

Evaluating The Efficacy of The Salivary Pacemaker – Tens Therapy in Xerostomia Patients - A Pilot Study



Medical Science

KEYWORDS : Saliva, salivary flow, transcutaneous electrical nerve stimulation

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ABSTRACT

Aim: This study was undertaken to evaluate the effectiveness of transcutaneous electric nerve stimulation (TENS) as a means of stimulating salivary function in dry mouth patients.

Materials and Methods: 20 adult subjects with DRY MOUTH were enrolled in the protocol. TENS electrode pads were placed externally on the skin overlying the parotid glands. Unstimulated and stimulated saliva was collected for 5 min into graduated tubes. TENS unit was then activated and the stimulated saliva collected for an additional 5 min. A paired "t" test was applied to look for statistically significant differences as a group between the amount of unstimulated and TENS-stimulated samples of saliva.

Results: ALL OF THE 20 subjects demonstrated increased salivary flow when stimulated via the TENS unit. The Mean Increase in the Unstimulatory And Stimulatory Flow Rate at baseline Was 0.26+0.11 And 1.14+0.26 and At 4th Week Was 1.57+0.45 And 2.84+0.47 respectively and the difference was highly Significant (P<0.001)

Conclusion: The TENS unit was effective in increasing the salivary flow In all of the Study Subjects. A further study in more number of Patients is warranted.

Introduction

An inherent and yet profound aspect of our wellbeing depends on a humble, unassuming fluid known as Saliva. Mandel (1990) eloquently has quoted "Saliva is not one of the popular bodily fluids. It lacks the drama of blood, the sincerity of sweat and the emotional aspect of tears." However, this unpretentious secretion is a multifaceted, multipurpose bodily fluid which is indispensable. Living with insufficient quantities of this essential, complex fluid leads to an appreciation of what has been lost.

Xerostomia refers to a subjective sensation of dry mouth; it is frequently, but not always, associated with salivary gland hypofunction¹. It is a common complaint found often among older adults, affecting approximately 20 % of the elderly². Several short and long term conditions can disrupt salivary secretion which include periods of stress and anxiety, mouth breathing, advancing age, local and systemic conditions, selected medical disorders like rheumatoid arthritis, diabetes mellitus, hypertension, autoimmune disorders, chemotherapy and radiotherapy of head and neck, smoking and recreational drug usage^{3,4}.

The salivary flow rates (SFR), that is, both stimulated and unstimulated, have been proposed as the test of choice, which is also known as the salivary flow index, based on which it can be classified as normal, low or very low^{5,6}. Unstimulated whole saliva (UWS) reflects basal salivary flow rate and it provides protection to oral tissues. Unstimulated salivary flow provides a precise parameter to analyze the salivary gland status; it also maintains the consistency in the sample collected. The stimulated saliva provides information about the functional reserves⁷.

In adults, normal unstimulated and stimulated salivary flow

ranges from 0.25-0.35 ml/min and 1-3ml/min respectively whereas hyposalivation is characterized by a salivary flow of less than 0.1ml/min and less than 0.7 ml/min respectively^{5,8,9}.

Decrease in saliva makes one vulnerable for increased plaque formation, rampant caries, opportunistic fungal infections, mucositis, difficulty in swallowing and eating. The general approach in treating patients with xerostomia is directed at palliative treatment and prevention of oral complications. Topical agents such as saliva substitutes and ice chips and application of lip balm, as well as increased water intake do help to ameliorate the condition. Salivary stimulation has been tried with chewing sugar-free gums and paraffin, sucking sour lemon drops and lozenges and rinses, with limited success¹⁰. Systemic agents like pilocarpine and cevimeline induce salivary flow but show side effects like profuse sweating, rhinitis, dyspepsia¹¹ and must also be used cautiously in disorders of cardiovascular, respiratory systems and glaucoma¹².

TENS (Transcutaneous Electrical Nerve Stimulation) is an extraoral device that has been studied as a means of stimulating salivary flow through electrostimulation. It is postulated that it might directly stimulate the auriculotemporal nerve that supplies the secretomotor drive to the parotid glands¹³.

Use of TENS in stimulation of saliva has been studied in the past which showed moderate promising results. However, it never became a part of the mainstream therapy.

