

“Comparative outcome of the placing graft medial or lateral to handle of malleus in Inlay technique of myringoplasty- A hospital based prospective study”

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Abstract-

Aim- To compare the outcome of placing graft, medial or lateral to handle of malleus in Inlay technique of myringoplasty in terms of graft take-up rate, hearing improvement and complications. **Material method-** Prospective randomized single blind study on a total of 52 patients (age 18-40 years) who had dry central, medium sized perforation secondary to Chronic Otitis Media(mucosal disease) were included in our study. These patients were divided into two groups. Group A had 23 patients, in which graft was placed medial to handle of malleus and group B had 29 patients in which graft was placed lateral to handle of malleus in modified inlay technique of myringoplasty. The results of two techniques were compared in terms of graft take- up rate, hearing improvement and complications at the end of 6 months of follow up. **Result-** The graft take-up rate and post operative gain in air conduction in group A was 91.30% and 3.57+/-6.61 dB (mean+/-SD) respectively whereas 96.55% and 6.62+/-6.86 Db (mean+/-SD) respectively in group B (p value is >0.05). Results was statistically analysed by Chi-square and T-test. **Conclusion-** We can conclude here that although there is no difference in graft take-up rate, gain in hearing and complications in both the technique, but in consideration of the duration of surgery, technicality, healing and lateral placement of graft was found better than medial placement in modified inlay technique of myringoplasty.

Keywords: Chronic Otitis Media, Inlay techniques, Myringoplasty

Introduction

Myringoplasty is the closure of the perforation of pars-tensa of the tympanic membrane to restore its integrity and improve hearing level¹. It was introduced in 1878² using skin grafts for the surgical closure of the perforation.

Many technique of myringoplasty have been described in literature like overlay, underlay, through and reverse through. Underlay techniques was introduced by **Austin and Shea**

(1961) later modified by **Hough** (1970)³. This study was planned to see the result of placement graft medial or lateral to handle of malleus in inlay technique of myringoplasty keeping all other influencing factors constant.

Aim

Comparative outcome of placement of graft medial or lateral to handle of malleus in inlay technique of myringoplasty in terms of graft take up rate, hearing improvement and complications.

Material and Methods

This was a prospective, randomized single blind comparative study conducted in the Department of E.N.T and Head & Neck Surgery in 52 patients of chronic suppurative otitis media from July 2015 to July 2016 after due clearance from the Institutional Ethics Committee.

Inclusion criteria:

1. Patients data- (a) Age group 18-40 years (b) Duration of dryness was more than 6 weeks.
2. Tympanic membrane- (a) Medium sized central perforation (b) No tympanosclerotic patch (c) Middle ear mucosa was healthy (no granulation, edema).
3. Pure Tone Audiometry- Shows conductive deafness <40 dB. (ie AC threshold of < 40 dB)
4. Eustachian tube function test by- Inflation- Deflation test was normal.
5. X-Ray mastoid (Schullers' View) - Only cellular mastoid were included.
6. No history of smoking and allergy.
7. No medical comorbidities like diabetes mellitus, hypertension, tuberculosis or autoimmune diseases.

Exclusion Criteria:

1. Age <18years or >40years.
2. Small, large and subtotal perforation.
3. Abnormal Eustachian tube function.
4. CSOM- squamosal disease, with or without complications.
5. Patients having history of acute mastoiditis in past.
6. Discharging ear, previous history of ear surgery, ossicular chain necrosis concomitant otitis externa.
7. Active focus found in nose, throat, oral cavity or history of allergy

Patients were properly informed regarding the nature of disease process, the surgical procedure including expected outcomes, potential complications and alternative treatments. Written informed consent was signed by patient.

Patients attending E.N.T O.P.D giving history of otorrhoea of variable duration that got resolved with medication and having dry central perforation for at least six weeks with conductive deafness were included.

METHOD:

Operative method of placing the graft medial or lateral to handle of malleus in inlay technique of grafting was done by lottery method (random digit) of randomization & operated by senior surgeon having experience of more than 10 years in ear microsurgery.

