



A Study on Duration of Effect of Transcutaneous Electrical Nerve Stimulation Therapy on Whole Saliva Flow

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ABSTRACT

Background: Saliva is a complex fluid, whose important role is to maintain the well being of oral cavity. Salivary gland hypofunction or hyposalivation is the condition of having reduced saliva production which leads to the subjective complaint of oral dryness termed xerostomia.⁷ Management of xerostomia includes palliative therapy using topical agents or systemic therapy. Electrostimulation to produce saliva was studied in the past and showed moderate promise but never became part of mainstream therapy. Hence, this study was undertaken to evaluate the effect of transcutaneous electrical nerve stimulation (TENS) on whole salivary flow rate in healthy adults and to evaluate how long this effect of TENS lasts on salivary flow.

Materials and methods: One hundred healthy adult subjects were divided into five age groups with each group containing 20 subjects equally divided into males and females in each group. Unstimulated saliva was collected using a graduated test tube fitted with funnel and quantity was measured. Transcutaneous electrical nerve stimulation unit was activated and stimulated saliva was collected. Saliva was again collected 30 minutes and 24 hours post stimulation.

Results: The mean unstimulated whole saliva flow rate for all subjects ($n = 100$) was 2.60 ml/5 min. During stimulation, it increased to 3.60 ± 0.39 ml/5 min. There was 38.46% increase in salivary flow. Ninety six out of 100 responded positively to TENS therapy. Salivary flow remained increased 30 minutes and 24 hours post stimulation with the values being 3.23 ± 0.41 ml/5 min and 2.69 ± 0.39 ml/5 min respectively. Repeated measures One way analysis of variance (ANOVA) test showed that the difference between these values were statistically significant.

Conclusion: Transcutaneous electrical nerve stimulation therapy was effective for stimulation of whole saliva in normal, healthy subjects and its effect retained till 30 minutes and a little up to 24 hours. Transcutaneous electrical nerve stimulation may work best synergistically with other sialagogues and can be used for the management of xerostomia.

Keywords: Duration, Effect, Saliva, TENS therapy, Xerostomia.

How to cite this article: 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 Pract 2015;16(6):479-485.

Source of support: Nil

Conflict of interest: None

INTRODUCTION

The oral cavity is a moist environment; a film of fluid called saliva constantly coats its inner surfaces and occupies the space between the lining oral mucosa and the teeth. Saliva is a complex fluid, whose important role is to maintain the well being of oral cavity.¹ There are three major salivary glands namely parotid, submandibular and sublingual, along with 300 to 500 minor salivary glands, which produce about 1 to 1.5 liters of whole saliva daily.²

The saliva circulating in the mouth at any given time is termed whole saliva and comprises of secretions from the major and minor salivary glands, gingival crevicular fluid, oral bacteria, desquamated epithelial cells and food debris.³ At rest, a small, continuous salivary flow (SF), denominated basal unstimulated secretion, is present. Stimulated saliva is produced under mechanical, gustatory, olfactory or pharmacological stimulus, contributing to around 80 to 90% of daily salivary production.

The salivary flow (SF) index is a parameter allowing stimulated and unstimulated salivary flow to be classified as normal, low, or very low (hyposalivation). In adults,

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normal total stimulated SF ranges from 1 to 3 ml/min, low-ranges from 0.7 to 1.0 ml/min, while hyposalivation is characterized by a SF of less than 0.7 ml/min. The normal unstimulated SF ranges from 0.25 to 0.35 ml/min, low-ranges from 0.1 to 0.25 ml/min, while hyposalivation is characterized by a SF of less than 0.1 ml/min. However, the values denominated exhibit large biological variations.⁴

Saliva has many important functions. It maintains neutral pH, is an essential for maintaining enamel mineralization, lubricates the mouth and upper pharynx, modulates oral flora, aids in digestion of food, facilitates speech and swallowing and plays a role in oral immunology.⁵