Since research in this area has been sparse, a study was undertaken to evaluate the effect of TENS as a means of increasing

salivary flow rate in patients with xerostomia.

MATERIALS AND METHODS

The study was conducted in the Department of Oral Medicine and Radiology, People's college of Dental Sciences, India after obtaining clearance from the Institutional Ethical Committee, People's University, Bhopal and it is in full accordance with the World Medical Association Declaration of Helsinki. All the participants were informed about the procedures and written consent was obtained.

SAMPLE SIZE- The study group comprised of 22 subjects (14 females and 8 males), in the age range of 20-69 years.

INCLUSION CRITERIA

1. Patients having UWS values <0.1ml/min.
2. Xerostomia due to any of the following causes: Drugs, History of salivary gland disorders, Presence of systemic disease like diabetes, Hypertension, Cardiovascular disease, Renal dysfunction, Liver disorders, History of head and neck radiotherapy

EXCLUSION CRITERIA

1. Complaint of dry mouth with normal salivary flow rate
2. Patients wearing pacemakers, defibrillators, hearing aids
3. Patients undergoing medical management for xerostomia
4. Pregnancy
5. Patients with neurological disorders.

SAMPLE COLLECTION - The participants were asked to refrain from eating, drinking, chewing gum, and smoking for at least 1 h prior to the appointment. Salivary samples were collected between 9 AM - 12 PM to minimize the circadian variation. Unstimulated whole saliva (UWS) was collected for 5 min by the "low forced spitting" method.

The TENS unit used for this study was TX-3T (dual channel). After placing the electrode pads externally on the skin overlying the parotid glands, they were activated, with pulse rate fixed at 50 Hz. The intensity control was gradually increased to a tolerable level of the patient and then administered for 15 min. Later, the stimulated saliva was collected by the "spitting method" i.e. once in a minute for 5 minutes, in a graduated test tube, fitted with a funnel.

TENS therapy was administered once in a week for 5 consecutive weeks, whereby UWS was collected prior to the treatment & Stimulated salivary flow rate - post treatment, in a manner described above. Salivary flow rates were calculated by dividing the amount of collected saliva (volume in ml) by duration of collection period (5 min).

RESULTS

A total of 22 subjects, diagnosed with xerostomia, were subjected to TENS for a period of 5 weeks with a 1 week interval. The baseline unstimulated saliva and stimulated saliva values were 0.26±0.11 ml/min and 1.14±0.26 ml/min respectively. At the end of 4th week, unstimulated saliva and stimulated saliva values were 1.57±0.45 and 2.84±0.47 respectively. (TABLE 1,GRAPH 1)

Paired "t" test showed an increase in both the unstimulatory and stimulatory salivary flow on weekly basis (p<0.001) (TABLE 2)

ANOVA test showed an increase in the SFR, both unstimulated and stimulated, from the baseline values to each subsequent week, and the difference was statistically significant.(p<0.001).

In Intragroup comparison, Tukey's post hoc analysis showed the mean difference between the pre-stimulatory and post stimulatory flow rate at each visit to be statistically significant. (p<0.001)

Table 1: Unstimulated & Stimulated Salivary flow rate by TENS at Baseline & 4th Week

FLOW RATE (ml/5min)	Baseline Mean ±SD	4 th Week Mean ±SD	Mean Difference	Paired Student 't' test value	p Value
Unstimulated Salivary flow Rate	0.26±0.11	1.57±0.45	1.31	15.537	0.001
Stimulated Salivary flow Rate	1.14±0.26	2.84±0.47	1.70	17.540	0.001

Table 2: Unstimulated & Stimulated Salivary flow rate by TENS on weekly basis

FLOW RATE (mL/5 min)	Baseline Mean±SD	1 st Week Mean±SD	2 nd Week Mean±SD	3 th Week Mean±SD	4 th Week Mean±SD
Unstimulated Salivary flow Rate	0.26±0.11	0.53±0.24	0.93±0.32	1.31±0.41	1.57±0.45
Stimulated Salivary flow Rate	1.14±0.26	1.54±0.41	2.01±0.49	2.50±0.39	2.84±0.47
Mean difference	0.88±0.15	1.01±0.17	1.08±0.17	1.19±0.02	1.27±0.02
Paired Student 't' test value	17.853	17.754	14.847	14.734	15.189
p Value	0.001	0.001	0.001	0.001	0.001

