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Article

Analysis of the Efficacy of Transcutaneous Electrical Nerve Stimulation (Tens) in Patients with Xerostomia

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Abstract: Objective: To analyze the efficacy of transcutaneous electrical nerve stimulation (TENS) on parotid glands in patients with xerostomia. **Material and methods:** A simple, blinded, randomized, longitudinal, and prospective study was performed with 50 patients with xerostomia, divided into two groups: 25 patients received TENS and 25 received a sham treatment. The treatment group took part in three sessions with TENS that lasted 15 minutes each for three weeks. The production of saliva was measured through sialometry at the start and end of the treatment. The perception of xerostomia was assessed with the Visual Analog Scale (VAS-X) and the Xerostomia Inventory (XI), also at the beginning and the end. The impact on oral health (OHIP-14) was assessed in the first and third sessions. **Results:** A progressive improvement was observed after three treatment sessions. With respect to the initial VAS scores, these significantly decreased from the start 7.52 ± 1.92 to the end 6.84 ± 1.84 ($p < 0.001$). The sialometry values significantly increased, showing an increase in the salivary fluid from the start to the end of the treatment ($p < 0.001$). With respect to the Xerostomia Inventory (XI) (Thomson), it was reduced from the initial 36.88 ± 7.78 to 35.60 ± 7.42 after the sessions ($p = 0.01$). No significant changes were observed in the OHIP-14 in patients treated with TENS. **Conclusion:** The TENS therapy is presented as a promising and non-invasive alternative for the management of xerostomia, as it is able to objectively increase the salivary flow and improve the subjective perception of mouth dryness.

Keywords: saliva; transcutaneous electrical nerve stimulation; dry mouth; treatment

Introduction

The subjective sensation of dry mouth is known as xerostomia, but when this is objectively measured through sialometry, as a decrease in the rates of salivary flow below 0.1-0.2 mL/min of total saliva at rest, and below 0.4-0.7 mL/min of total stimulated saliva, this is known as hyposialia or salivary hyposecretion [1,2].

The persistence over time of low rates of salivary secretion leads to changes in the oral environment and condition the appearance of lesions on the hard or soft tissues of the mouth [3]. The oral clinical manifestations that appear in these patients are caries, periodontal disease, infections, and talking, chewing, or swallowing difficulties. In addition, a decrease in the sense of taste may occur [3].

Despite the description of various alternatives for the treatment of xerostomia in the last few years, the therapeutic options are not completely satisfactory [2-8]. The treatment proposals have been mainly based on: a) General hydration measures, avoiding toxic habits, or oral hygiene; b) Saliva substitutes such as sprays, rinses, and gels based on mucin or methylcellulose with a neutral pH and electrolytes; c) Sialogogues such as pilocarpine, which is an effective muscarinic agonist in xerostomia, but can cause significant adverse effects (sweating, diarrhea, bronchospasm, etc.). Cevimeline is also a muscarinic agonist, with better tolerance and lower discontinuation rates. In cancer patients, strategies such as Moderate Intensity Radiation Therapy (MIRT), the use of amifostine, and salivary gland transfer have been applied to prevent radiation-induced xerostomia.

A significant challenge for many clinicians is the recovery of salivary flow. As an alternative to drugs, Transcutaneous Electrical Nerve Stimulation (TENS) has been suggested. This is a conservative technique, less invasive and cheaper, with little or no adverse effects [9-12]. Although the mechanism of action of TENS on the parotid glands is not completely clear, it is believed that it could stimulate the auriculotemporal nerve, offering a valuable option for managing hyposalivation, especially in patients who do not tolerate or are not candidates for pharmacological treatments [11-13].

This technique has been shown to be safe and potentially effective in stimulating salivary flow in patients with hypofunction of the salivary glands due to conditions such as Sjögren's syndrome, head and neck radiotherapy, or medication side effects [14-15]. As compared with saliva substitutes such as gels or rinses, TENS has the advantage of inducing the natural production of saliva with minimal secondary effects, without chemical toxicity and ease of use [10-12].

