



EVALUATION OF THE EFFECT OF TRANSCUTANEOUS ELECTRIC NERVE STIMULUS (TENS) ON WHOLE SALIVARY FLOW RATE AMONG DIABETIC PATIENTS

Clinical Research

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ABSTRACT

Background: Diabetes mellitus is one of the most prevalent metabolic disease frequently associated with hyposalivation or xerostomia. Transcutaneous electrical nerve stimulation (TENS) is a physical therapy, adopted for pain relief. **Aim:** To evaluate the effect of transcutaneous electric nerve stimulus unit on whole salivary flow rate among diabetes patients. **Material and Methods:** A total of 50 subjects with diabetes and 50 healthy individuals were included in the study. Unstimulated saliva was collected using low forced spitting for 5 minutes into a graduated test tube and stimulated saliva was collected by placing the electrode pads of the TENS unit bilaterally over the parotid glands region and activating it for 15 minutes. On second visit, only the stimulated saliva was collected. All the obtained values were analysed using SPSS version 23 where p value <0.05 was considered significant. **Results:** Significant increase in salivary flow rate was observed in both the groups after TENS therapy. More improvement was found in the stimulated salivary flow on the second visit. **Conclusion:** The study suggests that transcutaneous electric nerve stimulus unit has a significant effect in the stimulation of saliva in both healthy and diabetic patients. Thus, TENS therapy can be used as a safe, non-pharmacological method of saliva stimulation.

KEYWORDS

Diabetes, Salivary flow rate, TENS.

INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic disorders characterized by a sustained high level of glucose in the blood (hyperglycaemia) due to insulin deficits, either in function or production and is known to cause hyposalivation.¹ Due to global urbanization, the prevalence of DM has increased in the recent years. Globally, 415 million adults have diabetes, and by 2040, this number has been projected to rise by 642 million.²

Salivary gland hypofunction or hyposalivation is the condition of having reduced saliva production associated with diabetes and various other causes. It usually leads to the subjective complaint of oral dryness which is termed xerostomia.³

Saliva is a highly complex secretory product of major and minor salivary glands 1.5L of whole saliva daily.⁴ The three major salivary glands namely parotid, submandibular and sublingual, along with 300 to 500 minor salivary glands, produce 1 to 1.5 litres of whole saliva per day.⁵

The various treatment modalities of hyposalivation include medical management with drugs like pilocarpine, civemeline, amfstone which possess side effects like stimulation of nasal, bronchial & lacrimal secretions, submandibular gland transfer, hyperbaric oxygen therapy, acupuncture and Transcutaneous Electric Nerve Stimulation (TENS) therapy.⁶ It is a well-known physical therapy, which is also useful for the relief of pain.

Owing to few studies in the literature, the present study evaluated the effect of transcutaneous electric nerve stimulus on whole salivary flow rate in patients with diabetes.

MATERIALS AND METHODS

The current study was carried out in the Department of Oral Medicine & Radiology. Ethical clearance and approval for the study was obtained from the institutional ethical committee. A sample of 100

patients was selected from the subjects attending the department of Oral Medicine & Radiology which included two groups, each comprising of 50 subjects. Group I (n =50) included subjects with diabetes having random blood glucose (RBS) values >120 mg/dL and group II (n =50) included age and gender matched healthy controls with RBS values within <120 mg/dL. Group I included subjects with no systemic disease other than diabetes and the Group II included age and gender-matched healthy controls. The exclusion criteria for both the groups were the use of any medications interfering with salivation, alcohol, smoking, pregnancy, history of radiotherapy & chemotherapy, salivary gland diseases, and wearing dentures.

All the subjects were explained about the study and informed consent was obtained. Saliva was collected in the morning before breakfast and the subjects were asked to avoid eating, drinking, and brushing for at least one hour before saliva collection. On the first visit, the subjects were made to sit in an upright position with the head inclined forward. Then, with low forced spitting, unstimulated whole saliva of the subjects was collected every minute for five minutes in a graduated test tube fitted with funnel. Later, application of gel over the area of placement of electrode pads was done and the electrode pads of the TENS unit were applied on the same subject over the region of parotid salivary glands. The amplitude of TENS unit was adjusted to the maximum point where the subject felt comfortable. Now, the stimulation was performed for 2-3 minutes. (Figures 1,2 & 3).