Without saliva there will be dryness of mouth; altered taste; a deviant sense of smell; lack of singing; difficulty in speaking and swallowing; increased dental caries; wedge-shaped erosion; bad breath; heart burn and esophagitis; burning tongue; cracked lips; yeast infections.⁶ Salivary gland hypofunction or hyposalivation is the condition of having reduced saliva production which leads to the subjective complaint of oral dryness termed xerostomia.⁷ This is associated with various local and systemic conditions which include diseases of salivary glands (Sjögren's syndrome, sarcoidosis, diabetes mellitus, and others), iatrogenic causes (medications, radiation to head and neck region, chemotherapy, chronic graft *vs* host diseases) and other rare causes, such as salivary gland agenesis, amyloidosis etc.⁸

Palliative management of xerostomia includes topical agents, such as ice chips and saliva substitutes, increasing water intake, chewing sugar free gum, sucking sour lemon drops, paraffin and citric acid containing lozenges and rinses. Systemic agents, like pilocarpine and cevimeline stimulate salivary flow but often have unfavorable side effects, such as profuse sweating, rhinitis, dyspepsia, etc. Acupuncture also has shown improvement in xerostomic and healthy patients.⁹

Transcutaneous electrical nerve stimulation is well-known physical therapy. First described in dentistry by Shane and Kessler in 1967, it has been widely used for relief of acute and chronic pain.¹⁰ Electrostimulation to produce saliva was studied in the past and showed moderate promise but never became part of mainstream therapy.¹¹ Transcutaneous electrical nerve stimulation may be a viable treatment option in the management of salivary gland hypofunction. Research in this area has been sparse, and hence this study was undertaken to evaluate the effect of TENS on whole salivary flow rate in healthy adults and to evaluate how long this effect of TENS lasts on salivary flow.

MATERIALS AND METHODS

The present clinical study was planned and designed in the department of oral medicine and radiology, Hitkarini Dental College and Hospital, Jabalpur, Madhya Pradesh, India and was approved by the college ethical committee. One hundred healthy subjects of either sex were recruited in the age group of 20 to 69 years among the patients reporting to the outpatient department (OPD). Patients were informed about the study and written consent was obtained. One hundred healthy adult subjects were then divided into five age groups with each group containing 20 subjects equally divided into males and females in each group based on the following inclusion and exclusion criteria.

Inclusion Criteria

Healthy patients with no history of systemic diseases or medications and no history of salivary gland disorders were included.

Exclusion Criteria

Patients wearing active pacemakers, defibrillators, hearing aids, cochlear implants and pregnant female patients were excluded. Patients taking medications to increase salivary secretion in the past 6 months were also excluded from the study.

The subjects were placed into the following groups; group 1: (20–29 years), group 2: (30–39 years), group 3: (40–49 years), group 4: (50–59 years), group 5: (60–69 years).

All participants were asked to refrain from eating, drinking, chewing gum, smoking and oral hygiene practices for at least 1 hour prior to the investigation. On the first visit, the subjects were made to sit in the dental chair in an upright position, with the head inclined forward and with minimal body and orofacial movements. Patients were then asked to swallow saliva first and stay motionless. With 'low forced spitting' unstimulated saliva was collected every minute for 5 minutes in a graduated test tube fitted with funnel and quantity was measured (Fig. 1). The surface electrode pads were then placed externally on the skin overlying the parotid glands with the TENS unit in the 'off' position. HKD3T, a digital TENS machine, operates at frequency of 0.1 to 500 Hz and has five modes—'Tapping', 'Kneading', 'Rolling', 'Pinching', 'Complex'. The TENS unit was then activated. Kneading mode was kept constant and intensity was gradually increased to a maximum tolerable level of patient. Stimulated saliva was collected every minute for 5 minutes in a separate graduated test tube and the quantity was measured (Fig. 2).



