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Our Experience at Tertiary Care Center: Intraoperative Use of Sterile Medical Grade Honey (MGH) Versus Sodium Hyaluronate Carboxymethylcellulose (Seprafilm TM) in Preventing Postoperative Craniofacial Pain Following Temporalis Fascia Harvesting

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Abstract

Aim: The study's objective was to assess, evaluate and compare the efficacy of Intraoperative use of sterile Medical Grade Honey (MGH) and sodium hyaluronate carboxymethylcellulose (Seprafilm TM) in preventing postoperative craniofacial pain after temporalis fascia harvesting. ***Method:*** The study involved 120 adult patients aged 20-70 who underwent a postauricular incision to harvest temporalis fascia. Sixty patients received a seprafilm TM sheet (Group A) and the other sixty were given sterile Medical Grade honey (Group B). Quantitative data was recorded, and qualitative data was represented as percentages and frequencies. A p-value below 0.05 was considered statistically significant. ***Results:*** The study found no significant differences in temporal pain, tenderness, pain during mastication, and pain during lower jaw movement between groups A and B postoperatively across all follow-up visits at seventh and fifteenth postoperative days with the exception of thirtieth day and no significant issues were observed in either group three months after surgery, despite both groups' VAS scores remaining below 4. ***Conclusion:*** There was no statistically significant difference between the two groups suggests that the success rates of the Group A (Seprafilm TM) and Group B (Sterile Medical Grade Honey) were about equal. Nonetheless, both groups' success rates were marginally greater when our findings were contrasted with those of past studies.

Keywords: ***Seprafilm; Honey; Tympanoplasty; craniofacial; Temporal; pain.***

Introduction

The most popular graft material for middle ear surgeries in patients with chronic otitis media is now temporalis fascia. When compared to other materials, the graft has continuously proven to be robust and very easy to harvest [1-3]. Nevertheless, several patients suffer from post-operative craniofacial pain following the harvesting of the temporalis fascia. Postoperative craniofacial pain can manifest as temporal pain, tenderness, masticatory pain, and lower jaw movement pain. This pain can sometimes persist for three months or longer Unlike typical postoperative pain that goes away in five to seven days with analgesics, this pain can occasionally last for three months or more [4]. Medical personnel often ignore this less common side effect after Tympanomastoid exploration and tympanoplasty. For some individuals, the post-operative pain appears to be more severe and distressing than the incisional pain. The most likely mechanism causing the discomfort and tenderness brought on by the fascia harvesting is the myositis brought on by the initial handling of the muscle. Another important factor responsible is adhesion resulting from a disruption of the dynamic equilibrium between fibrinogenesis and fibrinolysis [5]. Several animal models and human investigations have shown that the bioresorbable membrane Seprafilm TM, which is composed of sodium hyaluronate and carboxymethylcellulose, reduces postoperative adhesions [6-8].

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Honey, a natural product from bees, contains flavonoids like luteolin and quercetin along with antioxidants. It has antibacterial, anti-inflammatory, and wound-healing properties due to its unique physical traits responsible for reducing postoperative adhesions [9].

This study aimed to assess, evaluate and compare the efficacy of intraoperative use of sterile medical grade honey (MGH) and sodium hyaluronate carboxymethylcellulose (SEPRAFILMTM) in preventing postoperative craniofacial pain following temporalis fascia harvesting.

Material & Methods

Study Design

This study was a prospective observational study conducted over one year from September 2023 to September 2024.

Participants

The study included 120 male and female patients, aged 20 to 70, who were being treated at the ENT department of our tertiary care center. A total of 120 adult patients who needed temporalis fascia harvesting via postauricular incision were included in our study. Patients receiving revision ear surgery, those undergoing canal wall down mastoidectomy, those with compromised immune systems, those with known honey allergies, and those with chronic squamosal type otitis media with or without complications were all eliminated. Furthermore, those who had preoperative craniofacial pain particularly in the temporal region were excluded. Of these total 120 study participants, sixty patients were randomly assigned to receive seprafilm TM sheet interposition between the temporalis muscle and the subcutaneous soft tissue (Group A) following the harvesting of the temporalis fascia, the remaining sixty patients received sterile Medical Grade Honey application between the subcutaneous tissue and the temporalis muscle (Group B).

