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Surgical versus Conservative Management of Granular Myringitis: A single-centre Randomized Control Trial

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Abstract

Background: Treatment of granular myringitis (GM) is diverse with no definitive management. **Objective:** The aim of the present study was to see the effectiveness of different interventions for treating granular myringitis. **Methodology:** This was a single centred, parallel, randomized control trial. This study was done at the Specialized ENT Hospital of SAHIC, Dhaka from July 2010 to June 2012. Patients presenting with granular myringitis of 18 years of age or more with both sexes were included. All patients were divided into two groups by simple random sampling method of which patients of group A were treated by surgical treatment and that of group B were treated by medical treatment. Medical treatment was given in the form of topical ear drops and surgical treatment was performed by surgical debridement of granulation tissue followed by chemical cauterization. Repeated follow up was performed up to 6 months in both groups of treated patients. The primary outcome was the resolution of granulation tissue. During follow-up the secondary outcome variables were recurrence, perforation of the TM and any other complications or complain from the patients. **Results:** A total number of 60 patients were studied of which 30 patients were treated medically and 30 patients were treated surgically. The cure rate was higher in surgical treatment (80%) than conservative (16.7%) (p=0.011). The recurrence rate (17.24%) is also less in surgical group compared to medical treatment group (77.27%) (p=0.001). **Conclusion:** Surgical treatment is a more successful treatment modality for granular myringitis. *[Journal of National Institute of Neurosciences Bangladesh, 2019;5(1):64-68]*

Keywords: Granular Myringitis; tympanic membrane; surgical management; conservative treatment

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Introduction

Granular myringitis is a localised chronic inflammation of the lateral surface of the tympanic membrane (TM), characterised by lateral squamous de-epithelialisation and granulation formation on the TM in the absence of middle ear disease[1-3] This minor disease of external ear causes considerable discomfort and concern to the affected individual & also draws the attention of the otolaryngologists due to the diagnostic dilemma and the intractable course of the disease.

The relative lack of attention given to granular myringitis in the literature can cause this condition to be overlooked in the care of patients with chronic ear complaints[1]. Such inattention can delay the initiation of appropriate treatment, and can further complicate management[4]. It is assumed that, left untreated for a long period, recovery involves scarring of the tympanic membrane and external auditory canal wall, and can lead to stenosis of the ear canal, thickening of the tympanic membrane and hearing impairment[5-7].

Three main treatment modalities are mentioned in the literature for granular myringitis. These are- topical

antibiotic with steroid drops; cauterisation of granulations or debridement of granulation tissue[1,5,8]. However, no universal treatment has been proven to be effective in every case[8]. The disease responds readily to the topical antibiotic and steroid drop treatment but recurrence is common. In fact, the condition typically has a relapsing and remitting course[1]. On the other hand, it is often mistaken for chronic otitis media and such confusion prolongs the initiation of the appropriate management and sometimes leads to needless tympanomastoid surgery. So the otologists should be aware of this clinical entity and its varied presentation. Moreover, a successful evidence based treatment guideline is necessary to treat and to prevent the recurrence of granular myringitis. The purpose of the present study was to compare surgical and medical treatment of granular myringitis.

Methodology

Design Overview: This study was designed as single centred, randomized control trial. This was performed at the specialized ENT Hospital of SAHIC, Dhaka, Bangladesh. The study was carried out from July 2010 to June 2012.

Participants and Selection criteria: All patients presented with granular myringitis with 18 years of age or more in both sexes were selected as study population. In all cases diagnosis was confirmed by examining the ears under the operating microscope. Any patient with perforation of the tympanic membrane with granulation

