

# Response of salivary flow rate to transcutaneous electrical nerve stimulation in haemodialysis patients

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Ali Mohamed Ali Ismail<sup>1</sup> , Mohamed Ibrahim Abdelhay<sup>2</sup> , Ramy Salama Draz<sup>1</sup> 

<sup>1</sup> Department of Physical Therapy for Cardiovascular/Respiratory Disorder and Geriatrics, Faculty of Physical Therapy, Cairo University, Giza, Egypt

<sup>2</sup> Department of Basic Science, Faculty of Physical Therapy, Cairo University, Giza, Egypt

## Abstract

**Introduction.** Hyposalivation is one of the common oral complications in end-stage renal disease. This study aimed to assess the immediate and 3-week effects of transcutaneous electrical nerve stimulation (TENS) on hyposalivation in end-stage renal disease patients on maintenance haemodialysis.

**Methods.** Overall, 80 haemodialysis patients with hyposalivation complaints (40 diabetics and 40 nondiabetics with a mean age of  $59.35 \pm 9.59$  and  $59.45 \pm 9.66$  years, respectively) were treated with 20-minute extraoral TENS (50 Hz and 250  $\mu$ s pulse duration) applied bilaterally to parotid glands for 3 successive weeks (3 sessions per week). Besides the baseline measurement, the whole resting saliva was collected immediately after the first and last TENS sessions in a graduated test tube via the 5-minute low forced spitting method. The whole resting salivary flow rate (WRSFR) (ml/min) was calculated by dividing the collected salivary volume by the 5-minute collection period.

**Results.** When the baseline WRSFR mean was compared with its value after the first or last TENS session, WRSFR showed a highly significant increase in diabetic and nondiabetic haemodialysis patients.

**Conclusions.** Extraoral electrostimulation via TENS is an effective therapeutic modality for hyposalivation in end-stage renal disease patients on maintenance haemodialysis.

**Key words:** saliva, electrostimulation, transcutaneous electrical nerve stimulation, haemodialysis, diabetes mellitus, chronic renal failure

## Introduction

The oral cavity is a mirror of the individual's general health status. Managing the oral manifestations of any systemic disease is a challenge to oral physicians. During the period of 2000–2015, the worldwide number of patients with chronic renal failure or end-stage renal disease (ESRD) induced by diabetes mellitus increased from 375.8 to 1016 per million. ESRD patients usually complain of complex oral manifestations caused not only by the disease itself but also by the therapy like haemodialysis (HD) [1].

HD is a blood passage through a dialysis venous catheter utilizing a dialysis fluid solution in an HD machine, with the blood returned to the patient after external filtration [2]. HD aim is to remove the waste products such as urea in addition to free water from the patient's blood when chronic renal failure occurs [3]. According to the Egyptian renal registry, in 2008, ESRD prevalence was 483 per million and the total recorded number of ESRD patients on dialysis were 40 000, using nearly 3000 HD machines in more than 600 dialysis units distributed in both governmental (25%) and private (75%) sectors [4].

Saliva is the most critical, valuable, slightly acidic, clear exocrine mucoserous secretion for the maintenance and preservation of oral health. The complex mixture of fluids from both major and minor salivary glands contributes to the whole resting unstimulated saliva (WRUS). The average daily WRUS volume is 1–1.5 l in healthy subjects. The different contribution of salivary glands to WRUS is 65% from submandibular, 20% from parotid, 7–8% from sublingual, and < 10% from

numerous minor glands. Parotid contribution of > 50% of the total secreted saliva dramatically changes the percentage of contributions from the particular glands [5].

In 41% of 17 HD patients, a study showed markedly atrophied salivary glands but there has been no study to determine why this atrophy happens [6] and, consequently, the oral health status of HD patients is negatively affected as a result. Oral tissues are influenced by ESRD, which leads to xerostomia (a subjective sensation of dry mouth), altered salivary composition, hyposalivation (an objective sign of low saliva flow), oral infections, mucosal lesions, and oral malignancies [7].

Quality of life and oral health are negatively affected by a 33–76% dry mouth prevalence in HD patients [8]. Dry mouth is a depressive symptom for HD individuals owing to a low saliva flow, which is a risk factor of an increased intake of fluids – because of thirst secondary to xerostomia – resulting in excess interdialytic weight gain [3]. In addition to chewing, swallowing, taste, and speaking difficulties, low saliva flow is associated with increased oral complications such as fungal and bacterial infections (periodontal disease, dental caries, and candidiasis), lesions of oral tissues (tongue, gingiva, and mucosa) [9], halitosis, and difficulty in wearing dentures [10].

