tensi+

Success rate: 68% after 12 weeks.

- 103 patients
- Main indication: overactive bladder
- 52% PGI score = 1 or 2 (Patient Global Impression of Improvement)

Efficacy of the TENSI+ posterior tibial nerve stimulation device: A multicentre study *

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*Independant Study

Stimuli TECHNOLOGY

Efficacy of the TENSI+ posterior tibial nerve stimulation device: A multicentre study

Objectives:
Posterior tibial nerve stimulation (PTNS) is a validated therapeutic option for the treatment of lower urinary tract symptoms (LUTS), with an efficacy rate of approximately 60% in the short term and few side effects. The objective of this study was to evaluate the results of the new TENSI+ transcutaneous PTNS device in the context of routine care.

Methods:
A retrospective multicentre study was carried out in 7 French centres. Patients treated with the TENSI+ device (Stimuli Technology, Boulogne-Billancourt, France) between September 2021 and February 2022 were included. Patients had received in-home therapeutic education from a service provider, with a daily 20-minute session prescribed. The data collected included demographic data, history, initial clinical symptoms and previous treatments (anticholinergics). Success was defined as the continuation of treatment at 3 months after the first visit. Efficacy was assessed by the Patient Global Impression of Improvement (PGI-I) score. Side effects were collected.

Results:
One hundred and three (103) patients were enrolled. Clinical characteristics are summarised in Table 1. The main indication was an overactive bladder. After a median follow-up of 12 [10–21] weeks, the success rate was 68%. Fifty-two percent of patients had a PGI-I score of 1 or 2, and 18% had a PGI-I score of 3 (Table 2). None of the initial parameters tested (age, gender, body mass index, neurological disease, urgenturia leaks, history of anticholinergic therapy) were significantly associated with success rates.
Four patients reported reversible side effects upon discontinuation of treatment (two cases of pelvic pain and two cases of leg pain at the stimulation site).

Conclusion:
Treatment with posterior tibial nerve stimulation using the TENSI+ device was associated with a short-term success rate of approximately 68% and a very low rate of reversible side effects. Further studies, including comparative studies, are needed to confirm the role of TENSI+ in the therapeutic arsenal.

Table 1 Baseline patient characteristics (n=103).

Age (average +/- standard deviation)	56	+/-6,4
Sex		
Male	17	(17 %)
Female	86	(83 %)
Body mass index (average +/- standard deviation)	25,9	+/-3,2
Previous Neurological disease	18	(17 %)
Lower urinary tract symptom		
Overactive bladder	99	(96 %)
Urine leak by urgency	64	(62 %)
Nocturia		
0	33	(32 %)
1	27	(26 %)
2	19	(19 %)
>2	24	(23 %)
Bladder-voiding problems	24	(23 %)
Anorectal disorders		
None	65	(63 %)
Constipation	19	(18 %)
Diarrhea	2	(2 %)
Fecal Incontinence	2	(2 %)
Not documented	15	(15 %)
Previous treatment by anticholinergic	30	(29 %)
Chronic pelvic pain		
Yes	10	(10 %)
No	72	(70 %)
Not documented	21	(20 %)
TENSI+'s primary indication		
Overactive bladder	87	(85 %)
Voiding difficulties	2	(2 %)
Mixed (storage and voiding)	11	(10 %)
Pelvic pain	2	(2 %)
Isolated nocturia	1	(1 %)

Table 2 Patient Global Impression of Improvement (PGI-I) at 3 months.

Very much Improved	28	(27 %)
Much improved	26	(25 %)
Minimally Improved	19	(19 %)
No change	24	(23 %)
Minimaly worse	4	(4 %)
Much worse	1	(1 %)
Very much worse	1	(1 %)

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