The Efficacy of Sternocleidomastoid Muscle Flap on Frey's Syndrome via a Novel Test: Galvanic Skin Response

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Abstract The aim of this study was to evaluate the effects of sternocleidomastoid (SCM) muscle flap on preventing Frey's syndrome by using, Galvanic skin responses (GSR). Forty-three patients who underwent superficial parotidectomy were randomly divided into two groups and their GSR were recorded. SCM muscle flap was applied over the surgical area only in one group. Six months after the surgery, GSRs were remeasured. In addition, the patients completed a questionnaire regarding their complaints about clinical Frey's syndrome. Four patients had symptoms of clinical Frey's syndrome. Postoperative GSR measurements revealed no significant difference between two sides in flap group ($p = 0.426$) but higher in without flap group ($p = 0.003$). The patients with clinical Frey syndrome had significantly higher GSR values than the remaining patients. The SCM muscle flap was an effective method in preventing Frey's syndrome. Moreover, GSR test was highly sensitive and specific for diagnosis.

Keywords Superficial parotidectomy · Frey's syndrome · Galvanic skin responses · Parotidectomy · Auriculotemporal syndrome

Introduction

Parotid gland tumors account for nearly 2% of all head and neck tumors [1]. Approximately 80% of parotid tumors are benign, and overall 60% of these tumors are pleomorphic adenomas [2]. Superficial parotidectomy is the appropriate modality for the treatment of benign parotid tumors. However, this procedure is associated with a number of complications including facial nerve paresis and paralysis, incisional scarring, keloid formation, volume deficit due to tissue removal, salivary fistula, skin anesthesia, and Frey's syndrome [3].

Frey's syndrome is characterised by flushing, warming and sweating at the skin of preauricular and temporal regions while eating. This syndrome is considered to be a result of cross innervation between the postganglionic secretomotor parasympathetic nerve fibres that innervate the parotid gland and the postganglionic sympathetic nerve fibres that innervate the sweat glands of the skin. Note that this risk of aberrant innervation increases with time in the course of follow-up postoperatively [4].

In the literature, the incidence of Frey's syndrome has been reported to vary between 4 and 97% [2–13]. This wide range can be explained by the usage of different objective and subjective diagnostic methods. The subjective evaluation was based on patients reported complaints related to this syndrome. However, several different tests were used to successfully determine the objective incidence of Frey's syndrome. Unfortunately, all of these objective tests are of relatively little value for assessment of the severity of this disease. Although in most of the trials, Minor's starch-iodine test was the major and gold standard objective diagnostic tool, it may show discordance between objective and subjective Frey's syndrome. The Minor's starch-iodine test may sometimes show positive

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results in asymptomatic patients [9, 13–16]. To overcome this disadvantage we contend that a more effective and accurate test is required for definitive diagnosis and quantitative analysis of Frey's syndrome. Thus, we instead utilized the noninvasive, simple, and convenient Galvanic skin response (GSR) method in our study.

GSR, also known as psychogalvanic reflex (PGR), electrodermal response (EDR), skin conductance response (SCR) and sympathetic skin response (SSR) may be defined as an instant change of electrical potential over skin resulting from external or internal impacts. In other words GSR analyses the change in electrical conductivity of the skin in response to autonomous nervous system stimuli [17, 18]. These stimuli which influences GSR changes may be stress, emotional status and excessive attention [19]. Furthermore, some neurological disorders like peripheral neuropathies, amyotrophic lateral sclerosis, Guillain-Barre syndrome, multiple sclerosis and coma may be related with GSR changes [20–25]. Since the sweat glands are also controlled by sympathetic nervous system and GSR changes reflects the sympathetic nervous system arousals then we concluded that by measuring GSR changes in patients who underwent parotidectomy, we can determine the improper stimulation of sympathetic nervous system and presence of Frey's syndrome quantitatively [26]. To the best of our knowledge, our study is the first to explore the use of GSR test in the course of Frey's syndrome.

Since first reported by Bernard in 1823, many modifications to the parotidectomy procedure have been introduced in order to avoid related complications [14]. Most of these modifications aimed at preventing Frey's syndrome. The most preferred method to prevent the abnormal reinnervation observed in Frey's syndrome is to place a barrier between the parotid gland and the skin covering its surface. The placement of sternocleidomastoid (SCM) muscle flaps, superficial musculoaponeurotic system (SMAS) rotation flaps, temporoparietal fascia flaps, and synthetic materials such as collagen injection, allogenic acellular dermal matrix, lyophilized dura implant, polyglactin 910-polydioxanone implant, polytetrafluoroethylene implant were shown to improve the incidence of Frey's syndrome [15, 27–35].

