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To evaluate the efficiency of transcutaneous electrical nerve stimulation (TENS) on stimulated and unstimulated salivary flow rates in diabetic patients: An original research

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Abstract---Aims and objectives: The aim of the present study is to assess the effectiveness of TENS as a means of stimulating salivary function in type2 diabetes mellitus patients. Methods: A sample of 100 patients having diabetes mellitus were enrolled for the study after taking the informed consent. Unstimulated saliva was collected by low forced spitting method for 10 minutes in a graduated measuring jar. Stimulated saliva was collected after placing TENS electrodes over the cheek for 10 minutes in a graduated measuring jar. The values were analyzed and compared. Results: Our study sample included 100 diab

etic patients, out of which 52 were males and 48 were females. The age of the patients ranged from 30 yrs to 78 yrs with a mean age of 48.8 yrs. The blood glucose level was found to be highest among males when compared to females. The improvement in salivary flow rates by using TENS was found to be significant in different age groups. Conclusion: The study suggests that in patients with Diabetes, TENS was found to be helpful to improve the salivary flow rate. Female diabetic patients showed a statistically significant improvement in salivary flow rates after using TENS.

Keywords---Diabetes, Transcutaneous electric nerve stimulation, unstimulated saliva, Stimulated saliva.

Introduction

The term diabetes mellitus (DM) encompasses a group of clinically as well as genetically heterogeneous metabolic disorders that share a common phenotype, characterized by persistent, abnormally elevated, blood glucose levels (hyperglycemia) with dysregulation of carbohydrate, protein, and lipid metabolism. The important feature of this disorder is chronic, persistent hyperglycemia, resulting from either a defect in the secretion of insulin from the pancreas or resistance to the action of insulin by the body's cells or both.[1] Diabetes is commonly classified as type 1 and type 2. Type 2 diabetes is the most common type of diabetes—often associated with obesity—and is characterized by a slow onset of symptoms, usually after 40 years of age.[2] Reported oral manifestations associated with diabetes that may be encountered by dental practitioners include xerostomia, tooth loss, gingivitis, periodontitis, odontogenic abscesses, and soft tissue lesions of the tongue and oral mucosa.[3] Normal resting whole saliva flow rates range from 0.3 to 0.5 mL/min, whereas those with hyposalivation appear in the range of 0.01 to 0.10 mL/min. Citric acid stimulated whole saliva flow rates are normally measured at 1.0 to 3.0 mL/min.[2] Several conditions and diseases may be associated with xerostomia and hyposalivation. Previous investigations have indicated that diabetic patients commonly report oral dryness and symptoms of decreased saliva flow.[4] TENS is a well-known physical therapy used for pain relief. With TENS, electrical stimulation is generated from a battery or electrically operated device and transmitted to pain areas via surface electrodes and reduce or eliminate pain.[5] It is widely used to relieve acute pain in various conditions like muscle and joint pain, back pain, lower and upper extremity pain, and head and neck pain, etc. The use of TENS in dentistry was first described in 1967 by Shane and Kessler[6], but it has yet to gain widespread acceptance in dentistry.[7] However, in recent times, many researchers have observed that in addition to the analgesic effects of TENS, it may also be used to increase salivary flow by stimulating the peripheral nerves. The application of an electric current through the oral mucosa to the afferent neuronal pathway causes neuroelectrical stimulation of the salivary glands and this has been reported to increase the production of saliva and to reduce the symptoms of xerostomia.[7] As there was a lack of systematic knowledge, we have conducted this study to compare the unstimulated and TENS stimulated salivary flow rates among diabetic patients.

The main aim of this study was to determine the effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) on salivary flow rates in diabetes mellitus patients. The objectives of the study were, measuring and comparing the unstimulated and TENS stimulated salivary flow rates in various age groups and gender having diabetes mellitus.