Figure 1: Application of TENS unit



Figure 2: Salivary flow measurement



Figure 3: Armamentarium

The saliva collection procedure was repeated after one week during the second visit. All the obtained values were recorded. Hyposalivation was considered when unstimulated salivary flow rates were under $0.1 \square \text{ mL/min}$ or when stimulated salivary flow rates were $0.7 \square \text{ mL/min}$.

Statistical Analysis:

The obtained values were tabulated and statistically analysed with SPSS version 23.0 (IBM, Chicago, USA). Paired 't' test and Chi-square tests were used for the analysis and a significance level of 0.05 was considered statistically significant.

RESULTS:

A total of 100 patients were included in the study and are divided into two groups with 50 patients in each group, including Group I- subjects with diabetes, Group 2- age and gender matched controls. The study group included 100 subjects with total of 61 males, 39 females. Group I included 32 males & 18 females and group II included 32 males & 18 females which showed slight male predominance.

Mean and standard deviation of unstimulated salivary flow rate of group I subjects were 1.302 ± 0.5857 ; and in group II, it was 1.752 ± 0.8 during first visit. The mean and standard deviation of stimulated saliva flow rate of group I subjects on first visit were 1.414 ± 0.58 ; and in group II, it was 2.146 ± 0.99 . The mean and standard deviation of stimulated saliva flow rate of group I subjects on second visit were 1.544 ± 0.56 ; and in group II, it was 2.288 ± 0.9 . (Table 1, Graph 1)

The mean difference in salivary flow rate between unstimulated salivary flow rate and stimulated salivary flow rate on first visit in group I subjects was 0.4 ± 0.03 , with t-value of -0.265 and p value of 0.792 , which was regarded as statistically significant. Also, the mean difference in salivary flow rate between unstimulated salivary flow rate and stimulated salivary flow rate on first visit in group II subjects obtained was 0.1 ± 0.0 , with t value of -0.235 and p value of 0.025 , which was considered significant and demonstrates a statistically significant difference in the unstimulated salivary flow rate and salivary flow stimulated using TENS on the first visit. (Table 2)

A t value of 3.144 and p value of 0.02 was obtained with the mean difference in unstimulated salivary flow rate on first visit between group I subjects and group II subjects which was considered as significant and the mean difference in stimulated salivary flow rate on first visit between group I subjects and group II subjects obtained a t value of 4.497 and p value of 0.00 which was highly significant which shows a highly significant difference in the stimulated salivary flow rates in the first and second visits. (Table 3)

The mean and standard deviation of stimulated salivary flow rate of group I subjects on second visit were 1.5 ± 0.08 ; and in group II, it was 2.2 ± 0.18 . The mean difference between unstimulated salivary flow rate on first visit and stimulated salivary flow rate on second visit between group I subjects was 0.2 ± 0.0 and obtained a t value of -3.601 and p value of 0.00 which is considered as highly significant which demonstrates the significant difference in the unstimulated salivary flow rate and salivary flow stimulated using TENS on second visit. (Table 3)

A statistically highly significant p value of 0.00 and a t value of 4.918 were observed with the mean difference in stimulated salivary flow rate on second visit between group I subjects and group II subjects obtained a and p value of 0.00 which demonstrates the significant difference in the stimulated salivary flow rates between first and second visits using TENS. (Tables 2 & 3)

Table 1: Mean and Standard deviation of salivary flow rates among groups

Particulars	Groups	Mean	Std.
Unstimulated salivary flow rate	I	1.302	0.5857
	II	1.752	0.8254
Stimulated salivary flow rate 1	I	1.414	0.5813
	II	2.146	0.9933
Stimulated salivary flow rate 2	I	1.544	0.5679
	II	2.288	0.9066

Table 2: Comparison of un-stimulated whole saliva flow rate (USF) and stimulated whole salivary flow rate on first visit (SSF1) among the groups

