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Tens as Novel Salivary Augmentation Device – A Systematic Review

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Abstract

Saliva plays a critical role in the maintenance of oropharyngeal health. Decrease in the production of saliva leads to xerostomia which is one of the major symptoms that causes significant distress to the patients. It is caused due to varied etiological factors, common in elderly individuals adversely affecting the quality of life. Treatment of this condition is a great challenge to the dentists all over the world. There are both pharmacological and non-pharmacological methods of management. Pharmacological methods are associated with certain side effects, hence non-pharmacological methods like Transcutaneous electrical nerve stimulation (TENS) therapy was introduced to improve the salivary secretion by stimulation of nerves by electrical energy of frequency and intensity tolerable to the patient. Many studies have been conducted to evaluate the efficacy of this Salivary Augmentation Device (SAD) in xerostomia patients and were found to increase the salivary flow rate and can act synergistically with other modalities of treatment. This article gives detailed information on extraoral TENS mechanism of action, preparation of patient and critical analysis of research in xerostomia patients and future recommendations.

Introduction

Xerostomia is caused due to decrease in the salivary secretion, a condition which is causing severe debility in the people all over the world. Etiology is multifactorial and has become a challenge to diagnosis and management. There are both pharmacological and non-pharmacological methods of management of this disorder. But there are certain side effects associated with pharmacological management, hence non-pharmacological methods are gaining importance in this new era. With the advent of new devices there is paradigm shift in the scope and management. Transcutaneous electrical nerve stimulation (TENS) is a new method, which was primarily introduced in the management of pain disorders. It is also found to be an effective Salivary augmenter hence considered to be a Salivary Augmentation Device (SAD).The secretion of saliva is a function of both parasympathetic and sympathetic nervous systems and also influenced by hormones**.** There are both intraoral and extraoral nerve stimulation devices in the management of xerostomia. Recent research on the effect of extraoral TENS therapy in the management of xerostomia has been documented, proving it to be a novel method of management of xerostomia. The objective of this review is to understand the effectiveness of extraoral electrical nerve stimulation in management of xerostomia and interpret the treatment outcome so that research can be explicitly aimed at holistic utilization of TENS in the management of xerostomia patients.

Salivary Secretion

Saliva volume and composition varies in response to physical and chemical nature of stimuli. The stimuli induce changes in gland size as well as secretory capacity. Salivary secretion is influenced by the interplay of different types of reflexes involving autonomic nervous system, different type of transmitters and various intracellular pathways. Sensory receptors are activated in response to food intake such as gustatory receptors, mechanoreceptors, nociceptors, and olfactory receptors [1-3].

The impulses of taste and mastication activities stimulate the salivary secretion. The afferent fibers carry impulses from the periphery to the salivation center in medulla oblongata and the efferent fiber stimulates the salivary glands. The efferent fibers constitute both parasympathetic and sympathetic nerve fibers that innervate the acini and blood vessels [4,5].The gustatory reflexes activate both types of autonomic nerves while masticatory reflexes predominantly causes the activity of the parasympathetic innervation (Jensen Kjeilen, et al. 1987) [6]. Since the accompanying flow of saliva is

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much greater in response to parasympathetic stimulation than to sympathetic stimulation, the salivary protein concentration is lower in parasympathetic saliva than in sympathetic saliva. Parasympathetic activity causes 20 fold increase in glandular blood flow as it causes vasodilation, and requires large water supply from circulation [3].

The parasympathetic innervation is by chorda tympani nerve of the facial nerve which joins the lingual nerve and reaches the submandibular ganglion and the post ganglionic fibers of the submandibular ganglion, innervates the submandibular and sublingual glands while the tympanic branch of the glossopharyngeal nerve, tympanic plexus and the lesser petrosal nerve relays in otic ganglion and the postganglionic fibers reach the parotid gland via auriculotemporal nerve. Sympathetic innervation of all the major salivary glands is by the fibers of superior cervical ganglion which travel along the arteries to reach the glands [4].

The flow rate of resting as well as of stimulated saliva is higher in the afternoon than in the morning (Ferguson and Botchway 1980), the greatest being occurring in the middle of the after-noon [7]. The salivary protein concentration follows this diurnal pattern. Resting saliva is higher during winter than during summer, indicating a circannual rhythm. Change in the temperature by 2°c in a warm climate is enough to inversely affect the flow rate (Kariyawasam and Dawes 2005) [8].

Xerostomia

Xerostomia is dry mouth which is derived from Greek word 'xeros' means dry and 'stoma' means mouth. xerostomia is caused due to decrease in the salivary secretion. Saliva plays an important role in maintaining the health of oral cavity, hence any changes can lead to loss of homeostasis in the oral cavity. It is most commonly seen in elderly individuals. In this condition there is alteration of quantity and even quality of saliva leading to difficulty in eating, swallowing and speech, altered taste sensation, caries, bacterial and fungal infections, burning mouth. There is multidimensional etiology associated with xerostomia. The underlying systemic diseases influence the mechanism of causation of xerostomia [9,10].

