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Original Article

Prevention of Craniofacial Pain Secondary to Harvesting of Temporalis Fascia – A Novel Technique

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OBJECTIVES: A lesser known after effect of harvesting temporalis fascia is the post-surgical craniofacial pain. The aim of the study was to evaluate this pain after tympanomastoid surgeries and the effectiveness of silastic sheet interpositioning to prevent this pain.

MATERIALS and METHODS: This pilot study that spanned one year, included patients who underwent tympanoplasty with or without mastoidectomy involving the harvesting of temporalis fascia. At the end of surgery, the wound was closed after silastic sheet was secured over the donor site in cases and without silastic sheet in controls. In the post-operative period, patients scored their temporal pain, tenderness and pain during opening of mouth and mastication on a visual analogue scale (VAS) on day 7, 15, 30 and 90.

RESULTS: Visual analogue scale (VAS) scores of the silastic group were lower than the control group on day 7 and 15 after surgery and the difference was statistically significant. In the control group, temporal pain and tenderness were 74% and 81% respectively on day 7. VAS scores of both groups decreased over time and were negligible after 3 months. There were no significant postoperative complications in either group and no reaction or rejection of silastic sheet in the cases.

CONCLUSION: Post-surgical craniofacial pain secondary to the harvesting of temporalis fascia is observed in a majority of the patients. This novel technique involving silastic sheet interposition can decimate early post-operative temporal pain, tenderness and masticatory pain.

KEYWORDS: Otitis media, fascia, craniofacial pain, tympanoplasty, silastic

INTRODUCTION

Temporalis fascia is currently the most popular graft material for middle ear surgeries in chronic otitis media. The graft has been consistently robust and very convenient for harvesting compared to other materials [1-3]. However, several patients complain of post-operative craniofacial pain following the harvesting of temporalis fascia [4], which is a lesser-known complication of tympanoplasty and mastoidotympanoplasty and often ignored by physicians. The post-surgical pain appears more predominant and distressing than the pain of surgical incision in some patients. Moreover, the duration and patterns of the pain have not been studied. The precise mechanism of this pain has not yet been understood or reported. Also, it is not known how this complication can be prevented. Hence, we conducted the present study to provide additional data on the subject.

MATERIALS AND METHODS

This pilot study was a non-randomized single-blind clinical trial conducted during 1 year in a tertiary referral, public hospital in a developing country. An ethical approval was obtained from the institutional review board. In total, 82 adult patients requiring temporalis fascia harvesting through postauricular incision were recruited. The patients were divided into two groups: 40 who underwent silastic sheet interposition and 42 controls who did not. The possibility of silastic sheet (silastic sheet; Decibell's ™, New Delhi, India) interposition was explained, and all patients provided written informed consent. The exclusion criteria were squamosal otitis media with or without complications, revision ear surgeries, canal wall down mastoidectomies, compromised immunity, and

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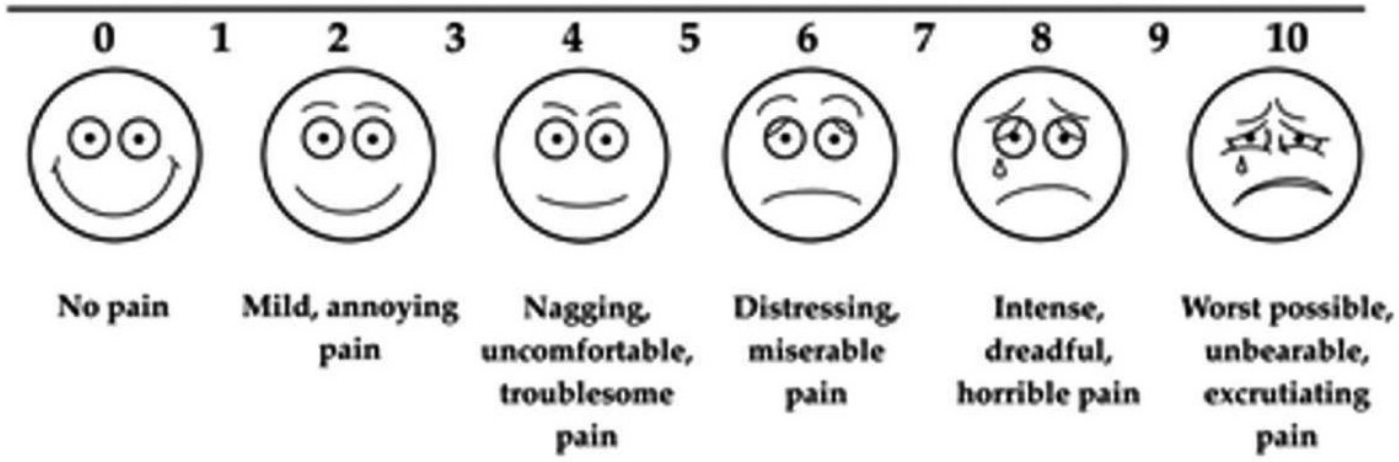

