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Research Article

The Effectiveness of Transcutaneous Electrical Nerve Stimulations Oral Exercise in Hypo Salivation Among Type II Diabetic Patients Over Submandibular Glands.

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Abstract: This study was conducted to improve the patient's oral function, especially dry mouth (xerostomia) and infection. The aim of this study is to analyse the effectiveness of transcutaneous electrical nerve stimulation vs. oral exercise in reducing hypo salivation among type II diabetic patients over the submandibular glands. The secretion of saliva is critical for oral health, digestion, prevention of infections, and the healing process. Hypo salivation is defined as a decrease in saliva in the mouth. It is the most common type II diabetic problem among adults and older people. It is estimated to occur in 10 of every 35 adults. Because of hypo salivation, Type II diabetic adults may experience infection, cavities, soreness, ulcers, a decrease in taste sensation, and difficulty in water balance. Hypo salivation leads to many complications that make the condition of the diabetic patient even worse. Hence, there is a wide need for treatment techniques to be searched for, and they must be applicable to all communities. There are various therapies to improve the salivary rate, but there is a need to analyse the technique that gives better outcomes with a short intervention with easy accessibility. The materials and method of this study follow a simple method and are evidenced with a non-invasive diagnostic tool. Saliometry by the low-spitting method was used to measure the salivary flow rate. The methodology was a comparative study design with a pre-post-test. Samples were selected from 40 volunteers based on inclusion criteria. Group A: Transcutaneous Electrical Nerve Stimulation, 8 sessions, 20 minutes each, twice a week for 4 weeks. Group B: Oral exercise, 16 sessions, 2 minutes each, in 3 sets for 4 weeks. At the end of 30 days of sessions, the salivary flow rate has increased from 0.36 to 1.03 ml/min and the SD from 0.12 to 0.91 for Group A, and from 0.34 to 0.56 ml/min and the SD from 0.2 to 0.4. The result concludes that both groups showed improvement, while group A, which received transcutaneous electrical nerve stimulation, was comparatively better than group B, which received oral exercise.

Keywords: Hypo salivation, Type II Diabetes, Low forced splitting method, Oral exercise, TENS.

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1. INTRODUCTION

Diabetes mellitus is a chronic metabolic disease characterised by a relative or absolute lack of insulin, which has an impact on increasing blood glucose levels and causing impaired metabolism of proteins and fats[1-2]. Insulin deficiency that occurs in diabetes mellitus is made possible by damage to the pancreas gland so that insulin secretion is reduced or the effect of insulin on the tissue is reduced. [3] In 1997, the American Diabetes Association (ADA) classified diabetes mellitus based on aetiology into four types. The four types include type I diabetes mellitus, type II diabetes mellitus, other types of diabetes mellitus, and gestational diabetes mellitus. [4] Type I diabetes mellitus occurs because of damage to pancreatic beta cells that produce insulin due to autoimmune or idiopathic causes. [5] Damage to pancreatic beta cells can cause absolute insulin deficiency. Type II diabetes mellitus is characterised by insulin resistance, damage to insulin secreted by pancreatic beta cells, and increased glucose production. Pancreatic beta cells produce insulin, but insulin resistance prevents its use at cellular levels. Type II diabetes mellitus with classic symptoms like polyphagia, polydipsia, polyuria, weight loss, xerostomia, hypo salivation, and dryness of the oral mucosa due to dehydration[6] Xerostomia is a subjective complaint of dryness of the oral cavity that can be caused by decreased salivary production[7]. Saliva has a significant role in maintaining oral cavity homeostasis[8]. The main functions of saliva are hydration, cleansing, digestion, remineralisation of teeth, maintaining oral mucosal integration, and being antimicrobial[9]. Decreased salivary production from average amounts is called hypo salivation. Lack of saliva in the mouth can cause significant morbidity[10]. Patients with a whole resting saliva flow rate 0.4 ml/min are considered to be abnormally hyposalted. Hyposalivation can have destructive physiological and psychological effects such as impairment of speech, mastication, deglutition, and poor oral hygiene[11]. Various evidence in the literature justifies the use of transcutaneous electrical stimulation to stimulate saliva flow[12]. Studies have agreed that oral exercises improve the oral health of elders by improving salivation, swallowing, and mastication and providing relief from dry mouth. Research is sparse on what would be a satisfactory and better therapy for patients with xerostomia and hyposalivation. So, this study is to compare the effectiveness of TENS vs. oral exercise in hyposalivation among type II diabetic patients over the submandibular glands.