It is manifested in various systemic diseases, radiotherapy of head and neck cancers, autoimmune disorders and drug intake which is reversible with discontinuation of medications. The Systemic diseases like Diabetes, Alzheimer's disease and infections like HIV, hepatitis, sarcoidosis, lymphoma, graft vs host disease can cause this condition [11]. Xerostomia is considered when the flow rates of unstimulated saliva is less than 0.1 ml/min and stimulated saliva is less than 0.7 ml/min (Ericsson and Hardwick 1978) [12].

Transcutaneous Electric Nerve Stimulation

Food and Drug Administration has approved TENS as a method of pain alleviation and classified it as class II device in 1972. During TENS therapy, pulsed electrical current is generated either by A.C. mains or using batteries and delivered across the intact skin surface via electrodes to stimulate superficial nerves for localized pain relief [13].

TENS therapy has been introduced as a non-pharmacological modality in the management of pain. It has been used in the management of conditions such as low back pain, myofascial and arthritic pain, bladder incontinence, neurogenic pain, visceral pain, post-surgical pain and has been proved beneficial. Many studies were conducted to evaluate the effectiveness of TENS in xerostomia patients, which gave significant results and hence became a novel method in the management of xerostomia [14].

Precautions and Contraindications of TENS therapy -

- Should not be applied over the carotid sinuses, as there is risk of acute hypotension through a vasovagal reflex.
- Should not be placed over the anterior neck, because laryngospasm may result due to laryngeal muscle contraction.
- Patients on pacemaker (especially of the demand type).
- During pregnancy, because it may induce premature labor.
- Can cause burns in area of sensory impairment.
- Should be used cautiously in patients with a spinal cord stimulator or an intrathecal pump [13].

TENS unit consists of central control unit with continuous frequency ranging from 500 Hz. Therapy involves application of surface electrodes over the parotid and submandibular salivary gland region. Exact mechanism is not known but was hypothesized that it causes stimulation of autonomic nervous system leading to salivary secretion. To electrically stimulate sympathetic salivation, higher frequencies and longer pulse duration is required, while electric stimulation of parasympathetic nerves of salivary glands produces large amounts of watery saliva at lower frequencies and this voluminous serous saliva would be clinically most useful for management of xerostomia. There are few side effects like twitching of facial musculature and anesthesia of facial skin [14]. At rest, salivary secretion ranges from 0.25 to 0.35 ml/min. Any Sensory, electrical or mechanical stimuli can raise the secretion rate to 1.5 ml/min [15].

Preparation of Patient

Patients are advised to refrain from smoking, eating at least one hour before the procedure. The patients are made to sit in an upright position, with the head inclined forward and with minimal body and orofacial movements. They are asked to swallow saliva first and instructed to stay still so that the saliva would collect passively in the anterior region of the floor of the mouth. With 'low forced spitting', unstimulated saliva should be collected every minute for five minutes and saliva quantity to be noted. Surface electrodes are placed over the skin in parotid region and submandibular gland region and are secured with surgical tape, while the main control unit is off. Then the frequency is adjusted to continuous or pulse mode .The intensity is gradually increased to the level of patients tolerability (optimal intensity) and the patient is made to spit into a graduated beaker for 5 minutes. Saliva thus collected pre and post stimulation should be compared [16].

Clinical Trials

In 1850 Ludwig's momentous discovered that electrical stimulation of chorda tympani nerve in the dog caused a copious secretion of submandibular saliva. Weiss et al, 1986

performed electrostimulation for 3 minutes each in 24 patients with xerostomia related to Sjogren's, radiation therapy, drugs or unknown etiology and found some response [17]. Stellar, et al. in 1988 reported improved salivary secretion in 3 subjects out of 29 after electrical neurostimulation in Sjogren's syndrome patients with Xerostomia and suggested evaluation in larger sample size [15].

Talal, et al. reported that electrical stimulation improves salivary function of patients with Sjogren's syndrome. In this placebo controlled study, patients received three treatments at 2 weeks interval over a 4-week period with an electrical stimulator (n = 34) or a placebo device (n = 37). Patients on electrical stimulation showed a statistically greater increase in salivary production than patients using placebo devices [18].

According to Hargitai et al electrical stimulation in healthy adults resulted in 8.5 fold increase in parotid salivary flow hence was hypothesized that TENS therapy accentuates salivary flow [19], While Strietzel, et al. demonstrated significant decrease in dryness in the mouth following TENS therapy. Its effectiveness depends on functional capability of glands, it will not be effective if there is absolute absence of salivary secretion [20]. The TENS unit was preset at a frequency of 100 Hz and a pulse width of 100-150μs, 65 out of 80 subjects showed increase in the salivary flow rate following the application of TENS. There was approximately 13% increase in the mean salivary flow rate in a study by Aggarwal H, et al. [21].