Fortunately most of the patients diagnosed with Frey's syndrome do not require treatment. However, it is essential to treat the patients (10–15% of cases) when this syndrome limits their social relationships and causes social distress (e.g., social embarrassment, incapacity, and anxiety). The treatment consists of oral and topical medications, surgery, and injections [36]. Among these modalities botulinum toxin type A injection provides satisfactory results and its reproducibility is another advantage even when the first treatment was insufficient [37–43].

The purpose of the present study was to evaluate the effects of the use of SCM muscle flap on preventing Frey's

syndrome via a novel test, namely GSR measurement. And also the validity of GSR measurement for determination of concordance between objective and subjective Frey's syndrome was evaluated.

Materials and Methods

The study was conducted at the between October 2006 and June 2010. Although 64 patients underwent superficial parotidectomy for benign parotid tumors during this period, the patients whose postoperative pathology revealed malignant cytology (17 patients) and those who did not agree to further follow-up (4 patients) were excluded from the study.

The exclusion criterias were as follows (i) who had another surgical procedure rather than superficial parotidectomy (such as enucleation, total parotidectomy, and partial superficial parotidectomy), (ii) who had a history of previous parotid surgery or radiation treatment to the head and neck area, (iii) whose postoperative pathology revealed malignant cytology, (v) who were operated for infectious reasons, and (vi) who did not agree to further follow-up. Prior to enrollment, the remaining 43 patients with an average age of 45 ± 13 were informed about the study and their written informed consents were taken.

These patients were then randomly divided into two groups before undergoing surgery. The first group (which we refer to as the “group with flap—GWF”) consisted of 22 patients and the second group (which we refer to as the “group without flap—GwoF”) consisted of 21 patients. The patients were neither aware of this classification nor informed which group they were assigned to. The SCM muscle flap reconstruction was considered to apply over the surgical area for all patients from the GWF group. Since an objective test was used for postsurgical evaluation, the study was not designed in a double blind manner.

Preoperative GSR measurements were performed at the Department of Physiology of Uludag University Medical School. The proper environmental conditions which may influence test results such as temperature, humidity, noise and stress were arranged with isolation and air conditioning. Upon arrival to the laboratory, the skin of bilateral preauricular and buccal regions of each patient was dried with a cotton swab. Biopac MP30 acquisition unit (Biopac System, Inc. USA) (shown in Fig. 1) was used to measure the GSR from the left and right parotid gland projections. The same procedure was followed for both sides. There were 2 electrodes placed over the skin of surgical area. The electrode bearing probes were placed just 2 cm above the jaw line horizontally and 4 cm from the mastoid tip side by side. The size of both electrodes attached to probes was 5 mm in diameter. So total sampled facial area was around

Fig. 1 The Biopac MP 30 unit used for GSR measurements

40 mm [2]. Later probes were fixed by an elastic head net (shown in Fig. 2). Then, ECG cables were connected to the electrodes placed on the right arm and both legs of the patient. The skin conductivity is measured in ‘mikroMho’ on a vertical scale with time in seconds. This conductivity is increased with an increment in sympathetic activity and vice versa. In patients with Frey’s syndrome with an influence of sialogogue agent administration because of caotic innervation the sympathetic fibers innervating to sweat glands were also stimulated beside salivary stimulus. This effect eventually was reflected as an increase on trace of GSR measurement. In each individual human, basal GSR measurements are different so we preferred to determine the percentage changes of GSR after sialogogue. Finally, a slice of lemon used as a sialogogue agent a minute after the GSR recording was initiated. The recording of each patient continued for one more minute

Fig. 2 The preparation of a patient for the GSR measurement

after that slice was eaten. A sample GSR recording collected for our study is shown in Fig. 3. Under proper conditions the results can be repeated with a high degree of consistency and the assesment of GSR changes revealed the same results.

Surgical Technique

The procedures were performed by same senior author (OB). The surgical procedure began with a standard modified blair incision. The skin flap was elevated in subplatysmal plane in the neck and in sub-SMAS plane in the buccal region. By using SCM muscle, digastric muscle, and tragal pointer as landmarks, the surgical plane was carried down to dissect parotid tissue. After the main truncus of the facial nerve was identified, all nerve branches were preserved and the superficial lobe of parotid gland and tumor was completely excised. The preserved nerve function was verified by using a neurostimulator. In all patients from the GWF group, a superiorly based SCM muscle flap was sutured with 3/0 polyglactin sutures in such that the whole bare surface of the facial nerve and deep lobe of parotid gland was covered (as shown in Figs. 4, 5). The amount of muscle to be transported was determined according to the size of defect area. Subsequently after a drain was placed, the flaps were closed according to two separate planes as deep plane corresponding to SMAS and platysma and superficial plane corresponding to skin in all patients.

