340

Sotelo T[1], Wahlgren S[2], Nohilly M[2], Jacobs D[2]
1. *The George Washington University,* ***2.*** *Ethicon Endo-Surgery*

HUMAN ASSESSMENT TRIAL TO EVALUATE A NOVEL, NON-INVASIVE, PATIENT-MANAGED NEUROMODULATION SYSTEM (PMNS) PATCH FOR WEARING COMFORT AND ADHESIVE PERFORMANCE

Hypothesis / aims of study

Overactive bladder (OAB) syndrome is a chronic and debilitating condition that is characterized by urinary urgency with or without urge incontinence, usually in combination with increased urinary frequency and/or nocturia in the absence of local pathological or metabolic factors that would account for these symptoms. While the precise cause of overactive bladder (OAB) syndrome symptoms (urge, frequency, incontinence) is not clear, most physicians and researchers accept the theory that a problem in the communication between the central nervous system and the bladder is a factor.

Neuromodulation to treat overactive bladder (OAB) syndrome is achieved by implanting an electrode near the sacral nerve in the spine. A new concept under investigation may achieve a similar effect via a transdermal amplitude-modulated signal (TAMS) composed of a carrier signal and pulse envelope through a patch applied on the skin over spinal nerves in the lower back. The objective of this study was to assess patients' comfort and performance of the adhesives applied to the sacral region for 7 days.

Study design, materials and methods

This was a single site, randomized, prospective study. Subjects were randomized to one of two sacral placement angles: horizontal or 30 degrees caudal from horizontal. Subjects wore the test patch for seven full days following normal everyday routines, and were asked to complete daily subjective evaluations for patch awareness, discomfort, bother and adherence and then upon return to the test clinic after the seventh full day when adhesion evaluation, patch removal, skin evaluation, comfort assessment, and debriefing by the investigator was performed. The investigator took photographs of all subjects at specified times on Day 1 and Day 8, documenting both patch adherence and skin conditions under the patch.

Subjects were recruited to one of three assessment groups:

Group	Subjects	Description
1	30 total: 15-horizontal 15-30 degree angle placement	Subjects did not tub bathe/exercise
2	10 total: 5-horizontal 5-30 degree angle placement	Subjects tub bathed or swam daily
3	10 total: 5-horizontal 5-30 degree angle placement	Subjects followed daily exercise regimen for a minimum of 30 minutes

Results

Fifty subjects were included (mean age of 57, mean BMI of 29.2 lbs/in²), all of whom completed the study. Subjects scored patch awareness, discomfort and bother on a visual analog scale of 1 to 10. Overall mean awareness, discomfort and bother caused by the patch was 1.4 (1.1), 1.2 (0.9) and 1.3 (1.0) respectively. Overall scores were highest in group 3 as compared to group 1 and 2. Awareness, bother and discomfort VAS scores for Group 1-30 degree configuration was slightly higher than the other two groups. Sixty-eight percent of patches remained attached at the completion on the 7 days of wear, and 30% experienced partial detachment of the patch. Only one adverse event was reported. Upon patch removal and assessment of skin the subject experienced papules/pustules and erythema over >50% of the patch site which resolved with conservative management.

Interpretation of results

This study demonstrated that the PMNS patch is well tolerated and could be worn with minimal awareness, bother and discomfort even in active, aquatic patients. The PMNS patch demonstrated good adhesion and there was only one moderate adverse event of skin irritation that was managed conservatively.

Concluding message

The PMNS patch seems to be a very viable medium to deliver transdermal neuromodulation for the treatment of OAB.

Specify source of funding or grant **Study funded by Ethicon Endo-Surgery**

Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Allendale Investigational Review Board (Old Lyme, CT, USA)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**