"Evaluation of the effect of Transcutaneous Electrical Nerve Stimulation on whole saliva flow in normal and xerostomia patients: a capital aftermath of cancer"- anin vivo study.

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Background: Saliva is a critical fluid necessary for oral health. Xerostomia & salivary gland hypofunction are associated with advancing age, autoimmune diseases such as Sjögren's syndrome, head & neck radiation, smoking and recreational drug usage. It increases the patient's risk for caries and other oral infections. Palliative management of xerostomia includes topical agents such as ice chips, saliva substitutes, increasing water intake, paraffin and citric acid containing lozenges. Systemic agents stimulate salivary flow but often have unfavorable side effects.

Aims and objectives: The present study was undertaken to compare and evaluate the unstimulated salivary flow with stimulated salivary flow after TENS therapy in normal healthy individuals and xerostomia patients and to compare the stimulated salivary flow rate in normal healthy individuals and xerostomia patients.

Materials and methods: The study design comprised of 50 individuals taken up as study subjects and 50 individuals as controls. The study group consisted of subjects who were complaining of dry mouth or who were clinically diagnosed to have xerostomia by performing tongue blade test. TENS electrode pads were placed externally on the skin overlying the parotid glands. Unstimulatedwhole saliva was collected for five minutes in a graduated tube, using a standardized collection technique. The TENS unit was then activated for 30 mins and stimulated saliva was collected for an additional five minutes.

Results: All the subjects in study and control groups showed increased stimulated salivary flow rates after stimulation. There was no significant difference in the rate of TENS stimulated salivary flow noticed based on the gender, age of the individual, treatment group allotted and the number of sessions of radiotherapy completed.

Conclusions: Transcutaneous electric nerve stimulation (TENS) as an extra-oral device is effective in stimulating whole salivary flow in all the individuals. Sequential stimulation by TENS would be beneficial to the patient to improve their quality of life.

Keywords: Transcutaneous electrical nerve stimulation (TENS), xerostomia, stimulated saliva, unstimulated saliva.

Date of Submission: 23-02-2018 Date of acceptance: 12-03-2018

I. Introduction

"Saliva is not one of the popular bodily fluids. It lacks the drama of blood, the sincerity of sweat and the emotional appeal of tears", stated by Mandel eloquently. However, this unpretentious secretion is a multifaceted, multipurpose bodily fluid which is indispensable. The oral cavity is a moist environment, wherein a film of saliva, constantly maintains the wellbeing of oral cavity. In a healthy individual the mean daily saliva production ranges from 1 to 1.5L. Saliva acts as a protective agent, lubricant, buffer, plays a role in digestion, tissue repair, immunology and aids in diagnosis (sialometry and sialochemistry).²

Salivation is overlooked as an obligatory constituent of accustomed function of the human body. However, when this apparently simple function fails and hypo salivation results, the impact is overarching. Presumably, more than 30% of the population over 65 years of age are experiencing xerostomia. It is attributed to various local and systemic conditions like medical conditions (diabetes), radiation therapy, usage of drugs etc. Comprehensive management of xerostomia include topical salivary substitutes, salivary stimulants, systemic

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agents like parasympathomimetic agents, vitamin supplementation and physical stimulants like electrostimulation etc.³

Various approaches have been bestowed in managing dry mouth among which Transcutaneous Electrical Nerve Stimulation (*TENS*) is a non-invasive, economical, well-known physical therapy. With TENS, electrical stimulation is transmitted to pain areas via surface electrodes, which reduces or eliminatespain. Apart from this it has been used as a treatment modality for various ailments besides which it also plays a role in saliva production by stimulating the salivary glands.⁴ Research in this area has been sparse, hence the present study is done to evaluate the effects of TENS on salivary flow in xerostomia individuals.

II. Material And Methods

An interventional study was carried out, which comprised of 50 individuals taken up as study subjects and 50 individuals as controls. The study group consisted of subjects who were complaining of dry mouth or who were clinically diagnosed to have xerostomia by performing tongue blade test. Patients with active pacemaker, defibrillator, hearing aid, cochlear implants, psychiatric patients and pregnant females were excluded.

The control group included healthy patients with no history of systemic diseases and patients with age group 18-75 years. Patients with a history of salivary gland pathology and patients taking medications to increase salivary secretion in the past six months were also excluded from the study. Consent was taken from all the study subjects and controls.