Study Procedure

The patient was placed under general anaesthesia. Painting and Draping was completed while taking all aseptic measures. After 2% lidocaine and adrenaline were infiltrated locally, a postauricular wildes incision was made. The uppermost part of the incision was retracted using a double hook retractor, and a self-retaining mastoid retractor was placed in the upper portion of the wound. Using a blunt method, the dissection was carried out until the Temporalis fascia was reached. A small amount of saline was injected to separate temporalis fascia from temporalis muscle. The white, glossy fascia was easily identifiable. The temporalis fascia was cut to a typical size of 3 by 4 cm, and both layers were removed with scissors before being squeezed and stretched. Group A underwent sodium hyaluronate carboxymethylcellulose (Seprafilm TM) sheet interposition between the subcutaneous soft tissue and the temporalis muscle. To stop migration and extrusion, a 3-0 Vicryl suture was used to attach a seprafilm TM sheet to the remaining fascia and muscle (**Figure I**). For every patient, the identical process and materials of comparable sizes were employed. Sterile Medical Grade Honey (MGH) was placed between the subcutaneous soft tissue and the temporalis muscle in Group B (**Figure II**). Closure of the wound was done. In both groups, thermal cautery for muscle haemostasis was not allowed. All of the patients had day care surgery and were released the same day with a standard prescription for rescue analgesics for 1 week, which included 100 mg of aceclofenac and 325 mg of paracetamol, as well as a week's supply of oral antibiotics. The sutures were removed on the seventh postoperative day.

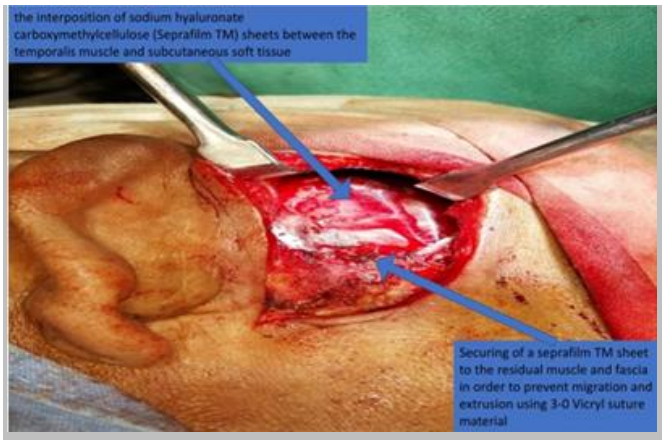

Fig. I: Photograph showing the interposition of sodium hyaluronate carboxymethylcellulose (Seprafilm TM) sheets between the temporalis muscle and subcutaneous soft tissue

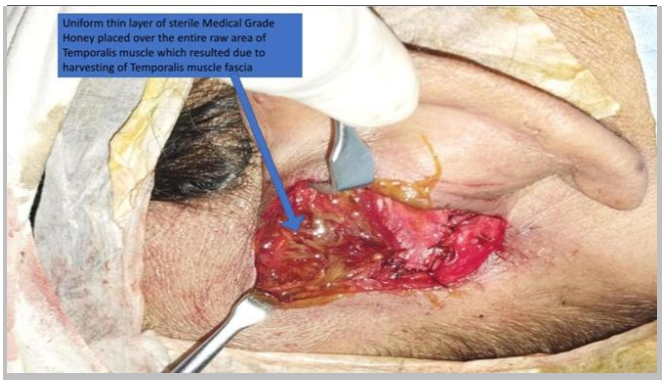

Fig. II: Photograph showing placement of Sterile Medical Grade Honey (MGH) between the subcutaneous soft tissue and the temporalis muscle.

Study outcomes

The primary outcomes were ipsilateral temporal pain and tenderness (palpated 1 inch above surgical incision), as well as pain during mastication and movement of the lower jaw. The secondary outcomes were postoperative otitis externa, gaping in the incision, and infection/abscess of the surgical incision.

