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Original Research Article

To Compare the Efficacy of Topical Platelets Rich Plasma (PRP) in Myringoplasty

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Abstract:

Aim: To analyse the use of autologous platelets rich plasma (PRP) in myringoplasty so as to improve graft uptake & beneficial on hearing.

Objective: To compare graft uptake percentage & hearing improvement between conventional myringoplasty & myringoplasty using PRP.

Methodology: Total 50 patients diagnosed with COM (inactive mucosal type) randomly divided into case &control with 25 patients in each group. Case (myringoplasty using PRP) & control myringoplasty without PRP. Postoperative graft uptake status & pre-post-operative PTA were performed in all the patients & outcome was compared.

Results: 25 patients in each group. 2 patients in case study & 4 in control group had residual perforation, i.e 92% & 84% graft uptake in case & control group respectively. Results were better in cases that underwent myringoplasty with PRP. Hearing improvement (>10db) were seen 84% in case group & 72% in control group.

Conclusion: The study shows definite clinical benefit using PRP. PRP can be routinely use in surgical field, as it can be easily prepared has minimal or no side effects.

Keywords: Platelets rich plasma (PRP) Pure tone audiometry (PTA), chronic otitis media (COM).

Introduction

Chronic & persistent inflammation and infection of middle ear cleft known as chronic suppurative otitis media(COM) which is one of the major otological problem in ENT clinics. [1] Acute inflammation, infection causes perforation of the tympanic membrane that heals spontaneously whereas chronic tympanic membrane perforation requires myringoplasty. [2] Myringoplasty using autologous temporalis fascia as a graft is gold standard & achieves high success rate, however due to recurrent upper respiratory tract infections, Eustachian tube obstruction or dysfunction(ETD), middle ear infections causes reperforation, thus it is essential to explore the options to improve the graft uptake. [3] The knowledge about platelets pertains to their role in clotting of the blood, patelets also contains large amount of proteins known as growth factors which plays essential role in healing of injuries. [4,5] Autologous platelet rich plasma is simple & can be easily prepared in operation theatre, it is minimal invasive contains growth factors can be used on surgical sites during procedure, addition of thrombin& calcium gluconate can stimulate release of growth factors. However it also induces antibodies formation against V & XI clotting factors can cause life threatening coagulopathies. [6,7] Our study evaluate graft uptake, improvement in air conduction(AC), bone conduction(BC) & incidence of reperforation in tympanic membrane postmyringoplasty, by using autologous topical PRP placed in middle ear cavity & on both sides of temporalis fascia.

Material & Method

The study was conducted as Randomised control trial (RCT) in the Department of ENT ,Head & Neck surgery of Atal Bihari Vajpayee Govt Medical College Vidisha (M.P) from January 2022 to February 2023, after approval of Institutional Medical Ethical Committee(IMEC). Total 50 patients of COM inactive mucosal type of age 10-

50 years were included in the study. Detail history & clinical as well as ENT examination included 0-degree endoscopy & otoscopic examination was done in all patients. Routine investigations, X-ray mastoid was also carried out along with consent for surgery.

Inclusion Criteria:

1. Tympanic membrane perforation (central perforation)
2. Dry middle ear of 2 months
3. No active foci of infections in nasopharynx & throat.

Exclusion Criteria:

1. Patient with active squammosal Com,
2. Signs of choleasteatoma & ossicular necrosis
3. Hearing loss >50db, SNHL.
4. Uncontrolled systemic illness(diabetes mellitus, hypertension, chronic liver disease, chronic renal disease)
5. Patients not willing for surgery.
6. Low platelets count, platelets dysfunction syndrome
7. Clotting & bleeding disorder

Patients was randomly allocated into two groups

a) Case (myringoplaty with PRP) n=25
b) Control (myringoplasty withput PRP) n=25

In all patients myringoplasty was done under GA, by postaural approach, Temporalis fascia as a graft material used & placed via underlay technique. In case study group 10 ml blood was collected in the morning of surgery in O.T, collected sample was centrifugate in centrifugation machine at 3000rpm for 20 min, top layer was discarded by pipette because it was platelet poor plasma, middle buffy coat was used rich in platelets, bottom layer was Rbc's rich layer. In case study group, before placing graft 0.1 ml calcium gluconate was added to approx 1.5ml of PRP & two drops of PRP applied both sides of temporalis fascia graft, edges of perforation, after placing graft gel foam soaked in PRP was kept over sealed perforation.

In control study group conventional myringoplasty was performed, gel foam soaked in saline kept over sealed perforation. Followed by both study group received i/v antibiotics for 2 days followed by 5 days oral antibiotics, antihistaminics, vitamin C. Ear drop should be avoided as it can be ototoxic.

Outcome was assessed by single blinded observer-

a) Graft uptake assessed by 0 degree endoscopy @ 1st & 3rd month postsurgical
b) Audiological benefit Hearing improvement >10db @ 3rd month post-surgical follow up used by Sergi et al. [8]
c) Statitical analyses done by Chisquare test, Fischer exact probability test & $p<0.05$ consider statistically significant.

Results

Total 50 patients with inactive mucosal Com of age 10-50 year full filling inclusion criteria were taken, randomly allocated into two groups case & control with 25 patients in each groups. Most of the patients were belongs to age group of 21-30 years in both study groups with male predominance 38 males & 12 females with ratio 3.1:1. Mean duration of symptoms was 6months to 2 years.