Figure 1. Visual analogue scale (VAS) chart used to assess symptoms and signs.

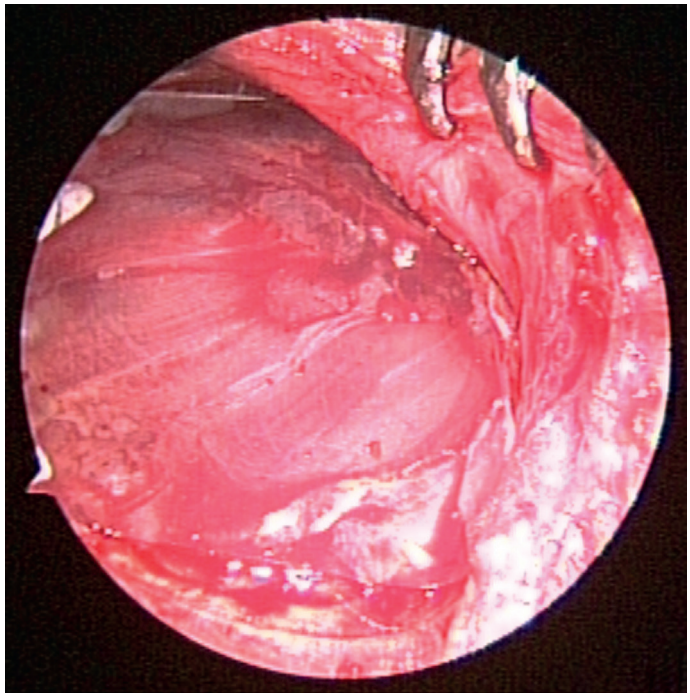

Figure 2. Silastic sheet secured over the temporalis muscle after the harvesting of temporalis fascia.

diabetes. Also, patients with preoperative craniofacial pain, particularly in the temporal region, were excluded. The same procedure and similar-sized materials were used for all patients. A standard size of 3×4 cm was used for temporalis fascia with both layers and harvested under general anesthesia. Further, a silastic sheet of thickness 0.012 cm was secured to the remnants of fascia and the muscle using a 3-0 Vicryl suture for preventing migration and extrusion (Figure 1). Wound closure was performed. Thermal cautery for hemostasis over the muscle was not permitted in both the groups. As the patients belonged to a low socioeconomic group with poor compliance, the hospital stay lasted for 1 week, and intravenous antibiotics and rescue analgesics were given. Patients were discharged with a week's course of oral antibiotics and standard rescue analgesics (a combination of aceclofenac 100 mg and paracetamol 325 mg) following suture removal. The assessment of outcomes was started on the seventh postoperative day in both groups. Follow up was performed on days 15, 30, and 90. The craniofacial pain and tenderness were assessed using the visual analog scale (VAS; Figure 2).

Ipsilateral pain and tenderness (palpated 1 inch above surgical incision) and pain during lower jaw movement and mastication were the primary outcomes. Infection/abscess of the surgical incision, gaping of the incision, and postoperative otitis externa were the secondary outcomes.

Statistical Analysis

All data were analyzed using in the Statistical Package for Social Sciences (SPSS™) software, version 17.0 (SPSS Inc.; Chicago, IL, USA). The level of significance was set at 95% confidence interval.