Study Assessment included four visits

The outcome assessment procedure was started on the seventh postoperative day for both groups. There were follow-ups on postoperative days 7, 15, 30, and 90. The visual analog scale was used to measure the pain and tenderness in the craniofacial region.

Statistical Analysis

The Statistical Package for Social Sciences (SPSSTM) software, version 22 (SPSS Inc.; Chicago, IL, USA), was used to analyze all of the data. The 95% confidence interval was used to determine the level of significance. While mean and standard deviation were used to communicate quantitative data, percentages and frequencies were used to represent qualitative data. The Mann-Whitney U test was used to assess results on the seventh, fifteenth, thirtieth, and ninetieth postoperative days. A statistically significant result was defined as a p-value of less than 0.05.

Results

There was no statistically significant difference seen (p value = 0.9083) between the mean age (± standard error of the mean) for Group A and Group B, which were 45.623 ± 1.4 and 47.162 ± 1.6 years, respectively. For Group A it was 45.6 (12.33) years, while for Group B it was 47.166 (12.1039) years (mean age, standard

deviation [SD]). Regarding gender distribution, patients in Group A were 26.66% male and 73.33% female, whereas patients in Group B were 28.33% male and 71.66% female. This difference in gender distribution was not statistically significant (p value = 0.6853). The demographic information for the research population is shown in Table I. Table II provides a detailed comparison of the various craniofacial pain manifestations between Groups A and B. Results were assessed with the Mann-Whitney U test on days seven, fifteen, thirty, and ninetieth following surgery (refer to Table III). For both groups, the prevalence of temporal discomfort and tenderness was rather similar, even though the Visual Analog Scale (VAS) values stayed below 4. Between Groups A and B, on the seventh and fifteenth postoperative days, there were no statistically significant variations in individual outcomes. Across all follow-up visits in both group A and B, there was no statistically significant difference in the trends for temporal pain, tenderness, pain during mastication, and pain during lower jaw movement. These trends declined from significant levels at postoperative day 30 to insignificant levels by postoperative day 90. In Group A and Group B, there were no notable problems noted in the three months following surgery. There were, however, a few small problems, such as a seroma in the temporal region of one patient from Group A and a slight gaping of the incision in two patients from Group B. By the fifteenth day, all of these issues had been resolved in both groups.

Table I: Characteristics of the research population's demographics

	Sodium hyaluronate carboxymethylcellulose/ Seprafilm TM (Group A)		**5% Menuka Honey (Group B)**		**Total**		
Age in years	Number	Percentage	Number	Percentage	Number	Percentage	
20 -39 years	19	31.66	17	28.33	36	30	X^2=0.1923 P=0.9083
40 -59 years	34	56.66	35	58.33	69	57.5	
60-70 years	07	11.66	08	13.33	15	12.5	
Total	60	100	60	100	120	100	
Mean age ± SEM	45.623 ± 1.4		47.162 ± 1.6				
Minimum age	24		22		22		
Maximum age	68		70		70		
Sex							
Males	16	26.66	18	30	34	28.33	
Females	44	73.33	42	70	86	71.66	X^2=0.1642 P =0.6853
Total	60	100	60	100	120	100	

Table II: Comparing the postoperative craniofacial pain in Groups A and B

Parameters	**POD 7**		**POD15**		**POD30**		**POD90**	
	Group A	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**
Temporal Pain (%)	34.5	33.8	24.2	22.2	12.4	10.3	4	4
Temporal Tenderness (%)	36	34	23	24	14.2	10	5	4.3
Pain during mastication (%)	19.2	18	12.5	14	8.3	7.2	2	2.5
Pain during lower jaw movement (%)	22	21	16	14	11.6	6	6	4.6

Table III: A comparative analysis of postoperative days 7, 15, 30, and 90 for craniofacial pain (VAS score).