Table 1: Gender wise distribution among both study groups

Gender	Case (n=25)		Control (n=25)	
	n	%	n	%
Male	18	72%	15	60%
Female	07	28%	10	40%
Total	25	100%	25	100%

Table 2: Age wise distribution of case & control groups

Age interval	Case group (n=25)		Control (n=25)	
	n	%	n	%
10-20 years	01	4%	02	8%
21-30 years	12	48%	15	60%
31-40 years	10	40%	5	20%
41-50 years	02	8%	03	12%
Total	25		25	

Table 3: Graft uptake @ 1st month with p value= >0.05

At the end 1st month	Case (n=25)		Control (n=25)	
	n	%	n	%
Success	23	92%	22	88%
Failure	02	8%	03	12%
Total	25	100%	25	100%

Table 4: Graft uptake at the end of 3rd month post surgically with p value= >0.05

At the end 3rd month	Case (n=25)		Control (n=25)	
	n	%	n	%
Success	23	92%	21	84%
Failure	2	8%	4	16%

Table 5: Audio logical benefit (PTA>10 db)p value= > 0.05

Hearing gain	Case n=25		Control n=25	
	n	%	n	%
10-15db	01	4%	03	12%
>15db	24	96%	22	88%
Total	25	100%	25	100%

In our study, we found O-positive blood group common among case study as well as control study group patient followed by B-positive. But it doesn't have any statistical significance with graft acceptance & failure.

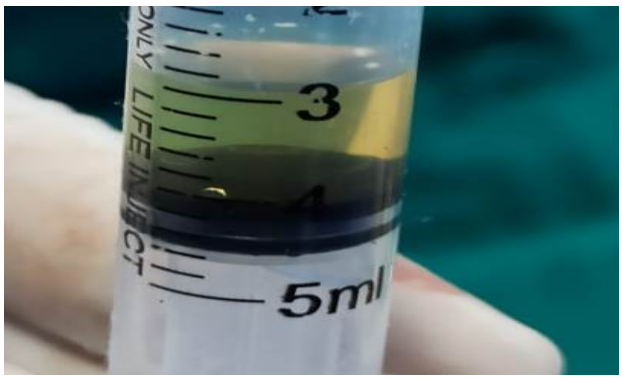

Figure 1: Showing approx 1ml of plasma rich in platelets

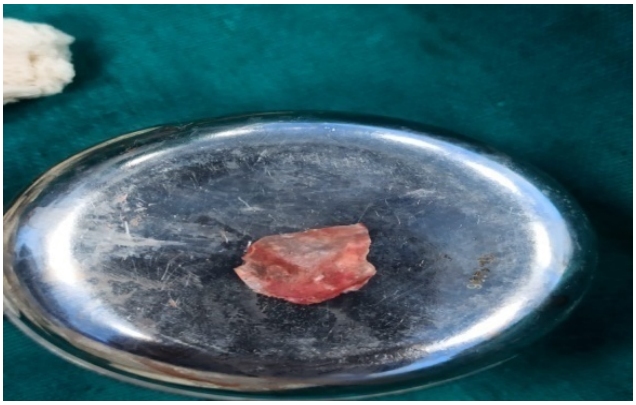

Figure 2: Showing Graft (Temporalis fascia)

Discussion

Platelets rich plasma (PRP) are rich in growth factors which help in healing process.It stimulates epidermal, epithelial, and endodermal regeneration & increase angiogenesis, collagen formation which decreases scaring of dermis & promotes haemostasis response to injury. [9] PRP contain high concentration of white blood cells (WBC's) & it is bactericidal. [10] PRP keep the graft in-place & prevents sagging of posterior wall of the ear canal & complications associated with external auditory canal pack. [11] Graft uptake with respect to size of perforation of tympanic membrane in myringoplasty varies from study to study.

In our study graft uptake percentage in case study group for small central perforation (87.5%)>medium central perforation (81.8%)>large central perforation (66.3%). Study conducted by EL-Anwar et al showed graft uptake in all cases of large central perforation with 100% success rate. [12] Graft uptake percentages of various studies at the end of 3rd month followup

Studies	Case study group	Control study group	Statistically significance
Our study	92%	84%	p value= >0.05
El-Anwar et al	100%	81.25%	p- 0.02
Sankanarayan et al	96%	80%	Not significant
Vignesh et al [13]	97.4%	89.5%	significant
PK Purushothaman et al	95%	92%	P value significant

Audiological improvement percentage of various studies (PTA >10db)

Studies	Case study group	Control study group	Statistical significance
Our study	84%	72%	p value= >0.05
El-Anwar et al	65.5%	40.6%	Not significant
Taneja MK et al [14]	78.0%	46.3%	significant

Shiomi et al stated that irrespective of the size of the perforation of tympanic membrane addition of platelets rich plasma to myringoplasty has significant increase in success rate of graft uptake. Study done by Nithin Prakasan Nair et al[15] showed success rate in case group (97.7%) , control group (81%) p value= 0.012 using plasma rich fibrin. Study done by Ruta Shanmugam in 2016 using PRP in 20 patients underwent myringoplasty. Out of 20, 11 patients graft uptake present with 85% of hearing outcome >10 db.

The reason for statistical insignificant p value is because surgeries done by different surgeon everyone has their own skill to perform, small group & single centre study. Our study aim to emphasize the effective role of PRP in myringoplasty clinically in our study it is proven but statistically it is found to be insignificant.The limitation of study are small sample size, & doesn't include the revisional cases.

Conclusion

Platelets rich plasma (PRP) can be considered as an effective material in tympanic membrane regeneration, it enhanced healing rate & provide potentially better hearing outcome. Autologous plasma has no side-effects like transmitting HIV, HepB & another bloodborne disease. It is cost-effective, simple, & easily prepared. Thus should be used during myringoplasty to increase success rate.

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