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RESEARCH ARTICLE
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"TO EVALUATE THE IMPACT OF PLATELET-RICH FIBRIN WITH CONCHAL CARTILAGE GRAFT AND PLATELET-RICH FIBRIN WITH TEMPORALIS FASCIA GRAFT ON ENHANCING AUDITORY FUNCTION FOLLOWING TYMPANOPLASTY: A RANDOMIZED CONTROLLED TRIAL."

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Abstract:
Background: Tympanic membrane perforations can lead to significant hearing loss and often necessitate surgical intervention. Conchal cartilage grafts and temporalis fascia grafts are commonly employed in tympanoplasty procedures. Recent advancements suggest that the incorporation of platelet-rich fibrin (PRF) may enhance the healing process [Saluja et al.,2011][1].
Objective: This study aims to evaluate and compare the effectiveness of PRF combined with conchal cartilage graft versus PRF combined with temporalis fascia graft in the repair of tympanic membrane perforations, with a focus on auditory function improvement [**Taneja et al.**, 2020][2].
Methods: This randomized controlled trial involved 100 patients with tympanic membrane perforations. The patients were randomly assigned into two groups, each consisting of 50 patients: Group A received PRF with conchal cartilage graft, and Group B received PRF with temporalis fascia graft. The primary outcome measure was the improvement in hearing function, assessed through audiometric tests pre- and post-operatively [Erkilet et al., 2009][3].
Results: Both groups exhibited comparable demographic characteristics (p-values: age 0.286; gender 0.423). The mean hearing gain was greater in Group 1 (14.63 dB) compared to Group 2 (13.47 dB), although not statistically significant (p=0.32). At three months post-operatively, complete tympanic membrane healing rates were 98% in Group 1 versus 94% in Group 2 (p=0.371) [Nair et al.,2019][4].
Conclusion: The study suggests that PRF combined with conchal cartilage grafts may provide better auditory function restoration and similar healing outcomes compared to temporalis fascia grafts in tympanoplasty. Further research is warranted to explore the clinical implications of these findings in larger populations [Sharma et al., 2018][5].

Introduction

Tympanic membrane perforations are a common otological condition, often resulting from chronic otitis media, trauma, or infections [Wahid & Nagar, 2018][6]. Such perforations can lead to varying degrees of conductive hearing loss and, if untreated, can result in chronic ear infections and further complications [Ahmed & Raza, 2015][7]. Tympanoplasty, the surgical repair of the tympanic

membrane, is the standard treatment to restore the integrity of the membrane and improve hearing [Dhingra & Dhingra, 2017][8].

Traditionally, graft materials like temporalis fascia and conchal cartilage have been used in tympanoplasty [Snow & Wackym, 2009][9]. Temporalis fascia is favored for its thinness and pliability, which mimics the natural tympanic membrane, while conchal cartilage offers greater structural support, particularly in cases of larger perforations or when the middle ear is at risk of retraction [Choukroun et al., 2007][10].

In recent years, the use of biologically active materials, such as platelet-rich fibrin (PRF), has gained interest due to its potential to enhance tissue healing and regeneration [Dohan Ehrenfest et al., 2009][11]. PRF is an autologous preparation that concentrates platelets and growth factors, which are believed to accelerate wound healing and improve surgical outcomes [Prakash & Thakur, 2011][12].

This study investigates the effectiveness of PRF when combined with conchal cartilage graft versus temporalis fascia graft in tympanoplasty, specifically in terms of tympanic membrane healing and auditory function improvement [Sankarnarayan et al., 2013][13].

Method

Eligible patients received detailed information in their native language about the study, including the procedure, associated risks, benefits, and compliance expectations [Taneja et al., 2020][2]. After verbal agreement, patients or their legal representatives provided written informed consent voluntarily [Taneja et al., 2020][2].

The study protocol included taking patient history, conducting a thorough general and ENT examination, necessary investigations, surgical interventions when indicated, and post-operative follow-up [Anwar et al., 2020][14]. Data collected from questionnaires included sociodemographic information, symptoms, duration, and any recurrent sinonasal issues, which were documented on a master chart.

All participants underwent comprehensive ENT evaluations, including otoscopic exams and tuning fork tests, and were instructed to have further investigations such as otoscopy profiles, mastoid X-rays, and pure tone audiometry (PTA) [Hosam et al., 2017][15]. PTA was performed in a soundproof booth using a MAICO MA 42 audiometer. Patient details, including names, ages, genders, registration numbers, contact numbers, and addresses, were recorded for identification and follow-up.