Fig. 1: Collection of unstimulated saliva



Fig. 2: Collection of stimulated saliva

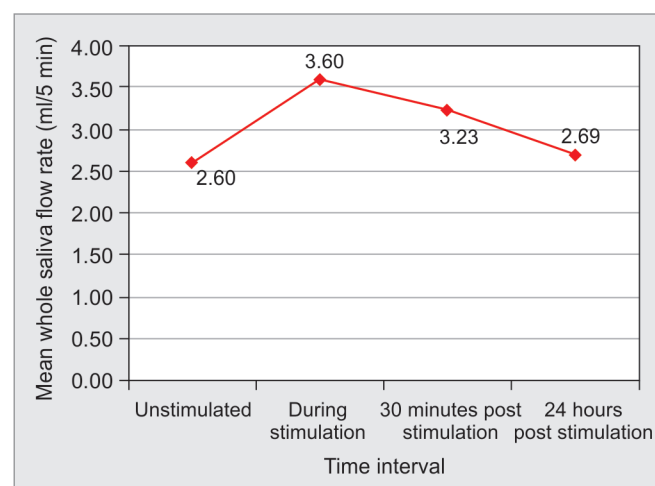
Thirty minutes and 24 hours post stimulation, saliva was collected in the same manner and quantity was measured.

Entire data obtained from this study was entered in a master chart and then tabulated. Frequency, percentage, mean, standard deviation (SD), minimum and maximum values of variables were calculated. Shapiro-Wilk test showed that whole saliva flow rate follow normal distribution hence, parametric test One way analysis of variance (ANOVA)/repeated measures One way ANOVA followed by LSD post hoc test and unpaired t-test were used for further data analysis. Gender distribution in different age groups (nominal data) was compared using Pearson's Chi-square test. $p < 0.05$ was considered statistically significant. Data analysis was done using statistical package for social sciences (SPSS) v.22 for windows.

RESULTS

The mean unstimulated whole saliva flow rate for all subjects ($n = 100$) was 2.60 ml/5 min . During stimulation it increased to $3.60 \pm 0.39 \text{ ml/5 min}$. Salivary flow remained increased 30 minutes and 24 hours post stimulation

with the values being $3.23 \pm 0.41 \text{ ml/5 min}$ and $2.69 \pm 0.39 \text{ ml/5 min}$ respectively. The range for unstimulated salivary flow was 1.90 to 3.80 ml/5 min, for salivary flow during stimulation was 2.70 to 4.90 ml/5 min, for 30 minutes after stimulation was 2.40 to 4.50 ml/5 min, for 24 hours after stimulation was 2.00 to 4.00 ml/5 min. Salivary flow was maximum increased during stimulation followed by 30 minutes after stimulation and then 24 hours

