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A RANDOMIZED CONTROL TRIAL OF ADENOTONSILLECTOMY WITH AND WITHOUT INSERTION OF GROMMET IN TREATMENT OF SECRETORY OTITIS MEDIA

ENT

Dr Sanjay Singh Junior Resident (Otorhinolaryngology) Krishna Institute of Medical Sciences, Karad, Maharashtra

Dr Vikas Kulkarni* Professor (Otorhinolaryngology) Krishna Institute of Medical Sciences, Karad, Maharashtra *Corresponding Author

Dr Abhay Havle Professor and Head of the Department (Otorhinolaryngology) Krishna Institute of Medical Sciences, Karad, Maharashtra

ABSTRACT

INTRODUCTION : Secretory otitis media (SOM) is a pathologic condition of the middle ear in which an effusion is present behind an intact eardrum without signs of acute inflammation. The primary line of management is medical but surgical intervention is needed in refractory and complicated cases. The various surgical treatment options recommended are adenoidectomy, myringotomy, adenoidectomy with myringotomy with or without grommet insertion and occasionally tonsillectomy. The aim of the present dissertation was to evaluate and compare the outcome of adenotonsillectomy with and without insertion of the grommet in the treatment of secretory otitis media.

MATERIAL & METHODS : A Prospective, Randomized Study conducted at KIMS, Krishna Hospital, Karad after the approval of the institutional ethical committee. The patients attending the outpatient department of ENT which fulfilled inclusion criteria and exclusion criteria, were enrolled. The study period was from December 2016 to June 2018. In this study 48 participants were divided into two groups, Group A is Study group (Adenotonsillectomy with grommet) of 24 cases and Group B is Control group (Adenotonsillectomy without grommet) (24 cases) by using simple random sampling technique, randomisation and allocation into either group was based on random number table. Follow up of study participants from both the groups was done after 6 and 12 weeks respectively and the result was studied.

RESULTS: Majority of the study subjects presented with Retracted TM (70.83% Vs 66.67%), followed by dullness over the tympanic membrane (62.5% Vs 70.83%). Air-fluid level and Pneumatic otoscopic findings were rarely observed. Majority of the study subjects presented with bilateral SOM (66.67% Vs 45.83%), followed by right-sided SOM (25% Vs 33.33%) and left-sided SOM (8.33% Vs 20.83%). The study subjects in both the groups presented with B type tympanogram (70.83% in group A and 66.67% in group B), followed by Type C (29.17% in group A and 33.33% in group B). The percentages of Symptomatic relief (95.83% Vs 58.33%) and Air-bone gap < 10 dB (75% Vs 20.83%) was comparatively found better in group A, as compared to group B. The air-bone gaps before and after surgery was compared. We reported that the reduction of mean air-bone gap was more in group A as than group B. The gaps further reduced after 12 weeks of the follow-up. (7.21 dB Vs 15.20 dB)

CONCLUSION : The management of Secretory otitis media in Group A (Adenotonsillectomy with gommet insertion) has shown better results as compared to Group B (Adenotonsillectomy without grommet).

KEYWORDS

Adenotonsillectomy, Secretory otitis media,Grommet

INTRODUCTION

Secretory otitis media (SOM) is defined as the presence of sterile fluid in the middle ear cleft. Non-suppurative otitis media and glue ear are another name frequently used for SOM. It results from alterations of the mucociliary system within the middle ear cleft and is frequently caused by dysfunction of the Eustachian tube. Especially prevalent in children with cleft palate and frequently occurs in association with upper respiratory tract infection and other disorders. Most of the time it is bilateral hearing impairment being the most common presentation leading to delayed speech , language development, poor academic performance and behavioural problems. Delayed presentation of secretory otitis media is due to its occurrence in young children who are not able to realize the hearing impairment. The prevalence of secretory otitis media is bimodal with the first and largest peak of approximately 20% at 2 years of age and a second peak of approximately 16% at around 5 years of age.[1][2]

The condition remains undetected for a long time as damage to produce hearing loss may be delayed. It is often detected on routine screening for frequent episodes of otalgia. Many studies have associated secretory otitis media and other middle ear conditions to chronic tonsillitis and hypertrophy of adenoids and URTI. Ever since adenotonsillectomy has been found effective and is advocated for treatment of SOM[3].

