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Surgical versus medical intervention for the treatment of concurrent otitis media with effusion in children undergoing adenotonsillectomy in the age group 5-15 years: a prospective comparative study

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ABSTRACT

Background: The aim was to study the prevalence of otitis media with effusion (OME) among children with concurrent chronic adenotonsillitis or adenoid hypertrophy and to study the outcomes of various modalities of treatment.

Methods: Over 2 years, 100 children in the age group 5-15 years undergoing adenotonsillectomy were included of which, patients diagnosed with concurrent OME were sequentially allocated into 2 groups. Group I was adenotonsillectomy and medical therapy and group II was adenotonsillectomy and myringotomy with grommet insertion.

Results: The prevalence of OME among children in the age group 5-15 years undergoing adenotonsillectomy is 21%. There is a statistically significant relationship between male gender, middle socioeconomic status, joint families, history of bottle feeding, history of exposure to parental smoking and prevalence of OME. Group II fared better in terms of clinical outcomes following surgical intervention, with a success rate of 100%.

Conclusions: Surgical treatment for OME has a better clinical outcome as compared to just medical therapy for the same.

Keywords: Otitis media with effusion, Adenotonsillectomy, Male, Bottle feeding, Parental smoking

INTRODUCTION

OME is a pathologic middle ear condition in which an effusion is present behind an intact tympanic membrane without signs of acute inflammation. It occurs due to alterations in the muco-ciliary system within the middle

ear cleft and is most commonly caused by malfunction of the eustachian tube. It forms a very significant cause of childhood morbidity and development delay and is the commonest reason in children for elective admission to hospital for surgery.^{1,2}

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Hypertrophied adenoids can form a mechanical obstruction to the Eustachian tube and contribute to the development of OME. Thus, adenoidectomy may improve the outcome of otitis media with effusion as an adjuvant surgical therapy, by improving the eustachian tube function.³⁻⁵ Other factors which are thought to contribute to the development and persistence of OME include recurrent infections of the adenoids and colonization of the nasopharynx.⁶

The treatment options for OME include conservative and surgical modalities. Conservative methods comprise of minimization of environmental risk factors and periodic follow-up, along with pharmacological therapy with antihistaminics, sympathomimetics, antibacterial agents, steroids or immune-stimulating agents. Surgical options include myringotomy with or without ventilation tube, adenoidectomy with or without tonsillectomy, either alone or with myringotomy and ventilation tubes optionally and also pressure equalization through Valsalva manoeuvre or application of Politzer balloon.⁷⁻⁹

There still exists enormous controversy regarding the efficacy of the various medical and surgical treatments of OME. Reports on the value of adenoidectomy or adenotonsillectomy in the management of OME are numerous and conflicting in opinion. The criteria for surgical intervention are uncertain and the decision to operate has always been considered difficult in view of the high rate of spontaneous resolution. This is particularly associated with the child's age and the presence or absence of intercurrent infection, which is often seasonally related. ^{10,11}

The objective of this study was to study the prevalence of OME among children with concurrent chronic adenotonsillitis or adenoid hypertrophy and to study the outcomes of various modalities of treatment. At present, there is limited literature which report a multifatorial analysis of risk factors for OME in children older than 3 years of age and there is almost no available recent literature which compares the outcomes of medical and surgical therapy for otitis media with effusion. Our study thus attempted to address these lacunae in the literature.

METHODS

This was a prospective comparative clinical study conducted in the Department of Otorhinolaryngology and Head and Neck Surgery, Mahatma Gandhi Medical College and Research Institute, Sri Balaji Vidyapeeth University, Pondicherry. Following approval of this study by the institutional medical ethics committee, from January 2018 until December 2019, 100 children in the age-group 5-15 years undergoing adenotonsillectomy were included by convenience sampling in this study due to the limited period of study. Written informed consent from the parents and assent from the children were obtained. Patients included in the study were those with complaints pertaining to and who fulfilled the clinical

criteria for chronic adenotonsillits or adenotonsillar hypertrophy. Patients with Down's syndrome, craniofacial mal-formations or submucous cleft or with contraindications to general anaesthesia were excluded from the study.