Operative Procedure:-

In all the selected cases, postaural approach with temporalis fascia graft and Houghs' inlay

technique of myringoplasty was used with slight modifications and performed under local anaesthesia.

Meatotomy was done by giving an incision from 12 O'clock to 6 O'clock position, thereafter, freshening the margins. Next a curvilinear incision was taken over the posterior wall of external auditory canal about 8 mm lateral to annulus from 7 O'clock to 2 O'clock positions. According to the original Houghs' technique tympanomeatal flap was elevated parallel to handle of malleus and not freed from it, thereby preservation of normal squamous epithelium was ensured, but here slight variation in the technique was done as the tympanomeatal flap was elevated from 7 O'clock to 2 O'clock through posterior wall positions and was freed from handle of malleus, anterior malleolar fold and adjacent outer wall of attic. Finally the condition of the middle ear ossicles and labyrinthine windows was checked and graft placement was done on the pre-determined basis medial or lateral to handle of malleus after keeping abgel in middle ear and Eustachian tube opening.

Group A: 23 Patients in which graft was placed medial to handle of malleus after making a 'V' shaped notch in the graft.

Group B: 29 Patients in which graft was placed lateral to handle of malleus

Tympanomeatal flap was repositioned. External Auditory Canal was packed abgel & BIPP (Bismuth Iodine Paraffin Paste) incision line closed in single layer and patient shifted to post-operative room.

Postoperatively: I.V Antibiotics for 3 days, oral for 12 days, Anti-histaminics and nasal decongestants for 1 week and stitch removal on 7th post-operative day was done

Patient was discharged and called in O.P.D for follow-up at weekly interval for 1 month, every 15 days for the next 2 months and every month up to 6 months.

Abgel was cleaned on 15th post-operative day.

The two techniques of myringoplasty were compared in terms of graft success rate (partial or full take, medialization or lateralization) and hearing improvement. At every visit, ear was examined with otoscope to see the graft uptake (any medialization or lateralization of graft, residual perforation or discharge). "Graft take-up was defined as full, intact healing of tympanic membrane graft at 6 months postoperatively". Hearing improvement was defined as the change in air conduction of 10 dB or more at 6 weeks and six months follow up period from baseline of preoperative level. 10 dB or more deterioration or loss in hearing at 6 weeks and 6 months follow up period from baseline of preoperative level was considered as significant. Air conduction was calculated as the average of air conduction at 0.5, 1 and 2 kHz. Results were statistically analyzed using SPSS (statistical package for social sciences). Results of two techniques of myringoplasty were compared between group A & B were compared utilizing Chi square test for graft success rate and complications. Paired and unpaired T-test was utilized to compare pre and postoperative air conduction change. Statistical significance was accepted as $p < 0.05$.

RESULTS

1. 57.69% (30) of patients were male while 42.30% (24) were female. In group A males were 60.86 % (14) and females were 39.13% (9) & group B 55.17% (16) were males and 44.82% (13) were females. Mean age of patients in group A was 26.7 +/-8.78 years (mean +/- SD) and in group B it was 23.24 +/-6.46 years (mean +/- SD). (Figure 1)

2. Pre-operative hearing threshold- on Pure Tone Audiometry showed a conductive deafness of <40 dB in all cases.(Figure 2)
3. Operating time- Average operating time in group A and group B was 70 min. B 60 min respectively.
4. Healing time- it was found to be of 8-10 weeks in group A whereas it was 6-8 weeks in group B. Difference in group A and group B was compared at 6 & 8 weeks and it was found to be statistically significant (p value .0016). (Figure 3).
5. Graft take-up rate in group A and group B were 91.30% and 96.55% respectively and it was found to be statistically insignificant (p value .8358). (Figure 4)
6. Preoperative average air conduction in group A was 35.35+/-5.64 dB, whereas it was 36.10+/-4 dB in group B and P value .57747 (p value >.05); difference was considered to be statistically insignificant. The average postoperative change in air conduction at 6 weeks and 6 months in group A was 3.57+/-6.61 dB, whereas it was in 6.62+/-6.86 dB in group B and P value .1114; by conventional criteria, this was statistically insignificant. (Figure 5)
7. Significant change in air conduction of 10 dB or more was found in 34.78% patients in group A while it was 58.62% patients in group B and the difference was statistically insignificant (p value-.1114).
8. Complications in both the groups are shown in Table 1.
9. Comparison of various parameters in medial (group A) or lateral (group B) placement of graft in inlay technique of myringoplasty) in Table 1.