Adenoid hypertrophy and the closeness of the adenoids to the ostium of the Eustachian tube seem to be the most important factors in the pathogenesis of SOM. we have recently found that adenoid bacterial biofilms (recognised causes of SOM) are significantly more prevalent near the ostium, thus suggesting that the adenoids are a reservoir for biofilm-producing bacteria that can spread through the Eustachian tube to colonise the middle ear.[4]

The clinical presentation of glue ear is often undramatic. The presenting features may be hearing difficulty, delayed language development, repeated an earache, recurrent upper respiratory tract infections, behavioural, and poor educational progress. Some children complaints of aural fullness, vertigo and tinnitus.

The examination may show an amber or blue discolouration of the eardrum with thickening and loss of landmarks. Bubbles or an air-fluid level may be visible.[5] Current medical options for the treatment of secretory otitis media include antihistamine, decongestant mixtures, mucolytics, steroids, antibiotics, various kinds of Eustachian tube manipulation (Valsalva and Politzer manoeuvres), and control of risk factors.

Conditions, where surgery may be indicated are secretory otitis media for >3 months with no benefit with medical management, bilateral secretory otitis media with hearing loss >20 dB for more than 6 months, recurrent secretory otitis media, balance disturbances, structural changes of the tympanic membrane (TM) and language delay[6]

The various surgical treatment options recommended are adenoidectomy alone, myringotomy alone, adenoidectomy with myringotomy with or without grommet insertion. Possible treatment includes myringotomy with or without insertion of a ventilation tube (grommet) either alone or with adenoidectomy and occasionally tonsillectomy. 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.

Adenoidectomy alone should be considered in children with secretory otitis media associated with nasal obstruction, chronic rhinosinusitis, adenoiditis, those who have previously undergone repeat surgery for secretory otitis media, and has been reported to be most beneficial in children aged >3 years regardless of adenoid size. Under these

conditions, the aim of surgery in patients with secretory otitis media and adenoidal hypertrophy should be the complete removal of the adenoids not only in order to restore.[5]

MATERIAL & METHODS :

A Prospective, Randomized Study conducted at KIMS, Krishna Hospital, Karad after the approval of the institutional ethical committee. The patients attending the outpatient department of ENT which fulfilled inclusion criteria and exclusion criteria, were enrolled. The study period was from December 2016 to June 2018. In this study 48 participants were divided into two groups by using simple random sampling technique,, Group A is Study group (Adenotonsillectomy with grommet) of 24 cases and Group B is Control group (Adenotonsillectomy without grommet) (24 cases) by using simple random sampling technique, randomisation and allocation into either group was based on random number table. Follow up of study participants from both the groups was done after 6 and 12 weeks respectively and the result was studied. institutional ethical committee were enrolled.

INCLUSION CRITERIA:

1. All patients aged between 5 to 14 years with signs of Secretory otitis media
2. Chronic cases of Secretory otitis media with Adenoid Hypertrophy.
3. An impendance audiometry with type 'B' or 'C' curve.
4. Willing to participate in the comparative surgical comparative trial by way of informed consent

EXCLUSION CRITERIA:

1. Patients with acute/ chronic suppurative otitis media
2. Patients with a congenital deformity – cleft palate, Downs syndrome and craniofacial anomalies

RESULTS :

This study was conducted among cases of secretory otitis media admitted under the department of ENT, Krishna Institute of Medical Sciences, Karad.

In our study, according to the objectives of the study, we divided cases of SOM into two groups: Group A Adenotonsillectomy with Grommet and Group B Adenotonsillectomy without the grommet. We enrolled 24 cases of SOM in each group.

Demographic characteristics:

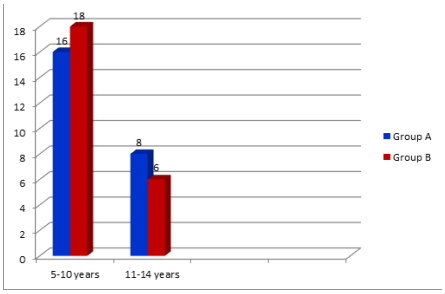
We assessed the demographic features in the study population. The study sample consists of cases of Secretory otitis media in paediatric age group, of either gender. Their distribution and comparison are given in subsequent tables:

Age distribution

In our study, Majority of the cases of Secretory otitis media belonged to 5-10 years of age group (66% in group A, while 75% in group B), followed by age group of 11-14 years (34% in group A and 25% in group B) table and graph given below.