Owing to diabetes mellitus, diabetic autonomic neuropathy, and uraemia [11], functional and organic changes of salivary glands are very common in HD patients. Besides the accumulation of fibrillar components, fibrosis, mouth breathing, dehydration, and restricted fluid intake [12, 13], the HD-induced salivary changes may be related to the direct uraemic salivary glandular dysfunction, inflammation, gland-

*Correspondence address:* Ali Mohamed Ali Ismail, Department of Physical Therapy for Cardiovascular/Respiratory Disorder and Geriatrics, Faculty of Physical Therapy, Cairo University, 12624, Giza, Egypt, e-mail: [ali.mohamed@pt.cu.edu.eg](mailto:ali.mohamed@pt.cu.edu.eg), [ali-mohamed@cu.edu.eg](mailto:ali-mohamed@cu.edu.eg), <https://orcid.org/0000-0003-1447-8817>

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dular atrophy, old age, psychological factors such as anxiety and depression, and the repeated use of xerostomia-related medications such as sympathomimetic anticholinergic, cytotoxic, and antihypertensive drugs, benzodiazepines, and opioids in addition to anti-migraine agents [9]. Salivary gland hypofunction in poorly controlled older diabetics may be caused by adverse microvascular, hormonal, and neuronal changes. Diabetic patients with oral dryness may complain of a poor salivary flow rate due to the disturbed glycaemic control and direct metabolic impact on salivary glands [14].

There are many techniques for salivary flow stimulation (including mechanical, taste, chemical, and electrical stimuli to salivary glands), with some limitations, side effects, and contraindications [15]. Unfortunately, no effective therapy exists for dry mouth in chronic HD patients [16]. Stimulating salivary glands by mechanical techniques (like chewing gum) among the elderly needs special attention to fitting with dentures, easily sticking to dentures, and problems with teeth and masticatory muscles [10].

Saliva substitutes (such as artificial saliva, disliked by HD patients owing to its flavour) [10], as well as pharmacological agents (such as angiotensin-converting-enzyme inhibitors alone or combined with angiotensin-receptor blockers and pilocarpine [16]) are all ineffective, with many side effects like profuse sweating, frequent urination, dyspepsia, rhinitis, etc. [17]. Further efforts should be taken to develop an economical, non-invasive, and effective therapy – with no side effects – for low saliva flow in HD patients [16]. Transcutaneous electrical nerve stimulation (TENS) is a strong tool in increasing the production of parotid saliva. TENS can be used with high comfort during the eating process in individuals who are not able to chew gum, e.g. those with temporomandibular joint disorders [17]. Since 1986, despite the evidence-based positive response of salivary flow to TENS, there has been a low evidence-based explanation in the literature to justify TENS use in the management of hyposalivation [18]. Because of the scarcity of research on electrostimulation effect on the salivary flow in ESRD patients on maintenance HD, this study aimed to find out the immediate and 3-week impact of extraoral TENS on hyposalivation in diabetic and non-diabetic HD patients.

## Subjects and methods

### Subjects

A total of 80 HD patients (40 diabetics and 40 nondiabetics) of both sexes aged 35–80 years were randomly selected from Meet Ghamr Urology and Kidney Hospital. The included patients had been receiving maintenance HD sessions – 3 times weekly – because of ESRD for at least 3 months. They complained of hyposalivation with a whole resting salivary flow rate (WRSFR) of  $\leq 0.15$  ml/min [19].

A physician excluded patients with a pathology of salivary glands (acute or chronic inflammation or tumours), oral cavity infection or inflammation, history of head and neck tumours, autoimmune disease, neurologic diseases, cardiac pacemaker, cardiac or psychogenic diseases. Besides, individuals undergoing pharmacological management of hyposalivation, alcoholics, smokers, and hypertensive patients were excluded.

### Intervention

The electrodes (circular shaped, 50-mm adhesive Polar Trode, made in China) of 20-minute continuous TENS (50 Hz,



Figure 1. Application of transcutaneous electrical nerve stimulation electrodes on the parotid gland to stimulate saliva production

250  $\mu$ s pulse duration, handheld Inter-Tens 668, modified version of TENS-Plus 2000, delivered by SAG International Company for physiotherapy devices in Egypt) were applied bilaterally in all patients on the skin overlying parotids, with an intensity reaching the maximal level of tolerability for each individual [17] (Figure 1). The sessions were applied 3 times weekly (day after day) for 3 successive weeks.