Six months after the surgery, all patients were invited for a control examination. All patients were quired whether they have a flushing, warming or sweating over skin of surgical area while eating and a questionnaire regarding to these complaints was filled. Each patient underwent the same bilateral GSR measurement that was performed pre-operatively. The unoperated side of the face was used as a control group for the analysis of the GSR recordings which was done by Biopac Student Lab. v 3.7.0 software (Biopac System Inc.). For each 1-minute period before and after the slice of lemon was eaten by the patient, the mean GSR value was calculated (in microMho). The percentage difference between these mean values was also computed for comparison purposes.

Ethical Consideration

This study protocol was approved by the Ethics Committee (approval number: 2006-25/7). All patients signed the written informed consent about the procedures before being included in the study, which was also approved by the ethics committee. The author and all co-authors signed and declared that the study was carried out according the principles of Helsinki Declaration.

Fig. 3 The GSR recording of a patient

Fig. 4 The appearance of the defect area and facial nerve truncus after the removal of tumor

Fig. 5 The same patient after a superiorly based muscle flap was placed on the defect area

Statistical Analysis

All statistical analysis was carried out using SPSS v.13.0 for Windows (SPSS inc.Chicago, USA). The Mann–

Whitney *U* Test was used for the comparison of two groups of data which were not normally distributed. The difference between the dependent variables which were not normally distributed was analysed by Wilcoxon signed rank test. For the relation between variables Spearman's rho correlation coefficient (*r*) was calculated and searched for significance. According to the value of *r*, relation was concluded as follows, respectively; very weak relation; between 0 and 0.25, weak relation; between 0.26 and 0.49, medium relation; between 0.50 and 0.69, strong relation; between 0.70 and 0.89, very strong relation; between 0.90 and 1. The percentage changes of values obtained by GSR test were calculated and ROC analysis was used for calculation of threshold value by assuming the symptomatic patients as reference. A *p* value <0.05 was accepted as statistical significance.

Results

As shown in Table 1, there was not a significant difference between the patients from the GWFgroup and those from the GWoF group with respect to age and gender (*p* = 0.063 and *p* = 0.454, respectively). Superficial parotidectomy was performed to right side in 20 patients whereas to the left side in the remaining 23 patients. In

Table 1 Distribution of patients with respect to age, gender, tumor size, and operated side

	GWF	GWoF	<i>p</i> Value
Age	41.45 ± 13.26	48.90 ± 12.29	0.063
Gender			
Male	7 (31.8%)	9 (42.9%)	0.454
Female	15 (68.2%)	12 (57.1%)	
Tumor size (cm ²)	6 (1–30)	6 (4–25)	0.802
Operated side			
Right	10 (45%)	10 (47%)	–
Left	12 (55%)	11 (53%)	

each patient, the area of the tumor was calculated by pre-operative ultrasonographic evaluation of parotid gland. The mean tumor size was 6 cm² (ranging from 1 to 30 cm²) in the GWF group and 6 cm² (ranging from 4 to 25 cm²) in the GWoF group. Moreover, there was no significant difference in mean tumor sizes between these groups ($p = 0.805$). There was no complication in the early postoperative period related to application of SCM muscle flap.

During the control examination, 4 patients (9.3% of all patients) were observed to have symptoms suggesting Frey's syndrome such as flushing and sweating (as shown in Table 2). All of these patients were included in the GWoF group. Thus, the incidence of Frey's syndrome corresponded to 19% (4/21) in the GWoF group and to 0% (0/23) in the GWF group 6 months after the surgery. In addition, the analysis of postsurgical questionnaire revealed that patients from the GWoF group had significantly higher ($p = 0.048$) subjective complaints related to the occurrence of this syndrome than the patients from the GWF group.

ROC analysis was applied to evaluate the sensitivity and specificity of GSR measurements in identifying patients who already have subjective symptoms of Frey's syndrome. A postoperative increase of at least 1,023% in GSR was considered as positive. In this setting the sensitivity was 100% and specificity was 92% AUC:0.949, $p < 0.05$) (As shown in Fig. 6).