Table 1: Distribution of study according to the age group

Age group	Group A		Group B	
	Number of cases	Percentage	Number of cases	Percentage
5-10 years	16	66%	18	75%
11-14 years	8	34%	6	25%
Total	24	100%	24	100%



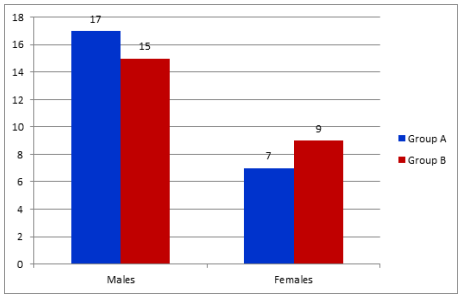
Graph 1: Distribution of study according to the age group

Gender distribution

In our study, the tables and graph given below, it shows that the number of male cases outnumbered the number of female cases in both groups. Group A consisted 17 males and 7 females while in group B 15 males and 8 females.

Table 2: Gender-wise distribution of study participants

Gender-wise distribution	Group A		Group B	
	Number of cases	Percentage	Number of cases	Percentage
Male	17	70.83%	15	62.50%
Female	7	29.17%	9	37.50%
Total	24	100%	24	100%



Graph 2: Gender-wise distribution of study participants

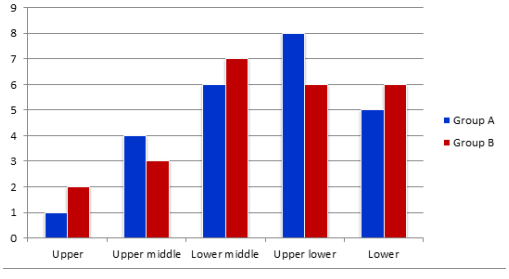
SOCIOECONOMIC CLASSIFICATION (Modified Kuppuswamy Scale)

In our study, we also assessed the socioeconomic status of our study participants, in order to interrelation with their epidemiological risk factors.

We observed that the cases were belonging to the lower middle class of SES, followed by the upper lower class of SES. The numbers and its percentages are shown given below in table and graph.

Table 3: Distribution of study participants according to their socioeconomic status (Modified Kuppuswamy scale)

Socioeconomic scale		Group A	Group B
I	Upper	1 (4.17%)	2 (8.33%)
II	Upper middle	4 (16.67%)	3 (12.5%)
III	Lower middle	6 (25%)	7 (29.17%)
IV	Upper lower	8 (33.33%)	6 (25%)
V	Lower	5 (20.83%)	6 (25%)
Total	24 (100%)	24 (100%)	



Graph 3: Distribution of study participants according to their socioeconomic status (Modified Kuppuswamy scale)

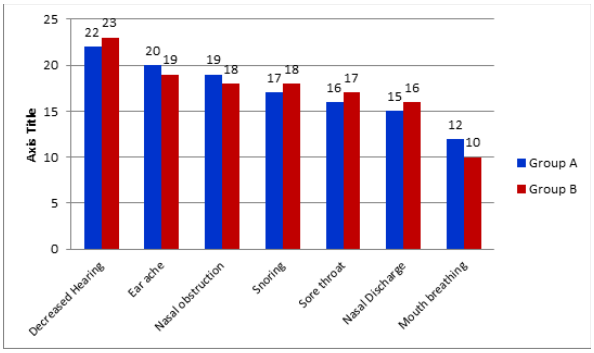
CLINICAL PRESENTATION

In our study, we evaluate the study according to their clinical presentation. We noticed that the most of the cases presented with Decreased hearing followed by Earache, Nasal obstruction, snoring, sore throat etc. The number and percentages of cases with respective complaints are given in the table and graph are given below.