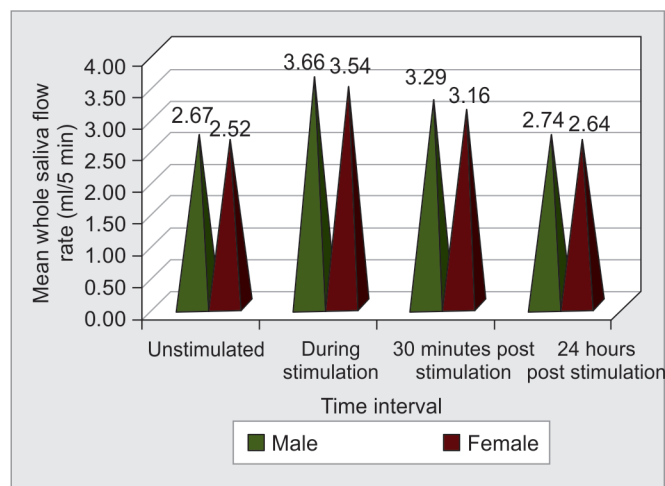


Graph 1: Comparison of whole saliva flow rate between different time intervals

Table 1: Comparison of whole saliva flow rate between different time intervals

Whole saliva flow rate (ml/5 min)	Time interval			
	Unstimulated	During stimulation	30 minutes post stimulation	24 hours post stimulation
Mean \pm SD	2.60 ± 0.39	3.60 ± 0.39	3.23 ± 0.41	2.69 ± 0.39
Minimum-maximum	1.90–3.80	2.70–4.90	2.40–4.50	2.00–4.00
Mean difference from unstimulated saliva flow rate	—	1.00 ± 0.23	0.63 ± 0.24	0.09 ± 0.19
Percentage difference from unstimulated saliva flow rate	—	38.46%	24.23%	3.46%
Repeated measures one way ANOVA	$F = 897.207$, $p = 0.000$ (< 0.001), Significant difference			
LSD post hoc test (Significant results)	During stimulation $>$ 30 minutes post stimulation $>$ 24 hours post stimulation $>$ unstimulated			

post stimulation compared to unstimulated salivary flow (Table 1 and Graph 1). The mean unstimulated whole saliva flow rate for male subjects was more than females (2.67 ml/5 min and 2.52 ml/5 min). During stimulation salivary flow increased to 3.66 ± 0.41 ml/5 min for males and to 3.54 ± 0.37 ml/5 min for females. Salivary flow remained increased 30 minutes post stimulation with the values being 3.29 ± 0.43 ml/5 min for males and 3.16 ± 0.39 ml/5 min for females. After 24 hours, it was 2.74 ± 0.37 ml/5 min for males and 2.64 ± 0.41 ml/5 min for females. There was no significant difference in whole saliva flow rate between males and females at different time intervals (Graph 2). The data was further analyzed to find out whether unstimulated salivary flow rate, salivary flow rate in response to stimulation, 30 minutes after stimulation and 24 hours after stimulation varied among subjects in different age groups. There was no significant difference in whole saliva flow rate (ml/5 min) among different age groups different time intervals (Graph 3).



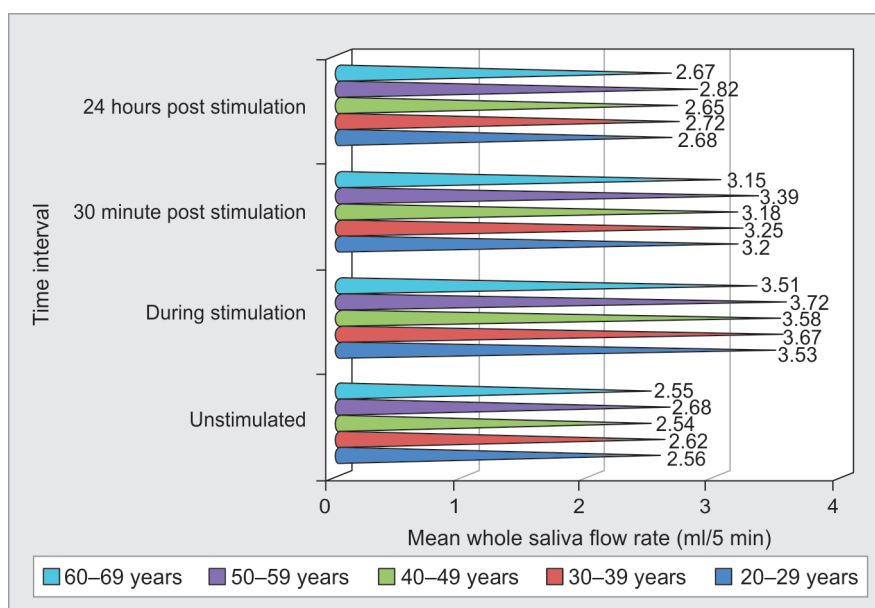
Graph 2: Comparison of whole saliva flow rate between sexes

DISCUSSION

Xerostomia is the subjective sensation of dry mouth, while hyposalivation is the objective finding of reduced salivary flow rate. Palliative management tried in xerostomia are topical agents such as ice chips, saliva substitutes, increase in water intake, applying lip balm, chewing sugar free gum, or sucking sour sugar free lemon drops. Systemic sialagogues have also been tried but have many side effects. All have met with limited success.¹²