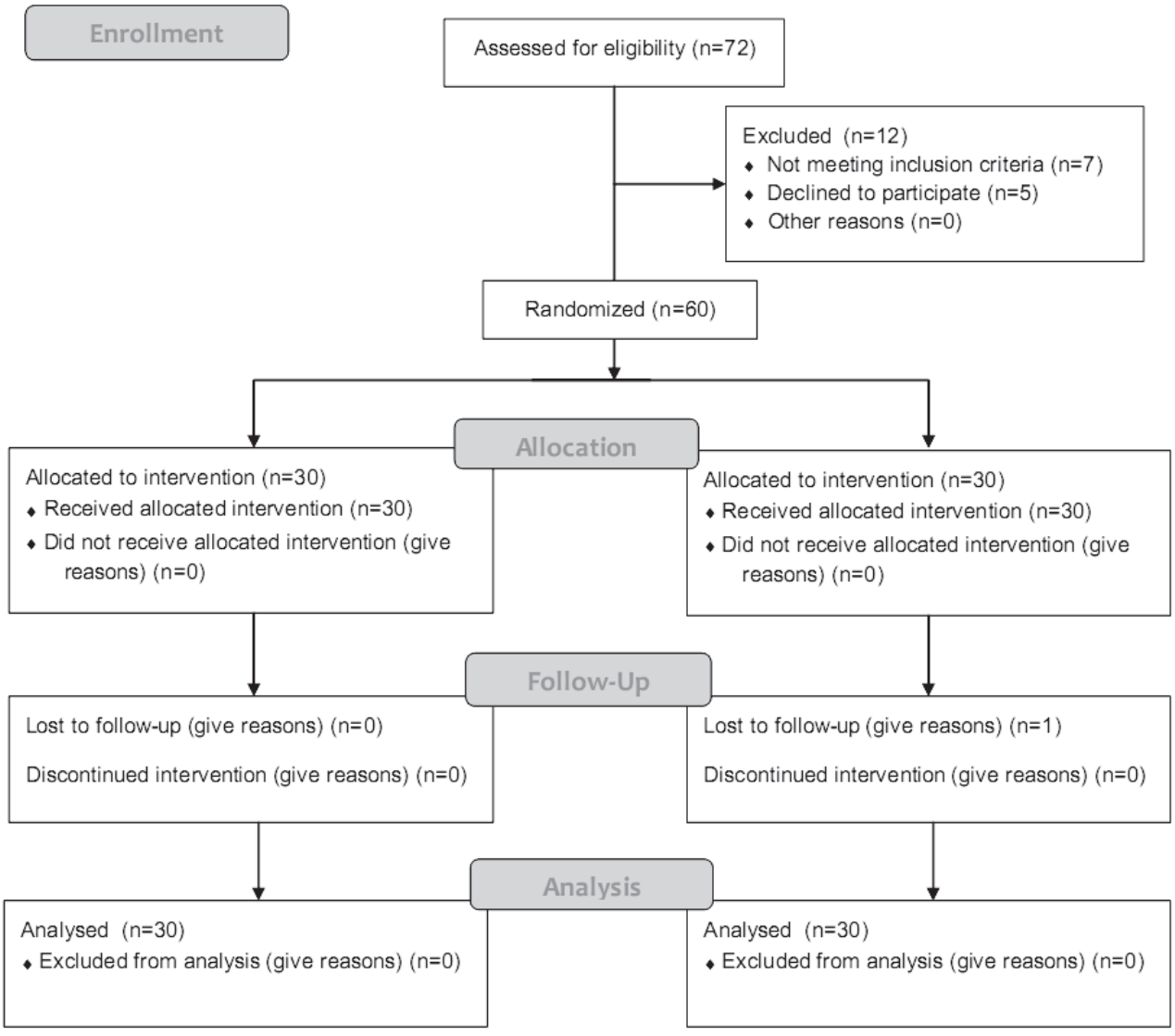

Figure 1: The CONSORT Flow Diagram showing the flow of participants through each stage of this randomized trial.

in the remaining part, pregnant women, patients with diabetes mellitus or other systemic diseases were excluded from this study. Impedence audiometry was also done to exclude an underlying perforation.

Randomization and Intervention: 60 patients were divided into two equal groups by computer generated simple random sampling method designated as group A and group B. In group 'A' surgical debridement of granulation tissue was performed followed by application of silver nitrate solution on the raw surface for chemical cauterization. In group 'B' medical treatment was given in the form of topical ear drops containing antibiotic (ciprofloxacin) and steroid (dexamethasone) for a period of 14 days.

Procedure of Surgical Intervention: For surgical treatment, local anaesthetic (lignocain with 1:100000 adrenalin) was administered in the external auditory canal at the junction of bony and cartilaginous part. A good view of the operative field was obtained by high microscopic magnification (X6 or X10). Granulation tissue was removed using small granulation forceps. After removal of granulation tissue, the raw surface was cauterized by 30% silver nitrate solution using a cotton tip applicator.