Table 4: Distribution of study subjects according to their Clinical presentation

Clinical presentation	Group A	Group B
Decreased Hearing	22 (91.66%)	23 (95.83%)
Ear ache	20 (83.33%)	19 (79.16%)
Nasal obstruction	19 (79.16%)	18 (75%)

Snoring	17 (70.83%)	18 (75%)
Sore throat	16 (66.66%)	17 (70.83%)
Nasal Discharge	15 (62.5%)	16 (66.66%)
Mouth breathing	12 (50%)	10 (41.66%)
Total	24 (100%)	24 (100%)



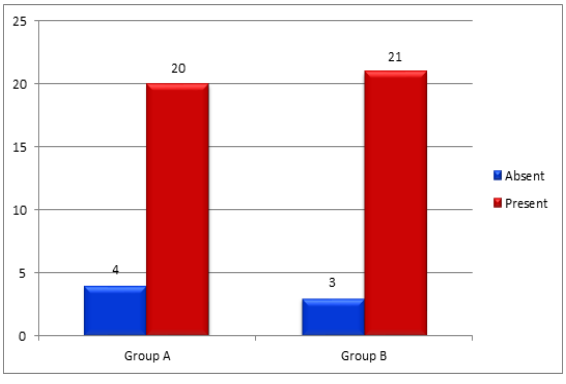
Graph 4: Distribution of study subjects according to their Clinical presentation

ADENOID FACIES

In our study, we also evaluate the study according to the presence of Adenoid facies, which is correlated with the Adenoid hypertrophy. It was observed that Group A 83.33% and Group B 87.5% of cases presented with adenoid facies (Table 5)(graph 5) given below.

Table 5: Distribution of study cases according to the presence of adenoid facies

Adenoid facies	Group A	Group B
Absent	4 (16.67%)	3 (12.5%)
Present	20 (83.33%)	21 (87.5%)
Total	24 (100%)	24 (100%)



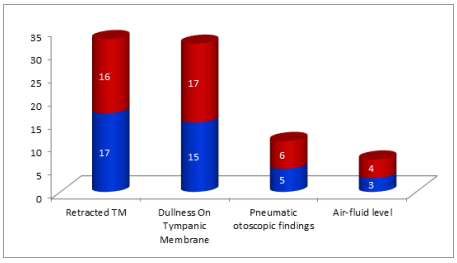
Graph 5: Distribution of study cases according to the presence of adenoid facies

OTOSCOPIC EXAMINATION FINDINGS

In our study, subjects were subjected for otoscopic examination. In which we assessed the presence of various features such as the presence of dullness over the tympanic membrane, Retracted TM, Air fluid level and Pneumatic otoscopic findings. According to our observations, the majority of the study subjects presented with Retracted TM (Group A 70.83% Vs Group B 66.66%), followed by dullness over the tympanic membrane (Group A 62.5% Vs Group B 70.83%). Air-fluid level and Pneumatic otoscopic findings were also observed ;table and graph given below.

Table 6: Distribution of study subjects according to their Otoscopic examination findings

Otoscopic examination findings	Group A	Group B
Retracted TM	17 (70.83%)	16 (66.67%)
Dullness On Tympanic Membrane	15 (62.5%)	17 (70.83%)
Pneumatic Otoscopic findings	5 (20.83%)	6 (25%)
Air-fluid level	3 (12.5%)	4 (16.67%)
Significance	X^2=0.281, p-value= 0.9638, Not significant	



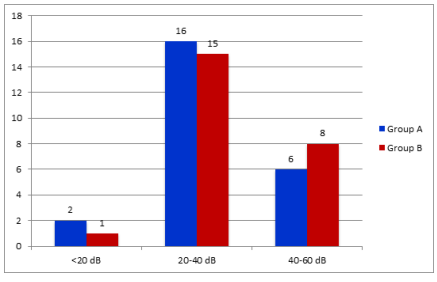
Graph 6: Distribution of study subjects according to their Otoscopic examination findings

DEGREE OF HEARING LOSS

In our study, we analysed that the study subjects according to decreased hearing present in the cases. We observed that most of the cases among both the groups were having a hearing loss between 20-40 dB (Group A 66.67% Vs Group B 62.5%) table 7 and graph are given below.