2. METHODOLOGY

2.1. Settings

This is an experimental study design with a pre-post-test type, conducted in the outpatient physiotherapy department of ACS Medical College and Hospital, Chennai-77, Tamil Nadu, and took nearly 4 months to complete the study (January 2022–April 2022). 20 samples were selected from 40 volunteers based on the inclusion criteria. Both genders are included in this study: subjects below 65 and above 20 years of age with type II diabetes, non-smoker diabetic patients, and non-alcoholic diabetes patients.

2.2. Research Approach

Once the study was approved by the IRB, a simple random sampling method was used to select and divide the samples into two groups, where 10 random patients were categorised in Group A and 10 random patients in Group B. The study and the questionnaires to be filled out were explained to the samples. They were then asked to fill out the consent form in acceptance of participating in the study, which was duly signed by the samples and therapist. Initially, demographic details like age and sex were collected, assuring confidentiality of the same. A pre-experimental design (two groups, pre-test and post-test) was used for this study.

2.3. Variables

The independent variables in the study were TENS and oral exercise, and the dependent variable was oral function (dry mouth symptoms, amount of salivary pH, salivary secretion).

2.4. Inclusion Criteria

Both genders are included in this study, subjects below 65 and above 20 years' patients, type II diabetes, non-smoker diabetic patients, non – alcoholic diabetes patients.

2.5. Exclusion criteria

Anxiety and depressed patient, terminally ill patient, Sensitive skin, Pregnant women, Cancer patient, Cardiac patient, Patients with neurological disorders

2.6. Outcome measures

Saliometry by low spitting method was used to measure the salivary flow rate and compare it.

2.7. Intervention

Group A (TENS)received 8 sessions, 20 minutes each twice a week for 4 weeks. Position of the patient: Supine lying with one pillow overhead, one pillow under the knee joint
Placement of electrodes: Electrodes placed over the bilateral salivary gland region; Intensity is placed according to the patient's tolerance.

Group B (Oral exercise) receive masticatory exercise, tongue stretching exercise, chewing exercise, jaw exercise 16 sessions, 2 minutes each, in 3 sets for 4 weeks.

2.8. Ethical Approval statement

The Institutional Review board of faculty of physiotherapy approved the manuscript (IRB REF NO: D -15 / PHYSIO/IRB/2021 -2022). All the procedures were performed in accordance with the ethical standard of the responsible ethics committee both (Institutional and national) on human experimentation. Statistical analysis: statistical analysis was performed using the SPSS software version. Paired t test was used to compare the pre-test and post-test values between and within the groups.

2.9. Research instruments

Description of instruments, scoring, and interpretation The tool consisted of two sections:
Section-A: Assessment of background variables
Section B: Assessment of oral function.

2.9.1. Section A: Assessment of background variables

Part-1: Demographic variables It included age (years), sex, education, source of income, and dietary pattern.
Part-2: Clinical variables This questionnaire had clinical characteristics of the elderly, such as difficulty in swallowing, any dry mouth while eating a meal, does amount of saliva in pt mouth seem to be too little, dryness of lips, dryness of buccal mucosa, experience bad breath, tooth brushing (times/day), medication, use of mouth rinse solution, and tongue cleaning.