Study Design

A prospective, randomized controlled trial was conducted at IMCHRC Indore.

Patients with tubotympanic disease attending the department during the study period.

Participants

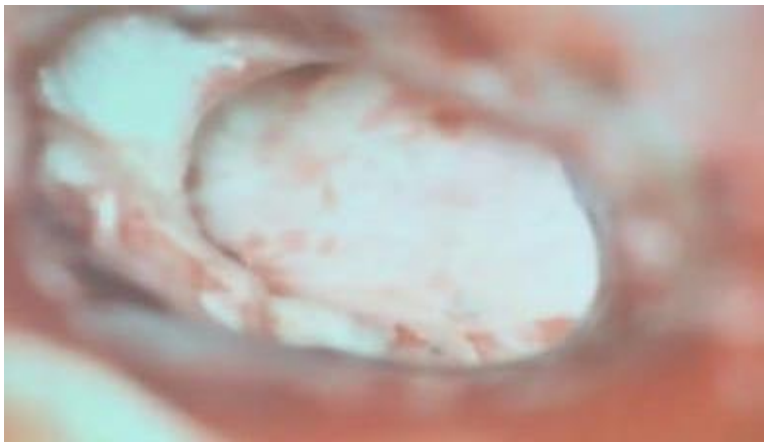
A total of 100 patients aged above 12 years with tympanic membrane perforation, inactive chronic otitis media, unsafe CSOM and patients who underwent revision surgery were enrolled. Patients below 12 years and active CSOM were excluded [Carlson, 2000][16].

Randomization and Groups

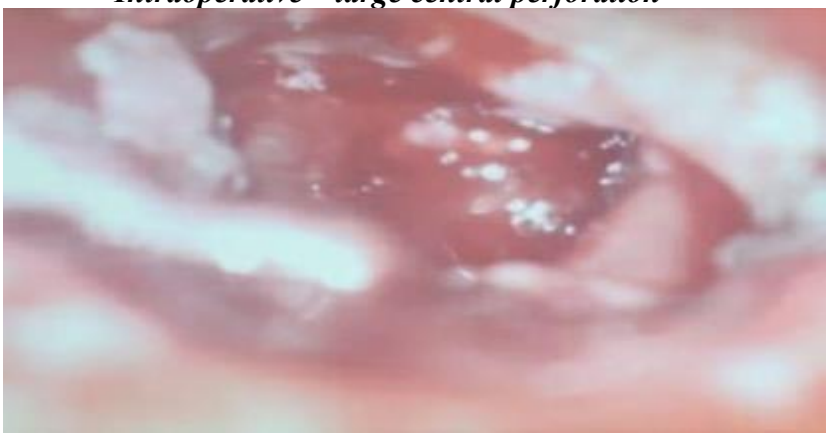
Participants were randomly assigned into two groups using computer-generated numbers:

- **Group 1 (n=50):** Tympanoplasty with conchal cartilage graft and platelet-rich fibrin.
- **Group 2 (n=50):** Tympanoplasty with temporalis fascia graft and platelet-rich fibrin.

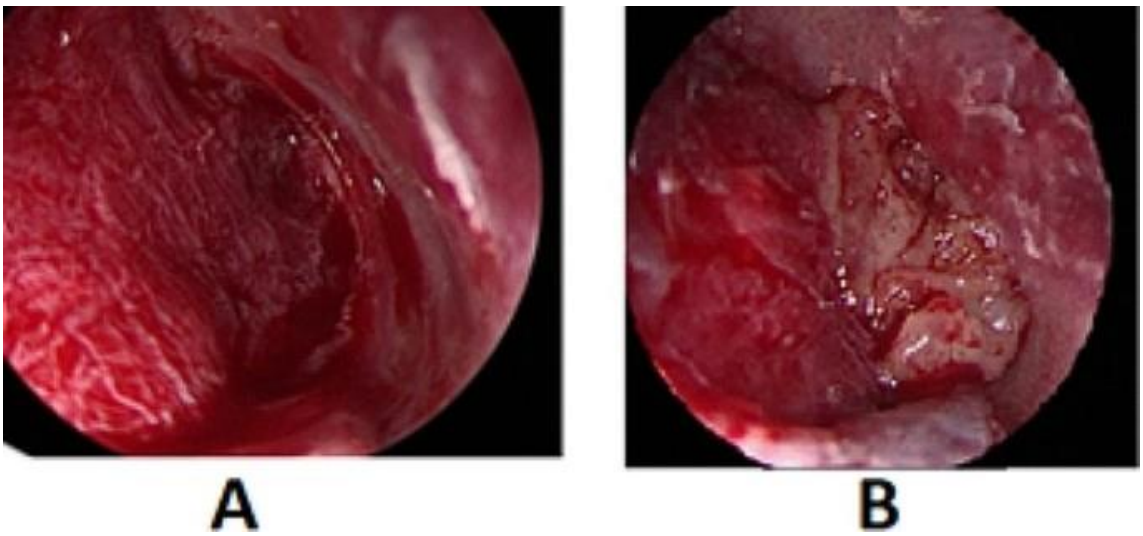
Graft materials were **Conchal Cartilage graft and Temporalis fascia graft** (***Figure 1 & 2***).