Materials and Methods

Patients reporting to the outpatient department of Oral Medicine and Radiology at Meghna Institute of Dental Sciences, Nizamabad were considered for the study, after obtaining the approval from Institutional ethical committee. A total of 100 patients with Diabetes mellitus have participated in the study. The Diabetes status was confirmed and values were evaluated by measuring random blood glucose levels with the help of a tabletop glucometer (My life Pura X blood glucose monitoring system). A random blood glucose level of 200 mg/dl or higher, were considered as diabetes according to American Diabetes Association. All subjects were under treatment for diabetes like dietary modifications, oral hypoglycemic agents, insulin, or a combination of these treatments. Patients having systemic disorders other than diabetes were excluded from the study.

Saliva collection

Method of collection of unstimulated salivary sample:

All the participants were asked to refrain from eating, drinking, chewing gum, smoking, and oral hygiene procedures such as brushing and mouth rinsing for at least one hour before the appointment. The subjects were made asked to sit straight, comfortable, and relaxed position, with the head inclined slightly forward and least possible orofacial movements. Subjects were then asked to swallow their saliva first and to stay motionless so that the saliva could collect passively below the tongue on the floor of the mouth. With the use of the “low forced spitting” i.e., Navazesh method, unstimulated saliva was collected for ten minutes in a graduated measuring cylinder fitted with a funnel. After thirty minutes of the unstimulated saliva collection, TENS electrodes were placed.

Method of Collection of the TENS stimulated salivary sample:

Surface electrode pads were placed externally on the skin overlying the parotid glands (anteroposteriorly between the tragus of the ear and the mid masseter region and superoinferiorly between the region of the head of the mandible and the inferior border of the mandible). The TENS unit is kept in the off position. Tabletop TENS unit [AccuRelief Dual Channel TENS Electrotherapy Pain Relief System (Carex ACRL-3001)] was then activated, the pulse rate was fixed at 50 Hz, and the intensity was gradually increased to a maximum tolerable level for each patient. At optimal intensity (the maximum intensity that the subject still perceived to be comfortable) stimulated saliva was collected in burst mode for 10 minutes. For 10 minutes, the collected whole saliva was allowed to settle down passively so that the bubbles would not interfere with the measured volume of the saliva. The amount of unstimulated and TENS-stimulated whole salivary flow rates were assessed and compared.

Results

The distribution of subjects by age and gender is shown in Table 1. There were 100 total participants in the study, of whom 52 patients were male and 48 patients were female. The subjects were subsequently separated into five groups based on their ages as follows: 22 participants were among the 30-39 age group, 34 subjects were among the 40-49 age group, 27 subjects were among the 50-59 age group, 13 subjects were among the 60-69 age group, and four subjects were among the 70-79 age group.

The distribution of individuals by age and gender is shown in Graph 1. Gender and age were recorded on the y-axis. According to this graph, there were 14 men and 8 women among the 22 subjects in the 30-39 age group, 17 men and 17 women among the 34 subjects in the 40-49 age group, 12 men and 15 women among the 27 subjects in the 50-59 age group, 6 men and 7 women among the 13 subjects in the 60-69 age group, and 3 men and 1 woman among the 4 subjects in the 70-79 age group.

Male and female blood sugar levels are contrasted in Table 2. Males were shown to have higher blood glucose levels than females, with a mean value of 218.75 mg/dl. The independent sample 't' test was used as a statistical analysis technique. It was determined that the difference between mean and standard deviation SD (37.29 + 27.29) was statistically significant ($p < 0.05$). Graph 2 compares the milligrammes per deciliter (mg/dl) blood glucose levels of males and females. Males had an average blood sugar level of 218.8 mg/dl, while females had an average of 181.5 mg/dl.

The unstimulated entire salivary flow collected in a graduated test tube for a period of 10 minutes was compared between boys and females using an independent sample 't' test in Table 3. Males had a slightly higher mean salivary flow rate per 10 minutes (0.75 ml/10 min) than females (0.71 ml/10min). With a p value of 0.337, the difference + standard deviation SD (0.04 + 0.01) was determined to be statistically insignificant when using the p value 0.05 as the statistical threshold. Graph 3 compares the average unstimulated salivary flow rate per 10 minutes for males and females, with the average male salivary flow rate (0.75 ml per 10 min) nearly matching that of females (0.71 ml per 10 min).

