Retrospective Study on Healing Outcomes after Placement of Dry Gel Foam Vs. Medicated Gel Foam in External Auditory Canal During Myringoplaty Post Graft Placement

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***Abstract*- Aim**: To study and compare the temporalis fascia graft uptake in myringoplasty in cases of inactive chronic otitis media (mucosal type) with medicated and without medicated gel foam in the external ear canal.

Objective: To compare the percentage of graft uptake (closure of tympanic membrane perforation)

Study design: Retrospective study

Setting: SRM Medical College Hospital, Kattankulathur

Study size: 100 patients, 50 with medicated gel foam, 50 with non medicated gel foam.

Patients:

1. Age: 15-65 years of age both sexes.
2. Patient with small, medium, large central and subtotal perforations.
3. Patients with only mild to moderate conductive hearing loss.
4. No evidence of active infection in nose, throat and paranasal sinuses.

Result: Of the total of 100 patients taken into the study 92 patients had successful outcome. Of them 45 belonged to the control group namely non medicated gel foam technique and 47 belonged to the test group namely the medicated gel foam group. Among the unsuccessful outcome 5 patients belonged to the control group and 3 belonged to the test group. The overall success rate was 92 %.

Conclusion: Medicated gel foam with ciprofloxacin and dexamethasone has broad spectrum coverage, shown to have a higher graft uptake than non medicated gel foam.

***Index Terms*-** medicated gel foam, myringoplasty, tympanoplasty, and temporalis fascia grafting.

I. INTRODUCTION

Myringoplasty is the surgical technique used to seal tympanic membrane perforations using graft materials.

In 1878 Berthold devised the term myringoplasty; in 1952 Wullstein formally announced a technique for closing tympanic membrane perforations. In 1958 Heerman used temporalis fascia as a grafting material which has become the gold standard now. Myringoplasty is done under local or general anaesthesia where raising a tympanomeatal flap, with visualization through an aural speculum. The rim of the perforation is excised and the under surface of the drum remnant denuded of squamous epithelium, the graft is then placed medial to the perforation. After the surgery Gel foam were carefully packed from the grafting surface, beginning from the anterior sulcus. In the control group non medicated gel foam was used while in the test group medicated gel foam was used .The new drum is usually formed in about a period of 1 to 3 weeks.

Initially gel foam was used according to Cushing's intentions as a haemostaticum in neurosurgeries.

Light & Prentice et al[1] (1945) noted that gel foam caused a mild cellular reaction dominated by an invasion of polymorphonuclear cells. Within 3-5 weeks the gelatin sponge had disappeared, however, leaving no reactions. Blaine et al[2] (1951) tried gel foam not only as a haemostaticum but also as a substitute for a destroyed tissue e.g. muscle.

Medicated eardrops have been used since time in memorial; in ancient times the Egyptians used ear candling to remove wax. Increased concentrations of drug levels in the affected regions and reduced systemic side effects have made ear drops the choice of treatment for ear infections. Penetrating through stratum corneum via transappendageal and epidermal routes the antibiotic preparations are able to attain MIC (Minimum Inhibitory Concentrations) easily when compared to systemic routes.

Ototoxicity of aminoglycoside ear drops is due to the free radical injury to the cochlea and the vestibule.

With the advent of fluroquinolone preparations the ototoxicity has been greatly reduced, data from human studies shows that ototoxicity from antibiotics is 1 in 10000 patients.

House JR 3rd, House LK [3] (2014) noted that the commonly used ear drops like polymyxin b , neomycin and hydrocortisone show no ototoxicity in tympanoplasty surgery.

II. AIM

To compare surgical outcomes of myringoplasty in inactive chronic otitis media with medicated gel foam and with non medicated gel foam in the external auditory canal during myringoplasty post graft placement.

III. OBJECTIVES

To compare the percentage of graft uptake (closure of tympanic membrane perforations).

IV. MATERIALS AND METHODS

This is a retrospective study consisting of 100 patients in a tertiary care hospital. All patients in our study were between 15-65 years of age; both sexes were included in the study. On examination of tympanic membrane small, medium, large and subtotal central perforations were seen. Pure tone audiometry was done in all patients and patients with only mild to moderate conductive hearing loss were included in this study. Patients had no evidence of active infection of nose, throat and paranasal sinuses.

Investigations included pure tone audiograms (preoperative and post operative), x ray both mastoids, laboratory investigations (complete blood counts ,renal function tests) and examination under the microscope.

Of the 100 patients who underwent myringoplasty under general anaesthesia in the study, medicated gel foam was placed in the external auditory canal of 50 patients and non medicated gel foam was placed in the external auditory canal of 50 patients.

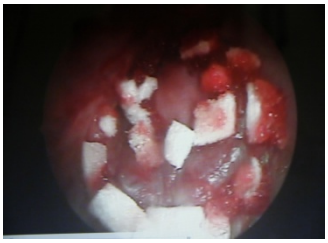

IMAGE 1 (per operative picture showing non medicated gel foam placed over the tympano meatal flap in the external auditory canal)

The outcome was deemed a success if temporalis fascia graft was taken up resulting in an intact and mobile tympanic membrane in 6 weeks.

V. RESULTS

The mean age in our study population was 30 years. In the control group (with non medicated gel foam) the mean age was 30 years and in the test group (with medicated gel foam) the mean age was 30years. There was no significant difference between the two groups.

The sex distribution in the study population consisted of 65 females (65%) and 35 males (35%) patients.

AIn each group male to female ratio was almost similar. In the control group 31 were female (62%) and 19 were male (38%). In the test population 34 were female (68%) and 16 were male (32%).

