

GENERATING NEW EVIDENCE OF EFFECTIVENESS OF PERCUTANEOUS TIBIAL NERVE STIMULATION (PTNS) AND SACRAL NERVE STIMULATION (SNS) THROUGH EFFECTIVE UTILISATION OF AUDIT DATA.

Hypothesis / aims of study

A recent pilot RCT⁽¹⁾ comparing PTNS to SNS within the faecal incontinence cohort deduced that adequately powered RCT's examining these treatments are probably not feasible. Therefore a less robust design is used to explore similar themes within the female OAB cohort allowing easy accrual of large numbers. NICE⁽²⁾ call for further research into comparative effectiveness of SNS and PTNS. This is the first comparative study within the female OAB cohort so a null hypothesis is utilised:

H₀ There is no difference in the effectiveness of SNS versus PTNS test phase in reducing OAB symptoms in adult females.

The aims of this study are:

1. Utilise local audit data to generate a pilot study evaluating which treatment test phase is most effective at reducing OAB symptoms for adult females.
2. Examine whether a multi site study would be useful to validate the results from the pilot.

Study Design, Materials & Methods

This is a quantitative non- randomised control group before and after trial involving two groups, PTNS and SNS. This retrospective audit of baseline and post bladder diary data for all patients who underwent PTNS or SNS test phase for symptoms of overactive bladder was undertaken at a single NHS site. The SNS service was commenced in August 2010, the PTNS service commenced in October 2011. All patients with completed pre and post test bladder diary data up until October 2016 were included. This led to a population of 24 participants within the PTNS treatment group and 50 within the SNS group (Power 80% 5% sig level). Baseline characteristics were compared utilising t test and Mann Whitney U to establish the groups were similar. Data was not normally distributed so non parametric tests were utilised for analysis. Overall response rates were calculated for both groups following the criteria that a responder $\geq 50\%$ reduction in at least one troublesome symptom from the bladder diary. The number of responsive symptoms were then calculated for each treatment group. Symptoms were analysed assessing if there is a higher response rate to a particular mode of treatment utilising chi square. Percentage reduction of symptoms were analysed and assessed for significance utilising Mann Whitney U test and symptoms were ranked from most responsive to least responsive based on response rate and percentage reduction in symptom severity, looking for patterns within both treatment groups. Methods, definitions and units conform to the standards recommended by the International Continence Society and the International Urogynecological Association.

Results

There were no significant differences between the groups regarding age or baseline symptom severity for incontinence, urgency, frequency or nocturia. The overall responder rate for PTNS was 54.2% (N=13) and SNS 86% (N=43). SNS had a significantly higher responder rate when analysed using chi square test ($\chi^2(1)=8.927$ P=0.003). SNS had the most participants who responded ($\geq 50\%$ reduction) in more than one symptom indicating a larger overall response (see table 1). SNS treatment effect is significantly bigger than PTNS treatment in three out of four OAB symptoms. Frequency, $\chi^2(1)=6.983$, P=0.08, Urgency, $\chi^2(1)=16.331$, P=<0.001, Incontinence, $\chi^2(1)=10.8$, P=0.001. Nocturia was the only symptom where the difference was not significant ($\chi^2(1)=0.922$, P=0.337). Percentage reduction in symptom severity showed a significant difference between the efficacy of PTNS and SNS treatments for symptoms of frequency (P=0.02), urgency (P=0.002) and nocturia (P=0.031) Results for symptoms of incontinence were not statistically significant (P=0.261). Symptoms were ranked from most responsive to least responsive based on overall responders (table 2) and percentage reduction in symptoms (table 3). This suggests that incontinence and urgency symptoms are most amenable to neuromodulation treatments.

Interpretation of results

Within this study the hypothesis under test is refuted, there is a significant difference in the effectiveness of the two treatments. SNS test phase is statistically more effective at treating OAB symptoms in females than PTNS. This is identified by analysing the data in a number of ways. SNS has a significantly higher overall responder rate, it also has a higher responder rate within more OAB symptoms and has the greater percentage reduction of symptoms than PTNS.

This study has generated new evidence within this cohort. However findings should be viewed with caution due to the studies retrospective design, lack of randomisation and small sample size. Findings from this pilot study may justify further evaluation as NICE⁽²⁾ recommend further research into the effectiveness and long term effectiveness of third line management for OAB sufferers. A multi site study utilising a similar design would represent a way to collate large data sets that can be easily accessed and data is likely to be already available at sites that provide either treatment for their patients.

Study limitations: This study does not take into account why patients are offered PTNS rather than SNS. These cohorts are likely to have different baseline characteristics, not examined within this study, which may introduce bias in favour of SNS treatment. If a future multi site study is undertaken additional baseline characteristic data including co morbidities, patient mobility status, and cognitive ability should be analysed as these factors are likely to influence clinician and patient treatment choice and treatment outcomes.

The ability to compare these results to other studies examining effectiveness for either treatment is poor. This is due to a lack of standardisation regarding treatment protocols, procedures and outcome measures within both treatments.

Concluding message

This study has generated new evidence about the effectiveness of SNS and PTNS treatments. Both treatments are effective however SNS is statistically more effective than PTNS at treating OAB in females. The study design and limited resources have restricted the validity of its findings. This pilot study has been useful and if recommendations are put into practice, a collaborative multi site study, accounting for differences in baseline characteristics, may yield more valid results.

Table1 No. of symptom responses	PTNS	SNS
0	11 (45.8%)	7 (14%)
1	6 (25%)	8 (16%)
2	3 (12.5%)	13 (26%)
3	2 (8.3%)	16 (32%)
4	2 (8.3%)	6 (12%)
Total	24 (100%)	50 (100%)

Table 2 PTNS	No.	Weighted no.	Rank	SNS	
Incontinence	9	18	Largest improvement	Incontinence	38
Urgency	7	14		Urgency	32
Frequency	6	12		Frequency	26
Nocturia	5	10	Smallest improvement	Nocturia	16

Table3			
PTNS		Rank	SNS
Incontinence -47.64%		Largest improvement	Incontinence -78.30%
Urgency -30.00%			Urgency -68.75%
Nocturia -24.81%			Nocturia -48.57%
Frequency -27.41%		Smallest improvement	Frequency -27.41%

References

1. Thin N, Taylor S, Bremner S et al (2015) Randomized clinical trial of sacral versus percutaneous tibial nerve stimulation in patients with faecal incontinence. British Journal of Surgery, Vol.102(4), pp.349-358
2. NICE (2013) Urinary incontinence in women, update. Available at: <http://www.nice.org.uk/guidance/cg171>

Disclosures

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