The TENS-stimulated entire salivary flow collected in a graduated test tube for a period of 10 minutes was compared between males and females using an independent sample 't' test in Table 4. In comparison to men (0.91 ml/10min), women had a slightly higher mean salivary flow rate per 10 minutes (0.94 ml/10min). With a p value of 0.5, the difference + standard deviation SD (0.03 + 0.01) was determined to be statistically insignificant when using the p value 0.05 as the statistical threshold. The average salivary flow rate in men (0.91 ml/10 min) and women (0.94 ml/10 min) is about the same, as seen in Graph 4's comparison of unstimulated salivary flow rates over 10 minutes.

Table 5 compares the mean salivary flow during unstimulated and TENS stimulation for a period of 10 minutes in a graduated test tube between males, females, and overall (males + females). For analysis, a paired "t" test was

conducted. Males had a lower mean + standard deviation SD difference ($0.16 + 0.11$) compared to females ($0.23 + 0.11$), and males + females as a whole ($0.20 + 0.11$) overall. The acquired results were statistically significant, with a p value (0.001) taken into consideration here being 0.05. The mean comparison of salivary flow rates with and without TENS stimulation is shown in Graph 5. The mean difference between men and women was determined to be 0.16 for men and 0.28 for women. The difference in mean between men and women as a whole was found to be 0.20, which was statistically significant.

The mean comparison of salivary flow rates with and without TENS stimulation is shown in Table 6 for various age groups. When using the p value of 0.05 as the threshold for statistical significance, the overall difference mean + standard deviation SD was $0.20 + 0.11$, which was statistically significant at 0.001. The reduced sample size is likely to be the cause of the mean difference + SD among the 70-79 age group being determined to be statistically insignificant ($0.13 + 0.04$ with a p value of 0.08 alone). The mean comparison of salivary flow rates with and without TENS stimulation is shown in Graph 6 for various age groups. There was a 0.20 difference in the mean values across the board.

Discussion

Several studies were conducted in the past to see the efficiency of electrostimulation in increasing salivary flow, but only a couple of studies have been conducted so far to demonstrate TENS as a means of stimulating salivary flow rate in non-diabetic adult subjects. So the need was felt to assess the efficiency of TENS as a treatment modality to improve salivary flow rate in diabetic patients. Hyposalivation is an objective reduction in salivary secretion and is defined as unstimulated whole saliva between 0.12ml/min to 0.16 ml/min and stimulated whole salivary flow rate below 0.5 ml/min according to Dyasnoor S et al.[8] The present study reported 100 patients with DM associated with hyposalivation. This can be explained by the microvascular and autonomic neuropathic complications of diabetes, both of which may affect salivary secretion. Though the patients had decreased salivation, they were not able to appreciate the difference. The explanation for this finding could be that subjects may have found ways to compensate for salivary hypofunction (eg., taking liquids with meals). Also, there may be psychological and multiple physiological factors, such as alterations in the oral mucosa or changes in baroreceptors, which contribute to decreased perception of xerostomia.[9]

The unstimulated salivary flow rate diminished as the age advanced. **In the present study**, the unstimulated salivary flow rate diminished as the age advanced, with a mean unstimulated salivary flow rate in 30-39 years age group found to be 0.81ml/10 min, 0.78 ml/10 min in 40-49 years age group, 0.66 ml/10 min in 50 - 59 yrs age group, 0.68ml/10 min in 60-69 yrs age group and 0.55ml/10 min in 70-79 years age group. By the above findings it was clear in present study that the unstimulated salivary flow rate was decreasing from the age group 30-39 to 70-79 years. The paired't' test performed to compare the levels revealed a statistically significant difference in unstimulated salivary flow rate between the age groups. A similar study was conducted by Gutman D et al (1974) revealed that the young adult age group had a mean salivary flow rate of 0.41