Intraoperative – large central perforation



PRF placed on lateral aspect of Conchal cartilage graft

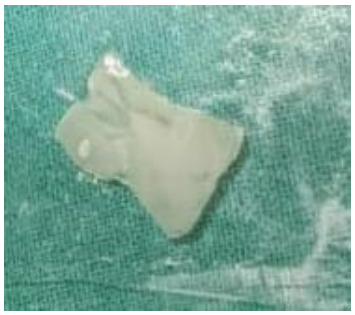


A: Placement of temporalis fascia graft. B: Application of the PRF clot

Preparation of PRF

It was prepared in the operative theater just after induction of anesthesia. Ten to twenty milliliters of blood was drawn from patient using aseptic procedures into specially designed tubes devoid of anticoagulants. The blood-filled tubes were subsequently centrifuged at a speed of 3000 rpm for approximately 25 minutes. The centrifugation process yielded three layers: layer of red blood cells at the base, PRF clot in middle, and a layer of platelet-poor plasma at top. Utilizing sterile instruments, the PRF clot was then carefully extracted from the tube.

Fig. 3. PRF Preparation.

		
10 ml of blood withdrawn	***Tube placed in centrifugation machine at 3000 rpm for 25 minutes***	***Platelet rich fibrin (PRF) formed in the middle of the tube***
		
Platelet Rich Fibrin obtained	***Blob of PRF placed on glass slide and gently pressed for three minutes***	***Thin gel like transparent PRF graft formed***

Procedure

All surgeries were performed by the same team of experienced otologic surgeons to minimize variability. PRF was prepared using a standardized protocol, which involved centrifugation of the patient's blood to obtain the fibrin clot. This clot was then applied to the graft material (either conchal cartilage or temporalis fascia) before placement at the site of the tympanic membrane perforation [Raja & Naidu, 2008][17].

Outcomes

The primary outcome measure was hearing improvement, assessed through pure-tone audiometry conducted pre-operatively and 3 months post-operatively [Garg,2000][]. Secondary outcomes included the rate of tympanic membrane healing (as observed through otoscopic examination) and patient-reported outcomes regarding ear discharge and pain [Sankarnarayan et al., 2013][13].

Result

The present study involved 100 patients with a dry large TM perforation. 50 patients underwent Conchal cartilage with PRF tympanoplasty, and 50 underwent Temporalis fascia graft with PRF tympanoplasty. Table (1) shows the demographic data of the patients. No statistically significant differences were found between groups regarding age and gender (p value – 0.286,0.423) [Erkilet et al., 2009][3].

Table 1. Demographic Data

Demographic Data	Group A (n=50)	Group B (n=50)	Test of Significance (p-value)
Age (years)	32.26 ± 10.97	29.88 ± 11.23	t = 1.072, df=98, p =0.286, NS
Gender			
Male	22, (44.0%)	26, (52.0%)	tvalue=0.641, df=1, P value=0.423
Female	28, (56.0%)	24, (48.0%)	

Table 2. Comparison of Hearing Gain in Group A and B (dB)

Variable	Groups	Mean	Standard Deviation	Standard Error	t-value	p-value
Preoperative Pure Tone Audiometry (PTA)	A	42.58	6.078	1.11	0.39	0.70
	B	41.80	9.21	1.68		
Postoperative PTA	A	27.95	4.456	0.81	-0.24	0.81
	B	28.33	7.561	1.38		
Hearing Gain	A	14.63	3.39	0.62	1.00	0.32
	B	13.47	5.352	0.98		

The present have achieved a mean hearing gain of 14.63 dB in the PRF with Conchal cartilage group compared to 13.47 dB in the PRF with Temporalis fascia group. The p-value was 0.32 was not statistically significant.
The mean hearing improvement in Group A was greater than in Group B. indicating better auditory function restoration in the conchal cartilage with PRF group.