It has been known that the nerves to salivary glands control the secretion of saliva. This became evident with Ludwig's momentous discovery in 1850 that electrical stimulation of chorda tympani nerve in the dog caused a copious secretion of submandibular saliva.¹³ Salivary secretion is normally controlled by reflex stimulation with effector nerve impulses traveling along sympathetic as well as parasympathetic nerves to the glands.¹⁴ Parasympathetic stimulation produces copious saliva of low protein concentration, whereas sympathetic stimulation produces little saliva but with high protein concentration.⁷

Transcutaneous electrical nerve stimulation has been evaluated in stimulating salivary flow and found effective even in patients with xerostomia secondary to radiation therapy for head and neck cancer, but the studies are very few.^{12,15} Therefore, the present study was conducted to evaluate the efficacy of TENS therapy in healthy, adult subjects. In our study, we collected whole saliva since whole saliva measurements are simple to perform and are useful as an indicator of general salivary performance. Also, they provide meaningful information concerning quantitative aspects of gland function and can be obtained easily in dental office.¹⁶



Graph 3: Comparison of whole saliva flow rate among different age groups

A wide range of the unstimulated and stimulated salivary flow was observed in our study. This variation of salivary flow rate was similar to the observation made by Vilas SK et al,² and others.^{6,17-20}

In our study, the mean unstimulated salivary flow was 2.60 ± 0.39 ml/5 min. There was 38.46% increase in salivary flow which was statistically significant. Ninety-six out of 100 responded positively to TENS therapy. This result was in agreement with the study by Hargitai et al in which 15 (out of 22) healthy subjects demonstrated significant increase in parotid salivary flow.¹² In a study by Vilas SK et al, 85 of the 100 subjects demonstrated increased whole salivary flow when stimulated via the TENS unit.² The study conducted by Mittal K et al demonstrated increased salivation with TENS, in 47 patients out of 50.¹⁸ Similar results were seen in studies by Damingo et al,¹⁵ and others.²⁰⁻²²

In our study, in four subjects, there was no increase in whole saliva flow. In a study by Vilas SK et al, 11 subjects out of 100 demonstrated no increase in saliva flow in response to TENS stimulation.² In the previous study by Hargitai et al, it was observed that TENS was unable to stimulate the parotid saliva and it was interpreted that TENS may act more efficiently as an accelerator of salivary flow rather than an initiator.¹² Therefore, it is likely to be more effective in cases of decreased salivary gland function rather than absolute absence of function. In our study, the subjects who failed to show response to TENS had normal unstimulated baseline saliva flow, and it could be due to patient's physical and mental condition at the time of saliva collection.

In a study by Vilas SK et al, four patients out of 100 reported decreased salivary flow with the application of TENS.² This finding was also similar to a study conducted by Hargitai et al.¹² The cause for this may involve the frequency and intensity settings. The stimulus perceived by the brain may be painful and the salivary reflex is enhanced when nociceptive input reaches the brain via trigeminal sensory nuclei. Not all preganglionic parasympathetic fibers are necessarily facilitated; some may be inhibited.

Newer finding elicited by this study was the duration of the effect of TENS therapy. In our study, salivary flow remained increased 30 minutes post stimulation by 24.23%. These results are similar to the study conducted by Dabholkar TY et al,²² where they studied TENS effect on 60 healthy subjects and found that salivary flow remained increased till 30 minutes after TENS effect. In our study, salivary flow remained increased by a small amount (3.46%) 24 hours after stimulation. The difference was statistically significant. In the study done by Dabholkar TY et al,²² there was no increase in salivary flow after

24 hours after the TENS effect on 60 healthy subjects. It could be due to the fact that TENS locally stimulates the auriculotemporal nerve that is responsible for secretomotor drive to the parotid gland, and the time period for this stimulatory capacity is limited and varies from individual to individual once the TENS unit is switched off.