ml/min. The older group showed 0.36 ml/min as the mean salivary flow rate. These results indicated a decrease in salivary gland function as age advanced which is in correlation with the present study.[10] The reason for this might be due to the reduced functioning of the salivary glands with age due to change in the activity of enzymes, namely fructose-1,6-diphosphate aldolase and, isocitrate lyase as stated by Gershon et al in their study on altered enzyme molecules in senescent organisms.[11] The unstimulated salivary flow rate in females (0.71) was less when compared to males (0.75). This can be explained based on female salivary glands being smaller than those of males according to the separate studies done by Ericson (1971) and Scott (1975) on parotid and submandibular glands respectively.[12] Similarly, in the study conducted by Panchbhai AS et al, higher salivary flow rates were recorded in diabetic males than in females, which is in correlation with the present study.[13]

In a similar study conducted by Percival et al, females had significantly lower mean salivary flow rates than males.[14] This can be related to the results of the present study. In the present study, females produced more saliva when stimulated with TENS than males with a mean salivary flow rate of 0.94 ml/10 min and 0.91 ml/10 min in males. The increased amount of TENS stimulated flow rate in females in our study was attributed to low blood glucose levels (mean 181.46 mg/dl) as compared with males (mean 218.75 mg/dl). In a similar study conducted by Hargitai et al (2005) on adult healthy subjects, 22 healthy adults (17 males and 5 females) were included. They revealed that the males produced more saliva with TENS than females with a mean value of 0.0308 and 0.0068 ml/min respectively. This might be due to the small number of female participants in the study.[9]

The present study reported that TENS stimulated saliva was more (mean 1.08 ml/10min) in the age group of 30 to 39 years and least (0.68 ml/10min) in the older age group (70 -79 years). This difference was statistically significant, suggesting that the stimulated salivary flow rates also change according to the age i.e., more in the younger age and decreases as the age is increasing. In a similar study conducted by Pattipati S et al, they found that there was a diminished stimulated salivary flow rate with advancing age which is in correlation with the present study.[15]

This technique may not work in every individual, but in those that have dramatic results, relief from dry mouth would be most welcome. 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.

Aspects for future study should include how long the increase in saliva flow lasts after turning off the TENS unit. Because the initial results are encouraging, further studies are required to evaluate the long-term clinical effectiveness of TENS in Sjögren syndrome and xerostomia secondary to head and neck radiation therapy.

TENS is an effective extra oral device having minimal side-effects, which are transient. TENS therapy can be used as an adjunctive method for the treatment

of xerostomia along with other treatment modalities. 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.

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. 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.

Conclusion

The present study has been one of the few studies to show TENS having a potential for increasing salivary flow in the diabetes mellitus patients with hyposalivation. To our knowledge, this study is the first of its kind to use TENS as a therapeutic modality in patients with diabetes mellitus. Possibly, TENS acts more efficiently as an accelerator of salivary flow rather than an initiator. The saliva collection method in the present study was an improvement over previous electrostimulation studies, which were very subjective and prone to contamination by nasal and gastric secretions as well as food debris. TENS is an effective extra-oral device having minimal side effects, which are transient. From the results of this study, TENS can be used as an adjunctive method for the treatment of xerostomia along with other treatment modalities. To conclude in this study, there was a remarkable increased salivary flow rate with basic settings of TENS. Thus in this study, an extraoral transcutaneous electric nerve stimulation was used to stimulate salivary flow rate in patients with diabetes mellitus and also compared the unstimulated and TENS stimulated salivary flow rate in diabetic patients. Thus, according to this study, TENS can be considered as a viable treatment option in the management of xerostomia in patients with diabetes in whom other treatment modalities like chewing gums, citric lozenges, and other therapies are failed or contraindicated.