Nevertheless, despite its benefits, there is lack of consensus in the literature about the optimal protocols for the application of TENS, including the frequency, intensity, duration, and location of the electrodes, as well as its long-term effectiveness [10-15]. This underlines the need to conduct additional studies that assess the safety, efficacy, and standardized TENS protocols in the specific population [12].

The lack of research in this field led us to propose a study to assess the viability and effectiveness of TENS in the treatment of xerostomia. The null hypothesis is that TENS applied to the parotid glands is not able to stimulate their salivary function.

The objective of the study was to assess the efficacy of a transcutaneous electrical nerve stimulation (TENS) treatment on patients with xerostomia, by assessing the objective and subjective changes in saliva production, and the quality of life related with oral health.

MATERIALS and METHODS

This study is simple, blinded, longitudinal, prospective with treatment and controls, and was conducted in the Department of Oral Medicine at the Faculty of Medicine and Odontology from the University of Murcia.

The study sample was composed by patients with a xerostomia diagnosis who attended the Department of Oral Medicine. The study protocol was designed in accordance with the principles of the Declaration of Helsinki and was approved by the Ethics Committee from the University of Murcia (ACATA 10/2024/CEI). The study was registered at ClinicalTrials.gov (ClinicalTrials.gov NCT06708195). All the patients participated voluntarily, having provided their Informed Consent after received detailed information about the study, and without receiving any economic compensation.

The inclusion criteria were: all the patients with a diagnosis of mouth dryness symptoms for more than three months and/or pathological sialometry.

- Age $\geq$ 18 years with xerostomia of any etiology
- Signed informed consent and commitment to attend the three study sessions.

While the exclusion were:

- Patients with resection of major salivary glands.
- Decompensated systemic disease.
- Medical conditions such as pacemaker implants, active skin infections, vertigo, continuous headaches, hearing problems, neuralgia or pregnancy. Motor problems or inability to follow instructions.

Participants:

A total of 54 patients were included in the study, of which 4 were excluded due to travel-related reasons or not wanting to participate. Ultimately, 50 patients completed the study (25 in the treatment

group and 25 in the sham (control) group). The patients were randomly assigned to the groups through a system of blocks (for example, AABB, ABAB, BABA) performed by a person not related to the study.

The design was a simple blinded study in which only the patients were blinded. The clinical protocol was performed by the same technician (FR), who had been previously trained. The characteristics of the patients were recorded, including age, sex, toxic habits (tobacco and alcohol), index of oral hygiene (good, average, bad), and number of medications consumed. Before the collection of saliva, the patients were instructed not to eat, drink, smoke, chew, or perform oral hygiene for at least 60 minutes prior.

Intervention with the TENS device:

The treatment was performed with the use of the commercial electro stimulator TENS EMS TN23 (Sale&Service SL, Langenhagen, Germany). The electrodes were placed bilaterally over the parotid glands for an effective stimulation. The intervention parameters were: Frequency: 50 Hz; pulse duration: 250 microseconds (μ s); duration of each session: 15 minutes. Three stimulation sessions were performed, with an interval of one week between them. At the end of each session, the patients were given a follow-up sheet to record the duration of the efficacy of the treatment every week.

The control (sham) group was treated with an inactive TENS device (sham treatment) for 15 minutes, following the same protocol as the experimental group. In both groups, sialometry, VAS-X, and Xerostomia Inventory (XI) measurements were performed, and the impact on quality of life was measured with the OHIP-14 questionnaire. However, the patients in the control group only participated in a single session. (figure 1)

Measurements.

A- Sialometry : Oral Schirmer test [16,17] through the impregnation of a strip of millimeter paper measuring 5 x 35mm, through which the salivary flow is displaced when it comes into contact with it

B-Questionnaires:

- **Visual Analog Scale for Xerostomia (VAS-X):** It measures the intensity of xerostomia perceived by the patient [0-10].
- **Xerostomia Inventory (XI):** It assesses xerostomia with a scale of 11 items. The total score can vary between 11 and 55, representing the severity of the xerostomia. A score of 11 indicates a very slight or non-existent xerostomia, while a value of 55 indicates severe xerostomia; it is considered that scores of 14 or higher indicate intense xerostomia [18].
- **Oral Health Impact Profile (OHIP-14):** It assesses the quality of life related with oral health. The total score varies from 0 to 70, where a higher score indicates a worse quality of life. It was given at the start and the end of the last session [19].