Anusha Rangare Lakshman, G. Subhas Babu, Suresh Rao conducted a study on 40 subjects. The apparatus used was a strong low rate conventional mode of TENS model-NS Electro pulse that generates current through AC at a continuous frequency of 500 Hz and sweep of 0.5-2 Hz. The control group (no xerostomia) showed increased salivary flow rate after stimulation by TENS therapy compared to the unstimulated salivary flow and patients who were undergoing radiotherapy with weekly TENS therapy (0th week, 3rd week, 6th week and after a month) there was no significant improvement in salivary flow. But TENS therapy was found to be effective when given concomitantly during complete course of radiation therapy .The authors proposed that TENS therapy will not cause effective improvement in salivary flow when there is no baseline of saliva owing to complete destruction of glands. As there is significant improvement in salivary flow rate when TENS is given throughout the course of radiotherapy, it was found that they work synergistically [22], it was in agreement with the study by Nathalie and William. Electrostimulation enhances the healing process, thereby reducing the side-effects produced by radiation [23].

Damingo's study revealed that six of the 18 postradiation head and neck cancer patients demonstrated significant increase in the saliva flow during the application of TENS [24], Vijayan, et al. and Ojha S, et al. observations are also in congruence with the other studies as it was found to be effective supportive therapy in the management of xerostomia in post irradiation patients of Oral cancer [25,26].

In a study by Vilas SK, et al. four patients out of 100 reported decreased salivary flow with the application of TENS. This finding was also similar to a study conducted by Hargitai, et al. The cause for this may involve the frequency and intensity settings. The stimulus perceived by the brain may be painful and the salivary reflex produced when nociceptive input reaches the brain via trigeminal sensory nuclei. Not all preganglionic para-sympathetic fibers are necessarily facilitated, some may be inhibited [27].

Mittal Kumud, Keluskar Vaishali, Kapoor Shekhar evaluated effect of Transcutaneous Electrical Nerve Stimulation (Tens) at pulse rate of 50 Hz on salivary flow in patients with xerostomia and revealed that there was statistically significant difference between the unstimulated and stimulated salivary flow by TENS therapy. It was concluded that TENS therapy can be given concomitantly with other modalities for effective treatment in xerostomia patients [28].

Neha bhasin, et al. reported no increase in whole saliva flow in four subjects and also Vilas SK et al, reported that 11 subjects out of 100 demonstrated absence of increase in saliva flow in response to TENS stimulation, [29] In the previous study by Hargitai, et al. it was observed that TENS could not stimulate the parotid saliva and was explained that TENS may not act as initiator rather acts as accelerator of salivary flow. Therefore, it is likely to be more effective in cases of decreased salivary gland function rather than complete absence of function [19].

While only salivary flow was evaluated in other studies, the duration of effect of TENS was evaluated in a study (Neha bhasin, et al.) with a HKD3T, a digital TENS machine which operated at frequency of 0.1 to 500 HZ, the five modes were '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, this study revealed that flow increase even after 30 minutes of post stimulation was 24.23% [29], similar results were obtained by Dabholkar TY, et al. and the increase in saliva was only 3.46% after 24 hours of stimulation which was statistically significant. So the time period for the stimulatory capacity was limited and varies from individual to individual once the TENS unit is switched off. 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 [30,31].

Manu Dhillon, et al. evaluated the relationship of TENS therapy and gender, age and found that there was difference in the stimulatory salivary output between the age groups of 20-40 years and more than 60 years but there was no difference between the genders [31]. Pattipati, et al. in 2013 showed an increase in salivary flow rate on giving TENS and Salivary flow was persistent even after one hour of the treatment. It has been shown in literature that 21% - 22% of the population demonstrates no parotid flow even when measured over five minutes [32].

Some of the drugs are causative factors in the etiology of xerostomia, like antidepressants, antipsychotic drugs or diuretic drugs, Jagdhari S, et al. evaluated the effect of TENS on patients who were on these drugs and also diabetics (2years), postmenopausal women above 50 years and observed the increased stimulated salivary secretory flow [33].

Conclusion

The effectiveness of extra oral Salivary Augmentation Device (SAD) in the management of xerostomia is quite encouraging. It's been a new lease of hope to patients due to positive measures of outcome, with no long lasting adverse effects over other modes of treatments. Most of the studies have given good results related

to its efficacy but there are reported cases of even decrease in salivary secretion which was attributed to nociceptive input and inhibition of preganglionic nerve fibers. In conscience with the fact that trophic changes occurs in any nonfunctional tissue, the nerve stimulation method should prevent gland atrophy which has to be evaluated. Many of the researchers opined that, it is a supportive treatment rather than therapeutic modality, but there are very few evidence based case control studies with no information on the duration of effect, consistency of secretion after stoppage of treatment, gender and age related variations and standardization of frequencies to be instituted. It does not interfere with mastication but only disadvantage of this device is that it may not be feasible for the patient to wear it all the time due to esthetic reasons, as it is an extra oral device. Future randomised control studies are required to compare TENS with intra oral electric stimulators and other modalities of treatments.

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