

#133 EMERGING NONSURGICAL, WEARABLE NEUROMODULATION SYSTEM SHOWS STRONG PATIENT SATISFACTION, LIKELIHOOD TO USE AND COMPLIANCE IN CLINICAL STUDY

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Introduction

Overactive bladder (OAB) is known to greatly affect the quality of life of those who suffer from it. Although several treatment options are available, there are significant drawbacks to each. We evaluated the tolerability, usability, and satisfaction of a novel wearable neuromodulation system on patients diagnosed with OAB. It is characterized by four symptoms; urgency, frequency, nocturia, and urge incontinence [1].

1. P. Abrams, C. J. Kelleher, L. A. Kerr, and R. G. Rogers, “Overactive bladder significantly affects quality of life,” *Am J Manag Care*, vol. 6, no. 11 Suppl, pp. S580–S590, 2000.



Methods

A prospective, open label study was conducted to assess the tolerability, usability, and satisfaction of the Avation Medical wearable neuromodulation system for OAB.

After signing the informed consent, subjects were required to demonstrate severity of their OAB symptoms using a 3-day diary and show that EMG signals could be recorded with the system. A patented custom-fitted garment embedded with electrodes was used to both stimulate the tibial nerve and record EMG signals from the sole of the foot. Using an app, the clinician set up the therapy parameters which allowed for when the patient was sent for them to control the system by an app. Enrolled subjects were instructed to use the system in their homes for 30 minutes for 3 days a week for 12 weeks. Subjects completed questionnaires that assessed their tolerability, usability, and satisfaction of the system as well as its effect on their OAB symptoms. The subject's overall compliance of the system was also assessed.



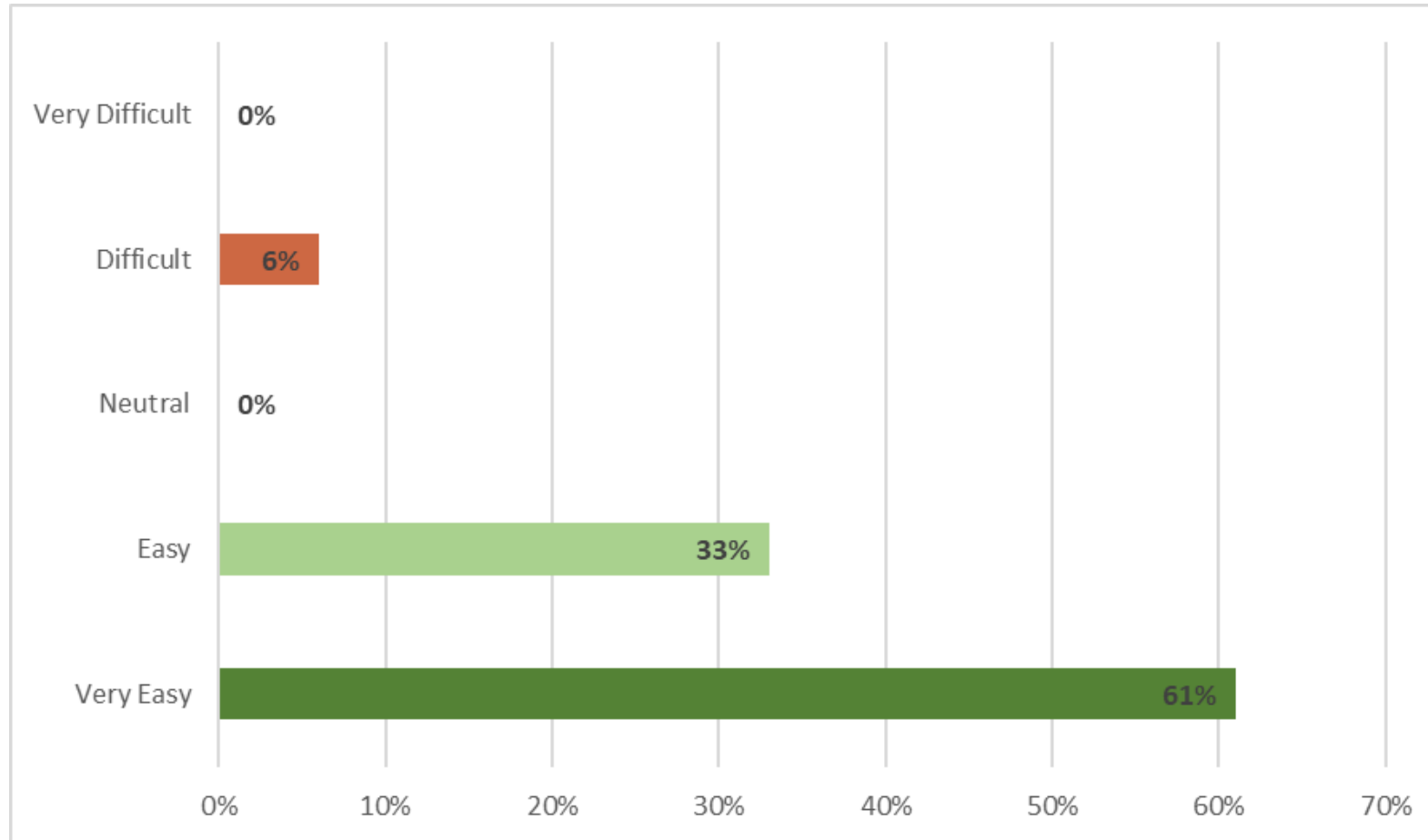
Results

A total of 21 subjects (1 male, 20 female) were enrolled into the study and 18 subjects completed 12 weeks of therapy. Of the 3 subjects that dropped out, one could not adhere to the visit schedule, one had foot pain, and one had device issues. Their mean age was 62 years (range 50-78). The mean duration of symptoms was 8.5 years (range 1-42 years). The most common words used to describe the stimulation were smooth, tingling and comfortable. Subjects most often administered their therapy while they were sitting (n=15) while watching TV (n=10). All subjects were found to be compliant with the therapy and treatment schedule. Quality of life improved from an average of 40% to 60% and symptom severity decreased from an average of 60% to 40% as measured using the OAB-q (HRQL). No serious adverse events were reported.



Results

Ease of use after 12 weeks of therapy



Results

Overall satisfaction with the system after 12 weeks

Overall satisfaction after 12-weeks of therapy		
Very satisfied	39%	Satisfied 68%
Somewhat satisfied	28%	
Neutral	22%	
Somewhat dissatisfied	11%	Dissatisfied 11%
Dissatisfied	0%	



Results

Likelihood to use in the future

Likelihood to use in future		
Very likely	44%	Likely to Use 72%
Likely	28%	
Neutral	11%	
Unlikely	11%	Unlikely to Use 17%
Very Unlikely	6%	



Conclusions

A non-surgical, wearable neuromodulation system for the alleviation of OAB symptoms was found to be well-tolerated. Subjects were found to be satisfied with the system and compliant with the treatment protocol. A majority of subjects indicated they would use this therapy. Additional research is required to ascertain the therapeutic effects, outcomes and long-term compliance