Particulars	No. of Cases	USF (ml/5min)	SSF1 (ml/5min)	Mean difference (ml/5min)	Significance	
					t*-value	p value
Healthy individuals	50	1.7 ± 0.11	2.1 ± 0.14	0.4 ± 0.03	-0.265	0.792
Diabetic patients	50	1.3 ± 0.08	1.4 ± 0.08	0.1 ± 0.0	-0.235	0.025
Healthy individuals vs Diabetic patients	t**	3.144	4.497	-	-	-
P value		0.02HS	0.00HS	-	-	-

t*: paired t test; t**: independent sample t- test; statistically significant if $p < 0.05$;

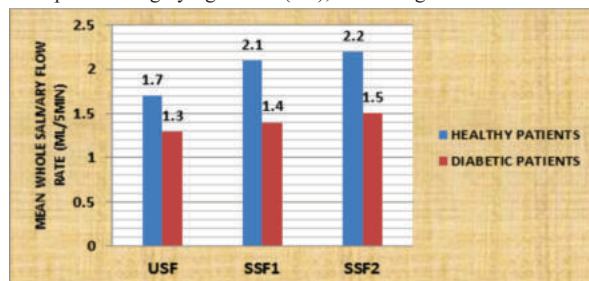
if $p < 0.001$ Highly significant (HS); NS: not significant

Table 3: Comparison of un-stimulated whole saliva flow rate (USF) and stimulated whole salivary flow rate on second visit (SSF2) in healthy individuals and diabetic patients

Particulars	No. of Cases	USF (ml/5min)	SSF2 (ml/5min)	Mean difference (ml/5min)	Significance	
					t*-value	p value
Healthy individuals	50	1.7 ± 0.11	2.2 ± 0.18	0.5 ± 0.07	-0.265	0.792
Diabetic patients	50	1.3 ± 0.08	1.5 ± 0.08	0.2 ± 0.0	-3.601	0.005
Healthy individuals Vs Diabetic patients	t**	3.144	4.918	-	-	-
P value		0.02S	0.00HS	-	-	-

t*: paired t test; t**: independent sample t- test; statistically significant if $p < 0.05$;

if $p < 0.001$ Highly significant (HS); NS: not significant



Graph 1: Comparison of salivary flow rate between the groups

DISCUSSION:

Diabetes mellitus (DM) is a global, increasing, silent epidemic with the potential to impair people's oral health all over the world. It is characterized by insulin insufficiency, cellular resistance to insulin action, or both, resulting in hyperglycemia and other oral manifestations like hyposalivation or xerostomia.

Saliva plays a critical role in oral homeostasis, as it modulates the ecosystem within the oral cavity with major functions such as providing lubrication and maintaining tooth integrity and other

functions including antibacterial, antiviral, antifungal and buffering effects. Primarily, salivary secretion originates from the major & minor salivary glands, the parotid gland contributes to 80% of the total saliva secretion.⁷ The range of normal flow rates in unstimulated condition is from 0.2 to 0.5 ml/min, and that of the stimulated flow rate is from 0.9 to 2.6 ml/min.⁸ The secretion of saliva is regulated by autonomic nervous system, with minor role played by hormones and autocoids. Though the mechanism by which TENS unit worked on parotid gland is unclear, it is possible that it directly stimulates the auriculotemporal nerve that supplies secretomotor drive to the parotid gland. The previous literature of electro stimulation postulated that normal physiologic salivary reflexes are augmented with electro stimulation.⁸

Therefore the present study was conducted to evaluate the effect of transcutaneous electric nerve stimulus unit in stimulating the salivary flow in patients with diabetes and healthy individuals. In previous studies unstimulated saliva was collected followed by TENS stimulated saliva in continuity for 5 minutes each whereas in the present study, TENS stimulated saliva was collected immediately after collection of unstimulated saliva and also with one week period after collection of unstimulated saliva collection.⁹

