

# Efficacy of daytime transcutaneous electrical stimulation of the genioglossus muscle in patients with obstructive sleep apnea syndrome: short report

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**Abstract** Obstructive sleep apnea syndrome (OSAS) is characterized by hypotonia of lingual and suprahyoid muscles. Genioglossus muscle is responsible for protrusion and depression of the tongue. Its dysfunction results in occlusion of the upper airways and greater incidence of apnea-hypopnea events during sleep. The aim of this prospective study was to compare the effects of daytime transcutaneous electrical stimulation of the genioglossus muscle and standard continuous positive airway pressure (CPAP) therapy on the quality of sleep, in patients with OSAS. During a 4-week study period, 19 patients with OSAS were subjected to daytime transcutaneous electrical stimulation of the genioglossus muscle before sleep and another 19 subjects underwent standard CPAP therapy. Polysomnography (apnea-hypopnea index, AHI), Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI) were used to diagnose OSAS and to verify the efficacy of both treatments. Electrical stimulation treatment was reflected by a decrease in PSQI ( $p = 0.012$ ) but did not influence ESS and AHI values ( $p > 0.05$ ). In turn, CPAP therapy resulted in a significant decrease in ESS and AHI values ( $p < 0.001$ ) but exerted no effect on PSQI ( $p = 0.089$ ). Despite improvement of sleep quality, electrical stimulation does not seem to reduce AHI values in patients with OSAS. Daytime electrical stimulation can be considered as an adjunct treatment in OSAS. Future

prospective studies should center on the identification of patients with OSAS who may benefit most from transcutaneous electrical stimulation.

**Keywords** Obstructive sleep apnea · Electrical stimulation · Genioglossus muscle · Sleep quality · Polysomnography

## Introduction

Obstructive sleep apnea syndrome (OSAS) occurs commonly in general population. Franklin and Lindberg analyzed results of 11 epidemiological studies published between 1993 and 2013, and estimated mean prevalence of obstructive sleep apnea (OSA), defined as apnea-hypopnea index (AHI)  $\geq 5$ , at 22 and 17 % for men and women, respectively [1]. A recent study conducted by Peppard et al. documented an increase in OSAS prevalence. According to these authors, prevalence of moderate to severe sleep-disordered breathing can be estimated at 10 and 17 % among 30 to 49- and 50 to 70-year old men, respectively, and at 3 and 9 % among 30 to 49- and 50 to 70-year-old women, respectively [2].

Results of many studies point to hypotonia of lingual and suprahyoid muscles as a factor influencing OSAS severity, especially during the REM phase [3, 4]. Genioglossus is an extrinsic muscle innervated by the hypoglossal nerve and responsible for protrusion and depression of the tongue. Dysfunction of this muscle leads to occlusion of the upper airways. Genioglossus fatigue during sleep is reflected by reduced or absent airflow and intermittent hypoxia in OSAS patients [3]. Although continuous positive airway pressure (CPAP) therapy is considered a standard treatment and proved effective in most

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OSAS cases, still alternative therapies for subjects with poor CPAP compliance are being tested [5]. Poor adherence to CPAP therapy is usually a consequence of adverse effects of this treatment, such as mask intolerance, choking, noise and nasal congestion [6].

Although electrical stimulation of the genioglossus muscle and hypoglossal nerve has been studied for many years as a potential alternative to CPAP therapy, most studies centered on the stimulation during sleep, and only few authors analyzed the efficacy of electrical stimulation or electro-acupuncture during wakefulness [7, 8].

The aim of this study was to compare the influence of daytime transcutaneous electrical stimulation of the genioglossus muscle and standard CPAP therapy on AHI reduction and sleep quality improvement in patients with OSAS. Our intention was to stimulate genioglossus muscle in a daytime to get improvement at night.

## Patients and methods

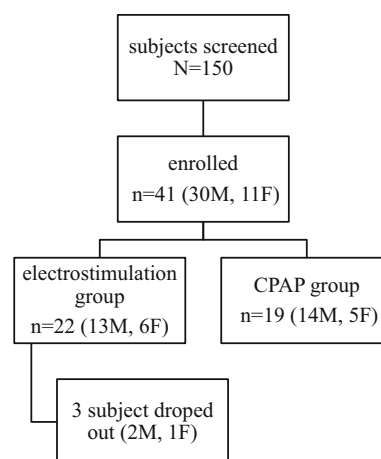
### Study and control group selection criteria

The study was conducted between September 2013 and March 2015. A total of 150 patients diagnosed with OSAS were screened at the Department of Lung Disease and Tuberculosis, Medical University of Bialystok. Finally, 41 subjects (30 men and 11 women) with OSAS were enrolled based on the presence of mild OSAS with increased daytime sleepiness or moderate OSAS, and documented intolerance to CPAP therapy. The latter was defined as an inability to maintain proper time of CPAP therapy ( $\geq 4$  h per night) and/or discomfort during the treatment (due to mask problems, noise, and high therapeutic pressure). OSAS was diagnosed according to the American Academy of Sleep Medicine (AASM) Scoring Manual ver. 2.1 [9].