The study was embraced with collection of salivary samples for 5min before and after stimulation using TENS apparatus on two consecutive days. With low forced spitting, unstimulated saliva was then collected every minute for five minutes, in a sterilized plastic bottle. The saliva collected over 5min was measured using a graduated test tube. Then the patients were subjected to neural stimulation by activating the prior positioned TENS apparatus. The pulse rate was fixed at 50 Hz and the amplitude was gradually increased to a maximum tolerable level of patient and was maintained for 30min. The stimulated saliva was collected for five minutes in the same manner as that of unstimulated in a separate bottle and the flow rate was compared with the unstimulated salivary flow rate. A log on adverse effects like muscle twitching was kept during and after the procedure. The salivary flow rate was obtained by dividing the amount of collected saliva (volume in ml) by the duration of collection period (five minutes), and a comparative analysis was performed with unstimulated and stimulated salivary flow by subjecting to statistical analysis. All the data was analyzed by using SPSS 21 (statistical program for social sciences) software and comparison was done statistically using paired t test and unpaired t test.

III. RESULTS

Comparison of stimulated and unstimulated salivary flow rates in the total sample showed increase in salivary flow after stimulation. This increase was statistically significant with a p value of <0.01on both the days.(Chart 1)) Comparison of salivary stimulation among case &control groups showed a drastic increase on stimulation with TENS in control group with a p value of <0.01on both the days when compared to the case group which was statistically significant.(Table1and2) Day wise mean comparison in salivary stimulation in case and control groups showed a higher increase in stimulated salivary flow rates on day 2 when compared to day 1. The increased rate of stimulation on day 2 was statistically significant with a p value of <0.01. (Table 3) The mean stimulated salivary flow rate was slightly higher in females than males, but the rate of enhanced stimulated salivary flow in females was not statistically significant with a p value of 0.53.Comparison of salivary stimulation among the individuals based on no of sessions of radiotherapy on both the days revealed that the mean salivary stimulation was little higher in individuals included under 11-20 session group than individuals in 21-30 session group but, the rate of stimulation was not statistically significant with a p value of 0.51 and 0.84 respectively.(Chart 2) Comparison of salivary stimulation among the individuals based on the group allotted on both the days showed that the salivary stimulation was higher in individuals who belong to radiotherapy group than those with combined therapy of radiotherapy and surgery and combined radiotherapy and chemotherapy group but, the rate of stimulation was not statistically significant on day 1 and 2 with a p value of 0.21 and 0.94 respectively. Among 50 individuals included in study group 4 individuals showed side effects, in the control group out of 50 individuals 9 of them showed side effects like muscle twitching's.

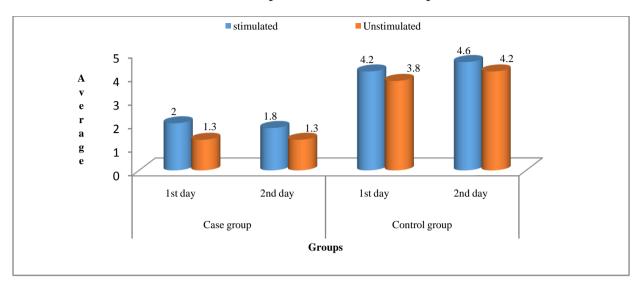


Chart 1:Descriptive statistics of entire sample

Table 1:Mean comparison of salivary stimulation among case &control groups - Day 1

Group	Parameter	Mean	t value	p value	Inference
Stimulated	Case group	1.05	18.11	< 0.01	HS
	Control group	2.99			

Table 2: Mean comparison of salivary stimulation among case &control groups - Day 2

Group	Parameter	Mean	t value	p value	Inference
Stimulated	Case group	1.18	20.039	< 0.01	HS
	Control group	3.19			

Table 3:Day wise mean comparison between Case & control groups in salivary stimulation

Group	Parameter	Mean	t value	p value	Inference
Case group	Stimulated 1st day	1.05	3.796	<0.01	HS
	Stimulated 2nd day	1.18			
Control group	Stimulated 1st day	2.99	5.431	<0.01	HS
	Stimulated 2nd day	3.19			

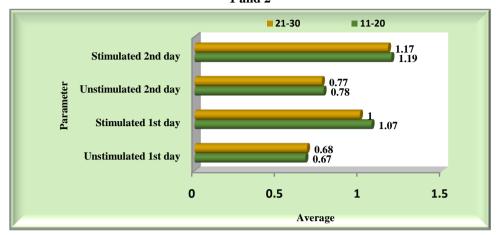


Chart 2: Comparison of stimulation among the individuals based on no of sessions of radiotherapy on day 1 and 2

IV. Discussion

Xerostomia is a term defined as a subjective perception of dry mouth and has often been related to salivary gland hypofunction. Its prevalence in the general population has been estimated to be 10%–29%, women being more commonly affected than men.⁵ Patients with severe xerostomia are 2.3 to 4.9 times more likely to experience negative impact on health.⁶ Definitive therapies for xerostomia include the use of systemic sialagogues, butoften have unfavorable side effects. Sudden rise in the number of patients suffering with xerostomia combined with lack of availability of medication have brought a rush to locate alternative therapies to manage xerostomia. So use of other physical treatment modalities has gained significance.

