ORIGINAL PAPER

Peroneal electric transcutaneous neuromodulation versus solifenacin in the treatment of the overactive bladder wet

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Introduction Peroneal electrical Transcutaneous NeuroModulation (peroneal eTNM®) is a non-invasive treatment for overactive bladder (OAB). In the previous randomized study in female patients with OAB, both dry and wet, peroneal eTNM® demonstrated significantly better safety and comparable efficacy to solifenacin. This subgroup analysis aimed to compare the safety and efficacy of peroneal eTNM® versus solifenacin in OAB wet population.

Material and methods In the primary study, eligible subjects were randomized in a 2 : 1 ratio to receive either 12 weeks of daily peroneal eTNM® for 30 minutes or solifenacin 5 mg daily. This subgroup analysis included participants who presented with at least one incontinence episode at baseline and completed the study according to protocol. The primary endpoint was safety, secondary endpoint was proportion of continent subjects after treatment. Additional efficacy assessments included change in bladder diary variables, OAB V8 score, and quality of life (QoL).

Results In the peroneal eTNM® group (n = 26), three treatment-related adverse events (TRAEs) were recorded, while nine TRAEs occured in the solifenacin group (n = 16). The proportion of patients who achieved continence after 4, 8 and 12 weeks of treatment was 50%, 62%, and 65% in the peroneal eTNM® and 56%, 50%, and 56% in the solifenacin group, respectively. Both treatments led to significant and similar improvements in all bladder diary variables, OAB V8 score, and QoL.

Conclusions The results of this secondary analysis confirm that peroneal eTNM® has significantly better safety profile and comparable efficacy versus solifenacin in the subgroup of incontinent OAB patients.

Key Words: neuromodulation ‹› transcutaneous electric nerve stimulation ‹› urinary bladder ‹› overactive ‹› peroneal nerve ‹› solifenacin succinate ‹› lower urinary tract symptoms

INTRODUCTION

Idiopathic overactive bladder (OAB) is defined as severe urgency with or without urgency incontinence, usually accompanied by daytime frequency and nocturia, in the absence of infection or other obvious pathology [1]. Urge urinary incontinence (UUI) or OAB wet affects approximately one third of OAB patients [2]. At the individual level, the UUI is considered the most bothersome lower urinary tract symptom for both genders [3].

Behavioral therapy and pelvic floor muscle exercises are considered the first-line OAB therapy, while pharmacotherapy using anticholinergics or betamimetics represents the most commonly used treatment option [4]. Unfortunately, the long-term adherence to the medical therapy of OAB is reported to be generally low [5]. Neuromodulation

or injections of botulinumtoxin may be offered to patients who have failed previous therapy due lack of efficacy or adverse effects [4].
Peroneal electrical transcutaneous neuromodulation (peroneal eTNM®) is a new treatment method for OAB based on highly selective bilateral transcutaneous neuromodulation of the peroneal nerve. Its main advantages include a precisely defined optimal stimulation point, ease of use, and the possibility of home self-treatment. The principle of the peroneal eTNM® is shown in Figure 1. In a prospective, randomized, active-controlled study that enrolled treatment-naïve women with OAB, peroneal eTNM® showed significantly better safety and tolerability with comparable efficacy compared to solifenacin [6]. Given the profound impact of UUI on quality of life (QoL) of affected individuals, we performed the prespecified subgroup analysis in subjects with OAB wet or mixed urinary incontinence who participated in the primary study.

MATERIAL AND METHODS

Design of the primary study

The study design has been described in detail previously [6]. In brief, the study enrolled adult treatment-naïve female patients with a clinical diagnosis of idiopathic OAB, both dry and wet, or mixed incontinence with the predominance of OAB symptoms lasting for at least 6 months. The inclusion criteria at baseline included one or more urgency episode grade 3 or grade 4 according to Patients Perception of Intensity of Urgency Scale (PPIUS) in 24 hours and voiding frequency ≥8 times/24 hours as documented using the 7-day bladder diary. The exclusion criteria included urinary tract infection, significant prolapse of the pelvic organs, history of previous malignant disease in the pelvic area, and any neurological disease that may affect urinary bladder function.
After signing an informed consent form, eligible subjects were randomized in a 2 : 1 ratio to receive 12 weeks of daily at-home treatment with peroneal eTNM® for 30 minutes or solifenacin 5 mg once daily.