Exclusion criteria of the study were: the presence of morphologic deformations of the maxilla confirmed on cephalometric analysis, nasal septum deviation, history of maxillofacial surgeries, use of a mandibular advancement device, cardiac arrhythmia, present or past neoplastic disease, goiter, or thyroid dysfunction diagnosed based on serum TSH, fT3, and fT4 levels.

### Study protocol

41 enrolled subjects were divided into two groups: (1) subjected to a 4-week daily transcutaneous electrical stimulation of the genioglossus muscle (TEGM group,  $n = 22$ ), and (2) subjected to a standard CPAP therapy with ResMed S9 Escape or Elite model for 4 weeks (CPAP group,  $n = 19$ ). Finally, 38 patients completed the study



**Fig. 1** Study population

and subjected to intention-to-treat analysis; 3 subjects from TEGM group were excluded due to unreliability Fig. 1.

### Transcutaneous electrostimulation of the genioglossus muscle (TEGM)

TEGM was conducted at the Department of Rehabilitation, Medical University of Bialystok.

Transcutaneous bilateral electrostimulation was performed during a daytime. After the preparation of the skin (shaving, if necessary, cleaning with standard 70 % isopropyl alcohol swabs), two skin electrodes (25 × 25 mm, Pals Platinum, Axelgaard) were placed in the submental region, as described previously by Steier et al. [10]. Parameters of electrical stimulation were as follows: frequency 40 Hz, time of impulse 75  $\mu$ s. The intensity of electric current was adjusted individually in each patient; the average tolerance approximated 16–28 mA (NeuroTrac Sports Stimulator, Verity Medical Ltd.). Duration of the procedure was prolonged each week for 20 to 40 min. Selecting the parameters of electrical stimulation, we followed the recommendation of Kezirian et al. [11], according to whom, a stimulation frequency of  $>30$  Hz should be used to achieve the tetanic contracture of the genioglossus muscle [11].

### Polysomnography study and sleep quality assessment

Full polysomnography (PSG) was performed and analyzed, in line with the AASM Manual for the Scoring of Sleep and Associated Events ver. 2.1 [9], using Alice 5 Sleep Diagnostic System (Respironics, Murrysville, Pennsylvania). The examination was performed prior to and after the 4-week treatments. OSAS severity was determined on the basis of apnea-hypopnea index (AHI). Daytime symptoms

were scored on the Epworth sleepiness scale (ESS) [12], and the quality of sleep was measured with the Pittsburgh sleep quality index (PSQI) [13].

### Ethical issues

Protocol of the study was approved by the Local Bioethics Committee at the Medical University of Bialystok (decision no. R-I-002/361/2013). All patients gave their written informed consent to participate in the study.

### Statistical analysis

The results were analyzed with STATISTICA 10.0 software (StatSoft, Inc.). Normal distribution of the study variables was verified with Kolmogorov–Smirnov test. Statistical characteristics of normally and non-normally distributed variables were presented as arithmetic means ( $\pm$ SD) and medians (interquartile ranges, IQR), respectively. Kruskal–Wallis test was used for intergroup comparisons, and the effects of electrical stimulation and CPAP within the groups were analyzed with non-parametric Wilcoxon test [14].

### Results

Demographic data and baseline clinical characteristics of the two groups of OSAS patients are presented in Table 1. Patients subjected to TEGM did not differ from individuals who underwent CPAP therapy in terms of their AHI, ESS, and PSQI values.

Seven patients from TEGM group presented with concomitant arterial hypertension, two with hypercholesterolemia and one with gout. One subject from TEGM group had a history of stroke. Comorbidities present in CPAP group included chronic sinusitis ( $n = 1$ ), arterial hypertension ( $n = 6$ ) and hypercholesterolemia ( $n = 5$ ).