RESULTS

In this study, 19 patients were aged ≤19 years, 30 were aged 20-29 years, 17 were aged 30-39 years, and 16 were aged ≥40 years. The mean (standard deviation [SD]) age for the silastic sheet interposition group was 26.7 (12) years and for the control group was 31.3 (14) years. Among the 82 patients who underwent surgery, 46 were females (silastic sheet interposition: 18 and controls: 28). Out of 36 males, 22 underwent silastic sheet interposition and 14 were controls. There was no statistically significant (p value 0.05) difference in the gender distribution between the two groups.

The various manifestations of the craniofacial pain were compared between the cases and controls and are presented in Table 1. The outcomes were analyzed on the postoperative days 7, 15, 30, and 90 using the Mann-Whitney U test (Table 2-5). Although the VAS scores did not exceed 4, the number of patients with temporal pain and tenderness among the controls far exceeded compared to the cases. All the individual outcomes measured were found to be statistically significant on the seventh and fifteenth postoperative day. Temporal pain and tenderness were significant on day 30 and insignificant on day 90. Four among the controls had pain and tenderness lasting 4 months.

No major complications were noted among the cases and controls in the 3-month postoperative period, except for minor gaping of incision in one patient and seroma in the temporal region in another, which resolved by day 15.

Table 1. Comparison of the craniofacial pain in cases and controls postoperatively

	7		15		30		90	
Postoperative day	**Cases**	**Controls**	**Cases**	**Controls**	**Cases**	**Controls**	**Cases**	**Controls**
Temporal pain (%)	32.5	73.8	20	62	10	32	5	5
Temporal tenderness (%)	35	81	20	69	10	38	5	12
Pain during mastication (%)	17.5	50	12.5	31	2.5	7.1	2.5	2.4
Pain during lower jaw movement (%)	20	61.9	15	43	5	11.9	5	4.8

Table 2. Evaluation of craniofacial pain (VAS scores) in cases and controls on postoperative day 7

	Median (min-max)		
Parameter	**cases**	**controls**	**p**
Temporal pain	0 (0-3)	1 (0-3)	<0.001
Temporal tenderness	0 (0-4)	1 (0-3)	<0.001
Pain during mastication	0 (0-3)	0.5 (0-2)	0.003
Pain during lower jaw movement	0 (0-3)	1 (0-2)	<0.001

Table 3. Analysis of craniofacial pain (VAS scores) in cases and controls on postoperative day 15

	Median (min-max)		
Parameter	**cases**	**controls**	**p**
Temporal pain	0 (0-3)	1 (0-3)	<0.001
Temporal tenderness	0 (0-3)	1 (0-3)	<0.001
Pain during mastication	0 (0-3)	0 (0-2)	0.052
Pain during lower jaw movement	0 (0-1)	0 (0-2)	0.005

Table 4. Analysis of craniofacial pain (VAS scores) in cases and controls on postoperative day 30

	Median (min-max)		
Parameter	**cases**	**controls**	**p**
Temporal pain	0 (0-2)	0 (0-2)	0.02
Temporal tenderness	0 (0-2)	0 (0-3)	0.004
Pain during mastication	0 (0-1)	0 (0-1)	0.33
Pain during lower jaw movement	0 (0-1)	0 (0-1)	0.27

Table 5. Analysis of craniofacial pain (VAS scores) in cases and controls on postoperative day 90

	Median (min-max)		
Parameter	**cases**	**controls**	**p**
Temporal pain	0 (0-1)	0 (0-1)	0.96
Temporal tenderness	0 (0-1)	0 (0-1)	0.78
Pain during mastication	0 (0-1)	0 (0-1)	0.97
Pain during lower jaw movement	0 (0-1)	0 (0-1)	0.96

DISCUSSION

The occurrence of chronic pain after elective surgeries, such as inguinal herniorrhaphy, breast surgery, orthopedic, and cardiothoracic surgery, is well known [5]. However, chronic post-surgical pain after ear surgery is less explored and is the primary reason for conducting the present study. Temporalis fascia is currently the mainstay in most myringoplasties performed globally and is also popular among most otologists [6]. Techniques for its proper harvesting have been described since 1967 [7]. However, it is associated with after effects. One of these after effects is the pain and tenderness at the harvest site immediately following surgery, which occasionally lasts for 3 months or more. This pain that manifests during mastication, restricts postoperative feeds. In the present study, we observed that the pain did not respond sufficiently to the rescue analgesics in the control group. As seen in this study, it is interesting to note that 74% and 81% of the patients in the controls had pain and tenderness, respectively, in the immediate postoperative period.