Sample size.

The sample size was calculated based on previous studies (Tabrez et al., 2022) [20], in which 70% of the patients with xerostomia and diabetes showed an improvement with TENS. Assuming a similar improvement, with a significance level of $\alpha = 0.05$ and a power of 80%, including 25 subjects per group was deemed necessary.

Satisfaction with the treatment: At the end of the treatment, patients evaluated their experience on a scale of 0 to 10, considering aspects such as comfort, perceived discomfort and general satisfaction.

Statistical analysis

The descriptive and inferential analysis of the data was performed with the free software R (R Core Team, 2024) [21]. An analysis of the general descriptive values of the variables studied were performed. Depending on compliance with the assumptions of normality and homoscedasticity, which was verified with the Shapiro-Wilk test, parametric tests (Student's t test or one-way ANOVA),

or non-parametric tests (Kruskal-Wallis K) were used. The post-hoc test was the Bonferroni test, while for the categorical data, Pearson’s Chi-square was used to verify their relationship. In all the analyses, a level of significance of 0.05 was used.

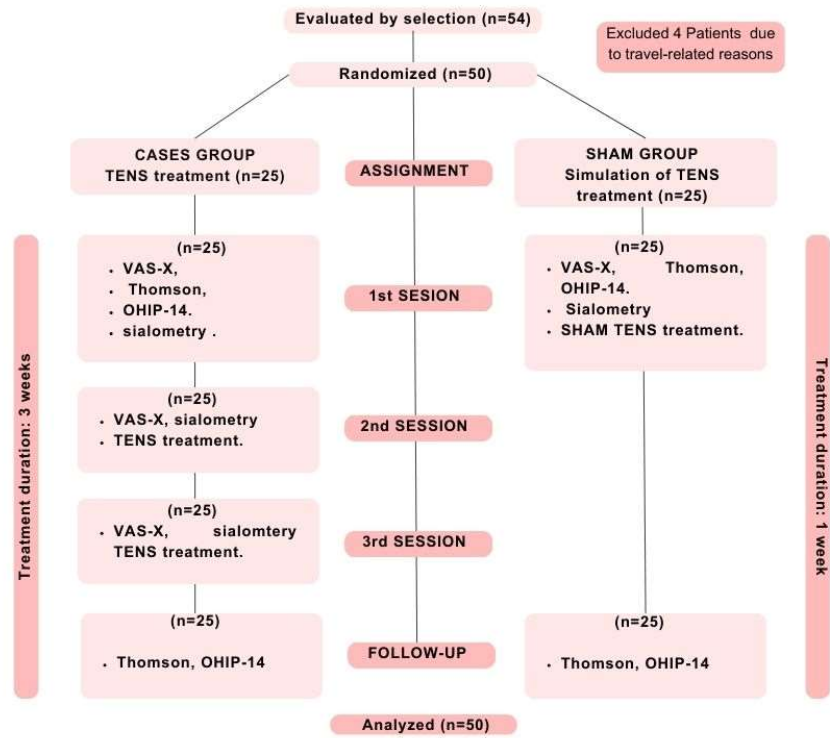


Figure 1. Flowchart of Included Patients.

RESULTS

Of the 54 eligible patients, 4 decided not to participate, so they were excluded. Ultimately, 50 patients were included in the study and randomly assigned to two groups without follow-up losses: the treatment group, with 25 participants, and the inactive TENS sham group (sham treatment) with 25 participants. Table 1 shows the sociodemographic data of the patients.

Table 1. Sociodemographic and Clinical Characteristics of the Participants.