Discussion

The two most widely accepted techniques of myringoplasty are overlay and underlay techniques⁴. Underlay technique is technically easier, less time-consuming and has high success rate⁵. Due to these advantages, it is the most commonly performed technique. The over-underlay myringoplasty (underlay myringoplasty in which graft was placed lateral to handle of malleus but medial to remnant ear drum and annulus) is relatively a new technique. In our prospective study of one year, we have tried to compare the graft placement either medial or lateral to handle of malleus in inlay technique of myringoplasty in dry medium size central perforation keeping all other factors constant. Most of the studies^{1, 6, 7, 8, 9, 10, 11, and 12} (as shown in table no. 2) which have compared this technique of myringoplasty have not kept other influencing factors constant.

We studied these two techniques regarding graft take-up rate, complications, hearing improvement and tried to find out that which technique was better. There was no uniform agreement in literature about the status of Eustachian tube function and myringoplasty results.^{1,6,7,8,10,11,14,15} We had taken only patient having good Eustachian tube function as tested by reliable inflation-deflation test for myringoplasty in our study. In previous studies^{1, 9-11} authors did not test Eustachian tube function, so postoperative complication like atelectasis or medialization was more common.

On Pure Tone Audiometry all cases showed a conductive deafness of <40 dB. Most of studies had not specified preoperative hearing threshold.^{1,6,10,11} Placement of graft lateral to handle of malleus but medial to remnant tympanic membrane and annulus act as a good alternative in perforations involving the area anterior to handle of malleus¹⁵ which is supported by the results of our study.

Most of patients in our study, in which graft was placed lateral to handle of malleus, took 6-8 weeks for complete healing whereas it was 8-10 weeks in which graft was placed medial to handle of malleus. This difference was statistically significant. It can be concluded that healing was faster in lateral placement of graft. Healing time was not studied in previous literature^{1, 6, 7, 8, 9, 10, 11, and 12}.

On comparing the two groups there was no difference in graft take-up rate and hearing improvement. However, when preoperative and post-operative hearing levels were compared both the groups showed significant improvement (> 10dB gain post-operatively).

Most of previous studies^{1,6,7,8,9,10,11,12} like have not taken into account all the influencing factors like status of medical co-morbidity, pre-operative hearing threshold, stage of disease, size of perforation, status of middle ear mucosa, tympano-sclerosis, type of anaesthesia given, experience of surgeon etc., that modified the results of myringoplasty. So our study was unique because we had made all the influencing factors constant. Only variable was placement of graft either medial or lateral to handle of malleus in modified inlay technique of myringoplasty.

Thus, our study and relevant literature showed that placement of graft medial to handle of malleus in inlay technique of myringoplasty had more technical problems at the time of operation in the form of more operating time, difficulty in placement of graft medial to handle of malleus and post-operative period healing time was more. Hence placement of graft lateral to handle of malleus is better than placing the graft medial to handle of malleus because it takes less time, technically easier; healing is faster although there is no difference in graft take-up rate, gain in hearing and complications.

Another significant inference is that it is better to check Eustachian tube function before myringoplasty to avoid postoperative complication in the form of retraction of graft.

