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Original Research Article

EVALUATING THE EFFECTIVENESS OF PLATELET RICH PLASMA IN TYPE I TYMPANOPLASTY

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ABSTRACT

Background: Tympanoplasty is a common surgical procedure done in the management of chronic suppurative otitis media (CSOM) and main aim of this procedure is to improve auditory function and preventing recurrent infections, thereby enhancing patients' quality of life and to enhance the outcome of surgery various adjunctive methods are tried and platelet rich plasma is one of the adjunctive therapies being tried. **Material and Methods:** Fifty patients who were grouped into PRP group and controls were included in the present study. Tympanoplasty Type I was done with and without PRP. The graft uptake and audiological improvement was done in both groups postoperatively and were compared to look for effectiveness of PRP application in Tympanoplasty. **Result:** There was no significant age and sex distribution between the groups. There was significant graft uptake with 2 failures in PRP group compared to control group. There was no significant hearing improvement between the groups with a p-value of 0.79. **Conclusion:** The study found no significant difference in the efficacy of autologous PRP compared to conventional techniques in Tympanoplasty regarding graft uptake success rate and audiological outcomes. Despite the promising potential of PRP for enhancing tissue regeneration and healing, the results suggest that its application in myringoplasty may not offer significant advantages over traditional methods.

INTRODUCTION

Tympanoplasty is a common surgical procedure done in the management of chronic suppurative otitis media (CSOM) and main aim of this procedure is to improve auditory function and preventing recurrent infections, thereby enhancing patients' quality of life. Traditional techniques for tympanoplasty have evolved over decades and to improve the outcomes following surgery so many adjunctive therapies have been tried.[1]

Different constituents have been used in the past to treat TM perforations and these include epidermal growth factor, hyaluronan, heparin, fibroblast growth factor, and transforming growth factor.[2] The autologous PRP is simple and easy to be prepared with no reported side effects and is effective in graft uptake.[3]

One such promising adjunctive therapy is the use of autologous platelet-rich plasma (PRP) and application of PRP in various fields of medicine including Orthopedics, Dermatology and Dentistry has demonstrated significant potential in accelerating healing processes and improving clinical outcomes. However, its role in otologic surgery, specifically in myringoplasty, remains underexplored.[4] PRP, a concentration of a patient's own platelets, helps in promoting tissue regeneration and healing, thereby enhancing graft uptake and hearing outcomes in cases of tympanic membrane perforation. PRP contains a high concentration of platelets, which are rich in growth factors and these play a crucial role in tissue repair and regeneration by stimulating cell growth, collagen synthesis, and angiogenesis.[5] This prospective case-control study aims to investigate the role and efficacy of autologous PRP in tympanoplasty. By comparing the outcomes following tympanoplasty with and without the use of PRP, this study looks for evidence on whether PRP can enhance the healing of the tympanic membrane, reduce postoperative complications and ultimately improve surgical success rates and this further explores the potential benefits of PRP in patients undergoing tympanoplasty.

MATERIALS AND METHODS

The present study was a prospective case- control study conducted in the Department of Otorhinolaryngology at a tertiary care center in South India after obtaining Institutional Ethics Committee approval (Lr.No.26/2022 dated 29-08-2022). The study included fifty patients of both genders aged between 15 and 55 years and attending the

Department of Otorhinolaryngology OPD. Patients with inactive mucosal type of chronic suppurative otitis media undergoing tympanoplasty type I were included. The patients were randomly allotted to two groups of 25 each, patients who are undergoing routine tympanoplasty as controls and other with application of PRP during surgery as cases. Data was collected from all the subjects in a standardized proforma which included details of age, gender, clinical history, complete ENT and head and neck examination, Puretone audiometry, blood investigations including complete blood count (CBC), radiological investigations including x-ray mastoids and x-ray of the paranasal sinuses. All the patients were admitted one day before the surgery.

Preparation of PRP

1. On the day of surgery, two hours prior to surgery 10ml of venous blood was taken into a tube containing an anticoagulant (1ml sodium citrate) to avoid platelet activation and degranulation.
2. The first centrifugation was done for 6 minutes at 1500rpm, which separates the blood into three layers, namely the topmost layer containing platelet-poor plasma (40% of total volume), an intermediate layer of platelet-rich plasma (5% of total volume) called "Buffy coat " and the bottom-most layer containing RBC (55% of total volume).
3. Using a syringe Platelet poor plasma (PPP), Platelet rich plasma (PRP) are transferred to another tube without anticoagulant. This tube undergoes a second centrifugation for 15 min at 2500 rpm, after Which platelet-rich plasma (PRP) settles in the bottom two third layers. The acellular layer stays at the top, which is discarded using a syringe. The Platelet-rich plasma (PRP) formed was then collected and brought to the operation theatre.

In both groups (cases and controls) Tympanoplasty Type I was done by post aural approach with placement of temporalis fascia by underlay technique. In the cases group, after placement of the graft and repositioning of the tympano-meatal flap gel foam soaked in PRP was kept over the sealed perforation. Where as in the control group, gel foam soaked in antibiotic ear drops (Neosporin -H) was kept over the sealed perforation. Postoperatively, both groups received antibiotics for five days and all patients were followed up for a period 12 weeks with intervals of 6,8 and 12 weeks. Audiological assessment was done by Puretone audiometry at the end of 12 weeks and recorded.

Statistical analysis: Continuous variables were expressed as mean ± standard deviation (SD). Frequency was expressed as number (percentage), (n (%). The difference in the means of hearing improvement in dB and Graft uptake was analysed by independent samples t-test. Data was analysed using Microsoft excel spread sheets and Statistical Package for Social Sciences (SPSS, Inc., Chicago IL) for windows version 16.0. A p value less than 0.05 was considered as statistically significant.