Before the surgery, there was a strong correlation between the GSR data collected from the control and operated sides of the parotid skin ($r = 0.947$, $p < 0.0001$). After the surgery, GSR scores measured for the control side were not significantly changed ($p = 0.885$) but GSR measurements were statistically significantly ($p = 0.016$) increased for the operated side (as shown in Table 3). In addition, postoperative GSR measurements for the operated side in patients from the GWoF group were higher than those of patients from the GWF group but the difference was not statistically significant ($p = 0.085$).

In patients from the GWF group, no significant difference was observed between postoperative GSR scores collected from the control and operated sides ($p = 0.426$).

Table 2 The percentages of occurrence of Frey syndrome in patients from GWF and GWoF groups

	Frey syndrome	
	Exists	Non-exists
Group	0/22 (0%)	22/22 (100%)
GWF	4/21 (19%)	17/21 (81%)
GWoF		
Total	4/43 (9%)	39/43 (91%)

Fig. 6 ROC analysis graph for sensitivity and specificity

Table 3 The percentage differences in GSR measurements before and after surgery for the control and operated sides

	Preoperative		Postoperative	
	Control	Operated	Control	Operated
Median (%)	82.60	94.01	112.46	207.55
Minimum (%)	-113.18	-118.86	-337.61	-390.83
Maximum (%)	1123.04	1160.00	845.16	1882.67

It was also observed that GSR measurements for the operated side were not significantly changed after the surgery ($p = 0.168$). Contrarily, postoperative GSR scores for the operated side were significantly higher than those of the control side in patients from the GWoF group ($p = 0.003$). Moreover, GSR measurements for the operated side were significantly increased in these patients after the surgery ($p = 0.035$).

Discussion

As it is the case in other surgical procedures, preventing complications related to parotidectomy before they emerge is more important than treating these complications. The application of SCM muscle flap, first introduced by Kornblut et al. [44], in 1974, is one of the most popular modalities used to prevent the occurrence of Frey's syndrome. Most of these studies showed that the use of SCM muscle flap can reduce objective measures of Frey's syndrome as well as improve subjective complaints of patients

Table 4 The review of literature presenting the incidence of Frey syndrome and type of surgical procedure applied

Author	Surgical procedure	Subjective Frey (%)	Objective Frey (%)
Casler and Conley [19]	SP	47	–
	SP + SCM	12	–
Sood et al. [18]	SP	18	82
	SP + SCM	0	18
Kerawala et al. [14]	SP	60	73
	SP + SCM	38	90
Filho et al. [17]	SP/TP	47	36
	SP/TP + SCM	0	0
Fee and Tran [28]	TP	44	22
	TP + SCM	13	20
Asal et al. [29]	SP	0	50
	SP + SCM	0	0
Rustemeyer et al. [45]	SP/TP	21	–
	SP/TP + SCM	24	–
Kornblut et al. [44]	SP	26	92
	SP + SCM	52	96

meanwhile some other studies also pointed out unfavorable outcomes with use of SCM flap (as shown in Table 4).

In the present study, our evaluations were conducted 6 months after superficial parotidectomy. None of our patients from the GWF group has presented with clinical Frey's syndrome at the end of this follow-up period. However, our findings revealed an incidence of this syndrome in 19% of patients from the GWoF group. Our results indeed coincided with prior studies from the literature which demonstrated that Frey's syndrome occurs more often in patients without flap compared to patients with flap. Although some studies reported increased incidence of Frey's syndrome in patients with flap in the long-term, this can be explained in part by the reduction of the volume of flap by time [15]. Since our follow-up period is relatively short, we did not observe such a presence of Frey's syndrome in our patients from the GWF group. But these patients may develop Frey's syndrome after a time interval because with time the volume of muscle flap may be attenuated. So further long term follow-up is required to conclude a statement that SCM flap was totally successful. In addition to providing functional benefits, the use of SCM muscle flap offers a satisfactory cosmetic outcome by preventing volume deficit and reconstructing parotidectomy defects [14]. Moreover, the application of SCM muscle flap was not associated with any complications and our findings were in agreement with those studies reported in the literature. In a few trials, synthetic graft materials and allografts have been used as a barrier to prevent Frey's syndrome [16, 35]. Although these materials have been shown to be effective, autogenous grafts exhibit superiority

compared to other available graft materials in terms of reduced cost and morbidity.