References

- 1) Aslam MA, Aslam MJ- Comparison of Over-Underlay and Underlay Techniques of myringoplasty. Pak. Armed Forces Med. J, 2006;56:276-9.
- 2) Berthold E, UeberMyringoplastik, Wier Med Bull, 1878, 1, 627–627, Cited By: Sismanis A. Tympanoplasty, In Glasscock-Shambaugh Surgery Of The Ear, BC Decker Inc., 2003;Vol. 1(5):463-486.
- 3) JVD Hough-Tympanoplasty with the interior fascial graft technique and ossicular reconstruction, Laryngoscope, 1970; 80(9): 1385-1414.)
- 4) Gersdorff M, Gerard JM, Thill MP- Overlay versus underlay tympanoplasty. Comparative study of 122 cases.Rev LaryntolOtolRhinol. 2003; 124(1): 15-22.
- 5) Singh M, Rai A, Bandyopadhyay S, Gupta SC- Comparative study of the underlay and overlay techniques of myringoplasty in large and subtotal perforations of the tympanic membrane. J Laryngol Otol. 2003 Jun;117(6): 444-8.
- 6) Rogha M, Berjis N, Taherinia A, Eshaghian- A Comparison of tympanic membrane grafting medial or lateral to malleus handle, Adv Biomed Res. 2014;3:56.
- 7) Panchal V, Gulia JS, Yadav S P, Hernot S, Kathuria B, Kaintura M- To evaluate and compare the results of over-underlay graft technique with conventional underlay myringoplasty. Indian J Otol2015;21: 274-9.
- 8) MylanahalliDoddarangaiahPrakash, BorlingegowdaViswanatha, JapneetKaur, SataksiSanyal- Comparative Study of the Underlay and Over-Underlay Techniques of tympanoplasty in Perforations of the Tympanic Membrane, Research in otolaryngology, 2014; Vol. 3(5): pp. 65-69.
- 9) Kulduk E, Dundar R, Soy FK, Guler OK, Yukkaldiran A, Iynen I, Bozkus F- treatment of Large Tympanic Membrane Perforations: Medial to Malleus Versus lateral to Malleus.Indian J Otolaryngol Head Neck Surg. 2015 Jun;67(2):173-9.
- 10) Yigit O, Alkan S, Topuz E, Uslu B, Unsal O, Dadas B- Short-term evaluation of over-under myringoplasty technique. Eur Arch Otorhinolaryngol2005; 262:400-3.
- 11) She W, Dai Y, Chen F, Qin D, Ding X- Comparative evaluation of over-under myringoplasty and underlay myringoplasty for repairing tympanic membrane perforation. Lin Chung Er Bi Yan HouTou Jing WaiKeZaZhi. 2008 May; 22(10):433-5.
- 12) Imran Saeed, Muhammad Akhlaq, Omar; Tympanoplasty Type 1- A Comparison between Underlay Technique of Myringoplasty with Over under Technique of myringoplasty.P J M H S Apr – Jun 2014;Vol. 8(2):291-294.
- 13) Mackinnon DM- Relationship of preoperative Eustachian tube functions to myringoplasty. ActaOtolaryngol1970; 69:100-6.
- 14) Holmquist J, Lindeman P- Eustachian tube function and healing after myringoplasty. otolaryngol Head Neck Surg1987; 96:80-2.
- 15) Stage J, Bak-Pedersen K- Underlay tympanoplasty with the graft lateral to the malleus handle. ClinOtolaryngol Allied Sci. 1992 Feb; 17(1):6-9.