Graph 1: Unstimulated & Stimulated Salivary flow rate by TENS at Baseline & 4th Week



Graph 2: Unstimulated & Stimulated Salivary flow rate by TENS at different time interval



Discussion

"You will never miss the water until the well runs dry". How precisely it has been quoted, especially for saliva. It serves as a multitasker as it moistens and cleanses the oral cavity, facilitates speech, lubricates food for chewing and swallowing, aids in full appreciation of taste sensation, helps in digestion, acts as a buffering agent to neutralize acid attack of bacteria, acts as an anti-

microbial agent, mineralizes the teeth¹⁴.

Oral dryness is a complex condition, expressed as a physiological deficiency with or without perceived dysfunction. Clinically, it may vary from a slight reduction in salivary flow with transient inconvenience to severe impairment of oral health with or without psychological indisposition¹⁵.

In patients with minimal salivary function, stimulation of secretion may be of benefit, both for relieving dryness symptoms and providing the protective effects of natural saliva. Topical agents can provide some symptomatic and intermittent relief, but not all patients report benefit from these agents. Ideally, to ensure both short and long term relief, any means of stimulating salivary secretion must be resorted to, which should be easy to administer, reliable, and free of adverse side effects. One promising modality which fits in the above mentioned categories is the use of electrical stimulation. This modality has grabbed the attention because of the following advantages like being painless, non-invasive and readily acceptable.

A number of studies have been reported by authors, after single application of TENS therapy. In a study by Mittal K et al (2012)¹⁶, there was 70.28% increase in salivary flow, which was statistically significant where 47 out of 50 patients responded positively to TENS therapy. Jagadhari SB et al (2014)¹³ found a significant increase in the salivary secretion after TENS stimulation in 30 patients with hyposalivation. In a study by Domingo DL (2004)¹⁷, 6 of the 18 post radiation head and neck cancer patients demonstrated significant increase in salivary flow after TENS application.

In the present study, commencing at the baseline (week 0) to the end of the study (week 4), all subjects showed an increase in the unstimulatory and stimulatory salivary production, which was highly significant ($p < 0.001$). These were similar to a study by Steller M et al (1988)¹⁸ in which unstimulatory and stimulatory whole saliva flow rate of 24 subjects was increased. Talal et al (1992)¹⁹, reported an increase in mean pre-stimulatory and post-stimulatory whole salivary flow rates at week 0, week 2 and week 4 in 40 subjects.

This study is one of its kind, where multiple sittings of TENS have been employed as a therapeutic measure for xerostomia demonstrating a 5-fold increase in the unstimulatory (503.8%) and one and a half-fold (149.12%) increase in the stimulatory salivation at the end of 5th week.

The salivary secretion controlled by a three-component reflex arch, including (a) afferent receptors and nerves that carry impulses created by taste and mastication activities, (b) a central connection and processing nucleus (salivation center) and (c) an efferent reflex arm constituted by parasympathetic and sympathetic nerves bundles. Impulses from the periphery are carried to the salivation center in the medulla oblongata, which in turn guides signals to the efferent part of the reflex arch leading to salivation.²⁰

It may be hypothesized that application of electric impulse to one of the three components of the salivary reflex arc should improve the salivary secretion. Hence it is posited that auriculotemporal nerve is stimulated neuroelectrically increasing the secretomotor drive to the parotid gland²¹

The present study using TENS therapy, has definitely shown encouraging results, in increasing salivary secretion. Though some authors²² have described side effects like anaesthesia of the facial skin and muscle twitching, we didn't encounter any side effects among the patients.

CONCLUSION

Xerostomia interferes with nutrition, leads to deterioration of oral hygiene and predisposes patients to oral candidiasis and dental pathologies. TENS may be used synergistically with other sialogogues for the management of xerostomia. The main advantage offered by TENS, which is an extraoral device, are its negligible side effects, feasibility of its usage, patient compliance and acceptability and the economy involved. This study complies with the statement "Neuroelectrostimulation of salivary glands takes the still remaining salivation reserves into therapeutic use"