### Assessment of salivary flow rate

The participants were instructed to prevent oral hygiene, drinking, eating, coffee intake, and chewing gum for at least 1 hour before the collection of the whole resting saliva. The saliva collection was performed between 9 and 11 a.m. via the 5-minute low forced spitting in a graduated test tube. The salivary flow rate was calculated by dividing the salivary volume – the liquid component of saliva, not the foam, in ml – by the 5-minute collection period. Each patient was ordered to sit facing the collection tube, with both arms resting on their knees. The collected saliva was accumulated in the anterior region of the floor of the mouth to be spatting for 5 minutes in the tube [17]. WRSFR was measured immediately before and after the first TENS session and immediately after the last TENS session in all patients [20].

### Statistical analysis

After being subjected to the Kolmogorov-Smirnov test, all data showed a normal distribution. The unpaired test was used to assess the non-significance of baseline data among diabetic and nondiabetic HD patients. The repeated measure test of variance was utilized to evaluate the significance of WRSFR differences within and between the subjects. Data were analysed with the SPSS program, version 18 (IBM Corp., Chicago, USA), with the recommended significance level of  $p < 0.05$ .

Version 3.1.9.2 of the G\*Power program was used to assess the *a priori* sized sample test via the *F*-test, MANOVA for repeated measures in HD patients. By conducting a pilot study among 10 HD patients, the gained size effect of WRSFR = 0.27 was acquired after setting the error rate – type I – at 5% and power for type II error at 80%; the minimal required size of the sample was 72 HD patients.

### Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies,

has followed the tenets of the Declaration of Helsinki, and has been approved by the Institutional Review Board of Faculty of Physical Therapy, Cairo University (approval No.: P.T.REC/012/002679).

**Informed consent**

Informed consent has been obtained from all individuals included in this study.

**Results**

To determine the treatment and time effects between the studied groups, the Wilks' lambda test was extracted from the ANOVA repeated measure test. It revealed a significant effect of time ( $p < 0.001$  and  $F = 78.16$ ) and a non-significant effect of treatment between the 2 groups ( $p = 0.742$  and  $F = 78.16$ ).

As shown in Table 1, no significant difference was found between the baseline data of the diabetic and nondiabetic HD groups. As presented in Table 2, the pairwise WRSFR comparison revealed a non-significant pre-intervention difference between the 2 groups. Very highly significant within-group differences were detected when comparing the pre and post-intervention WRSFR values either after the 1<sup>st</sup> or after the last TENS session in the 2 groups. Lastly, the between-group post-intervention WRSFR comparison exposed a non-significant difference ( $p > 0.05$ ).

Table 1. Baseline data of the studied HD patients

Characteristics	Diabetic HD group	Nondiabetic HD group	<i>p</i>
Age (years)	59.35 ± 9.59	59.45 ± 9.66	0.963
Males/females ( <i>n</i> )	20/20	20/20	–
HD (months)	45.92 ± 28.63	46.27 ± 28.52	0.956
IDWG (kg)	3.03 ± 1.08	3.28 ± 1.24	0.339
HbA1c (%)	7.38 ± 0.90	–	–

Data are expressed as mean ± standard deviation or number. HD – haemodialysis, IDWG – interdialytic weight gain (defined as the fluid amount removed during the dialysis session, i.e. the pre-dialysis weight subtracted from the post-dialysis weight), HbA1c – glycosylated haemoglobin

Table 2. Pairwise WRSFR comparison within and between the diabetic and nondiabetic HD groups

WRSFR (ml/min)	Diabetic HD group ( <i>n</i> = 40)	Nondiabetic HD group ( <i>n</i> = 40)	Between-group <i>p</i>
Before intervention	0.09 ± 0.04	0.08 ± 0.05	0.757 <sup>B</sup>
Immediately after 1 <sup>st</sup> session	0.13 ± 0.09	0.14 ± 0.09	0.922 <sup>B</sup>
Within-group <i>p</i>	0.006 <sup>A</sup>	0.002 <sup>A</sup>	
Immediately after last session	0.48 ± 0.27	0.50 ± 0.30	0.707 <sup>B</sup>
Within-group <i>p</i>	< 0.001 <sup>A</sup>	< 0.001 <sup>A</sup>	

Data are expressed as mean ± standard deviation. HD – haemodialysis, WRSFR – whole resting salivary flow rate  
<sup>A</sup> significant *p*-value  
<sup>B</sup> non-significant *p*-value according to repeated measure ANOVA

**Discussion**

Dry mouth has a wide prevalence in HD patients and underestimation of this symptom by nephrologists is common, as reflected in the small number of studies published [21]. In addition to salivary gland dysfunction and low salivary flow, a fluid restricted diet – to avoid fluid overload – must be followed by HD individuals. Hence, many of them complain of hyposalivation and thirst that negatively affect their quality of life. Oral complications of long-standing dry mouth are caries and an increased risk of mucosal inflammation and soreness. Slight dry mouth can be treated by mechanical stimulation, salivary substitutes, or artificial saliva, but all these have limitations [8]. TENS is effective in increasing the saliva flow and production [22] but there are few studies that assessed the immediate and long-termed effect of TENS on hyposalivation in diabetic and nondiabetic ESRD patients undergoing HD. Therefore, our study seems to be of considerable importance. It revealed that both immediate and 3-week extraoral TENS applications were able to produce a highly significant improvement of abnormal low salivation in diabetic and nondiabetic ESRD subjects undergoing HD.

