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ORIGINAL ARTICLE

EVALUATION OF EFFECTIVENESS OF MYRINGOTOMY AND MYRINGOTOMY WITH VENTILATION TUBE INSERTION AS TREATMENT OF OTITISMEDIA WITH EFFUSION IN CHILDREN

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ABSTRACT: BACKGROUND: Considerable uncertainty and controversies exists regarding the surgical treatment options of Otitis media with effusion (OME). As untreated or improperly treated longstanding OME causes problems in social and intellectual behavior in children, it is of great public health importance. **OBJECTIVES:** To compare the effectiveness of myringotomy with that of myringotomy with ventilation tube (VT) insertion as treatment of OME and to find out long-term sequlae of VT insertion. **METHODS AND MATERIALS:** Tertiary care hospital level prospective follow-up study was conducted in 50 children of 3 to 10 years of age with history of OME and adenoid hypertrophy. They were randomly divided into two groups. All children had adenoidectomy and along with that one group had myringotomy and other group underwent myringotomy and ventilation tube insertion. The patients' characteristics were prospectively recorded during the study period of one year starting from January 2013. Results were analyzed. There is significant improvement in hearing in myringotomised children than those with ventilation tube insertion. (Student t test, $p<0.05$) and tympanic membrane appear more towards normalcy (Fisher's exact test, $p<0.05$) in those children after one year. **CONCLUSION:** The insertion of ventilation tube after myringotomy has not much beneficial effects on hearing in long-term. Ventilation tubes also cause pathological changes in the tympanic membrane such as tympanosclerosis and perforation.
KEYWORDS: Longterm sequlae-Otitis media with effusion, ventilation tube, tympanostomy.

INTRODUCTION: Otitis Media with Effusion (OME) is very common in children, especially between one and three years of age with a prevalence of 10% to 30% and a cumulative incidence of 80% at the age of 10 years.(1) OME is defined as the chronic accumulation of mucus within the middle ear and sometimes in the mastoid air cell system.(2) The functional effect of OME is a conductive hearing loss of about 25-30db associated with fluid in the middle ear. Both the high incidence and high rate of spontaneous resolution suggest that the presence of OME is a natural phenomenon, its presence in some stage of childhood being a normal finding. But some children with OME may go on to develop chronic otitis media with structural changes like tympanic membrane retraction pockets, erosion of portion of ossicular chain, cholesteatoma etc. Language delay and behavioural problems are the sequlae of OME. (1)

Considerable uncertainty and controversies exists regarding the management of OME. The surgical treatment options include Ventilation tube (VT) insertion, adenoidectomy or both. Although it seems clear that ventilation tubes improves hearing in the short term, beneficial long term effects have been elusive.(1)

Various risks and benefits are attributed to each surgical option. As untreated or improperly treated longstanding OME causes problems in social and intellectual behaviour in children, it is of

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great public health importance. No much study has been documented on long-term follow up and benefits of children treated surgically for OME in south Indian school going children, including children of Kerala till now.

OBJECTIVES: Objectives of this study are to compare the effectiveness of myringotomy alone and that of myringotomy and ventilation tube insertion as treatment of OME and also to find out the long term sequlae of VT insertion.

MATERIALS AND METHODS: This is a Tertiary care hospital level prospective follow-up study. Fifty children aged above 3 and below 10 years attending ENT outpatient unit of medical college Trivandrum, for a period of January 2013 to December 2013 are included in the study.

INCLUSION CRITERIA:

1. Age above 3 and below 10.
2. Children suffering from OME as diagnosed by impedance audiometry (Tympanometry), Pure tone audiogram and pneumatic otoscopy. PTA air-bone gap should be at least 25db. They should have taken medicines for OME (Steroid nasal spray 200microns/day in two divided doses, systemic decongestants and antihistamines) at least for 12weeks but without any clinical benefit.
3. All children having associated adenoid hypertrophy(grade 3 or more)
4. Willing for randomisation into two groups and getting treatment specified in each group.

EXCLUSION CRITERIA:

1. Child known to have allergic rhinitis/taking medication for allergy/ bronchial asthma.
2. OME caused by any reason other than adenoid hypertrophy.
3. Not willing for randomisation and treatment strategy.
4. Children with cleft palate even if repaired.
5. Children with bifid uvula, Down/Turner syndrome.
6. Child having sensorineural hearing loss.

