CLINICAL INSIGHTS INTO PERCUTANEOUS TIBIAL NERVE STIMULATION (PTNS) VS. SHAM THERAPY FOR THE TREATMENT OF OVERACTIVE **BLADDER SYNDROME (OAB): SECONDARY ANALYSIS OF THE SUMIT TRIAL**

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NTRODUCTION:

The Study of Urgent[®] PC vs. Sham Effectiveness in Treatment of Overactive Bladder Symptoms (SUmiT) was a double-blind, randomized, shamcontrolled trial demonstrating the efficacy of PTNS in treating OAB. The purpose of this secondary analysis was to evaluate the potential differences in treatment efficacy based on



demographic and baseline health factors, and to analyze the treatment effect after 6 and 12 interventions.

Methods:

208 out of 220 enrolled in the SUmiT Trial were included in this per-protocol analysis. Potential differences in treatment efficacy were evaluated by age (<65 years vs. \geq 65 years), gender, history of OAB medication use, and baseline urge urinary incontinence (UUI). The differential effect of therapy after 6 and 12 interventions was also explored. Validated questionnaires and 3-day voiding diaries were used to analyze treatment efficacy.

Results:

Among the 208, 79% were women, 48% were \geq 65 years, 31% had previously been on OAB medication, and 79% reported baseline UUI. A differential effect of therapy on overall bladder symptoms was observed by gender in the sham group (p=0.03). While men and women experienced similar improvement in overall OAB symptoms in the PTNS group (68.2% vs 55.6%) the rate of improvement differed in men and women in the sham group (5% versus 26%) (Table 1). However, PTNS was superior to sham in both gender groups (both p<0.001). Those in the PTNS group with baseline UUI showed a trend towards greater reduction in moderate/severe urgency compared to

those without baseline UUI (p=0.07) (Table 2). No differences in efficacy were detected when results were stratified by age or history of OAB medication use. The percent of participants reporting \geq 50% improvement in moderate to severe urgency after 12 interventions was 46% and 28% for the PTNS and sham groups, respectively (p=0.007) (Figure 1). While, 47% of patients in the PTNS group and 34% in the sham group reported \geq 50% improvement for accidents per day (p=0.07) (Figure 1). No significant improvements were reported after 6 interventions. However, overall OAB symptoms significantly improved from the 6th to 12th intervention in the PTNS group (p<0.001), but not in the sham group (p=0.13) (Table 3).

Table 1: PTNS and Sham patients patients reporting moderately or markedly improved on the Global Response Assessment (GRA) at 13 weeks by gender

GRA Outcome	Subgroup	Sham	PTNS	Р
Overall Bladder Symptoms	Men	1/21 (4.8%)	15/22 (68.2%)	0.02
Markedly Improved	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 from baseline Mean (SD)		Р
		Sham	PTNS	
Moderate/ Severe Urgency	OAB wet at baseline	-2.2 (3.9)	-4.5 (3.6)	
	OAB dry at baseline	-2.0 (4.0)	-2.1 (2.4)	0.07



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 Sham	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:

This secondary analysis provides evidence that PTNS therapy is an effective OAB treatment in both men and women, regardless of age and prior use of OAB medications. Twelve weekly PTNS treatments are needed to realize the full treatment efficacy for those suffering with OAB.

PTNS Sham

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