Electrical stimulation resulted in a decrease in PSQI values ( $p = 0.012$ ), but did not cause significant changes in ESS and AHI scores ( $p > 0.05$ ). In turn, a decrease in ESS

and AHI ( $p < 0.001$ ), but not PSQI values ( $p = 0.089$ ), was observed after CPAP therapy. The results are presented in detail in Table 2 and on Fig. 2.

Patients subjected to TEGM and CPAP therapy differed significantly in terms of their post-treatment AHI values ( $p = 0.004$ ). However, no significant intergroup differences in ESS and PSQI scores were observed ( $p > 0.05$ ).

Three patients reported an attenuation of oral cavity dryness after TEGM. One subject treated with TEGM has a single episode of headache, which, however, did not result in discontinuation of the therapy.

### Discussion

Principal aim of OSAS treatment is to alleviate the symptoms of this condition due to an increase in the airway lumen during sleep. This objective can be achieved with CPAP, oral appliances, changes in sleep position, surgical treatment, and reduction of body weight. However, still new alternative therapies are needed, especially for patients who show poor tolerance to the standard treatments [5, 15]. The results of previous studies dealing with the application of electrical stimulation of the genioglossus muscle in OSAS patients are inconclusive. Electrical stimulation can be applied in two ways: with transcutaneous submental pads, or with implanted electrical stimulators of the hypoglossal nerve [lequex 7, steier 10, kezirian11, eastwood16]. Although the results of studies involving the electrical stimulators are promising, application of these devices seems to be limited due to presence of some adverse effects, such as infection at the incision site, pain, lip weakness, numbness, and cuff dislodgement. [15–17].

In most previous studies, electrical stimulation was performed during sleep, i.e., when occlusion of the upper airways occurred [10, 16]. Electrical stimulation during sleep resulted in a decrease in OSAS severity, as shown by a reduction of AHI values. Eastwood et al. observed a decrease in AHI scores, from 43.1 to 19.0 and 19.5 after 3 and 6 months of hypoglossal nerve stimulation therapy, respectively. Moreover, their patients presented with better

**Table 1** Demographics and baseline characteristics

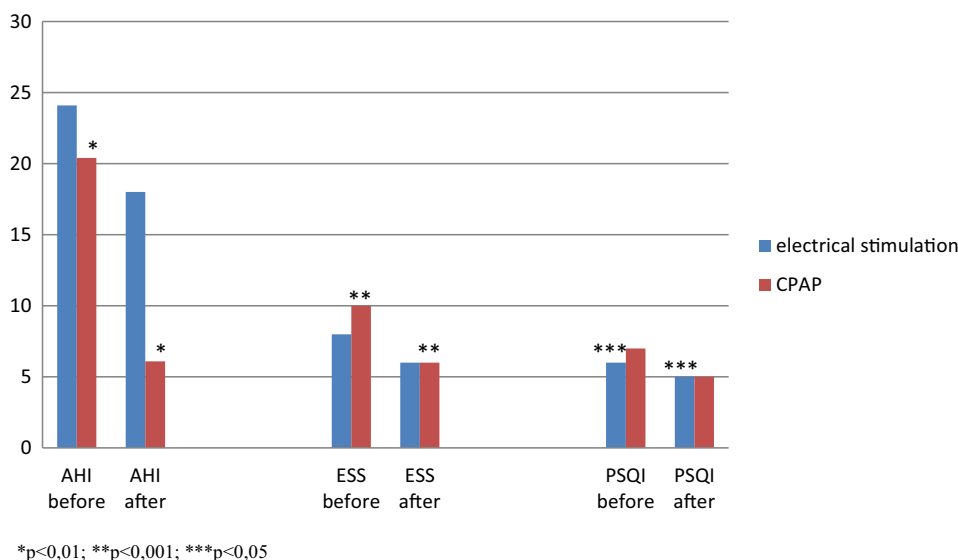
	Electrostimulation subjects $n = 19$	CPAP subjects $n = 19$	$p$
Age (years)**	55 (15.0)	54 (18)	0.6
BMI ( $\text{kg}/\text{m}^2$ )*	$29.8 \pm 5.1$	$33.1 \pm 7.06$	0.09
Neck circumference (cm)*	$41.7 \pm 300$	$43.5 \pm 2.4$	0.057
ESS (pts)**	8.0 (10.0)	10.0 (5.0)	0.31
PSQI (pts)**	6.0 (4.0)	7.0 (3.0)	0.3
AHI (events/h)**	24.1 (19.4)	20.4 (12.6)	0.76

\* The values were presented as mean  $\pm$  SD

\*\* The values were presented as median (interquartile ranges—IQR)