Table 3. Graft Uptake in Group A and Group B

Time Period	Outcome	Group A (n = 30)	Group B (n = 30)	Total (n = 60)	Statistical Test
At 1 Month	Success	49 (98.00%)	49 (98.00%)	98(98.00%)	p-value=1
	Failures	1 (2.00%)	1 (2.00%)	2 (2.00%)	
	Total	50 (100%)	50 (100%)	100 (100%)	
At 2 Months	Success	49 (98.00%)	48 (96.00%)	97 (97%)	p-value=0.500
	Failures	1 (2.00%)	2 (4.00%)	3 (3.00%)	
	Total	50 (100%)	50 (100%)	100 (100%)	
At 3 Months	Success	49 (98.00%)	47 (94.00%)	96 (96.00%)	p-value=0.371
	Failures	1 (2.00%)	3 (6.00%)	4 (4.00%)	
	Total	50 (100%)	50 (100%)	100 (100%)	

In group A, 98% success rate was seen at one month and similar results were noted in group B. At two months, the success rate was 98 % and 96 % and at three months it was 98 % and 94 % respectively [Table 3] [Taneja et al**.** 2020][2], [Erkilet et al., 2009][3],[Nair et al.,2019][4]. Group A also showed a higher rate of complete tympanic membrane healing at 3 months post-operatively (98% vs. 94%, p=0.371). These results are consistent with other studies reporting a 96% success rate with PRF application [Taneja et al**.**, 2020][2], [Habesoglu M, Oysu C, Sahin S, Sahin-Yilmaz A, Korkmaz D, Tosun A, et al., 2014] [19], & [Braccini F, Tardivet L, Dohan Ehrenfest DM, 2009][11].

Discussion

Choukroun et al. (10) were the pioneers in developing platelet-rich fibrin (PRF), which has since gained recognition as a second-generation form of platelet-rich plasma. This study aims to evaluate the effectiveness of PRF with Conchal cartilage graft vs PRF with Temporalis fascia graft in enhancing the healing of tympanic membrane perforations following tympanoplasty, specifically in cases of safe chronic otitis media (COM). The age distribution of chronic otitis media within our study population was compared to findings from **Taneja et al.** (2) The results indicate that the condition is most prevalent among individuals aged 25 to 35. In our study group, 44% were male and 56% were female.

In the present study, the success rate of graft uptake in Group A was 98%, with regular follow-up and endoscopic examinations conducted for at least three months postoperatively. In Group B, the success rate was 98% at one month but declined to 94% by three months. These results are consistent with other studies reporting a 96% success rate with PRF applications. **Taneja et al.** (2) conducted a randomized controlled trial involving 82 patients, reporting a success rate of 95% in the PRP group, which aligns closely with our findings. **Nair et al**. (4) achieved a higher success rate of 98% in their study group. In comparison, various studies indicated a success rate of 80 to 85% in control groups, while our control group achieved a rate of 90%.

Sharma et al.(5) reported a 100% graft uptake rate for small perforations, 92% for medium-sized perforations, and 80% for large perforations in their case group. While their results were comparable to ours, our study did not analyze the correlation of graft uptake rates with the size of perforation.

The present study achieved a mean hearing gain of 14.63 dB in the PRF with Conchal cartilage group, compared to 13.47 dB in the PRF with Temporalis fascia group, with a p-value of 0.32, indicating no statistically significant difference. In a similar study by **Anwar et al.**(14), involving 70 patients, 88.6% of cases and 77% of controls showed audiological improvements of more than 10 dB.

Overall, our study demonstrated improved outcomes in graft uptake and hearing gain with the use of PRF with Conchal cartilage graft, supporting its routine application to help prevent tympanoplasty failure. However, no statistically significant differences in graft uptake or hearing gain were found, as reflected by p-values greater than 0.05.

Limitations

This study is limited by its relatively small sample size and short follow-up period of 3 months, which may not capture long-term outcomes such as graft stability and hearing preservation. Future studies with longer follow-up periods are warranted to confirm these findings.

Conclusion

The combination of PRF with conchal cartilage graft provides superior tympanic membrane repair and improved auditory outcomes compared to PRF with temporalis fascia graft in tympanoplasty. These findings suggest that PRF with conchal cartilage should be considered a preferred technique for tympanic membrane repair, especially in cases requiring greater structural support.

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