To the best of our knowledge, no studies have been conducted to date that address the pain as an effect and describe silastic sheet interposition as the remedy. However, one study by Ahn JH et al. recommends the use of sodium hyaluronate carboxymethylcellulose to prevent this after effect [4]. The study was conducted on patients who underwent canal wall down mastoidectomy, and the follow up was for 2 months.

In a study by Prasad S et al., the occurrence of this postoperative pain was reported in 12 patients (N=60) who underwent temporalis fascia harvesting [8]. Most of the patients had pain for 3 weeks, while one had pain for 8 weeks.

Majeed J et al. also mentioned about the occurrence of this lesser-known after effect, but has suggested no specific remedy for its prevention [9].

There are various incision techniques, such as endaural, postauricular, and supra-auricular, for harvesting temporalis fascia. However, this study was designed to assess pain and tenderness in the region of harvesting temporalis fascia. The postauricular approach provides the best access to the perforation of any size and in any quadrant of pars tensa. Hence, this approach was chosen for in all the patients of both groups to ensure comparability.

Silastic is a known bio-inert and biofriendly material that has been extensively used as a barrier to prevent adhesion, particularly in the treatment of atelectatic tympanic membrane [10, 11]. This cost-effective material can be conveniently cut and sized as per requirement. Matthew Ng BS et al. studied the long-term effects of silastic sheets in the middle ear and found no adhesion or reaction with the tissue [12]. Hence, we chose this material to prevent a secondary effect. There were no cases of complication directly related to the use of silastic in this study. After surgery, less than 20% of the patients in the silas-

tic group had pain and tenderness compared to 80% in the control group. Also, pain in the silastic group lasted for a shorter duration compared to the controls.

In most cases, a deep layer of temporalis fascia is preferred over superficial fascia as the graft. The superficial layer of fascia is found to be thin, incomplete, and delicate and hence often difficult to separate completely from the deep layer, with a risk of tear in this process. Hence, the technique of preserving one layer against another becomes impractical. For repeat harvesting of the fascia in revision cases and in canal wall down mastoidectomies where large grafts are required, craniofacial pain is likely to be more severe than the primary cases. Therefore, the use of silastic as a mechanical barrier for preventing adhesion is justified.

Various surgical factors, such as trauma and inflammation of the tissues, stretching and crushing of the nerves, and prolonged surgery duration, have been implicated in the persistence of pain following surgery [13]. The probable mechanism of pain and tenderness induced due to the harvesting of fascia is the myositis caused by the initial handling of the muscle. Adhesion could be due to mechanical tissue damage and tissue ischemia. Both fibrinogenesis and fibrinolysis could be activated [14], with a distortion of the dynamic balance between these two processes leading to adhesion. The pain would probably not be present after the completion of adhesion formation. As silastic sheet mechanically prevents this adhesion and fibrosis, the postoperative pain is decimated.

The additional local application of a corticosteroid solution or hydrocortisone succinate gel along with silastic sheet might further reduce the percentage of cases with pain. Further studies could be performed to explain the phenomenon.

CONCLUSION

Post-surgical pain and tenderness in the temporalis region commonly occurs in a majority (80%) of the patients after harvesting of temporalis fascia. The pain is quite significant in most of them and requires a special procedure for its prevention. Silastic sheet interposition between the temporalis muscle and subcutaneous soft tissue decimates the pain, and it is a safe, simple, and economical solution. Since this craniofacial pain is observed in a majority of the patients and is unpredictable, we recommend silastic sheet interposition during surgery. Further, repeat harvesting of temporalis fascia in revision surgeries would be convenient.

Ethics Committee Approval: Ethics committee approval was received for this study from Ethics Committee of KIMS, Karnataka (No: PGS/452/2016-17).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

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