Figures and tables

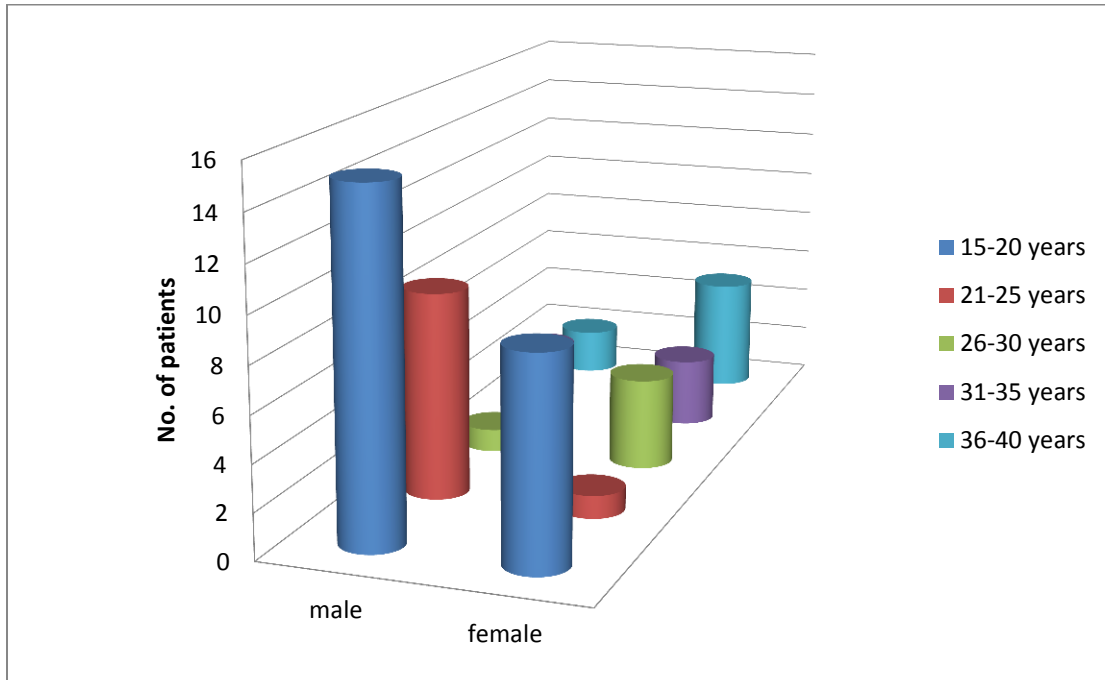


Figure 1: Age and sex distribution

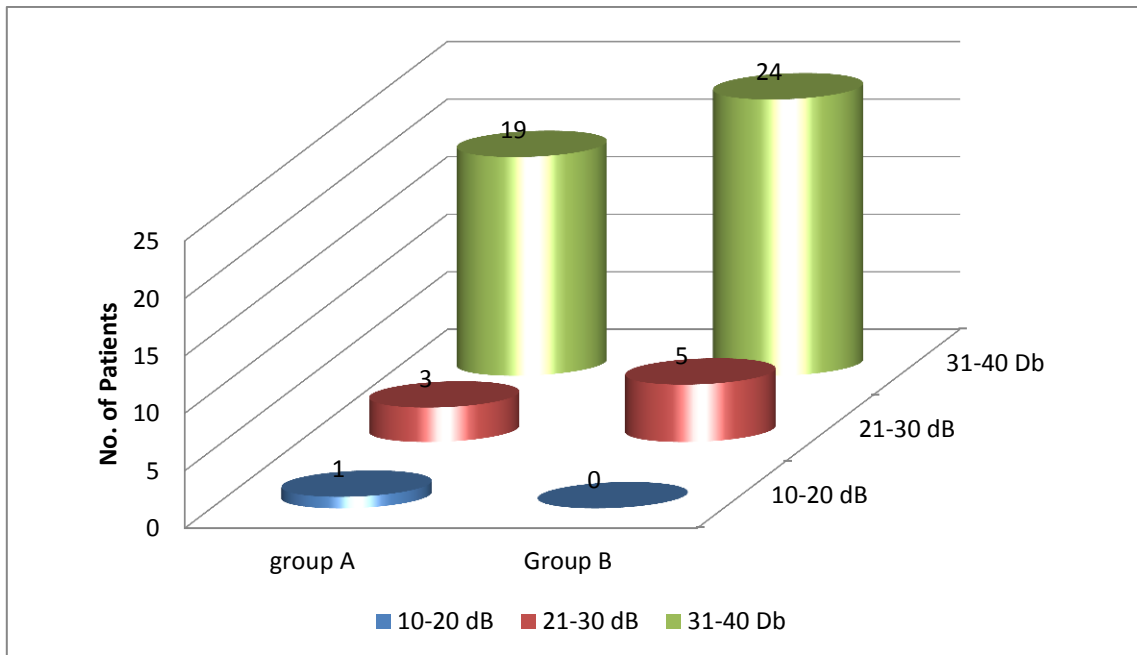


Figure 2: Air conduction threshold