Variable	Treatment group (n=25)	Sham Group (n=25)	p-Value
Age (mean ± SD)	61.92 ± 12.35	54.76 ± 12.44	0.06
Sex			0.17
- Men	3 (12%)	8 (32%)	
- Women	22 (88%)	17 (68%)	
Tobacco			0.17
- Yes	3 (12%)	8 (32%)	
- No	22 (88%)	17 (68%)	
Alcohol			0.49
- Yes	0 (0%)	2 (8%)	
- No	25 (100%)	23 (92%)	
Quality of hygiene			0.14
- Good	15 (60%)	10 (40%)	
- Average	7 (28%)	14 (56%)	
- Bad	3 (12%)	1 (4%)	

Variable	Treatment group (n=25)	Sham Group (n=25)	p-Value
Number of medications	3.28 ± 2.19	3.80 ± 4.25	0.62

A. Immediate Effects of the Treatment

In the first session, the immediate effects of the treatment with TENS were assessed with the VAS-X, Xerostomia Inventory (XI), sialometry , and OHIP-14 scales. The specific results are described below:

Table 2. In the first session, the immediate effects of the treatment with TENS were assessed with the VAS-X, Xerostomia Inventory (XI), sialometry ,

Group	Test	Baseline (Mean ± SD)	Post-session (Mean ± SD)	p-value	
				(Baseline vs Post)	vs
Treatment	VAS-X	7.52 ± 1.92 points	6.84 ± 1.84 points	< 0.001	
	Sialometry mm	21.00 ± 16.38 mm	27.68 ± 29.44 mm	< 0.001	
	Xerostomia Inventory (XI)	36.88 ± 7.78 points	35.60 ± 7.42 points	0.01	
Sham	VAS-X	5.24 ± 2.13 points	5.04 ± 2.15 points	0.04	
	Sialometry mm	29.56 ± 16.55 mm	29.80 ± 16.51 mm	0.68	
	Xerostomia Inventory (XI)	28.74 ± 9.30 points	28.74 ± 9.30 points	Not significant	

B. Interpretation of the Comparison between Groups:

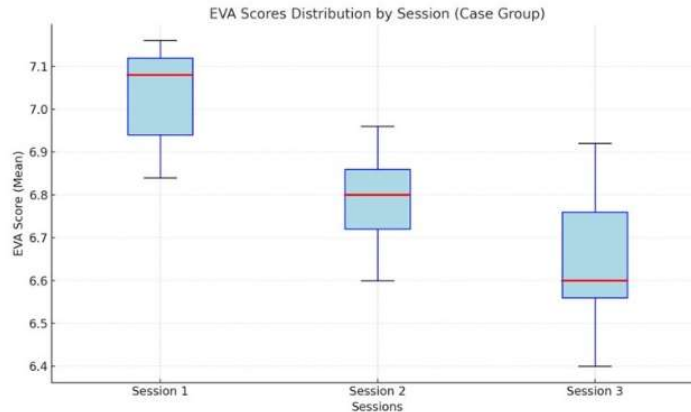
The comparison between the “Treatment” and “Sham” groups showed statistically significant differences (p<0.01). With respect to the sialometry mm, a significant difference was observed between groups (p = 0.02), with a stronger increase in the measurement of salivary flow. With respect to XI test: the difference between the groups was highly significant (p < 0.001); **OHIP-14**: both groups did not show significant changes in the post-session scores, which suggests that the impact on the perception of oral health was not considerable, but differentially significant at the statistical level.

C. In the treatment group, the TENS treatment led to significant changes in the perception of xerostomia VAS-X and XI(Thomson), sialometry, and a tendency for quality of life to improve was observed (OHIP-14).

In the treatment group, a progressive improvement was observed after the three treatment sessions. The initial VA-X scores significantly decreased from 7.52 ± 1.92 in the first session to 6.84 ± 1.84 after the third session (p < 0.001). Similarly, the production of saliva significantly increased from 21.00 ± 16.38 mm to 27.68 ± 29.44 mm after the first session, showing a continuous increase in posterior sessions (p < 0.001) (Figs 1, 2, and 3). As for the subjective perception of mouth dryness, the Xerostomia Inventory (XI) (Thomson) decreased from 36.88 ± 7.78 to 35.60 ± 7.42 after the sessions (p = 0.01).