Inclusion criteria for the prespecified subgroup analysis

The present subgroup analysis only included subjects who presented with at least one episode of urgency urinary incontinence during the 7-day bladder diary period, at least one episode of urgency per 24 hours, and voiding frequency ≥8 times per 24 hours. In addition, this subanalysis only included subjects who completed the primary study according to the protocol.

Subgroup analysis endpoints

The primary endpoint of this subgroup analysis was safety and tolerability, and the secondary endpoint was the proportion of subjects who became continent after 12 weeks of treatment. Additional efficacy assessments included change in number of voids, nocturia, severe urgency episodes, incontinence episodes, and UUI episodes/24 h, change in level of urgency, change in voided volume, change in OAB V8 questionnaire total score, and change in QoL questionnaire after 12 weeks of therapy.

Figure 1. *Peroneal electric transcutaneous neuromodulation (peroneal eTNM®) using the URIS® I neuromodulation system. Active electrodes are attached bilaterally to the optimal stimulation points in the popliteal fossae, while a self-adhesive neutral electrode is placed on the lower abdomen. Accelerometers attached to the feet are part of a closed biofeedback loop, continually assessing motor response to peroneal neuromodulation. This setup allows for continual adjustment of neuromodulation parameters throughout the stimulation session.*

Outcome measures

Each assessment was performed during clinic visits at screening, at baseline, and at weeks 4, 8, and 12 of treatment.

Safety measures: Included recording of the number and severity of treatment-related adverse events (TRAE), routine serum chemistry, hematology, and urine analysis.

Bladder diary: Patients recorded their fluid intake and voided volume with respective times during 7 consecutive days prior to each visit.

Patient Perception of Intensity of Urgency Scale (PPIUS): Patients graded their desire to void preceding every micturition using a 5-point categorical scale, ranging from 0 ("no urgency") to 4 ("urgency incontinence") during the bladder diary recording period [7]. Urgency Grade 3 and urgency Grade 4 were considered severe urgency episodes. Urine leakage without preceded urgency (Grade 0) was considered an episode of stress urinary incontinence

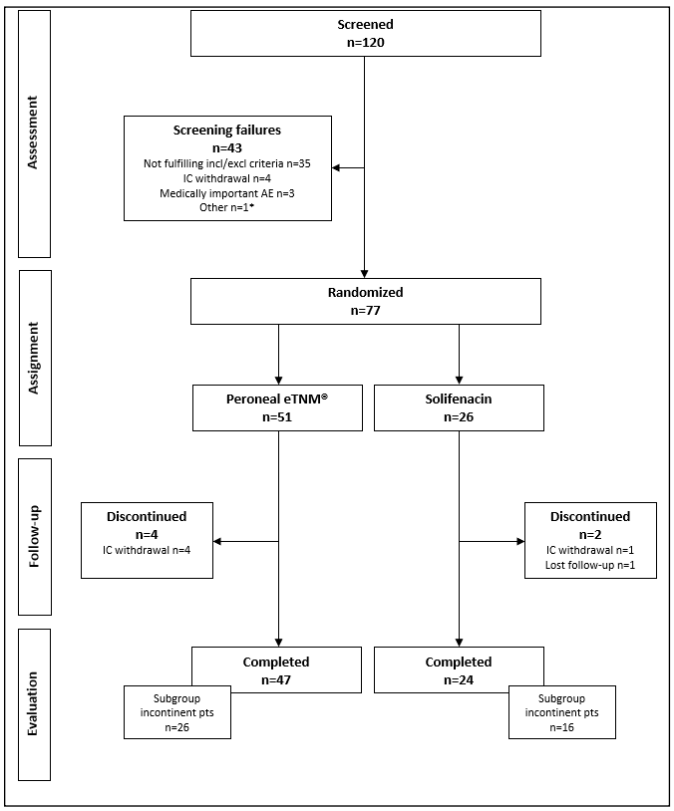

Figure 2. *Consolidated Standards of Reporting Trials (CONSORT) diagram of the primary study.*

*The patient withdrew before using the first dose of solifenacin and was not included in the safety evaluation set.