It is not yet obvious how electrostimulation affects the function of salivary glands but the auriculotemporal nerve may be involved in this process via a reflex mechanism between the afferent and efferent pathways. The increased impulses of electric current applied to the salivary nuclei (salivation centre) in the medulla oblongata may be the cause of intensified stimulation to the efferent pathway of salivation control [18].

Our results are in line with those obtained by Yang et al. [23], who found that 3-week 250-µs 50-Hz TENS – on ST 6 and TE 17 acupoints – was able to increase the salivary flow rate from 0.09 ± 0.08 to 0.30 ± 0.14 ml/min in chronic HD patients.

Another study – supporting the use of continuous extraoral TENS mode – revealed that after 1 session, the salivary flow rate (ml/10 min) increased from 1.34 ± 0.23 ml to 1.55 ± 0.31 ml/min in 15 complaints of hyposalivation among 40 diabetic patients aged 30–75 years [14]. Again, one 5-minute extraoral TENS session with the continuous mode applied bilaterally to parotids led to a saliva flow increase from 0.10 ± 0.10 to 0.15 ± 0.09 ml/min in 90 out of 100 diabetic patients with hyposalivation with a recommendation of adding TENS to the mainstream therapy of hyposalivation [17]. After 1 extraoral TENS session, 6 diabetics (4 females and 2 males) presented a saliva flow increase from 2.53 to 3.33 ml/min [24]. Also, after a 5-minute extraoral TENS session, 19 out of 25 subjects with hyposalivation complaints exhibited an increased parotid saliva flow [25]. Electrical stimulation of saliva via TENS showed a statistically significant improvement in the whole salivary flow rate among postmenopausal females with or without dry mouth [26].

Moreover, 20 minutes of TENS increased the salivary flow rate from 0.05 to 0.10 ml/min in 15 patients aged 56.8 ± 6.46 years with a complaint of hyposalivation that was induced by radiotherapy treatment of head and neck cancer [15]. Consistently, 30 individuals treated with radiotherapy for oral cancer with a resting saliva flow of 0.21 ± 0.13 ml/min showed an increase in their saliva flow (0.25 ± 0.13 ml/min) after a 5-minute extraoral TENS session [27]. Overall, 29 patients out of 30 presented an increase in the mean salivary flow rate from 0.056 to 0.12 ml/min. It is possible to add extraoral TENS as an effective adjunctive therapeutic application in the post-radiation management of hyposalivation in oropharyngeal/oral cancer patients [28]. Owing to the potentially

increased blood supply to the parotids, 3 TENS sessions weekly for 30 minutes, alone or combined with mechanical salivary stimulation, improved the low saliva flow and prevented severe oral mucositis induced by chemotherapy [29].

In agreement with the results of this study, 37 patients with head and neck cancer with a complaint of radiotherapy-induced hyposalivation showed an increase of salivary flow rate from 0.16 to 0.58 ml/min after 8 extraoral TENS sessions (twice weekly, 20 minutes for each session) [18].

Against our results and perhaps owing to the complete damage of the salivary gland caused by a high dose of radiation therapy, continuous TENS did not improve the salivary flow after a radiotherapy course of 1 month because TENS is likely less effective with no baseline saliva flow [30].

## Limitations

This study has several limitations, such as the lack of long-term follow-up and no TENS comparison with other therapeutic pharmacological or non-pharmacological methods.

## Conclusions

Within the limitations of this study, the results showed that the immediate and long-term extraoral TENS bilateral application on the skin over the parotids is a strong alternative and/or main non-pharmacological modality that could be safely used in the treatment of hyposalivation to maintain the oral health in diabetic or nondiabetic ESRD patients undergoing HD. Future studies are needed to compare the response of hyposalivation to long-term TENS application versus other non-pharmacological methods, such as low-level laser, lip muscle trainer, and hyperbaric oxygen therapy.

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## Disclosure statement

No author has any financial interest or received any financial benefit from this research.

## Conflict of interest

The authors state no conflict of interest.

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