Diagnosis of OME is confirmed by same specialist using PTA, Tympanogram and x-ray-nasopharynx lateral oblique view for adenoids. They were randomized into group A and group B as per randomisation table. Group A is treated by adenoidectomy, myringotomy and suction of middle ear fluid on both ears. Group B is treated by adenoidectomy, myringotomy and ventilation tube insertion bilaterally. Every surgery was done under general anaesthesia. Myringotomy was done with myringotomy knife in the anteroinferior quadrant of tympanic membrane. Shepard type ventilation tube was used for insertion. All children received systemic antibiotics, analgesics, anti-inflammatory and decongestant nasal drops for 7 postoperative days. Both group is followed up at 1month, 3months, and 6months and 1year periods. During each visit pure tone audiogram, tympanogram and otoscopy done and recorded. The outcome studied were:

1) Post-operative hearing level as measured by PTA.
2) Duration of middle ear effusion as measured by tympanogram.
3) Status of tympanic membrane as measured by otoscopy.

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Ethical Considerations: Protocol of this study was approved by the Institutional Review Board of Medical College Trivandrum and is in accordance with the Helsinki Declaration of 1975 revised in 2000.

Statistical Analysis: Various possible factors were statistically compared including age, sex, cigarette smoking, attendance at daycare and other risk factors. Data was analyzed using Fischers Exact test, Students t test and Chi square test using SPSS version 17. P value less than 0. 05 is considered significant. Data was presented as the mean +/- standard deviation.

RESULTS: Among the 50 studied patients 22(44%) were males and 28(56%) females with a mean age of 5. 8+/_ 1. 8 years. All variables have got almost equal distribution among group A and group B. 36(72%) children went to daycare from 2 years of age. All children had adenoid facies.

In the right ear pre-operative mean air bone gap (A-B gap) in dB was 38. 6+/_ 7. 4 in group A and 34. 6+/_ 7. 3 in group B. After 1year it was 11+/_ 4. 4 and 15. 6+/_ 11 respectively (Fig. 1). In the left ear, pre-operative mean A-B gap was 34. 6 +/_ 6. 4 in myringotomised ear and 33. 5+/_ 7. 4dB in those who had VT insertion. After one year it became 9. 7+/_ 1. 7 and 14. 1+/_ 9. 9 in group A and B respectively. t value is 2. 17 (p = 0. 03) which is statistically significant (Fig. 2)

Preoperatively all children had B curve in tympanogram. 24(96%) children of group A had A curve in both ears by one month. All of them gave a curve by 6 months and all except one remained normal tympanogram after one year. 1(4%) showed B curve at the end of one year. In tubed ears B curve persisted in all at one month tympanogram. At 3 months 21(84%) had B curve, 4(16%) had A curve. 21(84%) of tubed ears showed A curve at the end of one year, 3(12%) had B curve and 1(4%) gave C curve. (Table 1)

Regarding right ear; Otoscopic finding in both groups preoperatively was as retracted tympanic membranes (TM) in 22(88%) and air bubble in 3(12%). After 3 months among group a, 3(12%) TM became normal appearing. 22(88%) showed retracted TM. In all those of group B, VT was in situ at third month visit. VT got expelled in all except one at the end of 6months. After one year 17(68%) of myringotomised TM became normal in appearance. 7(28%) were retracted and 1(4%) showed tympanosclerotic patch. Among group B, only 6(24%) TM became normal by otoscopy after one year. Remaining 14(56%) were retracted, 2(8%) showed tympanosclerotic patch and 3(12%) TM showed perforation in the anterior quadrant. This is significant by Fishers exact test (p<0. 01). (Fig. 3)

In the left ear, group A had retracted TM in 18(72%) and air bubble in 7(28%) in the preoperative period, and that of group B had 21(84%) retraction, air bubble in 3(12%) and hairline in 1(4%) patient. VT was present in all patients in the 3rd month follow-up and it was expelled in all except one at the 6th month visit. In one case VT got blocked at 3rd month and it was removed under local anaesthesia. After one year, among the myringotomised ears, 19(76%) had normal TM by otoscopy and other 6(24%) showed retracted TM. Tubed ears on otoscopic examination, showed normal TM in 9(36%) cases, retraction in 12(48%), tympanosclerotic patch in 1(4%) and perforation in 3(12%) after one year (Fig 4). All perforations were in the anterior quadrant. This on comparison between group A and B showed significant difference by Fishers exact test (p<0. 05).

DISCUSSION: For public health reasons, parenteral smoking has frequently been reported as a risk factor for the occurrence of OME and that is evident from present study. Attendance at daycare is

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shown to have an association with OME in this study. In this study the preoperative hearing loss (as mean A-B gap) is almost comparable among both groups. But in those cases that had only myringotomy, hearing became better over one year, as evident from reduction in A-B gap. But in those children who underwent myringotomy and insertion of VT, showed improved hearing in the early postoperative period but it worsened at the end of one year. Difference in A-B gap between groups after one year is statistically significant. This is matching with the results of Cochrane Database systematic Review.[1] and Freemantle et al.[3]