AE – adverse event; IC – informed consent; pts – patients; peroneal eTNM® – peroneal electrical transcutaneous neuromodulation

Level of urgency: Represents the mean value of all PPIUS scores recorded during the bladder diary period.

OAB V8 questionnaire (OAB V8): This tool consists of 8 items to evaluate the inconvenience caused by OAB symptoms. Patients were asked to rate their symptom severity using a 6-point Likert scale ranging from 0 ("not bothered at all") to 5 ("bothered a very great deal"). The total score ranges from 0 to 40; the higher score, the higher the burden and symptom severity [8].

European Quality of Life 5 Dimensions questionnaire (EQ-5D-5L): This tool represents a standardized measure of health-related QoL, comprising questions from 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The higher the EQ-5D-5L index, the better the health-related QoL. In addition, the EQ Visual Analog Scale (EQ-5D-5L VAS) provides a quantitative measure of the patient's perception of their overall health status. EQ-5D-5L VAS is numbered from 0 ("the worst health status you can imagine") to 100 ("the best health status you can imagine") [9].

Statistical methodology

Due to the mainly non-normal data distribution, descriptive statistics are presented using median and 25% and 75% interquartile ranges (IQRs) of the median, unless indicated otherwise. The changes between the baseline and study intervals are primarily shown as relative changes to indicate trend. Fisher's exact test was used to test the parameters in respective bladder diary-derived variables between the study arms. Differences between study arms over time in raw continuous variables were tested separately using the non-parametric alternative to ANOVA, and the Friedman test with post hoc Dunn's multiple comparisons to compare the mean rank of each interval with the mean rank of the baseline. The Wilcoxon signed rank test was used to evaluate the differences in voided volume/micturition due to non-normal data distribution. Outcomes of the EQ-5D-5L are presented with 95% confidence intervals to indicate trends in the changes from baseline. Descriptive statistical analyses were performed with GraphPad Prism 10.3.0 (GraphPad Software, Inc., San Diego, CA).

Bioethical standards

The primary study was conducted in compliance with the ethical principles laid down in the Declaration

of Helsinki and applicable local regulations. The study protocol was approved by the national regulatory authority and independent Ethics Committee at each center. The study was registered as EudraCT reg. Nr. 2019-003321-14. All patients provided written informed consent.

RESULTS

Patients

Overall, of the 120 patients screened for the primary study, 77 were randomized and 71 completed the study. In total, the present subgroup analysis included 42 patients (26 in the peroneal eTNM® group and 16 in the solifenacin group). A CONSORT diagram showing the patient flow in the primary study is depicted in Figure 2. Patient demographics and baseline characteristics are summarized in Table 1.

Safety and tolerability

In the peroneal eTNM® group, 17 adverse events were recorded, 3 of which were considered TRAE. One patient had mild abdominal pain for 2 days, one patient reported erythema/discomfort at the stimulation point, while one patient experienced moderate headache for 12 days. All TRAE resolved without sequelae, and all patients were able to complete the study protocol.
In the solifenacin group, 22 adverse events were recorded, 9 of which were considered TRAE. They included dry mouth (n = 6), sore throat (n = 1), rash (n = 1), and dyspepsia (n = 1).
One TRAE was judged as moderate severity (rash), while 8 were considered mild.