The incidence of Frey's syndrome can be assessed by both subjective and objective techniques. Subjectively, patients are considered to have this syndrome if complaints of sweating, warming, and flushing over preauricular region are present after food ingestion. However, the presence of these symptoms should be confirmed by means of objective testing. Minor's starch iodine test is the most common and highly accurate objective test for Frey's syndrome. In the test, the skin over preauricular region is painted with an iodine solution and then sprayed with powder starch. Later, the patient is given a sialogogue and the appearance of gustatory sweating is examined for a while. A color change of the starch is accepted as a positive result and affirms the presence of Frey's syndrome. The grading of the severity of Frey's syndrome (i.e., mild, medium, and severe) is usually determined by assessing the size of the hyperhidrotic area. Unfortunately, a common threshold value for each class was not enforced by different studies [9, 46, 47]. Since, assessing the size of the surface area involved is not an easy task and may vary from researcher to researcher, the objectivity of this test is not fully constituted.

Up to now, no objective test has been standardized for Frey's syndrome. Although Minor's starch iodine test is the most preferred objective test, it has two major shortcomings. First, there is a fairly high chance of discordance between subjective and objective Frey's syndrome. For example, some studies showed positive test results in almost all patients who underwent parotidectomy [7, 9]. There also exists some studies where Minor's test was positive in cases where the incidence of subjective Frey's syndrome was not observed (as shown in Table 4). Second, this test is not suitable for measuring the severity of disease. Other objective tests have also been experimented in the literature. Laccourreye et al. [8], used a biosensing method in which L-lactate level was measured on intact field. Although being sensitive, this method requires the use of complicated and expensive equipment thus is not viable for routine use. Dulguerov et al. [16], applied two different methods in their study. In the first method, they measured the amount of sweat absorbed by a blotting paper that is placed over the skin. Although this method enables the quantitative assessment of the amount of sweat generated, it does not provide topographic data. The second iodine-sublimated paper histogram method was a modification of the original Minor's starch iodine test where the digital image (in a 8 bit grayscale mode) of an iodine sublimated office paper (which changes color when wet) was subjected to a histogram algorithm in order to measure the area of color change. Although the topographic data of this method is excellent, it does not provide quantitative data. The increase

in the temperature of the skin over the preauricular region is one of the symptoms of Frey's syndrome. In their study, Isogai and Kamiishi [48] used medical thermography to identify the presence of this syndrome by measuring such temperature changes. However, they mentioned that this method is not appropriate as a quantitative measure to grade the severity of this syndrome.

In contrast to prior studies, we used an easily measured, highly sensitive, and relatively reliable GSR method to record alterations in electrical activity of the skin over preauricular region. To our knowledge, our study is the first to explore the use of GSR for determination of Frey's syndrome. In the study, we considered a postoperative increase of at least 1,023% in GSR as positive. 7 patients (16.3% of all patients) were identified as having a positive GSR increase but only 4 of these patients (9% of all patients) had subjective complaints of Frey's syndrome. The symptoms of Frey's syndrome may occur several months or years after surgery [27, 49], and patients with superficial parotidectomy who have been free of these symptoms for a long period of time may develop Frey's syndrome. Thus, we anticipate that the remaining 3 asymptomatic patients may experience Frey's syndrome in the long-term. Since this method enabled us to obtain quantitative data, we also identified patients whose GSR increase was close to being accepted as positive. We contend that these patients are also under risk of Frey's syndrome over the long term and hence should be clinically monitored periodically.

Notably, we argue that GSR measurements can be successfully used to objectively compare the effectiveness of different preventive methods for Frey's syndrome, and to evaluate the efficacy of treatment modalities of this syndrome. Unfortunately, GSR measurement has some drawbacks. For example, surface skin electrodes of GSR device have the disadvantage of being small, and thus cannot cover the whole surgical field. We believe that this problem can be solved by producing large electrodes. In addition, GSR measurements should be carefully conducted in a noise-free isolated environment since physical stress and emotional factors were shown to have an impact on changes in GSR [19]. Moreover, the localization of sweating region is not practical with this method, thus topographic information can not be provided.

The most preferred management modality for Frey's syndrome is botulinum toxin administration [12, 37, 50]. Since none of our 4 patients with Frey's syndrome suffered any discomfort, we did not apply botulinum toxin to these patients.

Conclusion

In our study, we observed a significant similarity between GSR measurements collected for the operated and control

sides of patients from the GWF group. Contrarily, increases observed in GSR values of the operated sides were higher than those observed on the control sides for the patients from the GWoF group. These findings demonstrated the efficacy of easily applicable and reliable SCM muscle flap for the treatment of Frey's syndrome. Moreover, we also conclude that in the diagnosis of Frey's syndrome, the use of GSR testing is 100% sensitive and 92% specific, and it can provide quantitative results which can be further used for comparison purposes.

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