As mentioned in different studies done by Ghezzi et al,²³ Ikbe et al,²⁴ functional changes in salivary glands have been reported to be associated with aging; however, there is no evidence to show that xerostomia is likely to result from aging process. One study by Narhi et al reported that over a 5-year period an elderly individual's stimulated salivary flow had significantly decreased.²⁵ Pattipati S et al in their age and sex matched study on 90 subjects reported increased stimulated salivary rates among individuals aged 36 to 50 years.¹⁹

In present study, which was age and sex matched, it was found that in all the age groups there was statistically significant increase in TENS stimulated saliva compared to unstimulated saliva. The unstimulated and stimulated salivary flow rates in different age groups was not statistically significant. Similar results have been observed in the study by Tylanda CA et al,²⁶ and others.^{2,12,18,27}

In our study, which was age and sex matched, there was no significant difference in whole saliva flow rate (ml/5 min) between males and females at unstimulated, during stimulation, 30 minutes post stimulation and 24 hours post stimulation phase/time interval. The gender difference in salivary flow rate was similar to study conducted by Ghezzi et al,²³ Nimma VB et al²⁰ and Mittal K et al,¹⁸ where it was shown that there was no significant gender differences in salivary flow rates. Percival RS et al in their study on 116 subjects,²⁸ and Vilas SK et al in their study on 100 subjects found that males had higher stimulated salivary flow rates than females and it was stated that the reason for the lower salivary rate in women could be attributed to the fact that they had smaller salivary glands, and postmenopausal changes.²

The only side effect of TENS therapy seen in our study was mild twitching of the facial musculature which was also described by Hargitai et al¹² and Vilas SK et al,² it was minimal and transient and ceased immediately after the TENS unit was switched off.

The mechanism by which TENS unit worked on parotid gland is not clear. It is possible that it directly stimulates the auriculotemporal nerve that supplies secretomotor drive to the parotid gland. It is believed that afferent nerves carry such impulses to the salivary nuclei (salivation center) in the medulla oblongata which in turn directs signals to the efferent part of the reflex leading to initiation of salivation.^{2,12} On the other hand,

electric stimulation of parasympathetic nerves of the salivary glands produces copious amounts of watery saliva of the parotid gland at lower frequencies, and it is this voluminous serous saliva would be clinically most useful for management of xerostomia.¹²

Professional assessment is warranted for certain potential users, such as patients with pacemakers, or defibrillators (by cardiologists) or hearing aid [by an ear, nose and throat (ENT) specialist] and psychiatric patients (by psychiatrist). Pacemakers have built-in safety features to protect them from interference from other electrical devices that may disrupt their operation. Similar to concomitant use of cochlear implants and pacemakers, which were found to be compatible with absolutely no interference.²⁸

The main advantage offered by TENS over other non-pharmacologic measures, such as chewing gum or citric lozenges; is that it is an extraoral device with minimal side effects; it can be used while eating food and will not affect normal mastication process. Thus, the potential for salivary production while eating would be beneficial which is not possible with the intraoral devices. Chewing gum bases may need to be avoided in those with temporomandibular disorders and have had favorable but mixed results in studies.¹² Artificial saliva preparations can be used but have some limitations. The majority of commercial products available are based upon carboxymethylcellulose (CMC). These products do not stimulate non-newtonian properties of saliva and do not contain specific antibacterial components (including antibodies) and enzyme and other components of saliva. There are very few studies comparing currently available mouth-wetting agents.²⁹

CONCLUSION

There are very few studies published to show TENS having a potential for increasing salivary flow. The present study evaluated the duration of the effect of TENS on whole salivary flow rate. It was found that it is effective for stimulation of whole saliva in normal, healthy subjects and its effect is retained till 30 minutes and a little up to 24 hours. As the results are encouraging, further studies are required to evaluate the long term clinical effectiveness of TENS in the Sjogren's syndrome patients, patients of xerostomia secondary to head and neck radiation. Transcutaneous electrical nerve stimulation therapy is given extraorally, so can be used for such patients even during eating to assist the same without causing any significant side effect. Transcutaneous electrical nerve stimulation may work best synergistically with other sialagogues and can be used for the management of xerostomia.

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