All children were having B curve in tympanogram in preoperative period. After one year majority of myringotomised ears gave A curve (Normal) in tympanogram but only 84% of tubed ears showed a curve. The overall prevalence of eardrum pathology was around 24% in myringotomised ears and 64% in tubed ears after one ear, which is comparable to the 70-75% found in tubed ears after 3-4 years by Johnston et al.[4] As per one study, the prevalence of tympanosclerosis was around 50% in previously tubed ears at all points of follow-up.[5] In the present study, of the ears with VT insertion,48% showed retracted TM,4% had tympanosclerosis and 12% had perforated TM. VT insertion leads to marked increase of tympanosclerosis prevalence which has been documented by present and number of previous studies [1, 4, 6, and 7]. Kay et al showed early postoperative otorrhoea in 9%, secondary granulation tissue formation in 1%, permanent perforation in 2% and tympanosclerosis in 31. 7 %.[1]

CONCLUSION: It is evident that the benefits of ventilation tube in children appear small. Adverse effects on tympanic membrane are common after ventilation tube insertion. Tubed ears showed complications such as persistent retraction, tympanosclerosis and perforation. From this study it is evident that in children having otitis media with effusion and coexisting adenoid hypertrophy, adenoidectomy and myringotomy is more effective than insertion of ventilation tube as a treatment option.

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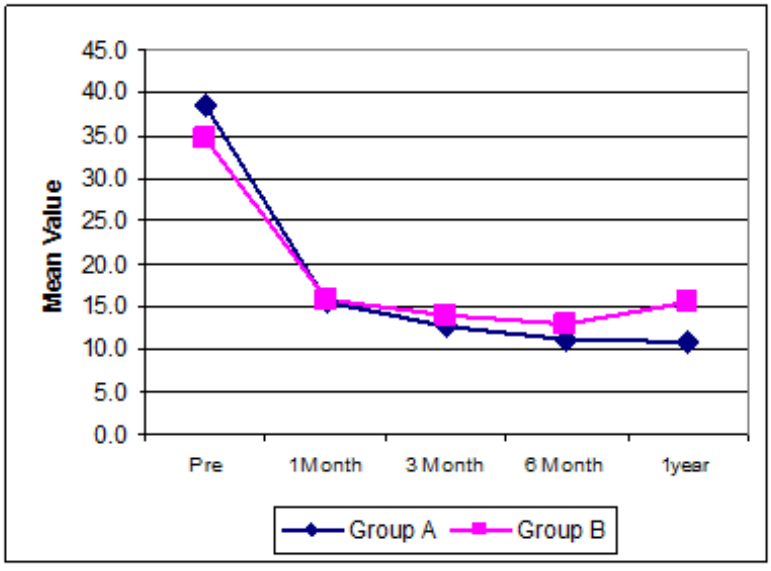

Fig. 1: Comparison of A-B gap in d B in right between groups

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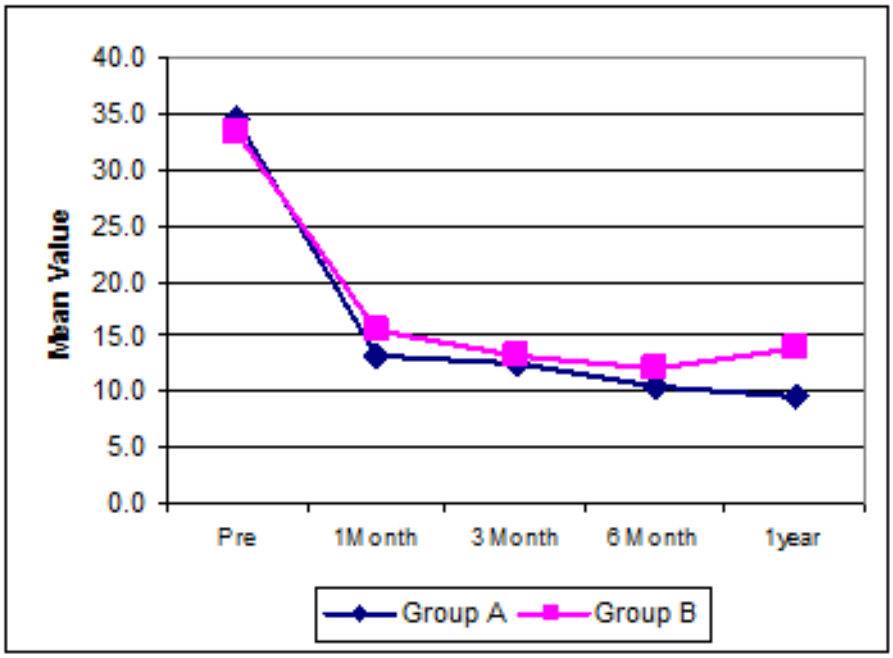