in 52 patients of group A and B

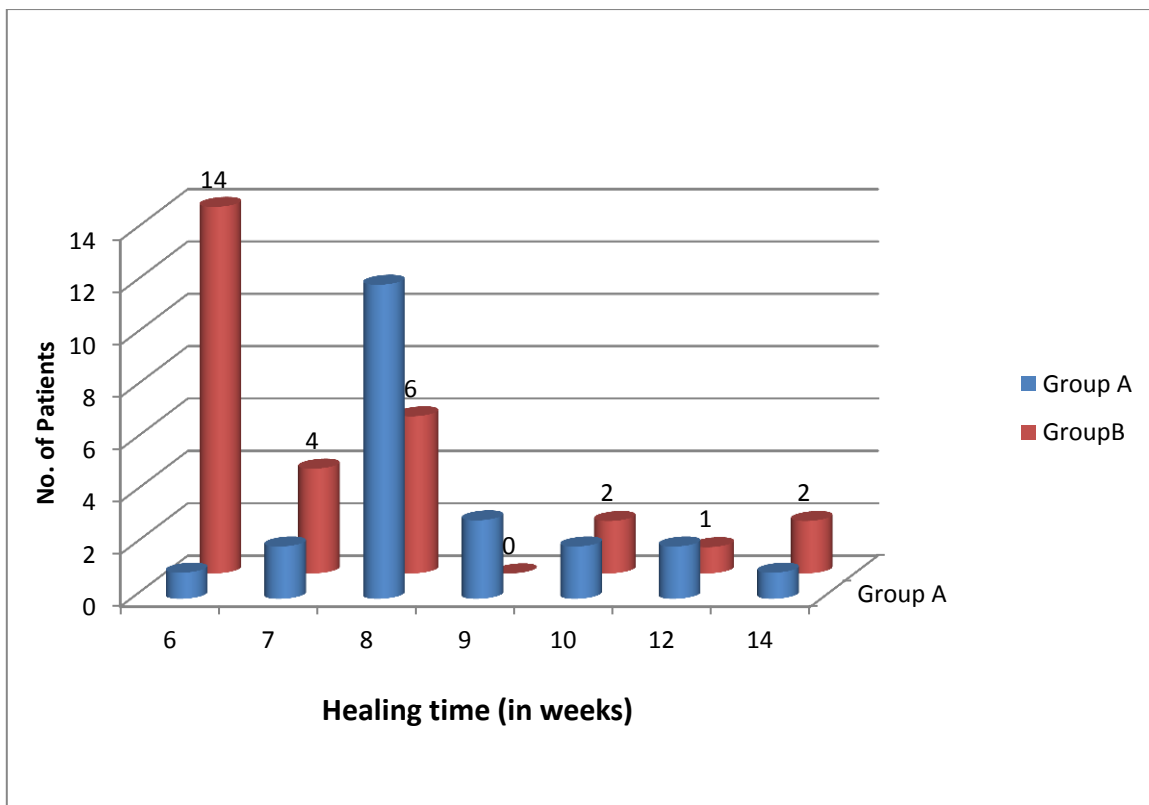


Figure 3: Healing time of graft in group A and group B

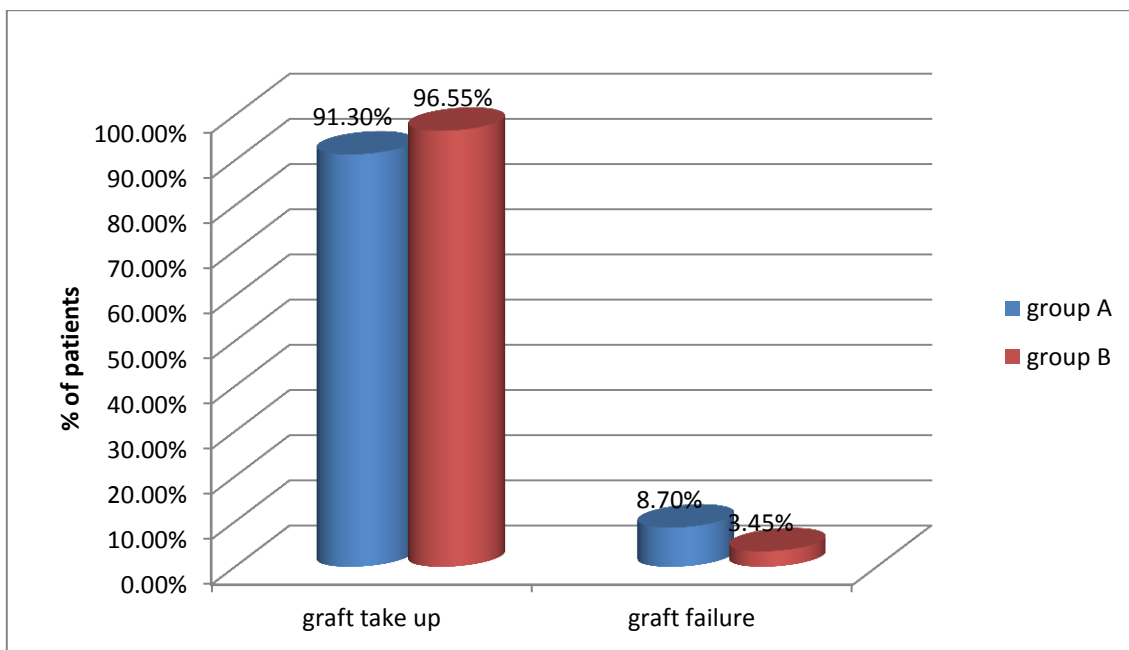