The most common symptoms with which the patient presented were hard of hearing and previous history of ear discharge. The mean duration of the ear discharge in the control group was 75 months and in the test group was 63 months.

The other important detail is the duration of dryness of the ear (inactive).

The discharge free period was 4 months in both the control and test group.

The mean duration of hard of hearing in control group was 23 months and in the test group it was 30 months.

The distribution of the size of the perforation between the two groups is discussed. Among the 100 patients 58 patients had medium sized perforations. Medium sized perforations are those that had perforation involving either 2 or 3 quadrants of the tympanic membrane. Perforations involving the 4 quadrants were named as large central perforation. Perforations involving only a single quadrant were termed as a small perforation. 30 patients had subtotal perforation and 12 patients had small perforations. By comparing the size of the perforation in relation to the outcome of the study population, all small sized perforation was successful. Medium sized perforation had maximum successful outcome 55 out of the 92 successes and subtotal perforation had maximum unsuccessful outcomes 5 out of the total unsuccessful outcomes.

It was noted that the patients with medium sized perforation the graft take up or the healing was better when compared to the subtotal perforations. In the 15 patients who had subtotal perforation in the control group, 2 of them had a residual or reperforation in the follow up period. Among the successful outcomes subtotal perforation was 27.12%. With small perforations the procedure was successful in 100% of the cases. In the test group medium sized perforation had the maximum success rate among the patients with successful closure of the perforation. 61.6 % of the successful cases in the test group had a medium sized perforation. With small perforations the procedure was successful in 100% of the cases.

In the control group the mean pre operative air bone gap 29dB, post operative air bone gap was 19dB. In the test group the pre operative air bone gap 26dB, post operative air bone gap was 14dB. The pneumatisation of the mastoid in the study population revealed that 68 patients had pneumatised mastoid and 32 had sclerosed mastoid. In the test group 31 patients had pneumatised mastoid and 19 patients had sclerosed mastoid. In the control population 36 patients had pneumatised mastoid and 14 patients had sclerosed mastoid.

Of the total of 100 patients taken into the study 92 patients had successful outcome. Of them 45belonged to the control group namely non medicated gel foam technique and 47 belonged to the test group namely the medicated gel foam group. Among the unsuccessful outcome 5 patients belonged to the control group and 3 belonged to the test group. The overall success rate was 92 %.

VI. DISCUSSION

The aim of our study was to find the outcome of myringoplasty with using medicated gel foam and non medicated gel foam, in the external auditory canal post graft placement .

The choice of medication used in all the cases was ciprofloxacin and dexamethasone ear drops (ciprofloxacin 0.3% with dexamethasone 0.1%) in accordance with Roland and colleagues [4] who did a multicenter study that compared the clinical efficacy of various topical antibiotics. The study showed

that ciprofloxacin plus dexamethasone showed higher bacterial eradication and more rapid symptom improvement.

Rosenfeld and colleagues[5] showed that fluroquinolone topicals have 8% higher bacteriologic cure rate when compared to the non quinolone topicals.

In contrast to the aminoglycoside topicals , ototoxicity has not been suggested in fluroquinolone topicals in both animal and human data [7],

The 100 patients were distributed in the control group (50) and test group (50). The age group included in the study was from 15-65 years. The reason was to exclude the confounding factor of upper airway infection and Eustachian tube dysfunction that happens in younger children. This factor was considered taking into account the study of Vrabec et al [8] who found better success with advancing age. In both our study groups the mean age group was 30 years which was comparable to the study conducted by Mani Lal Aich et al[9] where the mean age was 27 years. All our cases have been operated by transcanal route and has a success rate of 92% is comparable to the study Mani Lal Aich et al[9] which showed 87.5% success rate

The audiological evaluation of the patients was analysed. The average preoperative pure tone average was 39dB and 38dB in control and test group. The average air bone gap was 29dB and 25dB in the control and test group. The improvement in hearing was 10 dB and 13 dB in the control and test group.

The closure of air bone gap was 10 dB band 12dB in the control and test group. The closure of the air bone gap was comparable to the study by Sudhangshu Shekar Biswas et al[10] in which the closure was 11dB.

Medium sized perforation was the most common in our study (58/100) which was similar to the study by Sudhangshu Shekar Biswas et al[10]. The distribution of perforation in both groups was closely matching each other. The success rate with small size perforation was high which was comparable to Mani Lal Aich et al[9] where the success rate was 100% with small sized perforations. The success rate with subtotal perforation was 76.6 % in our study population which was almost similar compared to the study of Mani Lal Aich et al[9] where it was 75% and Sudhangshu Shekar Biswas et al[10] showed a success rate of 77.7%. Tympanosclerotic patches were found in 4 patients and 3 patients had successful outcome.

The use of only non medicated absorbable gel foam for packing in otological surgery in animals showed increased case of adhesions and post operative inflammatory reaction according to Sten Hellstrom, Bengt Salen and Lars-Eric [11].

Wiesenthal AA, Garber LZ [12] compared the conventional method of packing external auditory canal with medicated gel foam to a newer packing technique of gel foam powder, thrombostat, bacitracin ointment and acetic acid. There was not much difference in the success rate of both the procedures.

VII. CONCLUSION

Medicated gel foam with ciprofloxacin and dexamethasone when used during myringoplasty in external auditory canal post graft placement showed to have a better temporalis fascia graft uptake level. Thus the medicated gel foam has broad spectrum coverage for bacteria and the steroid reduces the chances of local inflammatory reactions. With other studies indicating the same . Thus the usage of medicated gel foam holds a higher ground than the non medicated gel foam in the external auditory canal during myringoplasty .Endoscopy in otological surgeries has opened new vistas and gained popularity in otological procedures

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