**Table 2** The results of electrical stimulation and CPAP treatment in OSAS patients

	Electrical stimulation (median and IQR)	<i>p</i>	CPAP (median and IQR)	<i>p</i>
ESS before	8.0 (10.0)	0.13	10.0 (5.0)	<0.001
ESS after	6.0 (6.0)		6.0 (4.0)	
PSQI before	6.0 (4.0)	0.012	7.0 (3.0)	0.089
PSQI after	5.0 (5.0)		5.0 (3.0)	
AHI before	24.1 (19.4)	0.49	20.4 (12.6)	0.001
AHI after	18.0 (22.6)		5.4 (5.6)	

**Fig. 2** The changes of AHI, ESS and PSQI after electrical stimulation and CPAP therapy (presented as median)

quality of life, as manifested by lower ESS values (from 12.1 to 8.1 after 6 months of the stimulation,  $p < 0.001$ ) and PSQI scores (from 10.1 to 7.5 after 3 months,  $p = 0.025$ ) [16]. Principal limitation of all the studies mentioned above stems from the fact that electrical stimulation induced arousals from sleep [15].

Campbell et al. analyzed patient preferences with regards to OSAS treatment. They presented the pictures of CPAP, mandibular advancement device, hypoglossal nerve stimulators and TEGM to 162 patients, among them 89.5 % with OSAS. The most preferred therapeutic modality was TEGM (56.7 %), followed by hypoglossal nerve stimulation (21.7 %), CPAP (17.8 %) and mandibular advancement device (3.8 %) [18].

In this study, we used daytime non-invasive superficial transcutaneous electrical stimulation to improve the function of the genioglossus muscle in OSAS patients. However, the treatment resulted in only subjective improvement of sleep quality, determined on the basis of PSQI scores ( $p = 0.012$ ), and did not induce significant changes in ESS and AHI values. Aside from examining the efficacy of electrical stimulation directly, we also compared its outcomes to those of routine CPAP therapy. The latter turned out to be more effective than electrical stimulation in terms

of AHI and ESS score reduction. Surprisingly, however, 4-week CPAP therapy did not result in significant changes in PSQI values ( $p > 0.05$ ).

Our findings stay in opposition to the results published by Lequeux et al. These authors used daytime neuromuscular electrical stimulation along with muscular exercises. Their study included 13 patients with OSAS, treated three times weekly for a period of 10 weeks; no control group was involved. Treatment resulted in a decrease in AHI values, from 32.9 to 20.6 ( $p = 0.017$ ); 7 patients completed the study with AHI scores lower than 10 [7]. Unfortunately, the authors of this study did not determine the quality of life in OSAS patients, either prior to or after the therapy. The discrepancies between our findings and the results published by Lequeux et al. may result from differences in the study protocols: (1) while we compared transcutaneous muscle stimulation solely to CPAP therapy, the other study included also daily muscular exercise regimen; (2) also the parameters of electrical stimulation differed between the studies: we used 75  $\mu$ s pulses with  $f = 40$  Hz and  $I = 16$ –28 mA as compared to 16  $\mu$ s pulses with  $f = 33$  Hz and  $I \geq 25$  mA in Lequeux et al. study; (3) none of our patients had a history of any anti-OSAS treatments prior to TEGM, while seven patients examined

by Lequeux et al. were previously subjected to CPAP and other two used mandibular advancement devices.

Freire et al. analyzed the effects of a single session of manual acupuncture and electro-acupuncture in a group of 40 patients with moderate OSAS. Genioglossus muscle electro-acupuncture was applied at 10 and 2 Hz to two groups of patients, 10 subjects each. Both manual acupuncture and 10 Hz electro-acupuncture resulted in a reduction of AHI scores and decrease in the incidence of respiratory events. Similar effects were not observed in patients subjected to 2 Hz electro-acupuncture group and in untreated controls [8].

Owing to inconclusive results of previous studies dealing with the problem in question, the true effectiveness of transcutaneous electrical stimulation in treatment of OSAS still remains unknown. Well-designed studies including larger groups of patients are needed to determine the optimal duration of electrical stimulation and to identify the individuals with OSAS who may benefit most from the physiotherapy. Until then, electrical stimulation can be considered an adjunct treatment in OSAS patients. Although CPAP therapy still remains the “gold standard” in OSAS management, there is a growing demand for more accepted and less burdensome treatment modalities.

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#### Compliance with ethical standards

**Conflict of interest** Authors declare that they have no conflict of interest.

**Ethical standards** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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