CLINICAL INSIGHTS INTO PERCUTANEOUS TIBIAL NERVE STIMULATION FOR THE TREATMENT OF OVERACTIVE BLADDER SYNDROME: SECONDARY ANALYSIS OF THE SUMIT TRIAL

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PURPOSE:

The Study of Urgent[®] PC versus Sham Effectiveness in Treatment of Overactive Bladder Symptoms (SUmiT), a double-blind, randomized, sham-controlled trial, demonstrated the efficacy of percutaneous tibial nerve stimulation (PTNS) in treating overactive bladder (OAB). Here, we evaluate potential differences in treatment



efficacy by demographic and baseline health factors, and analyze the effect of treatment duration, since these factors have not yet been explored.

METHODS:

208 of the 220 participants with OAB symptoms enrolled in the SUmiT Trial were included in this per-protocol secondary analysis to explore potential treatment differences by age, gender, prior OAB medication use, and baseline urge urinary incontinence (UUI). We analyzed treatment efficacy through the use of questionnaires and 3-day voiding diaries. We further explored the differential effect of therapy after 6 and 12 interventions and graded improvement differences by treatment group in voiding diary parameters.

Results:

Among these 208 patients, 79% were women, 48% were aged \geq 65 years, 31% had previously been on OAB medications, and 79% had baseline UUI. A differential effect of treatment in overall bladder symptoms was observed by gender (p=0.03, Table 1), driven by a higher improvement rate in the female sham group than the male sham group (26% versus 5%), though PTNS was superior to sham in both gender groups (both p<0.001). Those with baseline UUI also tended to have greater reductions in moderate/severe urgency than patients without baseline UUI (p=0.07, Table 2). No other differences in

GRA or voiding diary parameters by age, gender, or history of OAB medication use were detected (all $p \ge 0.16$). Improvement in overall bladder symptoms significantly improved from the 6th to 12th intervention in the PTNS group (p<0.001), but not the sham group (p=0.13, Table 3). Improvements in both arms were not significant after 6 interventions.

Table 1: PTNS and Sham patients reporting moderately or markedly improved on the Global Response Assessment (GRA) after 12-weekly interventions

GRA Outcome	Subgroup	Sham	PTNS	Ρ	
Overall Bladder Symptoms	Men	1/21 (4.8%)	15/22 (68.2%)	0.02	
	Women	22/84 (26.2%)	45/81 (55.6%)	0.03	

Table 2: Change in voiding diary parameter of PTNS vs. Sham after 13 weeks

Voiding Diary Parameter	Subgroup	Change fro Mean	Р		
		Sham	PTNS		
Moderate/ severe urgency	OAB wet at baseline	-2.2 (3.9)	-4.5 (3.6)	0.07	
	OAB dry at baseline	-2.0(4.0)	-2.1 (2.4)		

The percent of patients reporting <50%, 50 to <90% and ≥90% improvement in moderate to severe urgency after 12 interventions was 54%, 30%, and 16% for the PTNS group, and was 72%, 18%, and 10% for the sham group (p=0.009). The same percent improvement categories for accidents per day were 53%, 20%, and 27% for PTNS, and were 66%, 23%, and 11% for sham (p=0.02, Figure 1).

Figure 1: Proportion of PTNS and Sham patients reporting improvement in voiding diary parameters



Table 3: PTNS and Sham patients reporting moderately or markedly improved on the Global Response Assessment (GRA) at weeks 7 and 13

GRA Outcome	Group	7-Week	P for Tx	13-Week	P for Tx	P for Improvement
Overall Bladder Symptoms	PTNS	27/103 (26.2%)	0.08	60/103 (58.3%)	< 0.001	< 0.001
	Sham	17/105 (16.2%)		23/105 (21.9%)		0.13

CONCLUSION:

Secondary analysis of the SUmiT trial provides evidence that PTNS therapy is effective in treating OAB symptoms in both men and women regardless of age, and in patients with a history of OAB medication use. Twelve weekly PTNS treatments are needed to realize the full treatment efficacy for those suffering with OAB.

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