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Table 1

Age	Gender		Total Sample
	Male	Female	
30-39	14	8	22
40-49	17	17	34
50-59	12	15	27
60-69	6	7	13
70-79	3	1	4
Total	52	48	100

Table 2

Mean comparison of blood glucose level mg/dl between Males and Females

Gender	MIN	MAX	MEAN	SD	Difference Mean±SD	t value	P value
Male	133.00	432.00	218.75	87.86	37.29±27.29	2.451	0.016 S
Female	120.00	432.00	181.46	60.57			

Statistical Analysis: Independent sample t test. Statistically significant if P<0.05

Table 3

Mean comparison of Unstimulated rate /10 min between Males and Females

Gender	MIN	MAX	MEAN	SD	Difference Mean $\pm$ SD	t value	P value
Male	0.30	1.00	0.75	0.18	0.04 $\pm$ 0.01	0.965	0.337 NS
Female	0.40	1.10	0.71	0.17			

Statistical Analysis: Independent sample t test. Statistically significant if P<0.05

Table 4

Mean comparison of Stimulated rate /10 min between Males and Females

Gender	MIN	MAX	MEAN	SD	Difference Mean $\pm$ SD	t value	P value
Male	0.40	2.00	0.91	0.29	0.03 $\pm$ 0.01	0.535	0.594 NS
Female	0.50	1.50	0.94	0.28			

Statistical Analysis: Independent sample t test. Statistically significant if P<0.05

Table 5

Mean comparison between Unstimulated rate /10 min and Stimulated rate/10min in Males, Females and overall (Males+Females).

Gender	Variables	MIN	MAX	MEAN	SD	Difference Mean $\pm$ SD	t value	P value
Male	Unstimulated rate /10 min	0.30	1.00	0.75	0.18	0.16 $\pm$ 0.11	4.348	<0.001 S
	Stimulated rate/10min	0.40	2.00	0.91	0.29			
Female	Unstimulated rate /10 min	0.40	1.10	0.71	0.17	0.23 $\pm$ 0.11	5.350	<0.001 S
	Stimulated rate/10min	0.50	1.50	0.94	0.28			
overall	Unstimulated rate /10 min	0.30	1.10	0.73	0.17	0.20 $\pm$ 0.11	6.861	<0.001 S
	Stimulated rate/10min	0.40	2.00	0.93	0.28			

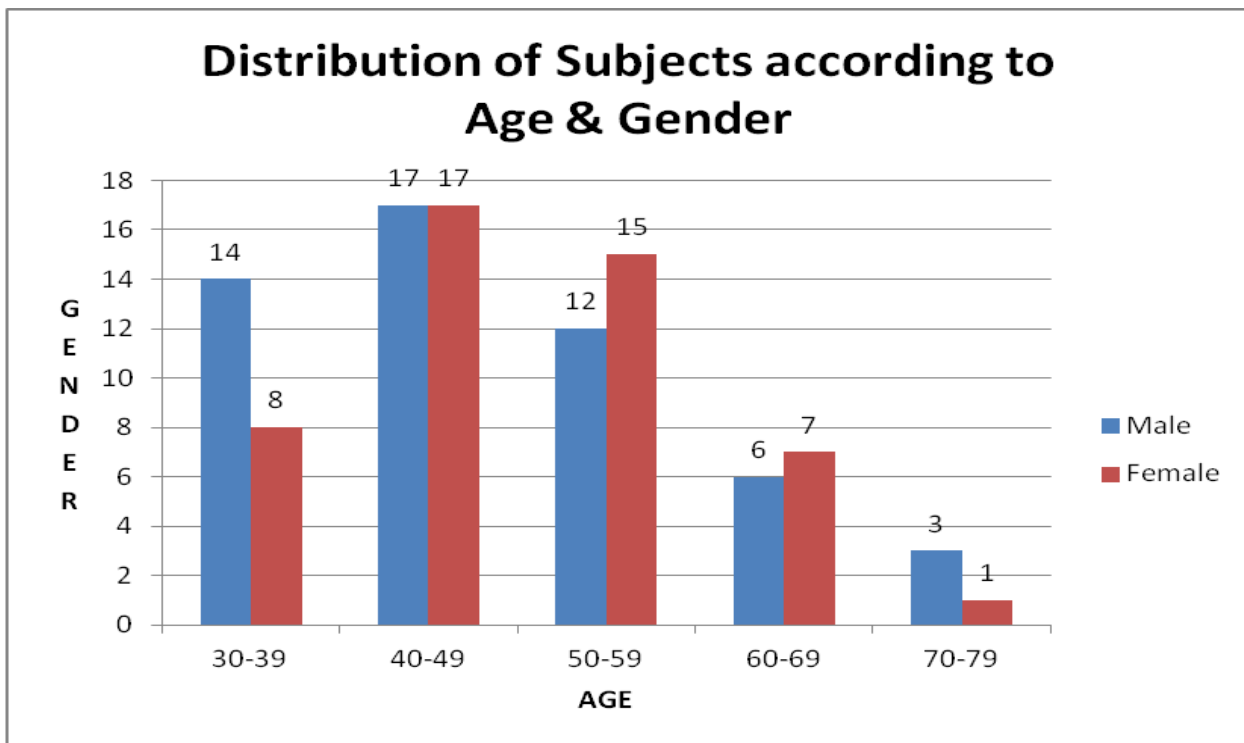
Statistical Analysis: Paired t test. Statistically significant if P<0.05