Outcomes Measures and Follow-up: Patients were followed up to assess the outcome at the end of 1 month and 6 months. The primary outcome was the resolution of granulation tissue. This was evaluated by further microscopical examination of the TM. During follow-up the secondary outcome variables were-recurrence, perforation of the TM and any other complications or complains from the patients.

Ethical clearance: Prior to the commencement of this study the research protocol was approved by the local Ethical Review Committee (ERC) of the Hospital. The aims and objectives of the study along with its procedure, methods, risks and benefits were explained to the patient in easily understandable local language and informed consent was taken from each patient. There was no extra financial burden to patient's party. All the information and records were kept confidential.

Statistical Analysis: Data collection, treatment and analysis were conducted by the author. All data were recorded systematically in a preformed data collection form. The quantitative data was expressed as mean and standard deviation and qualitative data was expressed as frequency distribution and percentage. All data in the questionnaire was coded. The chi-square test was used to compare categorical data. A probability (p) value of less than 0.05 was considered statistically significant, and a value of 0.01 or less was considered highly statistically significant.

Results

The mean ages of group A and B were 34.23±14.734 and 30.60±7.93 years respectively. The age difference between the groups was not statistically significant (p=0.241) (Table 1).

Table 1: Distribution of age among the study population (n=60)

Age group	Group A(Surgical)	Group B(Medical)	Total
<25 years	9(30.0%)	8(26.7%)	17(28.3%)
25 - 34 years	11(36.7%)	14(46.7%)	25(41.7%)
> 35 years	10(33.3%)	8(26.7%)	18(30.0%)
Total	**30(100.0%)**	**30(100.0)**	**60(100.0)**
Mean age±SD	34.23±14.73	30.60±7.93	P value*= 0.241

*Independent t test was done to see the association
*p value less than 0.05 was taken as statistically significant

After 1 month of treatment the granulation tissue was resolved in 29(96.7%) and 22(73.3%) patients in groups A and B respectively. Failure to improve was considered as treatment failure. This was occurred in 1(3.3%) case in group A and 8(26.7%) cases in group B. The difference between treatment outcome of surgical and medical groups was statistically significant (p=0.011) (Table 2).

Table 2: Distribution of Outcome at 1 month (n=60)

Treatment outcome	Group A	Group B	P value*
Resolved	29(96.7%)	22(73.3%)	0.011
Treatment failure	1(3.3%)	8(26.7%)	
Total	**30(100.0%)**	**30(100.0%)**	

*Chi-square test corrected by Fishers' exact test
*p value less than 0.05 was taken as statistically significant

The complication rate was 23.7% (in 7 cases) in the surgical group. Among them perforation of the TM was in 4 (13.3%) and scarring of the TM was in 3 (10%) cases. The only complication in the medical treatment group was otomycosis in 3 (10%) cases. The statistical difference between surgical group and conservative group was significant (p=0.016) (Table 3).

The disease recurred in 5(17.24%) cases in group A and 17(77.27%) cases in group B among the resolved cases. The difference of recurrence rate was statistically significant (p=0.0001) (Table 4).

Regarding the final outcome of treatment, it is evident that complete resolution occurred in most of the patients-24(80%) in group A and only

Table 3: Complications after Treatment among the Study Population (n=60)

Complications	Group A	Group B	P value*
Perforation of TM	4(13.3%)	0(0.0%)	0.016
Scarring of TM	3(10.0%)	0(0.0%)	
Otomycosis	0(0.0%)	3(10.0%)	
No complication	23(76.7%)	27(90.0%)	
Total	**30(100.0%)**	**30(100.0%)**	

*Chi-square test corrected by Fishers' exact test
*p value less than 0.05 was taken as statistically significant

Table 4: Recurrence at Four Month among the Resolved Cases

Recurrence	Group A	Group B	P value*
No recurrence	24(82.75%)	5(22.72%)	0.0001
Recurrence	5(17.24%)	17(77.27%)	
Total	**29(100%)**	**22(100%)**	

*Chi-square test was performed
*p value less than 0.05 was taken as statistically significant

5(16.7%) patients in group B. On the other hand, treatment failure and recurrence is very high 25(83.3%) in group B patients. The final treatment outcome of the group B patients was given a statistically significant result (p=0.001) (Table 5).