2.9.2. Section B: Assessment of oral function.

Part – 1: Measuring container to measure saliva Based on previous studies, saliva was collected in a sterile measuring container for 10 min using the spitting method and it was gravimetrically measured. The protocol for saliva collection is derived from "Salivary Proteome Handbook Procedures and Protocols" (National Consortium for the human saliva proteome, 2004). The unit of measurement was ml/min.
Part – 2: dry mouth symptoms assessed by questionnaire.
Part -3: The salivary pH was measured using digital pH meter.
Part 4: The size of mouth opening was estimated by using a Vernier caliper.
Part 5: oral function variables by questionnaire.
Part 6: oral motor function was assessed using the Sunnybrook facial grading system.

3. RESULTS

On comparing saliometry (low spitting method between Pre-test 0.36 and Post-test 1.03 mean values within Group A (TENS) shows highly significant difference between Pre-test and Post-test mean values at P <0.05 the Post-test values have shown improvement when compared with pre-test. Hence, the null hypothesis is rejected. On comparing saliometry (low splitting and Post-test 0.56 mean values within Group B (ORAL EXERCISE) shows highly significant difference between Pre-test into and Post-test mean values at P ≤ 0. 001.The Post-test values have shown improvement when compared with pre-test. Hence the null hypothesis is rejected.

Table 1: Distribution of the patients according to their background variables

Demographic Variables	n	%
Age (in years)		
20 – 39	9	45
40 – 59	9	45
60 - 65	2	10
Gender		
Male	9	45
Female	11	55
Dietary pattern		
Vegetarian	3	15
Mixed vegetarian	17	75

Table 1 Explains the age, gender, dietary pattern distribution which gives information about correlation with disease.

Table 2: Assessment of saliva

	Tens				Oral Exercise			
Salivary secretion	Pre-Test (N)	Pre-Test (%)	Post Test (N)	Post Test (%)	Pre-Test (N)	Pre Test (%)	Post Test (N)	Post Test (%)
Hypersalivation	0	0	0	0	0	0	0	0
Normal	0	0	8	80	0	0	10	100
Hyposalivation	10	100	0	0	10	100	0	0
Not increased	0	0	2	20	0	0	0	0
Statement			Shows salivary	high rate			Shows salivary	minimal rate
Dry mouth symptoms								
No Xerostomia	3	30	8	80	3	30	5	50
Mild Xerostomia	6	60	2	20	6	60	5	50
Marked xerostomia	1	10	0	0	1	10	0	0
Salivary pH								
Acidic	7	70	6	60	4	40	5	50
Normal	2	20	3	30	3	30	4	40
Alkaline	1	10	2	20	3	30	1	10
Size of mouth opening								
Normal male	3	30	4	40	2	40	4	40
Normal female	4	40	6	60	4	80	5	50
Restricted mouth opening	3	30	-	-	4	40	1	10
Oral function variables								
Absence of odour	3	30	8	80	1	10	7	70

Questionable odour	6	60	2	20	5	50	3	30
Slight malodour	0	0	0	0	2	20	1	10
Moderate odour	1	10	0	0	1	10	0	0
Strong malodour	0	0	0	0	1	10	0	0
Oral motor function								
Normal	1	10	9	90	1	10	2	20
Mild dysfunction	8	80	1	10	7	70	8	80
Moderate dysfunction	1	10	0	0	2	20	0	0
Moderate severe dysfunction	0	0	0	0	0	0	0	0
Severe dysfunction	0	0	0	0	0	0	0	0
Total palsy	0	0	0	0	0	0	0	0

This table shows effect of oral exercise on hypo salivation before and after treatment in terms of xerostomia, salivary ph., mouth opening, oral functions. After the post-test, there was significant improvement in dry mouth status of the diabetic people and marked xerostomia (10%) was decreased to 0% of subjects as same in oral exercise and in TENS. Normal salivary secretion was observed in 80% of diabetes which significantly increased after post-test in TENS than oral exercise as 10 %. There were also significant differences observed in oral motor function and variables as shown in Table 2.

Table -3: comparison of saliometry (low splitting method) between Group A and Group B, The table shows more significant difference in group A in post-test values of Mean and SD.