Fig. 2: Comparison of A-B gap in dB in left between groups

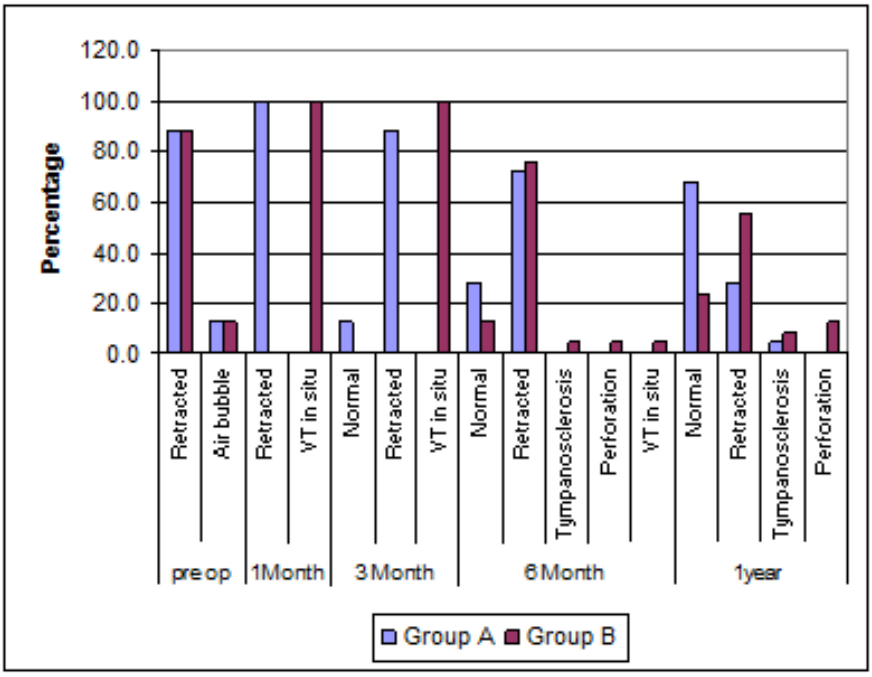

Fig. 3: Distribution of otoscopy in right based on group

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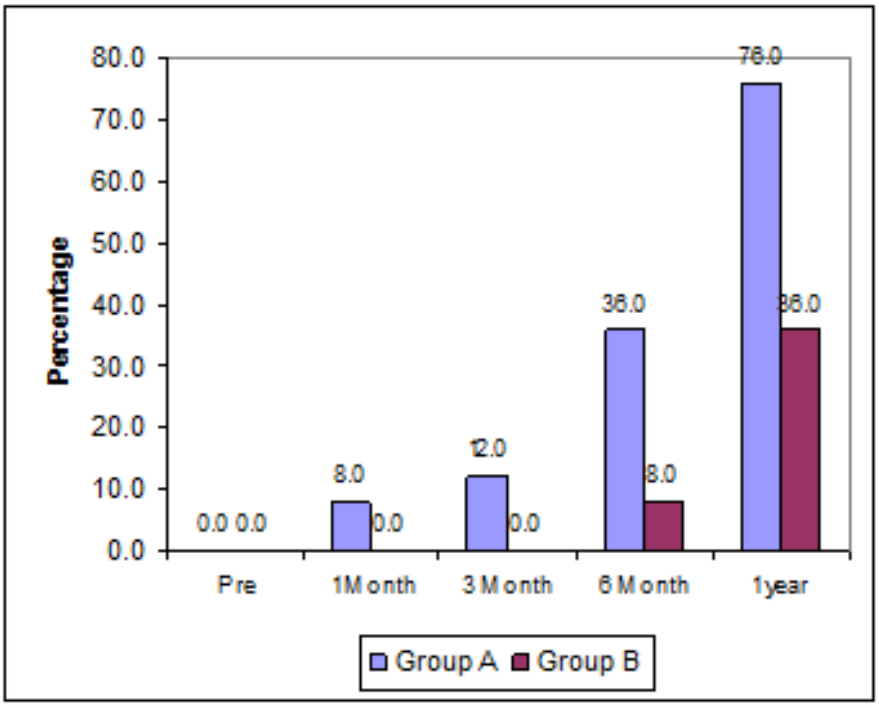

Fig. 4: Comparison of Otoscopy (Normal) in left based on group

Tympanogram		Group A		Group B		p #
		Count	Percent	Count	Percent	
Pre	A Curve	0	0.0	0	0.0	-
	B/C Curve	25	100.0	25	100.0	
1 Month	A Curve	24	96.0	0	0.0	p<0.001
	B/C Curve	1	4.0	25	100.0	
3 Month	A Curve	25	100.0	4	16.0	p<0.001
	B/C Curve	0	0.0	21	84.0	
6 Month	A Curve	25	100.0	23	92.0	0.490
	B/C Curve	0	0.0	2	8.0	
1 Year	A Curve	24	96.0	20	80.0	0.349
	B/C Curve	1	4.0	5	20.0	

Table 1: Comparison of Tympanogram based on group

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