All patients underwent thorough history taking and clinical examination, which was promptly recorded on a proforma. The patients were then subjected to basic preoperative blood investigations, plain X-ray soft tissue nasopharynx (lateral view), pure tone audiometry, impedance audiometry and otoendoscopy. In addition, older children underwent diagnostic nasal endoscopy using 0 and 45 degree endoscopes. All patients were treated with antibiotics and nasal decongestants and were posted to undergo adenotonsillectomy. Those patients who were diagnosed with OME were sequentially allocated into 2 groups. Group I was adenotonsillectomy and medical therapy and group II was adenotonsillectomy and myringotomy with grommet insertion. Patients in the first group who were found to be resistant to medical therapy up to 4 months of treatment were then taken up for adenotonsillectomy and myringotomy with grommet insertion. The patients were discharged on the 4th postoperative day and were followed up after 1 week and then at 3 months, 6 months and at 1 year. In the followup, the patients were assessed in terms of resolution of complaints, hearing improvement, efficacy of grommets and rate of recurrence. Pure tone audiometry and impedance audiometry were repeated at 6 months follow up when the patient's pure tone audiometry was compared with preoperative levels.

Statistical analysis was carried out using SPSS version 19.0 (IBM SPSS, US) software with regression modules installed. Data was analyzed using percentage and ratio analysis with suitable diagrams and Chi square test.

RESULTS

The prevalence rate of OME among children in the age group 5-15 years undergoing adenotonsillectomy in the present study was found to be 21%. The mean age of the population studied was 9±2.57 years (median 8 years). The majority of the patients were found in the 5-10 years age group and the prevalence of OME was also found to be maximum in the same age group (76.2%). The prevalence of OME was much lesser in older children. But no statistically significant relationship between age and prevalence of OME could be established. This study shows a statistically significant relationship between male gender and prevalence of OME (66.6%, p=0.01, male:female ratio=1.86:1) (Table 1).

Patients with co-existing OME were found to be most symptomatic in the monsoon (47.6%) and winter (38.1%) seasons respectively, but this was not found to be statistically significant. Middle socioeconomic status families (61.9%, p=0.0278), joint families (61.9%, p=0.007), a history of bottle feeding (61.9%, p=0.0024)

and history of parental smoking (90.5%, p=0.0121) were all found to be strongly associated with the presence of OME (Table 2).

76.2% patients had hearing loss in the 0-10 dB range, out of which 38.1% had a conductive hearing loss in the range of 0-5 dB, 38.1% had a conductive hearing loss in the range of 6-10 dB and 23.8% patients had conductive

hearing loss in the range of 11-15 dB (Table 3). Group II fared better in terms of clinical outcomes following surgical intervention, with a success rate of 100% compared to 45.45% for group I. Due to ethical considerations, all 6 patients in group I who were resistant to medical therapy were subsequently added to group II and underwent myringotomy with grommet insertion (Table 4).

Table 1: Gender distribution.

Gender	Total population (%)	Total patients with OME (%)	Group I (%)	Group II (%)
Male	65 (65)	14 (66.6)	8 (38.1)	6 (28.6)
Female	35 (35)	7 (33.3)	3 (14.3)	4 (19.1)
Total	100 (100)	21 (21)	11 (52.4)	10 (47.6)
Chi square=6.54730				
P value=0.0105				

Table 2: Factors affecting the prevalence of otitis media with effusion and the distribution of symptoms in the population studied.

Factors	Variables	Total population (%)	Total patients with OME (%)	Chi square	P value
Season	Summer	12 (12)	3 (14.3)	_	0.1654
	Winter	37 (37)	8 (38.1)	3.59867	
	Monsoon	51 (51)	10 (47.6)		
Socioeconomic status	Lower	24 (24)	6 (28.6)	_	0.0278
	Middle	71 (71)	13 (61.9)	7.16199	
	Upper	5 (5)	2 (9.5)		
Family type	Nuclear	54 (54)	8 (38.1)	7.26029	0.0070
	Joint	46 (46)	13 (61.9)	7.26038	
H/O	Yes	69 (69)	8 (38.1)	0.10140	0.0024
breastfeeding	No	31 (31)	13 (61.9)	9.19149	
H/O parental	Yes	59 (59)	19 (90.5)	6 2052	0.0121
smoking	No	41 (41)	2 (9.5)	6.2952	0.0121

Table 3: Conductive hearing loss prior to intervention.

Conductive hearing loss (in dB)	Group I (%)	Group II (%)	Total (%)
0-5	2 (9.5)	6 (28.6)	8 (38.1)
6-10	5 (23.8)	3 (14.3)	8 (38.1)
11-15	4 (19.1)	1 (4.8)	5 (23.8)

Table 4: Results of medical and surgical interventions on the clinical outcomes of OME co-existing with chronic adenotonsillitis.

Groups (in %)	Total number of patients (%)	Success (%)	Failure (%)
Group I	11 (52.4)	5 (45.45)	6 (54.54)
Group II	10 (47.6)	10 (100)	0 (0)

Table 5: Hearing gain following medical and surgical interventions.