Table 1. *Baseline demographic and clinical characteristics (subgroup analysis set)*

N	Peroneal eTNM® group	Solifenacin group
	26 (100%)	16 (100%)
Demographics		
Sex (Female)	26 (100%)	16 (100%)
Age (years) (mean ±SD)	50.6 ± 17.0	49.9 ±15.2
BMI (mean ±SD)	30.0 ± 6.0	27.6 ± 6.1
Postmenopausal	14 (54%)	7 (44%)
Symptoms		
OAB wet	10 (21.2%)	11(44.0%)
Mixed urinary incontinence (OAB predominant)	17 (36.2%)	6 (24.0%)
OAB symptoms duration (months) (mean ±SD)	59 ± 54	49 ± 39
Concomitant diseases		
Asthma	0 (0%)	1 (6%)
Depression	1 (4%)	0 (0%)
Diabetes	4 (15%)	0 (0%)
Hypertension	11 (42%)	3 (19%)
Hypothyroidism	4 (15%)	2 (13%)
Bladder-diary variables		
Voids/24 h median (IQR)	10.2 (8.9, 13.0)	9.3 (8.7, 13.1)
Nocturia episodes/24 hmedian (IQR)	1.9 (1.3, 2.5)	1.1 (0.9, 1.6)
Severe urgency episodes/24 h median (IQR)	5.3 (3.6, 7.9)	6.5 (3.6, 10.1)
Incontinence episodes/24 h median (IQR)	0.8 (0.3, 1.9)	1.9 (0.8, 4.9)
PPIUS level median (IQR)	2.5 (2.1, 2.8)	2.9 (2.3, 3.4)
Voided volume (ml) median (IQR)	167 (140, 206)	183 (138, 239)
Questionnaires		
OAB V8 total score median (IQR)	26 (21, 30)	25 (18, 31)

BMI – body mass index; EoT – end of treatment; IQR – interquartile range; OAB – overactive bladder; OAB V8 – OAB V8 questionnaire; peroneal eTNM® – peroneal electrical Transcutaneous NeuroModulation; PPIUS – Patients Perception of Intensity of Urgency Scale; SD – standard deviation

Efficacy

In the peroneal eTNM® group, 13 (50%), 16 (62%), and 17 (65%) patients became continent at week 4, week 8, and week 12, respectively. The proportion of patients who became dry in the solifenacin arm was 9 (56%), 8 (50%), and 9 (56%) at week 4, week 8, and week 12, respectively. In contrast to the patients treated with peroneal eTNM®, no further improvement in the proportion of continent individuals was observed at weeks 8 and 12 in the solifenacin group. Both treatment methods showed a significant and similar level of improvement in all bladder diary-derived variables. In addition, we observed comparable improvement in symptom severity score as measured by OAB V8. The results are shown in Tables 2 and 3.

There was an improvement in EQ-5D-5L index from a median of 0.808 (IQR 0.722; 1.000) at baseline to 0.879 (0.796; 1.000) at week 12 in the peroneal eTNM® group. In the solifenacin group, the median EQ-5D-5L index improved from 0.858 (0.774; 1.000) to 0.940 (0.746; 1.000) at week 12. The number of patients reaching the 1.000 index, indicating full health, increased from 39% to 46% in theperoneal eTNM® group during the study period, and from 44% to 50% in the solifenacin group. EQ-5D-5L VAS showed a slightly greater numerical trend of improvement in the eTNM® group. The results are summarized in Table 4.

Table 2. *Absolute change in bladder diary-derived variables and symptom score over the study period*