TENS has been evaluated in stimulating salivary flow and found effective even in patients with xerostomia secondary to radiation therapy for head and neck cancer. Therefore, the present study was conducted to evaluate the efficacy of TENS therapy in patients with xerostomia.

In the present study the stimulated salivary flow rate was increased in all the individuals of study and control groups, on both the days. The mean stimulated salivary flow rate was slightly higher in females than in males. This could be attributed to unequal distribution of the sample. These results were similar to the results in earlier studies done by Vijayalaxmi Bhoomanna Nimma etal⁸, Kummud Mittal etal⁷

In contrary to our result Istvan A. Hargitai etal⁹, Saraf Kedar Vilas etal¹⁰ and Sreenivasulu Pattipatietal¹¹concluded that males produced more saliva on stimulation with TENS than females, yet these differences probably have no clinical significance. This was attributed to small number of female participants in that study.

In the present study the study sample was divided into three groups the radiotherapy group, combined radiotherapy and surgery group and combined radiotherapy and chemotherapy group. The salivary stimulation was higher in individuals who belong to radiotherapy group than those with combined therapy of radiotherapy and surgery and combined radiotherapy and chemotherapy group but, the rate of stimulation was not statistically significant on both the days. This difference in stimulated salivary flow rates among the individuals belonging to different groups could be due to the effect of these therapies on salivary gland parenchyma. The radiotherapy group has less of salivary gland tissue damage when compared to the other groups as the individuals belonging to combined radiotherapy and chemotherapy has synergistic effect of drugs and radiation thus enhancing the chance of damage to salivary gland parenchyma. In the individuals who were under the radiotherapy and surgery group there was more damage than radiotherapy group as there will be loss of salivary gland tissue during surgery. In the present study as there was no involvement of salivary gland tissue while performing surgery in most of the individuals under combined radiotherapy and surgery group there was no much difference noticed in the TENS stimulated salivary flow rates on both the days in all the individuals under the study group The increase in salivary flow after stimulation in the studies by Saraf Kedar Vilas etal, ¹⁰Vijaya Laxmi Bhoomana Nimma etal, ⁸ Istvan A. Hargitai etal, ⁹ Kumud Mittal etal, ⁷ Sreenivasulu Pattipati et al, ¹¹ was similar to the present study. In the present study all individuals responded with increase in salivary flow after TENS application. This is because most probably all the individuals in the study sample showed a baseline unstimulated salivary flow.

The results showed a drastic increase in stimulated salivary flow rates in the control group when compared to study group and this difference in stimulated salivary flow rates was statistically significant. This increased stimulated salivary flow rates in control group can be attributed to the presence of more amount of

healthy salivary gland tissue when compared to the study sample who were under radiotherapy and might have an associated atrophy of salivary gland parenchymal tissue.

In the present study there was increased stimulated salivary flow rates noticed on day 2 when compared to day 1. This gives us an evidence that prolonged stimulation of salivary gland tissue using TENS results in better stimulation of the functional salivary gland parenchyma. So TENS can be used as a therapeutic aid which on prolonged use showed better results than short term stimulation.

In the present study the individuals were divided into two groups based on number of sessions of radiotherapy received by the patient. There was a higher increase in stimulated salivary flow rates in the 11-20 sessions group when compared to 21- 30 sessions group. This could be attributed to less dose of radiation received by the individual. This implies there was more amount of functional healthy salivary gland tissue in those individuals, so more salivary flow rates would be present.

"Every rose has its thorn, every good thing has an unpleasant side", similarly there have been adverse effects reported following TENS therapy. The most common side effects noticed were muscle twitching's, allergic reactions due to the application of gel. In our study 13 individuals showed side effects like muscle twitching's in the total sample. Out of them 9 individuals belong to control group and 4 belong to study group. This was quite minimal and was not statistically significant. Twitching was controlled immediately after the TENS unit was switched off. This finding was similar to that observed in studies done by Saraf Kedar Vilas etal.¹⁰ and Istvan A. Hargatai etal.⁹

V. Conclusion

These results warrant further studies on the aspects of how long the enhanced saliva flow lasts after turning off the TENS unit moreover on the ability of TENS to stimulate parotid salivary flow in presence of xerostomia, on the patient's acceptance and on usefulness of TENS alone versus in combination with other sialagogues in the patients with xerostomia.

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Praveena Talasila, Ponnaganti SC, Samata Y, Alaparthi RK, Narni H. ""Evaluation of the effect of Transcutaneous Electrical Nerve Stimulation on whole saliva flow in normal and xerostomia patients: a capital aftermath of cancer"- aninvivo study."IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 17, no. 3, 2018, pp 41-45.