#Saliometry (Low Splitting Method)	Pre-Test Mean± S.D	Post Test Mean ± S. D	t-Test	Significance
Group A	0.36 ± 0.12[a]	1.03 ± 0.91[a]	7.09	.000***
Group B	0.34 ± 0.2[b]	0.56 ± 0.4[b]	2.83	.000***

The above table reveals the Mean, S.D, T value and p value between pre-test and post-test of Group A and B. In table, on comparing the pre -test and post -test within Group A and Group -B on saliometry shows highly significant difference in mean values at p< 0.001. On comparing the mean values of Group A & Group B on saliometry, it shows a significant increase in the post – test mean values in both groups, but (Group – A TENS) shows 1.03 which has higher mean value is more than (Group -B oral exercise 0.56 at p<0.001. There is statistically highly significant difference between the pre-test and post-test values within Group A and B. (*** - P ≤ 0.001)

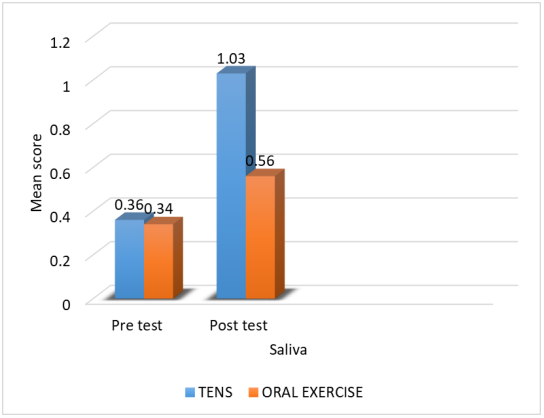

Fig 1: Comparison of mean score of salivary rate before and after TENS and oral exercise

On comparing the mean values of group, A and group B on saliometry (low spitting method), it shows significant increase in the post test mean values in both groups but (group A-TENS) shows 1.03which has the higher mean values is more effective than (group B – ORAL EXERCISE) 0.56 at P ≤ 0.001. On comparing pre-test and post-test within group A and B on saliometry scores that improves hypo salivation conditions. The study suggests that type II diabetic in hypo salivation patient treated with TENS was more beneficial.

3. DISCUSSION

Diabetes mellitus is a metabolic disorder where there is poor utilization of glucose in the peripheral tissue resulting in accumulation of glucose in the tissues.[13] It is due to the poor activity seen in the pancreatic gland. It is characterised by hyper glycemia resulting in defective insulin secretion or action or both.[14] Studies have shown that patients with diabetes mellitus have mostly reported oral dryness and symptoms of decreased saliva flow.[16]Multiple treatment choices exist for management of hypo salivation and oral dryness. Some of them are topical preparations (toothpastes, mouthwashes, gums, or moisturizers), medicinal drugs, electro stimulation, lifestyle changes, like increasing water intake, avoiding breathing through mouth, etc. [17]The aim of the study is to examine the effectiveness of TENS and Oral Exercises in Hypo salivation among Type II patients. This study was undertaken to assess the effectiveness of oral exercises on oral