Figure 4: Graft take-up rate and graft failure in group A and B

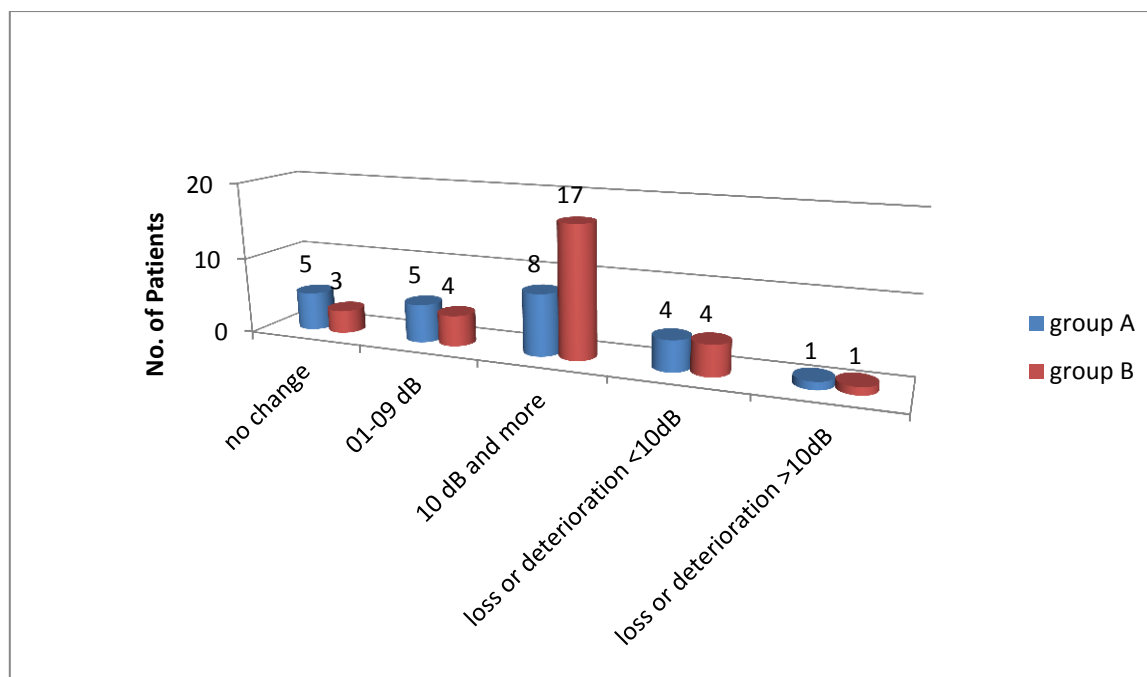


Figure 5: Pre and post-operative status of hearing in group A and B)