	BL	Week 4	Week 8	Week 12	Friedman test p-value	BL vs Week 4	BL vs Week 8	BL vs Week 12
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)		Post hoc Dunn's multiple comparisons tests p-value		
Voiding frequency/24 h								
Peroneal eTNM®	10 (9; 13)	7.7 (6.3; 9.2)	7.6 (6.3; 8.8)	7.5 (6.7; 9.2)	<0.001	<0.001	<0.001	<0.001
Solifenacin	9.3 (8.7; 13)	6.8 (6.1; 8.6)	7.4 (6; 9.1)	7.5 (6.4; 8.9)	<0.001	<0.001	<0.001	0.001
PPIUS Grade 3+4 episodes/24 h								
Peroneal eTNM®	5.3 (3.6; 7.9)	1.9 (1; 3.4)	1.1 (0.075;2.6)	1.3 (0.075; 2.2)	<0.001	<0.001	<0.001	<0.001
Solifenacin	6.5 (3.6; 10)	1.4 (0.38; 3.1)	1.9 (0.78; 3.3)	1.1 (0.7; 3.7)	<0.001	<0.001	<0.001	<0.001
PPIUS Grade 4 episodes/24 h								
Peroneal eTNM®	0.65 (0.1; 1.8)	0 (0; 0.33)	0 (0; 0.18)	0 (0; 0.33)	<0.001	<0.001	<0.001	<0.001
Solifenacin	1.5 (0.63; 3.8)	0 (0; 0.3)	0 (0; 0.83)	0 (0; 0.75)	<0.001	<0.001	<0.001	<0.001
Incontinence episodes/24 h								
Peroneal eTNM®	0.8 (0.3; 1.9)	0.05 (0; 0.4)	0 (0; 0.18)	0 (0; 0.4)	<0.001	<0.001	<0.001	<0.001
Solifenacin	1.9 (0.8; 4.9)	0 (0; 0.6)	0.05 (0; 0.93)	0 (0; 0.8)	<0.001	<0.001	<0.001	<0.001
Nocturia episodes/24 h								
Peroneal eTNM®	1.9 (1.3; 2.5)	1.1 (0.68; 1.9)	1.1 (0.98; 1.4)	1 (0.85; 1.5)	<0.001	0.013	<0.001	0.004
Solifenacin	1.1 (0.93; 1.6)	0.85 (0.48; 1.2)	0.95 (0.45; 1.3)	1 (0.48; 1.3)	0.140	0.301	0.166	0.166
Voided volume/micturition								
Peroneal eTNM®	167 (140;206)	–	–	199 (152; 243)	–	–	–	<0.001*
Solifenacin	183 (138;239)	–	–	238 (167; 313)	–	–	–	0.117*
Level of urgency								
Peroneal eTNM®	2.5 (2.1; 2.8)	2.1 (1.5; 2.3)	1.9 (1.6; 2.2)	1.8 (1.4; 2.2)	<0.001	<0.001	<0.001	<0.001
Solifenacin	2.9 (2.3; 3.4)	2 (1.7; 2.4)	2.1 (1.6; 2.6)	1.9 (1.6; 2.3)	<0.001	<0.001	0.003	<0.001
OAB V8 total score								
Peroneal eTNM®	26 (21; 30)	17 (12; 23)	12 (7.3; 17)	13 (5.8; 14)	<0.001	0.022	<0.001	<0.001
Solifenacin	25 (18; 31)	15 (8.3; 21)	10 (5.8; 18)	13 (6; 17)	<0.001	0.004	<0.001	<0.001

Raw bladder diary-derived variables and symptom score over the study period and Friedman test with post hoc Dunn's multiple comparisons to compare the mean rank of each interval with the mean rank of the baseline

* Wilcoxon matched-pairs signed rank test was used

BL – baseline; IQR – interquartile range; OAB V8 – OAB V8 questionnaire; peroneal eTNM® – peroneal electrical Transcutaneous NeuroModulation; PPIUS – Patients Perception of Intensity of Urgency Scale

DISCUSSION

In this prespecified subgroup analysis in female patients with OAB wet and mixed urinary incontinence with OAB symptoms being predominant, the peroneal eTNM® clearly showed a favorable safety profile compared to solifenacin. Despite the higher number of patients treated with peroneal eTNM® due to uneven 2 : 1 randomization, both the absolute and relative numbers of TRAEs in the peroneal eTNM® group were lower compared to those in the solifenacin group.

All TRAEs in the peroneal eTNM® group were considered mild, did not require intervention, and resolved quickly. In contrast, the most reported TRAE in the solifenacin group – dry mouth, reported by 38% of patients - persisted throughout the study treatment period.