Postoperative Day	Temporal Pain Median (min - maximum)			Temporal Tenderness Median (min - maximum)			Pain during mastication Median (min - maximum)			Pain during lower jaw movement Median (min - maximum)		
	Group A	Group B	P value	Group A	Group B	P value	Group A	Group B	P value	Group A	Group B	P value
POD 7	1 (0-3)	0.5 (0-3)	0.00831	1.5 (0-4)	1 (0-3)	0.0076	0.5 (0-3)	0.4 (0-2)	0.003	0.5 (0-3)	0.6 (0-2)	0.002
POD15	1 (0-3)	0.5 (0-3)	0.00831	1 (0-3)	1 (0-3)	0.001	0 (0-3)	0 (0-2)	0.001	0 (0-1)	0 (0-2)	0.001
POD 30	0 (0-2)	0 (0-2)	0.001	0 (0-2)	0 (0-3)	0.001	0 (0-1)	0 (0-1)	0.001	0 (0-1)	0 (0-1)	0.001
POD 90	0 (0-1)	0 (0-1)	0.001	0 (0-1)	0 (0-1)	0.001	0 (0-1)	0 (0-1)	0.001	0 (0-1)	0 (0-1)	0.001

Discussion

The main driving force for this study is the comparatively understudied topic of chronic post-surgical pain after ear surgery [10]. Many otologists prefer to use temporalis fascia in myringoplasties, which is why it is extensively used worldwide [11]. Temporalis fascia can be obtained by several incision procedures, such as endaural, postauricular, and supra-auricular approaches. It was shown that the postauricular approach provided the best access to perforations of different sizes in any pars tensa quadrant. Therefore, in order to ensure uniformity throughout the study, this strategy was chosen for each patient in both groups. The objective of this investigation was

to evaluate and compare the effectiveness of sodium hyaluronate Carboxymethylcellulose (SEPRAFILM TM) and Sterile Medical Grade Honey (MGH) in Prevention of Postoperative Craniofacial Pain after Temporalis Fascia Harvesting. Numerous successful harvesting techniques of Temporalis fascia have been described since 1967. But there are various negative effects associated with this surgery. The pain and tenderness at the harvesting site, which can start immediately after surgery and last for three months or more, is one of the serious adverse effects. After surgery, this pain, especially when chewing, may make it difficult to eat [12]. In research by Prasad S and colleagues, 12 out of 60 patients who had temporalis fascia harvesting reported experience of postoperative pain [13]. Most of these patients were in pain for three weeks or longer; one patient was in pain for eight weeks. While acknowledging this less well-known adverse effect, Majeed J and colleagues did not suggest any particular prevention measures [14]. In our study, we found that during the early postoperative period, 34.5% of patients in Group A and 33.8% of patients in Group B reported experiencing Temporal pain, and 36% of Group A patients and 34% of Group B patients reported having Temporal Tenderness.

For grafting, it is generally recommended to use a deep layer of temporalis fascia as opposed to the superficial fascia. Because the superficial fascia is frequently weak, thin, and partial, it might be difficult to separate it entirely from the deeper layer without running the danger of ripping. Because of this, it is impractical to preserve one layer over another. Patients may feel more severe craniofacial discomfort during revision surgeries if they require recurrent fascia harvests or if larger grafts are required during canal wall down mastoidectomies. Ongoing pain following surgery has been related to a number of surgical parameters, including tissue trauma and inflammation, nerve stretching and compression, and longer operative timeframes [15].

Myositis from the initial muscle manipulation may be the cause of the discomfort and tenderness that follow fascia harvesting. Decreased blood flow and mechanical injury to the tissue can both trigger fibrinogenesis and fibrinolysis, upsetting the delicate balance between the two processes and resulting in adhesions. Once adhesion development is finished, pain will probably go down. Placing a silastic sheet between the temporalis muscle and the subcutaneous soft tissue significantly reduces craniofacial pain and provides a safe, simple, and economical solution. Postoperative pain can be considerably decreased by using a seprafilm sheet to mechanically inhibit adhesions and fibrosis [16]. The sterile, bioresorbable Seprafilm Adhesion Barrier is made to stop adhesions. It is made up of carboxymethylcellulose (CMC) and sodium hyaluronate (HA), two anionic polysaccharides. By momentarily dividing adjacent tissue surfaces, this barrier aids in preventing the formation of adhesions while the body heals naturally. After application, the membrane turns into a hydrated gel that progressively disintegrates over the course of a week in 24 to 48 hours. The components leave the body in less than 28 days [6-8]. Sodium hyaluronate carboxymethylcellulose is suggested by Ahn JH and colleagues' study as a means of reducing the temporal pain. Patients who had undergone canal wall down mastoidectomy with a two-month follow-up period were included in the study [4].

