthetic, aims to alleviate the time and travel costs on patients undergoing traditional PTNS treatment due to the frequency of hospital appointments. These devices are not yet available outside of clinical trials. Other methods to improve uptake of neuromodulation for OAB includes the use of transcutaneous tibial nerve stimulation (TTNS), where patients can apply surface electrodes to the ankle, and undertake treatments at home.

The strengths of this study include the use of validated PROMs, which allow clinicians to measure success of treatment from the patient perspective. The study was performed in a single centre, which allows for homogeneous execution in a team thereby limiting different outcomes due to different practices. Few studies have ascertained the safety of repeated 'top ups' with PTNS, which we have been able to capture in this cohort. We acknowledge that the recommended manufacturer 'top up' intervals are monthly, however, we offer 'top ups' every two months due to clinical capacity.

The limitations of the study include its retrospective nature, which may allow for introduction of bias. There was also missing data for a proportion of patients, including for subjective and objective outcome measures, which can influence the precision of statistical analysis. A proportion of patients were lost to follow up, and as they have not been contacted to identify the reasoning for this, we cannot ascertain whether this was due to inefficacy of treatment, logistic difficulties or potential side effects, although this is unlikely. We did not assess the patients that continued using medication for their OAB, whilst undertaking treatment with PTNS, which may impact their response to treatment. The majority of patients offered PTNS in our unit have proven DO, which may also demonstrate a different response to women that have OAB symptoms and normal UDS.

5. Conclusion

PTNS remains a safe treatment option for patients with refractory OAB with evidence of both subjective and objective improvement to most symptoms and quality of life scores. The risk of significant adverse effect is low.

The majority of our patients completed a 12-week cycle but only 1 in 3 chose to have further PTNS 'top ups' and only 1 in 5 are continuing with PTNS for long term management of their OAB.

A standardised definition of treatment 'success' is required, in order to allow for valid comparison between treatment choices. Appropriate identification of patient expectations and treatment goals will aid patient counselling and allow them to make more informed choices regarding the management of their refractory OAB.

CRediT authorship contribution statement

R. Mohamed-Ahmed: Data collection, Manuscript writing/editing. **K.Y. Lor:** Data collection. **A. Taithongchai:** Data collection, Manuscript editing. **A. Rantell:** Project development, Manuscript editing. **G. Araklitis:** Project development, Manuscript editing. **D. Robinson:** Project development, Manuscript editing.

Declaration of competing interest

Mr Dudley Robinson reports personal speaker fees from Laborie, Abbvie, Astelles and Pierre Fabre during the conduct of the study. Dr Angie Rantell report personal speaker fees from Laborie during the conduct of the study. The other authors report no other conflicts of interest in this work.

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