Although the quality of life measured with the OHIP-14 was not significant (30.72 ± 11.73 to 30.12 ± 11.19, p = 0.06), the data show a cumulative positive impact of the treatment in the treatment group.

Figure 2 shows the distribution of Visual Analog Scale (EVA) scores for each session (Session 1, Session 2, and Session 3) in the case group.



With respect to the mean duration of the treatment (0h is immediately after the session, and 144h is just before the next session, we found that the mean duration of the effect was 6.21 ± 9.81 hours. After analyzing the data according to the number of sessions, it was found that in the first session, the mean duration was 5.65 ± 9.03 hours, in the second session 6.56 ± 9.49 hours, and in the third session, 6.42 ± 10.81 hours. These results indicate a considerable variability in the response to the treatment between the subjects throughout the sessions.

The device was well accepted in terms of comfort, discomfort perceived, and overall score. In comfort, the treatment groups reported a mean of 9.00 ± 0.58 , while the sham group provided a mean of 8.64 ± 0.81 ($p = 0.28$). The discomfort was minimal, with a value of 0.20 ± 0.64 in the treatment group and 0.12 ± 0.60 in the sham group ($p = 0.36$). The mean of the overall score was 8.84 ± 0.69 in the treatment group, and 8.60 ± 0.71 in the sham group ($p = 0.64$). The differences were not significant, indicating a uniform positive perception among the participants.

Discussion

The use of TENS in the management of xerostomia has been investigated in different etiological contexts, which encompass radiotherapy-induced xerostomia, to cases linked to systemic, pharmacological, or hormonal conditions [10-12]. The mechanism of action of TENS on the parotid glands is not yet clear, although it may have an effect when stimulating the auriculotemporal nerve. In our study, we found that the application of TENS bilaterally on the parotid glands in 15-minute sessions once a week for three consecutive weeks resulted in a significant reduction in the perception of mouth dryness (VAS-X and XI, and a significant increase in the production of salivary fluid. In addition, the quality of life tended to increase (OHIP-14), although this increase was not statistically significant.

Talal et al. [22] assessed electrostimulation devices in a clinical assay, showing a statistically significant increase in the production of saliva in the group of patients with Sjögren syndrome. These results suggest that TENS can stimulate functional residual glands with a profile of reduced secondary effects as compared with pharmacological therapies. Nevertheless, the study did not explore the subjective impact of the symptoms or the quality of life.

In another non-randomized clinical study in post-menopausal women with xerostomia associated to hormonal changes, conducted by Konidena et al. (2016) [16] the application of TENS found that 90% of the participants showed a significant increase in salivary flow, independently of the initial severity of mouth dryness.

The study results suggest that the treatment may have a dose-dependent effect, as the VAS-X scores progressively decreased after each session. This underlines the need for a more in-depth assessment. After analyzing the protocols, a lack of consensus in the literature was found on the optimum duration and frequency of the TENS sessions for the treatment of xerostomia. In Wong et al. [23,24], the total duration of the treatment was 12 weeks, with two sessions per week, and each session lasting 20 minutes, while in Vijayan et al. [25] and Lakshman et al. [26], the authors did not specify the total duration of the treatment, only the duration of each session (5 minutes and 10 minutes, respectively). On the other hand, in Paim et al. [27], the treatment lasted 4 weeks, with two 20-minute sessions per week.