Honey has been used to cure burns and other wounds for more than two millennia. The production of it occurs when honeybees gather nectar from flowers and other plant exudates. The flavonoids that give honey its antioxidant properties include luteolin, quercetin, apigenin, fisetin, kaempferol, isorhamnetin, acacetin, tamarixetin, chrysin, and galangin. It has proven to be effective in preventing the growth of both gram-positive and gram-negative bacteria, which gives it antibacterial, immunostimulatory, anti-ulcer, and the ability to heal burns and wounds. Honey's unique physical characteristics such as its low pH, hypertonic capabilities, and hygroscopic nature are assumed to play a major role in enhancing its therapeutic benefits [9,17]. In order to determine how honey affects the healing of tympanic membrane perforations, Calli et al. conducted study on guinea pigs. According to their research, the guinea pigs in the honey treatment group had a greater rate of perforation closure than the saline solution group, which was given drops as a control. Furthermore, a histological examination showed that the group that had honey treatment had connective tissue that was both thicker and showed a better structure [18]. A number of honey kinds, including Medical Grade Honey (MGH), have been reintroduced into modern medicine recently. The requirements for MGH, according to Hermann et al. (2020) [19], are as follows: it must adhere to all safety and legal requirements, as well as standardized production and storage procedures; it must be pure and organic; it must be free of pollutants and harmful materials; it must also be free of harmful microbes and sterilized by gamma radiation using established protocols; and it must meet the physicochemical requirements needed to be used in the treatment of wounds. MGH reduces inflammation, encourages regeneration, and expedites the healing process of the injured area in addition to encouraging collagen deposition and fibroblast migration [20].

For all follow-up visits, the trends for temporal pain, tenderness, pain during mastication, and pain during lower jaw movement decreased from significant levels at postoperative day 30 to insignificant levels by postoperative day 90 in both groups: sterile Medical Grade Honey (group B), sodium hyaluronate carboxymethylcellulose, and Seprafilm TM (group A). Since there was no statistically significant difference between the two groups, the success rates of the two groups were probably comparable. Both groups did, however, have marginally higher success rates when our findings were contrasted with those of past studies.

Conclusion

Following the harvesting of Temporalis fascia, pain and tenderness in the temporalis region were more common than discomfort during mastication and jaw movement features of craniofacial pain. Both group A and group B received sodium hyaluronate carboxymethylcellulose, Seprafilm TM, and sterile Medical Grade Honey. The trends for temporal pain, tenderness, pain during mastication, and pain during lower jaw movement decreased from significant levels at postoperative day 30 to insignificant levels by postoperative day 90 across all follow-up visits in both sodium hyaluronate carboxymethylcellulose, Seprafilm TM (group A) and sterile Medical Grade Honey (group B). There was no significant statistical difference between the two groups, indicating that both groups' success rates were roughly similar. However, when our results were compared to earlier research, both groups had slightly higher success rates.

Relevance to clinical Practice

1) Study the relatively unexplored subject of persistent post-operative pain following ear surgery
2) Intraoperative use of both Seprafilm Tm (sodium hyaluronate carboxymethylcellulose) and Sterile Medical Grade Honey shown roughly similar success rates in preventing post-operative craniofacial pain following temporalis fascia harvesting with postauricular approach

Limitations of the study

The limitation of our study was the small sample size and non randomization. In future a more elaborative and larger studies with randomisation are needed to confirm the same.

List of Abbreviations

VAS: Visual Analogue Scale
MGH: Medical Grade Honey
Seprafilm: Sodium hyaluronate carboxymethylcellulose
SD: Standard Deviation

Declarations

Funding

Not relevant

Conflict of interest

Every author affirms that they have no competing interests.

Ethical Approval

All procedures performed in study involving human Participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration. Ethical approval taken from institutional ethical committee of our Institution as per ICMR guidelines.

Informed Consent

For every individual participant in the study, informed consent was obtained.

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