Although the primary study was not specifically designed to compare efficacy outcomes, there was a notable numerical trend favoring the peroneal eTNM® arm in the proportion of subjects who achieved continence by the end of study.

In addition, peroneal eTNM® showed similar efficacy to solifenacin in all assessed bladder diary-derived variables and symptom severity measures. Importantly, the results of this subgroup analysis in incontinent OAB patients were consistent with findings in the overall OAB population, both dry and wet, in the primary study.

Urinary incontinence, particularly UUI, has a profound impact on individuals' QoL [10]. The pathophysiology of OAB is complex, multifactorial, and not yet fully understood [11]. Some researchers suggest that OAB wet may have a distinct underlying pathophysiology compared to OAB dry. Evidence increasingly indicates that age-related changes in the bladder and nervous system contribute significantly to the pathophysiology of OAB wet [12]. It has been documented that the proportion of patients with OAB wet among all OAB patients tends to increase with age, and older age has been identified as an independent risk factor for OAB wet [13]. This subgroup analysis provides evidence that peroneal eTNM® is an effective treatment option for individuals suffering from OAB wet and mixed urinary incontinence with OAB symptoms being predominant, offering an excellent safety profile compared to solifenacin. Based on these results, we propose that non-invasive neuromodulation should be considered prior to anticholinergics in the treatment algorithm for both OAB dry and wet. This approach may be especially relevant for patients over 65 years old, who are considered a high-risk population due to a greater prevalence of comorbidities, particularly cardiovascular, neurological, and psychiatric [14]. This population is often subject to polypharmacy, with many commonly prescribed drugs having significant anticholinergic effects. When co-administered with OAB medication, this raises the overall anticholinergic load, increasing the risk of cognitive impairment and dementia [15]. Other common anticholinergic side effects, such as dry mouth, constipation, and QT interval prolongation – to which older individu-

Table 3. *Relative change in bladder diary-derived variables and symptom score over the study period*

	Week 4 Change from BL	Week 8 Change from BL	Week 12 Change from BL
	Median (IQR) [%]	Median (IQR) [%]	Median (IQR) [%]
Voiding frequency/24 h			
Peroneal eTNM®	–25 (–36, –13)	–30 (–40, –11)	–27 (–37, –8)
Solifenacin	–33 (–46, –28)	–32 (–39, –20)	–30 (–41, –21)
PPIUS Grade 3+4 episodes/24 h			
Peroneal eTNM®	–60 (–79, –36)	–82 (–97, –47)	–80 (–95, –59)
Solifenacin	–73 (–88, –61)	–69 (–85, –30)	–76 (–88, –33)
PPIUS Grade 4 episodes/24 h			
Peroneal eTNM®	–96 (–100, –59)	–100 (–100, –75)	–100 (–100, –81)
Solifenacin	–100 (–100, –86)	–100 (–100, –54)	–100 (–100, –64)
Incontinence episodes/24 h			
Peroneal eTNM®	–92 (–100, –52)	–100 (–100, –75)	–100 (–100, –82)
Solifenacin	–100 (–100, –86)	–96 (–100, –50)	–100 (–100, –71)
Nocturia episodes/24 h			
Peroneal eTNM®	–30 (–40, –19)	–39 (–50, –22)	–38 (–54, –9)
Solifenacin	–50 (–59, 13)	–42 (–69, 14)	–38 (–59, –8)
Voided volume/micturition			
Peroneal eTNM®	–	–	18 (3, 24)
Solifenacin	–	–	20 (–13, 95)
Level of urgency			
Peroneal eTNM®	–16 (–27, –4)	–19 (–30, –11)	–26 (–45, –11)
Solifenacin	–18 (–36, –12)	–25 (–34, –5)	–22 (–37, –7)
OAB V8 total score			
Peroneal eTNM®	–26 (–45, –10)	–48 (–63, –33)	–55 (–70, –38)
Solifenacin	–29 (–60, –21)	–54 (–75, –26)	–52 (–75, –11)