Table 7: Distribution of study subjects according to their degree of hearing loss

Hearing Loss	Group A		Group B	
	No. Of Cases	Percentage	No. Of Cases	Percentage
<20 dB	2	8.33%	1	4.17%
20-40 dB	16	66.67%	15	62.5%
40-60 dB	6	25%	8	33.33%
Total	24	100%	24	100%
Significance	X^2=0.6513, p-value= 0.722, Not significant			



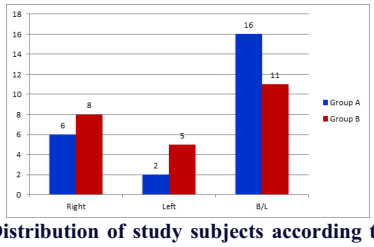
Graph 7: Distribution of study subjects according to their degree of hearing loss

LATERALITY OF SOM

In our study, we assessed the laterality of the SOM among study subjects. We observed that both the groups (A and B), the most of the study subjects presented with bilateral SOM (66.67% Vs 45.83%), followed by right-sided SOM (25% Vs 33.33%) and left-sided SOM (8.33% Vs 20.83%). The number and percentages of cases presented with a respective side of SOM are shown in the table and graph are given below.

Table 8: Distribution of study subjects according to their side involved in SOM

Side involved in SOM	Group A		Group B	
	Number of cases	Percentage	Number of cases	Percentage
Right	6	25%	8	33.33%
Left	2	8.33%	5	20.83%
B/L	16	66.67%	11	45.83%
Total	24	100%	24	100%
Significance	X^2=2.44, p-value= 0.286, Not significant			



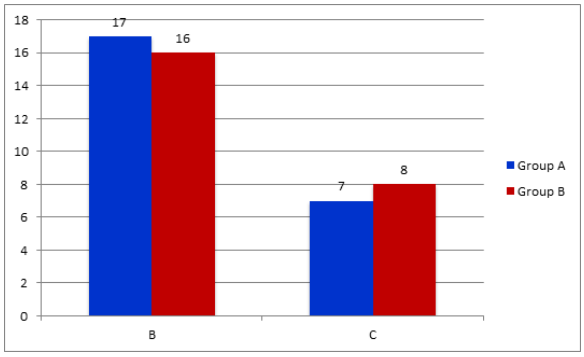
Graph 8: Distribution of study subjects according to their side involved in SOM

TYMPANOMETRY FINDINGS

In our study, we evaluated the study subjects according to their tympanometry findings. In the tables and graph given below that majority of the study subjects in both the groups presented with B type of Tympanogram (70.83% in group A and 66.67% in group B), followed by Type C (29.17% in group A and 33.33% in group B)

Table 9: Evaluation of the study subjects present their tympanometry findings

Tympanometry findings	Group A	Group B
B	17 (70.83%)	16 (66.67%)
C	7 (29.17%)	8 (33.33%)
Total	24 (100%)	24(100%)
Significance	X^2=0.097, p-value= 0.755, Not significant	



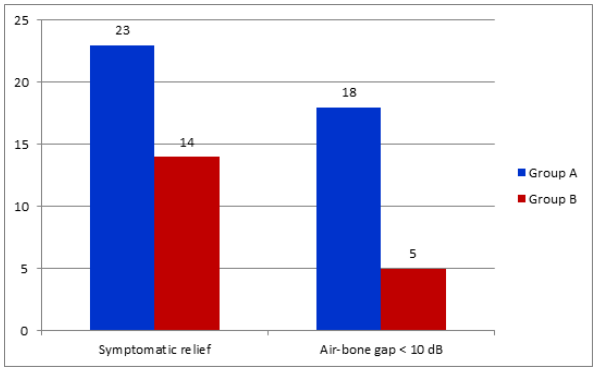
Graph 9: Evaluationof the study subjects present their tympanometry findings

AFTER INTERVENTIONS

In our study, cases were evaluated after proposed interventions according to the groups. In was observed that percentages of Symptomatic relief (95.83% Vs 58.33%) and Air-bone gap < 10 dB (75% Vs 20.83%) was comparatively found better in group A, as compared to group B. The numbers and its percentages are shown in the tables and graph are given below.

Table 10: Evaluation of the study subjects after interventions

Outcomes after surgical management	Group A (n=24)		Group B (n=24)		Significance
	Number of cases	Percentage	Number of cases	Percentage	
Symptomatic relief	23	95.83%	14	58.33%	X2=9.55, p-value= 0.001, Significant
Air-bone gap < 10 dB	18	75%	5	20.83%	X2=14.10, p-value= 0.0001, Significant