functions, such as, dry mouth symptoms, amount of salivary secretion per minute, salivary pH, size of mouth opening, halitosis, and oral motor function [Table 2] and demographic variables [Table 1] among diabetes patients in Chennai. This Study also demonstrate on Saliometry (low spitting method) in terms of measuring salivary flow, it shows a significant increase in amount of saliva in the both group but GROUPA – Transcutaneous Electrical Nerve Stimulation has more effective than GROUP B – Oral Exercises. In this study, 20 subjects were selected and 10 subjects was in Group A and 10 subjects in Group B. Subjects in Group A received TENS and Group B received Oral Exercises in Hypo salivation among type II Diabetic patients over sub mandibular gland. The outcome measures were evaluated by using Saliometry (low spitting method). Group A followed by treatment for a period of 4 weeks with 2 sessions per week and Group B followed a course of treatment for a period of 4 weeks with 4 sessions per week.) found a significant difference in the pre- and the post-test subjective dry mouth symptoms ($P < 0.01$), which supports our study findings. We expected a significant improvement in dry mouth symptoms and saliva production is more in TENS and oral exercise. In accordance with current study, evaluated the effectiveness of extra oral TENS in 10 diabetic patients (4 males and 6 females) with hypo salivation. Mean stimulated saliva increased 1.03 ml/minute) in comparison to resting one (0.36 ml/minute). Consistent with this, reported that 8 of the10 healthy subjects demonstrated an increase in the salivary flow rate on application of 20-minutes extra oral TENS. 8 subjects demonstrated increase in the salivary flow rate while 2 subjects showed a decrease while oral exercise shows that minimal increase in salivary flow rate in all 10 subjects. One study has explained the cause for above 2 subjects further decrease of salivary flow, it 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 fibres are necessarily facilitated; some may be inhibited thus leading to the decrease in salivary flow rate [18]. Another study suggested the effectiveness of TENS in stimulating salivary flow was not dependent on age. The literature has shown that salivary flow does not diminish with age, and our results are in agreement with this observation. Comparing the mean values of Group, A and Group B On saliometry (low spitting method), both the groups show significant increase in the post-test values but Group A- Transcutaneous Electrical Nerve Stimulation which has the higher mean value is more effective than Group-B Oral Exercise. In table 3, On comparing the pre-test and post-test within Group A and Group B on saliometry shows highly significant difference in mean values at $p \leq 0.001$. on comparing the mean values of Group, A & Group B on saliometry, it shows a significant increase in the post-test mean values in both groups, but (Group -A TENS) shows 1.03 ± 0.91which has the higher mean value is more effective than (Group -B Oral exercises)0.56 ± 0.4 at $P \leq 0.001$. [Table 3]. Early studies used electro stimulation device in groups of dry mouth sufferers, TENS has a proven safety record and has been used in some cases of paediatric dental anaesthesia and physical therapy centres [20-21]. Talal *et al.* used TENS acupuncture in patients with radiation induced xerostomia. All the studies suggested that electro stimulation increases salivary flow. However, the employed saliva collection methods are subjective and through expectoration which are not completely reliable. [22]Jenkins et al indicated that daily gum-chewing over a prolonged time period resulted in functional increase in parotid salivary flow.[23]Weereponge*t al*. suggested that salivary gland massage increases the blood flow and parasympathetic activity in the surrounding area of the salivary glands increase the amount of salivary secretion. [24]Cho *et al*. Study found a significant difference in the pre- and the post-test subjective dry mouth symptoms, which supports our study findings. We expected a significant improvement in dry mouth symptoms after oral exercise. Therefore, [table 3] in this study based on the mean values of overall pre and post-test of TENS shows a significant improvement on salivary flow and oral Function than oral exercise in hypo salivation among type II patients at $p \leq 0.001$. [figure 1]

4. CONCLUSION

This study concludes that TENS is more effective when compared to oral exercise on hypo salivation among type II diabetic patients. This study shows that TENS is more effective in increasing salivary flow. From the results of current study, it was concluded that Group A TENS showed a marked improvement in increasing salivary flow and it also decreased dry mouth and oral infection on hypo salivation among type II diabetic patients, then Group B oral exercise. With its encouraging results, it was recommended to study the response of hyposalivation after several sessions of oral exercise in type II diabetic.

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6. AUTHORS CONTRIBUTION STATEMENT

K. Kirupa - Continuous guidance, suggestions during the performance of experiments and helped to draft the manuscript. S.M. Divya Mary - Contributed in statistical analysis. R. Nithya Nisha - Analysis of the results and writing of the manuscript. K. Saraswathi -Critical revision of the article. D.P. Kaviya contributed to the design and implementation of the research and coordination, N. Nimshalakshmi - carried out TENS in Group A, B. Aishwarya - carried out the oral exercise in Group B., K. Swetha - participated in the design of the study. All authors read and approved the final manuscript.

7. CONFLICT OF INTEREST

Conflict of interest declared none.

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