Hearing gain (in dB)	Group I (%)	Group II (%)	Total (%)
5-10	1 (4.8)	3 (14.3)	4 (19.1)
11-15	0 (0)	3 (14.3)	3 (14.3)
16-20	1 (4.8)	7 (33.3)	8 (38.1)
21-25	3 (14.3)	3 (14.3)	6 (28.6)
Chi square=8.20731			
P value=0.0419			

A majority of patients (38.1%) benefitted from the study with a hearing gain in the range of 16-20 dB. The mean hearing gain for group I was 17.29±3.43 dB and for group II was 20.98±4.03 dB; this difference was found to be statistically significant (p=0.0419) (Table 5).

DISCUSSION

This study showed the prevalence rate of OME in children in the age group 5-15 years with concurrent chronic adenotonsillitis to be 21%. Sinha et al found a higher prevalence rate of 33%. The higher prevalence rate in their study may be explained by the inclusion of children less than 5 years of age in the study and this is reflected in the studies by Kadhim et al and Nguyen et al both showing higher prevalence rates of OME among children in the 1-3 years age group. A large population study by Kadhim et al showed higher rates (59.3%) of OME co-existing with chronic adenotonsillitis among male children and this finding is supported by the evidence from other studies and the present study.

Tos et al, Rovers et al and Midgley et al have shown a higher prevalence of OME in the pediatric age group during the winter season, which agrees with the findings of our study, which also found a higher prevalence in the monsoon season. 12,13,15 Studies conducted by Martines et al in Sicily and Sophi et al in South India do not show any statistically significant relationship between socioeconomic status and the prevalence of OME. 16,17 This is in contrast to the findings of the present study, which showed a statistically significant relationship between middle socioeconomic status and OME. This may be explained by the smaller sample size involved in the present study. Some multivariate studies have suggested associations between contact with other children, either siblings or attendance for daycare and OME, which could potentially double the risk. 18,19 The finding in this study of a strong correlation with joint families reflects this same risk. Our study also showed a statistically very significant association between a history of bottle feeding and the prevalence of OME. Abrahams and Labbok reviewed the literature on the association of bottle feeding and otitis media and concluded that the introduction of infant formula in the first 6 months of life is associated with increased incidence of otitis media in early childhood.20 Dewey et al showed an association between parental smoking and OME for smokers of up to 20 cigarettes per day, which agrees with the results of this study; but a multivariate analysis by Engel et al could not detect any effect of parental smoking. 19,21

Patients with OME who underwent concurrent medical therapy and adenotonsillectomy showed a success rate of 45.5%, compared to the high success rate of 100% for patients who had undergone concurrent myringotomy and grommet insertion and adenotonsillectomy. This high success rate for group II may be explained by the smaller sample size. Although there are several studies regarding the use of medical therapy for the treatment of OME, no recent literature could be identified which compared success rates between medical and surgical therapy for

OME.²²⁻²⁵ All six patients who were resistant to medical therapy subsequently underwent myringotomy with grommet insertion.

Among the 16 patients who underwent concurrent myringotomy with grommet insertion, the majority of patients (75%) were found to have thick glue-like fluid. This is in contrast to the study by Sinha where glue-like fluid was found in only 6% of patients and thin serous fluid was found in 27% of patients.¹

Maw study concluded that children less than 6 years of age may be expected to respond less well to adenoidectomy than children more than 6 years of age. 4 Casselbrant et al did not recommend adenoidectomy concurrent with tympanostomy tube insertion as first line surgical treatment in children of 2-4 years of age for chronic OME. 6 But the positive outcomes of our study serve to show that adenotonsillectomy with concurrent myringotomy and grommet insertion is an effective treatment option for the treatment of OME with concurrent chronic adenotonsillitis in children in the age group 5-15 years.

The absence of any complications in our study population could be explained by the smaller sample size, careful surgical technique, comprehensive patient education and regular follow-ups. None of the subjects reported recurrences, which could be in part due to the short follow-up period of the study.

The major limitations of this study included limited period of study and follow-up, use of convenience sampling due to limited study period and limited sample size. Further large multi-centre randomized controlled trials would help eliminate these limitations.

CONCLUSION

This study showed that male gender, middle socioeconomic status, joint families, history of bottle feeding and history of exposure to parental smoking are all associated with a higher risk for OME co-existing with chronic adenotonsillitis in children in the age group 5-15 years. The results of this study also showed that surgical management for otitis media with effusion (imyringotomy with grommet insertion along with adenotonsillectomy) has a better clinical outcome as compared to medical therapy alone for the same. This is significant as there is almost no other available recent studies which compare the outcomes of medical and surgical therapy for OME with concurrent chronic adenotonsillitis in children in the 5-15 years age group.

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