BL – baseline; EoT – end of treatment; IQR – interquartile range; OAB V8 – OAB V8 questionnaire; peroneal eTNM® – peroneal electrical transcutaneous neuromodulation; PPIUS – Patients Perception of Intensity of Urgency Scale

Table 4. *Change in quality of life over the study period as measured by EQ-5D-5L questionnaire*

	BL	Week 4	Week 8	Week 12
	Median (IQR) Mean ±SD	Median (IQR) Mean ±SD Change from BL 95%CI	Median (IQR) Mean ±SD Change from BL 95%CI	Median (IQR) Mean ±SD Change from BL 95%CI
EQ-5D-5L Index				
Peroneal eTNM®	0.808 (0.722; 1.000) 0.827 ±0.178	0.877 (0.802; 1.000) 0.877 ±0.137 (–0.011; 0.110)	1.000 (0.767; 1.000) 0.899 ±0.127 (–0.001; 0.150)	0.879 (0.796; 1.000) 0.871 ±0.156 (–0.002; 0.120)
Solifenacin	0.858 (0.746; 1.000) 0.864 ±0.136	0.837 (0.774; 1.000) 0.843 ± 0.168 (-0.093; 0.051)	0.939 (0.774; 1.000) 0.892 ±0.122 (-0.005; 0.062)	0.940 (0.746; 1.000) 0.882 ±0.132 (-0.012; 0.048)
EQ-5D-5L VAS				
Peroneal eTNM®	85 (70; 92) 80 ±17	86 (72; 95) 83 ±14 (–2.8; 9.7)	91 (75; 95) 86 ±14 (0.4; 13)	92 (87; 99) 89 ±12 (1.9; 17)
Solifenacin	86 (80; 95) 84 ±11	86 (66; 95) 78 ±22 (–17; 3.8)	90 (76; 95) 84 ±16 (–6.0; 6.0)	86 (79; 95) 84 ±14 (–6.0; 5.2)

BL – baseline; CI – confidence interval; IQR – interquartile range; peroneal eTNM® – peroneal electrical transcutaneous neuromodulation; SD – standard deviation; VAS – visual analog scale

als are particularly susceptible – should also be taken into consideration [16].

The trend toward including non-invasive neuromodulation as the first-line treatment is reflected in the latest edition of the AUA/SUFU guidelines on the diagnosis and treatment of OAB [17].

This subgroup analysis has several strengths. First, the primary study was designed in a prospective, randomized manner. Second, solifenacin was chosen as an active comparator.

Solifenacin is one of the selective anticholinergics most frequently used in the treatment of OAB and has been extensively studied in numerous large-scaled trials, which have documented its high efficacy [18, 19]. Therefore, the comparison of peroneal eTNM® to solifenacin underlines the validity of the results of this study.

Along with these strengths, some limitations should be acknowledged. These include the relatively small sample size, a fixed treatment schedule for the solifenacin arm without option for dose escalation, and the absence of long-term follow-up. Nonetheless, another one-year follow-up study demonstrated the long-term safety and sustained therapeutic effect of peroneal eTNM® [20].

Despite these limitations, we believe that this subgroup analysis provides convincing initial data on the use of peroneal eTNM® in the treatment of incontinent OAB patients.

CONCLUSIONS

The data collected in this subgroup analysis confirm that OAB treatment using peroneal eTNM® has a better safety profile and comparable efficacy to solifenacin in the subgroup of incontinent OAB patients. A larger, randomized, multicentre study is, however, necessary to draw a definitive conclusion regarding the efficacy of peroneal eTNM® in this specific group of patients.

CONFLICT OF INTERESTS

J.K. is a consultant for Coloplast, Medtronic, Stimvia, and Promedon; M.R. is an investigator for Stimvia; M.S. and L.P. are part-time employees of Stimvia; P.Z. has nothing to disclose.

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ETHICS APPROVAL STATEMENT

The study protocol was approved by the national regulatory authority and independent Ethics Committee at each center.

The study was registered as EudraCT reg. Nr. 2019-003321-14.

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