Table 5: Final outcome at 6 months among the study population

Outcome	Group A	Group B	P value*
Complete Resolution	24(80%)	5(16.7%)	0.001
Treatment failure and Recurrence	6(20.0%)	25(83.3%)	
Total	**30(100.0%)**	**30(100.0%)**	

*Chi-square test was performed
*p value less than 0.05 was taken as statistically significant

Discussion

Granular myringitis can present in different forms, in recurrent episodes, with bilateral involvement and is encountered not infrequently in otolaryngology practice. A study from Israel[9] has shown that 0.41% of patients' population attending an otology centre presented with granular myringitis.

The age of our study population ranged from 18 to 70 years. Most patients were ranged between 25 to 34 years of age in both groups. Mean age for surgical group was 34 years and the conservative group was 31 years. Of the study group, 55% were male and 45% were female (male female ratio was 11: 9). The mean age in the study conducted by Jung et al[11] was 29 years and male to female ratio was 7:23. However, in El-seifi and Foud's study[10] the mean age was 38 and male to female ratio was 49:45. So it is quite evident that age and sex at the presentation can be variable in different studies.

Poor hygine, nutritional condition and hot humid temperature are said to increase the chance of granular myringitis formation[12]. This explains why granular myringitis is more common in Bangladesh and the Indian subcontinent. However, no study has been found in the subcontinent to see the prevalence of granular myringitis.

Outcome of treatment was first assessed after 1 month. Out of 30 patients in the surgically treated group, 29 resolved after 1 month (96.7%). One patient did not improve and was considered as treatment failure (3.3%). On the other hand, 22 patients (73.3%) resolved after 1 month of treatment in medical group and remaining 8 patients (26.7%) failed to improve, which were considered as treatment failure.

Repeated follow up was performed at the end of the 1 month and the final assessment was done at the end of the six months. 5(17.24%) out of 29 surgically treated patients showed recurrence of granulation tissue whereas 17 (77.27%) out of 22 patients in medical treatment group developed recurrence of the disease. So it is evident that recurrence rate is quite high following conservative treatment in our series. Finally it can be said that 24 patients (80%) recovered completely following surgical treatment and only 5 patients (16.66%) recovered without recurrence following conservative management (p =.001). These findings in our study are in line with other international studies. In the Eygypt El- seifi and Fouad[10] showed that out of 48 surgically treated patients 46 recovered with no recurrence. Conversely, all 26 patients developed recurrence after topical antibiotic and steroid drop therapy. The study concluded that the surgical excision reduced the recurrence by 80%.

According to the hypothesis posed by El-seifi and Fouad[10], complete excision of all granulation tissue may have a place in the long term management of granular myringitis. Another study supported this hypothesis where endoscopy aided laser ablation of all granulation tissue leads to resolution of 18 out of 21 cases after single treatment[13-14].

Lee[15] suggested another treatment modality with daily irrigation of external auditory canal by dilute vinegar solution. Subsequently Jung et al[11] demonstrated that 96.0% reduction in recurrence of granular myringitis

following treatment with dilute vinegar compared with ofloxacin ear drop. Observing all these results, a systematic review[16] concluded that alternative therapies should be considered when granular myringitis is encountered.

Although complications are not very frequent, it is a risk of the surgical debridement procedure. In this study, 4 patients (13.07%) had accidental perforation during the procedure and this complication may be far worse than the symptoms of the disease. Scarring of tympanic membrane was observed in another 3 patients (10%) which may be due to the cauterisation with silver nitrate that could lead to loss of the middle fibrous layer of the tympanic membrane. The only complication in conservative group was development of otomycosis in 3 patients (10%).

Conclusion

It can be concluded from this study that complete surgical excision of all granulation tissue with silver nitrate cauterisation of the raw surface is a more efficacious treatment of granular myringitis compared to the topical antibiotic drop therapy, as also shown by the quoted studies. Our recommendation for the management of granular myringitis is to start the treatment with topical antibiotic and steroid ear drops. If the disease recurs, surgical management should be considered. To avoid accidental perforation during the procedure, careful removal of granulation tissue under high magnification is strongly recommended.

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