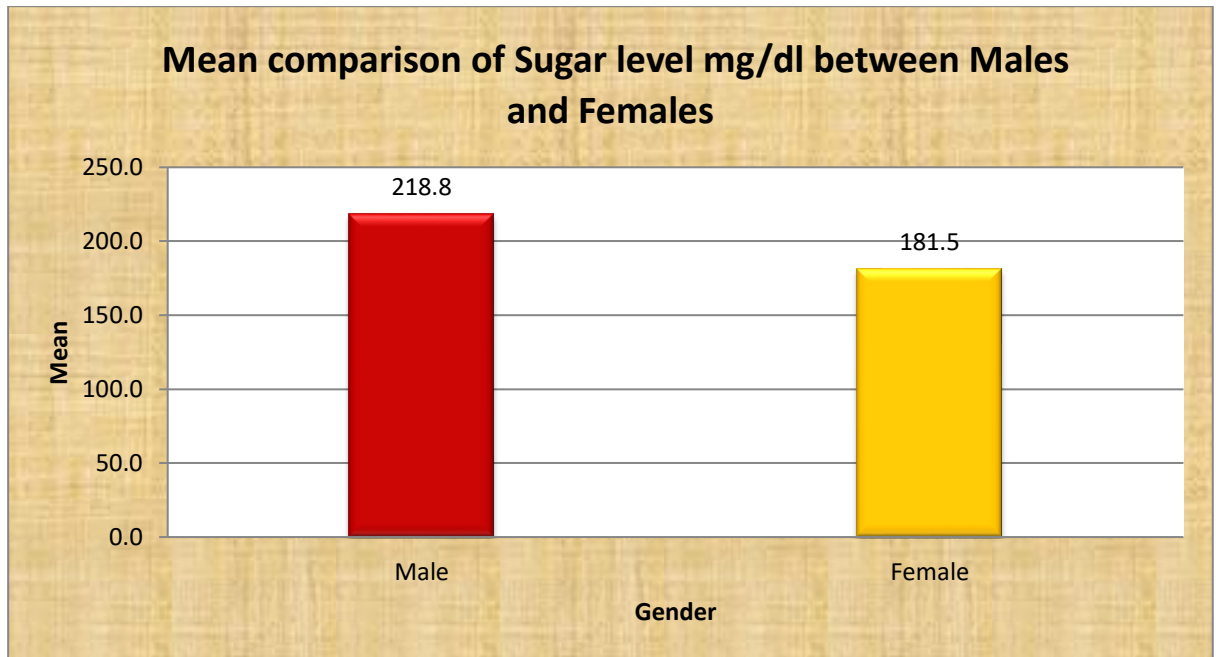
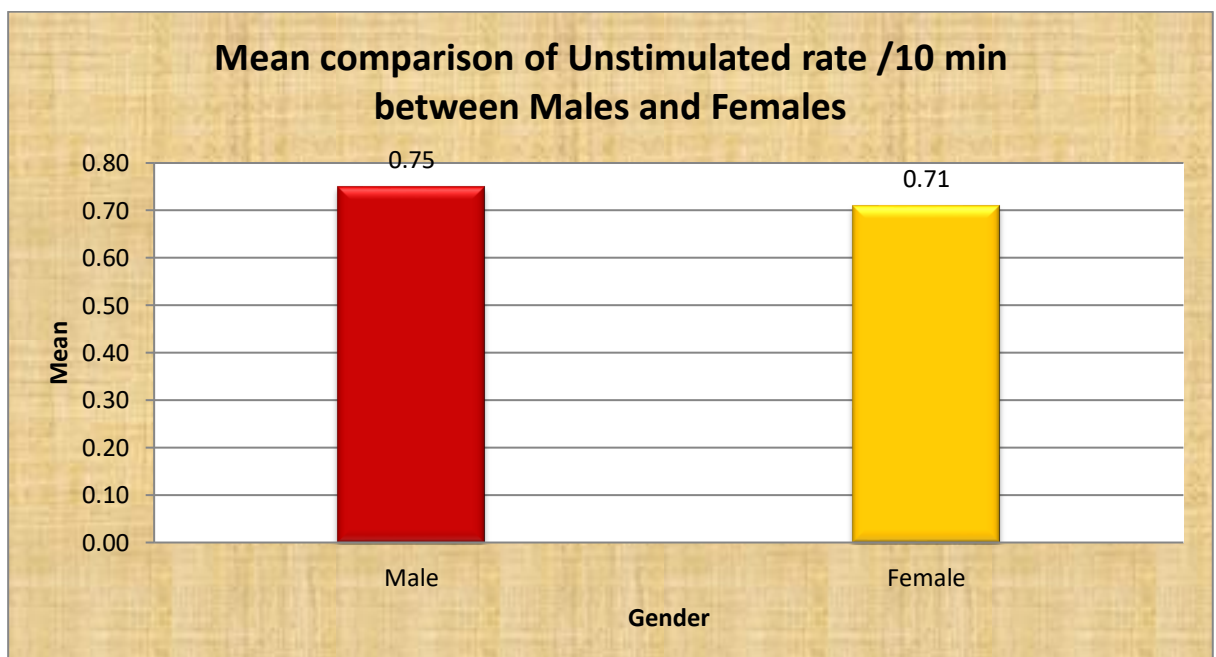
Table 6