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

- Goel R, Vedi A. Xerostomia: A common problem of the Geriatric Population. *Int J of Adv Res* 2015; 3:52-56
- Sultana N, Sham EM. Xerostomia: An overview. *Int J of Dent Clin* 2011;3:58-61
- McMillan R. Dry mouth – A Review of this common Oral problem. *Dental Nursing* November. 2013;9.
- Gupta A, Epstein JB, Sroussi H. Hyposalivation in Elderly patients. *J Can Dent Assoc.* 2006;72:841-6
- De Almeida PV, Greggio AM, Machado MA, De Lima AA, Azevedo LR. Saliva Composition and Functions: A Comprehensive Review. *J Contemp Dent Pract.* 2008 Mar;9.
- Badiyani B, Kumar A, Maru VP. Role of Saliva in Dental Practice – A Review. *Research and Reviews: J Dent Sci.* 2013 Apr-Jun;1:1-6.
- Fenoll-Palomares CF, Munoz-Montagud JV, Sanchiz V, Herreros B, Hernandez V, Minguez M, Benages A. Unstimulated Salivary flow rate, pH and buffer capacity of Saliva in healthy volunteers. *Revista Espanola de Enfermedades Digestivas.* 2004;96:773-783
- Lofgren CD, Wickstrom C, Sonesson M, Lagunas PT, Christersson C. A systematic review of methods to diagnose oral dryness and salivary gland function. *BMC Oral Health* 2012;12:29.
- Pattipati S, Patil R, Kannan N, Kumar BP, Shirisharani G, Mohammed RB. Effect of transcutaneous electrical nerve stimulation induced parotid stimulation on salivary flow. *Contemp Clin Dent* 2013;4:427-31.
- Singh D, Agrawal S, Shashikanth MC, Misra N. The effects of transcutaneous electric nerve stimulation (TENS) on salivary flow: A study. *J Indian Acad Oral Med Radiol* 2015;27:16-9.
- Bhasin N, Reddy S, Nagarajappa AK, Kakkad A. A study on duration of effect of transcutaneous electrical nerve stimulation therapy on whole saliva flow. *J contemp dent prac* 2015;16:479-485
- Greenberg MS, Glick M, Ship JA. *Burket's Oral Medicine.* 11 th ed. Hamilton: BC Decker;2008.
- Jagdhari SB, Patni VM, Motwani M, Gangotri S. To Evaluate the Effectiveness of Transcutaneous Electric Nerve Stimulation (TENS) in patients with hyposalivation: A Pilot Study. *IOSR Journal of Dental and Medical Sciences.* 2014 sep;13:74-77
- Lakshman AR, Babu GS, Rao S. Evaluation of effect of transcutaneous electrical nerve stimulation on salivary flow rate in radiation induced xerostomia patients: A pilot study. *J Can Res Ther.* 2015 Jan-Mar;11:229-233
- Löfgren CD, Wickström C, Sonesson M, Lagunas PT, Christersson C. A systematic review of methods to diagnose oral dryness and salivary gland function. *BMC Oral Health.* 2012;12:29.
- Mittal K, Keluskar V, Kapoor S. Evaluation of TENS on salivary flow rate in patients with xerostomia. *Annals of Dental Research* 2012;2:44-50.
- Domingo DL. The effects of electrostimulation on saliva in postirradiation head and neck cancer patients. *Oral surg, Oral Med, Oral Pathol, Oral Radiol Endod.* 2004 Apr;97:464.
- Steller M, Chou L, Daniels TE. Electrical stimulation of salivary flow in patients with Sjogren's Syndrome. *J Dent Res.* 1988 Oct;67:1334-7.
- Talal N, Quinn JH, Daniels TE. The clinical effects of electrostimulation on salivary functions of Sjogren's syndrome patients. *Rheumato Int.* 1992;12(2):43-5.

20. Sarapur S, Shilpashree HS. Salivary Pacemakers: A review. *Dent Res J* 2012;9(1)
21. Fedele S, Wolf A, Strietzel F, Lopez RM, Porter SR, Konttinen YT. Neuroelectrostimulation in Treatment of Hyposalivation and Xerostomia in Sjögren's Syndrome: A Salivary Pacemaker. *J Rheumatol* 2008;35(8):1489-94
22. Hargitai IA, Sherman RG, Strother JM, Bethesda, Harbor P. The effects of electrostimulation on parotid saliva flow: A pilot study. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2005;99(3):316-20.