80% of the subjects on the first visit and 79% subjects on the second visit responded to TENS therapy with an increase in stimulated whole saliva flow rate. This result is in accordance with previous studies by Weiss WW et al and Dawes C et al which showed similar response in healthy individuals to TENS therapy for saliva stimulation.^{9,10} A wide range of unstimulated and stimulated salivary flow rates were observed in the present study, these variations of salivary flow rates were similar to observations made in previous three studies^{9,11,12} which can be related to varying factors like age, treatment of the underlying systemic disease and the use of medications. 20% of the subjects on first visit and 22% of the subjects on second visit did not respond to TENS which was a similar observation to the previous study conducted by Anush Rangare et al¹³ which observed that TENS was unable to stimulate the saliva and interpreted that TENS may act more efficiently as an accelerator of salivary flow rather an initiator. In 8% of subjects on first visit and 10% of subjects on second visit, there was decrease in the quantity of TENS stimulated saliva which was in correlation with previous studies where the cause for this reduction in saliva was attributed to the frequency and intensity settings of TENS. The stimulus perceived by brain may be painful and salivary reflex is enhanced when nociceptive input reaches the brain via trigeminal sensory nuclei.^{9,11}

The current study supports the findings of previous two studies that TENS therapy was effective in stimulating the whole salivary flow rate among diabetics and healthy individuals.^{14,15} In the present study, diabetes patients had a higher increased rate of stimulated saliva than controls. The stimulated salivary flow rate in diabetic patients was slightly lower in our study than in some other investigations conducted by S Tabrez et al¹⁶, M Dhillon et al¹⁷, Neha B et al¹⁸ and higher than the results of a study done by Singh D et al¹⁹.

Stimulated salivary flow rates were significantly higher in diabetic patients (Group I > Group II) compared with controls (Group II). It was similar to the earlier study conducted by Chandra R et al²⁰. When the stimulated salivary flow rates were compared on first and second visits, it was discovered that there was a statistically significant mean difference between the two groups. This is in accordance to study conducted by Pandey M, et al.²¹ Similar to this study, where an increase in stimulated saliva was seen, studies carried out by Tabrez S et al.¹⁶ reported that 90 out of 100 individuals responded positively to TENS therapy. Moreover, in the study conducted by Hersheal et al.¹⁴, it was stated that 15 out of 22 healthy adult individuals also showed a significant increase in stimulated salivary flow. In the present study, the mean unstimulated saliva in healthy patients was 0.9ml which increased to 1.91ml post-stimulation. This data was consistent with the study conducted by Bhasin et al.¹⁸ and Anusha Rangare et al.¹⁴ where they also noticed an increase in saliva after stimulation by TENS.

The significant increase in the whole salivary flow rate in the current study among diabetes patients in accordance with few other previous studies^{14,16} when compared to controls suggests that Transcutaneous Electric Nerve Stimulation (TENS) therapy, being a safe, non-invasive modality, is highly effective in stimulating the whole salivary flow rate. Periodic administration of TENS therapy among diabetic patients

is encouraged, as it would enlighten the judicious use of TENS in such patients. Further studies should be conducted to evaluate the possibility of using TENS in relieving the symptoms of hyposalivation.

Based on the above mentioned observations, subjects responded to TENS therapy with significant increase in salivary flow in both the groups and it can be stated that TENS can be an adjuvant in the treatment of whole salivary rate among diabetic patients with hyposalivation. Among all the available treatment modalities of hyposalivation, Transcutaneous Electric Nerve Stimulation (TENS) therapy is considered as most effective as it is non-invasive, safe and easy to master and generally well-accepted by the patients.⁸ Further studies for periodic administration of TENS among diabetes patients may be encouraged to validate the judicious use of TENS among diabetic patients with hyposalivation.

CONCLUSION:

The following conclusions can be drawn from the above-mentioned findings of this study:

- TENS can be a safe and effective therapy in increasing whole salivary flow rates in patients with diabetes.
- The stimulated salivary flow rates among diabetics and non-diabetics showed significantly strong positive correlation.
- TENS can be considered as a non-pharmacological alternative to improve salivation for longer period in diabetic patients thereby improving the oral health related quality of life.

Conflicts Of Interest:

Nil.

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