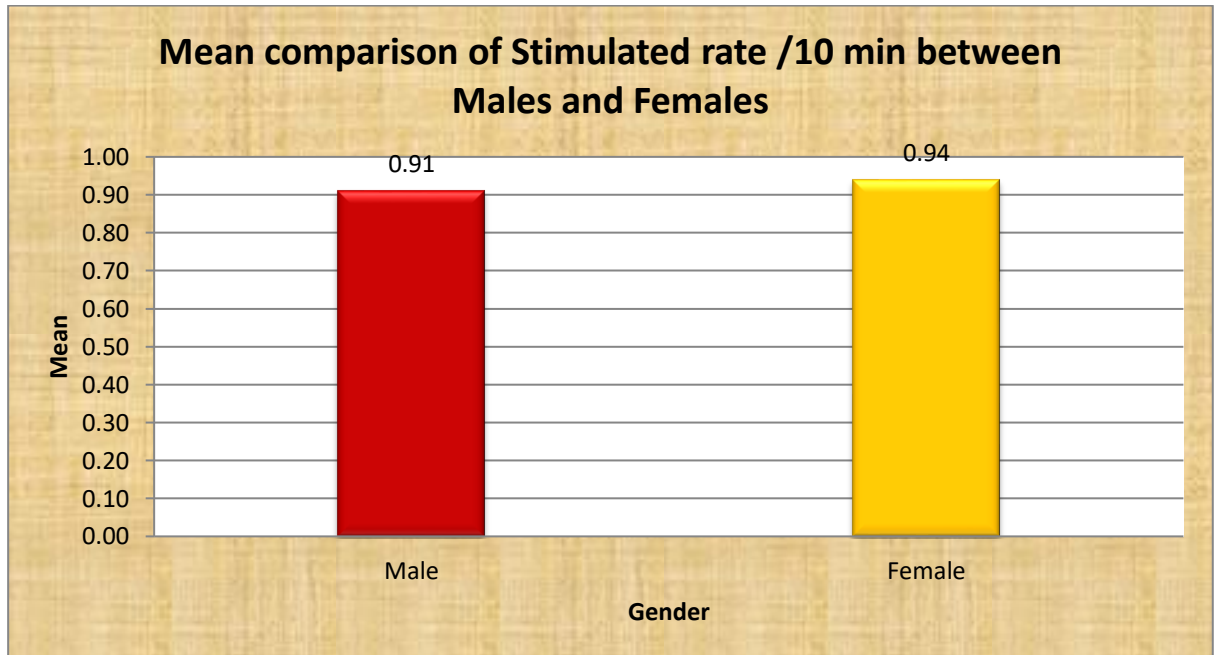
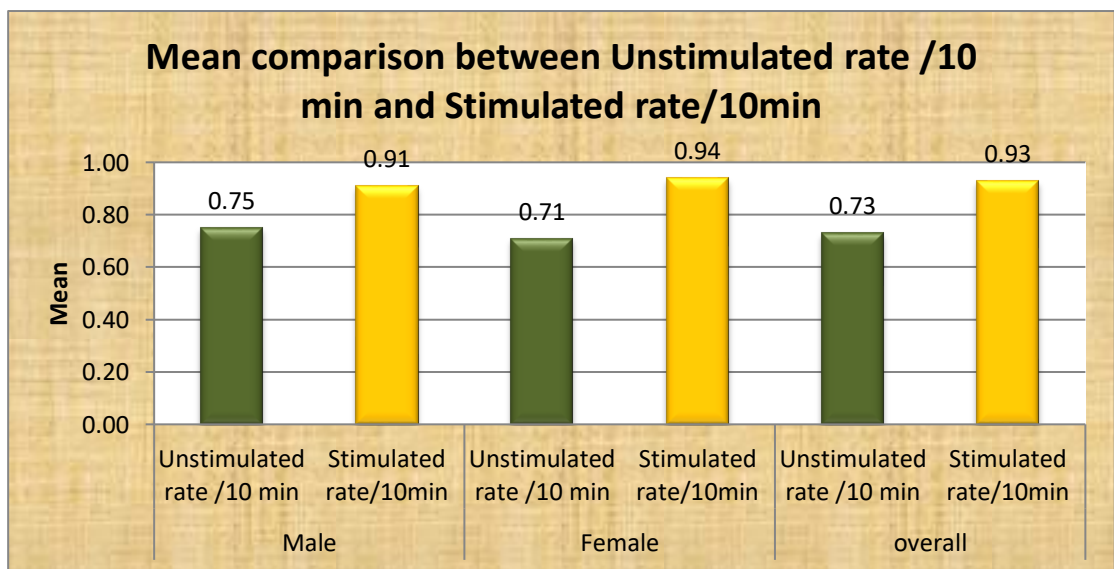
Mean comparison between Unstimulated rate /10 min and Stimulated rate/10min in different age groups.

AGE	Sample size	Unstimulated rate /10 min		Stimulated rate/10min		Difference Mean±SD	t value	P value
		Mean	SD	Mean	SD			
30-39	22	0.81	0.16	1.08	0.35	0.27±0.19	2.975	0.007 S
40-49	34	0.78	0.16	0.98	0.24	0.20±0.08	4.288	<0.001 S
50-59	27	0.66	0.14	0.80	0.19	0.14±0.05	3.606	0.001 S
60-69	13	0.68	0.20	0.88	0.29	0.19±0.09	3.584	0.004 S
70-79	4	0.55	0.13	0.68	0.17	0.13±0.04	2.611	0.080 NS
Overall	100	0.73	0.17	0.93	0.28	0.20±0.11	6.861	<0.001 S

Statistical Analysis: Paired t test. Statistically significant if P<0.05

Graph 1

Graph 2**Graph 3**

Graph 4**Graph 5**

Graph 6