The importance of adjusting the TENS parameters to optimize its benefits and minimize the possible adverse effects are underlined in diverse studies. Vilas SK et al. (2009) [28] performed a clinical study with 100 patients with xerostomia due to diverse causes, finding that in 85%, an increase in saliva production was observed after the application of TENS. Nevertheless, 4% indicated a decrease in salivary flow, which was attributed perhaps to the use of inadequate intensity parameters or frequency of stimulation, as the salivary reflex may be altered when the brain perceives a stimulus to be painful. Similarly, Yang et al. (2022) [29] assessed hemodialysis patients affected by xerostomia, dividing the patients into two groups with different configurations of TENS. The results showed that group 1 (G1), with a configuration of 50 Hz and 250 μ s, obtained better results than group 2 (G2), configured with 2 Hz and 50 μ s. Based on these findings, a dose of 50 Hz and 250 μ s were used in the treatments in the present study. The criteria to define the intensity of the current in all of the studies was defined according to the comfort of the subjects. Only Paim et al. [26] reported the intensity tolerated by the patient during the intervention, which was 38.8 ± 7.5 mA.

Our results show that the TENS therapy provides an average relief of 6 to 7 hours after each treatment session, with a notable decrease in the subjective scores. This efficacy, together with the absence of secondary systemic effects, establishes the TENS therapy as a promising option as compared with conventional treatments, such as mechanical methods, sialogogue drugs, and saliva substitutes. Thus, it is consolidated as an efficient alternative that is less invasive and more convenient for the management of xerostomia. TENS is generally safe and well-tolerated, and none of the patients experienced significant secondary effects.

Although our study was not initially centered on exploring immediate effects, the results highlight a notable impact right after the first session. After the comparison between the treatment and sham groups, it was observed that after a single intervention, the reduction in the scores was significantly more pronounced in the treatment group. This finding underlines that even a single session can have a considerable effect, which is fundamental for understanding the immediate efficacy of the treatment.

The treatment through TENS was also effective in post-radiotherapy xerostomia. Wong et al. (2003) [23] conducted one of the first controlled randomized assays where ALTENS (Acupuncture-Like Transcutaneous Electrical Nerve Stimulation, low amplitude TENS) was compared with pilocarpine in 37 patients. The results demonstrated that ALTENS was more effective in improving salivary flow and alleviating xerostomia, laying the foundations for considering TENS as a viable alternative to pharmacological treatment. Afterwards, Vijayan et al. (2014) [25] assessed the application of TENS in 30 patients, showing that it doubled the production of saliva measured through the spitting method. However, this study did not assess the impact on quality of life, limiting its perspective on the comprehensive effect of the treatment.

In 2015 [24], Wong et al. expanded the findings of their previous study with a controlled randomized trial with 96 patients, once again comparing ALTENS with pilocarpine. This study confirmed that ALTENS was not only superior in terms of efficacy, but also showed less toxicity.

On their part, Lakshman et al. (2015) [26] investigated the impact of the daily application of TENS in 40 patients, finding a significant increase in salivary flow. Paim et al. (2019) [17] complemented this evidence with a controlled randomized assay with 15 patients, where they

showed that the effects of TENS, aside from increasing salivary production, were maintained until after six months, improving the quality of life perceived.

Despite the limitations inherent to the unequal number of sessions between the treatment and sham groups, this methodological decision was crucial for our study. The design intentionally limited the sessions of the sham group to a single session, due to the ethical and logistical considerations, thus allowing us to focus the assessment on the cumulative effects of the treatment exclusively in the treatment group.

Thus, the assessment of the immediate effects in the first session in both groups allowed for a direct comparison of the initial response to the treatment, which is essential for establishing the immediate effect of TENS.

The variability in the intensity and frequency of the stimuli underlines the importance of adapting TENS to the individual needs of each patient, and future research studies must focus on optimizing the application protocols, assessing its long-term effect, and exploring combinations with other therapies to maximize its benefits. This will consolidate TENS as a comprehensive and effective therapeutic option in the management of xerostomia. The main advantage of TENS is that it is an extraoral device with minimal secondary effects, which makes it more practical than other non-pharmacological methods, such as intraoral devices or artificial saliva.

Conclusions

TENS is a non-invasive, safe, and well-tolerated therapy that can be used as an effective alternative in the treatment of xerostomia, especially when drugs are contraindicated or have severe secondary effects. The results show that the treatment with TENS was effective in reducing the VAS-X scores and increasing salivation.

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