RESULTS

Twenty (40 %) of the total subjects included in the study were males and Thirty (60 %) were females. There were equal number of female patients in the cases group (n=15) when compared with the control group (n=15) and the distribution of male patients was same in both groups (n=20). Majority of patients in the cases and controls belonged to 26-35 years (n=20,40 %) followed by 36-45 years (n=15,30%). The diagnosis of CSOM was bilateral in 9 subjects (18 %) and in rest of the subjects right side disease was in 23 subjects (46%) and in 18 subjects (36%) the disease was on Left side. The tympanoplasty Type I was done in 27 (54%) subjects on right side and in the rest (n=23) the surgery was done on Left side.

The Figure 1 showing the graft uptake outcomes between two groups. In the cases (PRP) group (n=25), there were two failures and 23 successful graft uptakes, while in the control group(n=25), there were four failures and 21 successful graft uptakes. The chi-square test was done to determine the difference in the failure rates between the groups. The resulting p-value of 1 indicates no statistically significant difference between the PRP group and controls regarding graft uptake, suggesting that the differences observed are likely due to random chance rather than any systematic difference between the two groups.

The audiological changes were compared between the two groups across different air conduction dB ranges:15-25 dB, 26-35 dB, and 36-45 dB pre-operatively and post-operatively and postoperative hearing gain in dB was calculated. (Table 1) The distribution is as follows: in the 15-20 dB gain range, there are 10 cases and eight controls; in the 10-15 dB gain range, there are 8 cases and seven controls; in the 5-10 dB gain range, there are 5 cases and six controls; and in the <5 dB gain range, there are 2 cases and four controls.A chi-square test was conducted to assess the significant difference in hearing improvement between the two groups. The p-value of approximately 0.79 indicates that there is no statistically significant difference between the cases and controls in hearing. This suggests that the differences in postoperative hearing gain could be due to random chance rather than the treatment method.

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TABLE 1 : Post-operative hearing status -calculation of hearing gain in dB			
db gain	Cases(n=25)	Controls(n=25)	Total
15-20	10	8	18
10-15	8	7	15
5-10	5	6	11
<5db	2	4	6
	25	25	50

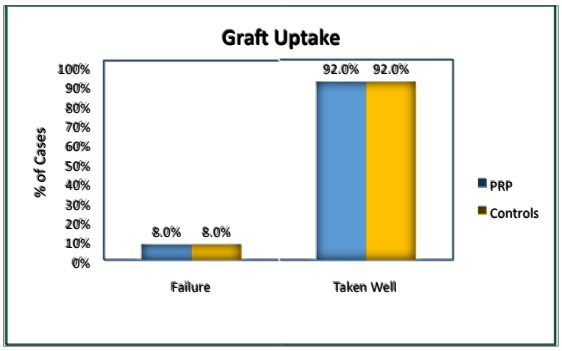

Figure 1: The pictogram showing Graft uptake

DISCUSSION

Chronic suppurative otitis media (CSOM) is a common clinical condition which is being managed with a surgical procedure called tympanoplasty and in inactive cases of CSOM Tympanoplasty type I is commonly performed. To improve the surgical outcomes in the form of graft uptake and hearing improvement, application of PRP during placement of temporalis facia graft and the effectiveness of its application was studied in the present study.

Age can be a significant factor in the outcomes of tympanoplasty. Younger patients often have better tissue regeneration and healing capacities, which can lead to higher success rates in surgical procedures like tympanoplasty. Shanmugam et al,[6,7] study showed a clear trend where younger patients, particularly those below 40, experienced better healing and hearing improvements and our study didn't show any age-related improvement. The gender is not a factor in improving the results following surgery which was consistent with other studies.[8]

Several studies have investigated the efficacy of autologous platelet-rich plasma (PRP) in enhancing graft uptake rates in myringoplasty compared to conventional techniques. While many studies report significant improvements in graft uptake with the use of PRP, there are instances where the results do not show substantial differences. These mixed results suggest that the success of PRP in myringoplasty may be influenced by various factors that need to be carefully considered.[9] Possible Reasons for discrepancies in the study subjects are due to various factors like patient selection, surgical technique followed by different surgeons. The current study might not have standardised the surgical procedures as rigorously as others. Other factors like PRP Preparation and application, postoperative care may influence the results of the surgery. The effectiveness of audiological improvement in the form of dB gain was not significant in our study compared to other similar studies.[10,11,12]

This can be overcome by standardizing PRP preparation methods to ensure optimal concentration and quality, ensuring precise application of PRP to the surgical site to maximize its regenerative potential, enhancing postoperative care.

Limitations of The Study

1. Small Sample Size The study included only 50 participants, which may not provide enough statistical power to detect subtle differences between the groups.
2. **Single-Centre Study:** Conducting the study in a single centre limit the generalizability of the findings to other settings.
3. **Short Follow-Up Period:** The follow-up period may have been insufficient to capture long-term results and potential late complications.
4. Variability in PRP Preparation: Differences in platelet concentration, activation methods, and application techniques can influence the effectiveness of PRP.
5. **Lack of Blinding:** The absence of blinding may introduce potential bias in assessing outcomes.
6. Postoperative Care Variability: Variations in postoperative care and patient adherence to follow-up protocols can affect the outcomes.
7. **Measurement of Outcomes:** The methods used to measure audiological outcomes and graft uptake may have limitations in accuracy and consistency.
8. **Uncontrolled Confounding Factors:** Patient age, overall health, and other ear conditions may influence the results.

CONCLUSION

Patient optimisation, meticulous surgical technique, and proper postoperative care are essential to prevent graft failure. PRP, when prepared and applied correctly, can play a significant role in improving the outcomes of myringoplasty.

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