Table – 1: Comparison of various parameters in medial (group A) or lateral (group B) placement of graft in inlay technique of myringoplasty)

| Parameters | Group A | Group B | P value |
|--|---|--|---------|
| Operating time | 1 hour 10 minute | 1 hour | |
| Healing time | 8-10 weeks | 6-8 weeks | .0016 |
| Success rate- | | | |
| A) Graft take-up rate | 91.30% | 96.55% | .8358 |
| B) Hearing improvement (change in air conduction threshold postoperatively) | 3.57+/-6.67 dB (34.78% patients show significant change) | 6.66+/-6.86dB (58.62% patients show significant change) | .1114 |
| Complication | | | |
| A) Lateralization of graft | No | No | |
| B) Cholesteatoma pearls | No | No | |
| C) Tympanosclerosis | 4.35% (1 out of 23 cases) | No | |
| D) Retraction of graft | 4.35% (1 out of 23 cases) | 3.45% (1 out of 29 cases) | |
| E) Deterioration in hearing | 4.35% (1 out of 23 cases) | 3.45% (1 out of 29 cases) | |
| F) Residual perforation | 8.69% (2 out of 23 cases) | 3.45% (1 out of 29 cases) | |

Table 2: Comparison of different parameters and results of previous studies

| S N o. | Name of authors | Success rate | | | | Complications | |
|--------------|---|--------------|----------------------------|---------------|----------------------------|--|--|
| | | Group A (UT) | | Group B (OUT) | | Group A (UT) | Group B (OUT) |
| | | GTR | HI | GTR | HI | Medialization/lateralization Atelactasis/cholesteatoma | Medialization/lateralization Atelactasis/cholesteatoma |
| 1 | Stage J et al. ⁵ in 1992 | | | 97% | | | Lateralization-00% choesteatoma pearl-00% |
| 2 | Yigit O et al. ¹⁰ in 2005 | 91.5 % | 16.55 dB | 94.9 % | 16.96 dB | Lateralization-00% Atelactasis-19.5% | Lateralization-00% Atelactasis-12% |
| 3 | She W et al. ¹¹ in 2008 | 89% | 4.9dB | 87.5 % | 9.7 dB | Lateralization-00% Atelactasis-17.8% Re-perforation-5.9% Anterior blunting-6.8% | Lateralization-00% Atelactasis-15% Re-perforation-6.25% |
| 4 | Aslam MA et al. ¹ in 2015 | 92.8 % | 11.3+/ - 5.84d B | 94.1 % | 10.8+/ - 5.56d B | Lateralization-00% Medialization-2.9% | Lateralization-00% Medialization-17.8% |
| 5 | Imran S et al. ¹² in 2014 | 83.3 % | 11.7+/ - 7.2dB | 90% | 12.2+/ -7dB | Lateralization-00% Blunting-00% Infection -00% | Lateralization-00% Blunting-00% Infection-00% |
| 6 | MehradRougha et al. ⁴ in 2014 | 96.42 % | 16.10 +/- 4.89d B | 92.85 % | 15.78 +/- 3.40d B | Re-perforation-3.57% | Re-perforation-3.57% Blunting-3.57% |
| 7 | Panchal V et al. ⁷ in 2015 | 90% | 14.5+/ - 7.236 dB | 95% | 18.75 +/- 5.35d B | Not mentioned | Not mentioned |
| 8 | MylanahalliDoddarangaiahprakash et al. ⁸ in 2014 | 92% | 4.78d B | 96% | 8.50d B | Not mentioned | Not mentioned |
| 9 | Kuldec E et al. ⁹ in 2015 | 89.1 % | | 90.5 % | | Lateralization -00% Retraction-8.2% | Lateralization-5.6% Retraction-3.8% |
| 10 | Our study 2015 India | 91.3 % | 3.57+/ - 6.61d B | 96.55 % | 6.62+/ - 6.86d B | Retraction-4.35% Tympanosclerosis-4.35% Deterioration in hearing-4.35% Residual perforarion-8.70% | Retraction-3.45% Tympanosclerosis-00% Deterioration in hearing-3.45% Residual perforarion-3.45% |

Abbreviations- UT-conventional underlay technique, OUT-over-underlay technique, GTR- graft take-up rate, HI-hearing