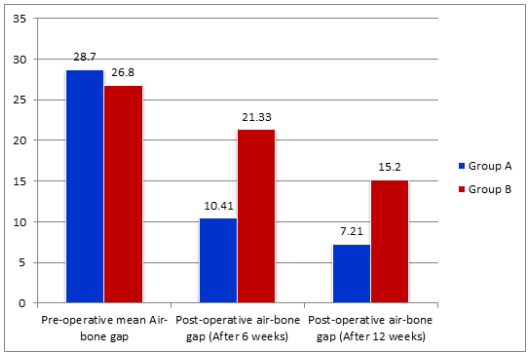
Graph 10: Evaluation of the study subjects after interventions

COMPARISON OF AIR-BONE GAPS BEFORE AND AFTER INTERVENTIONS

In our study, we compared the air-bone gaps before and after surgery. We reported that the mean air-bone gap was reduced more among group A (7.21 dB) cases compared to B group cases (15.20 dB) after 12 weeks of the followup table and graph given below.

Table 11: Evaluation of the air-bone gaps in study subjects

Air-bone gaps	Group A	Group B	p-value
Pre-operative mean Air-bone gap	28.7 dB	26.8dB	0.38
Post-operative air-bone gap (After 6 weeks)	10.41 dB	21.33 dB	<0.005
Post-operative air-bone gap (After 12 weeks)	7.21 dB	15.20 dB	<0.005



Graph 11: Evaluation of the air-bone gaps in study subjects

DISCUSSION

Our study was conducted with the objective to evaluate the outcome of adenotonsillectomy with and without insertion of grommet in the treatment of secretory otitis media. In our study 48 cases of Secretory otitis media (24 in each group A and B). In which group A was managed with adenotonsillectomy with grommet insertion, while cases in group B were managed with adenotonsillectomy alone.

Secretory otitis media continues to be a problem in the paediatric age group. We recorded the demographic details like age, sex, address, religion, occupation etc., clinical history, chief complaints, duration of symptoms, predisposing factors etc. of the study participants.

All cases were evaluated to detailed general physical and systemic clinical and radiological and routine pathological examination. Special investigations such as pure tone audiometry and tympanometry were also carried out. Our study cases are followed up for a period of six and twelve weeks. Results and findings were noted and analysed

Demographic characteristics

Male children have more incidence of childhood infection as they are more exposed to allergic and infectious agents compared to female children. The study subjects were the of cases of secretory otitis media of paediatric age group, of either gender. Majority of the cases of secretory otitis media belonged to 5-10 years of age group (66% in group A, while 75% in group B), followed by age group of 11-14 years (33.34% in group A and 25% in group B).

In our study, Male cases outnumbered the number of female cases in both groups. Group A consisted 17 males and 7 females while in group B there were 15 males and 8 females. However, **Engels et al, Rovers et al**[7], has suggested that there is more risk in boys when compared to girls. In our study also incidence was more in boys (58%).[7]

Ajayan PV et al[8], they conducted a prospective study conducted on 35 children between the age group 4-15 years, they observed that the mean age of the patients being 8 years, the most prevalent age group was 4-6 years (37.2%) followed by 7-9 years (31.4%). There were 13 females and 22 male children in their study.

SOCIOECONOMIC CLASSIFICATION (Modified Kuppuswamy Scale)

In our study, we also assessed the socioeconomic status of our study participants, in order to interrelation with their epidemiological risk factors. We observed that most of the cases were belonging to the lower middle class of SES followed by the upper lower class of SES, among both the groups A and B.

Ajayan PV et al[8], In their study, measured the socioeconomic status using a modified Kuppuswamy scale. The patients were stratified into 3 classes- lower, middle and upper classes. The lower class comprised of 48.57%, middle class 42.86% and upper class 8.57%.

CLINICAL PRESENTATION

In our study, we evaluate the study according to their clinical presentation. We observed that most of the cases presented with Decreased hearing followed by Earache, Nasal obstruction, snoring, sore throat etc.

In our study, we also evaluate the study according to the presence of Adenoid facies, which is correlated with the Adenoid hypertrophy. It was observed that most of the cases presented with adenoid facies in our study.

Ajayan PV et al[8], In their study, assessed the clinical presentations of the study subjects. They observed that most children presented with more than one symptom. It was observed that 97.1% presented with mouth breathing and 91.4% presented with nasal obstruction, which was the commonest symptoms. Other symptoms were nasal discharge, snoring, ear pain, difficulty in a hearing and recurrent sore throat. They observed adenoid facies among 91% of the cases.

In a study conducted by Ila Upadhya et al[9], the most common presenting symptom was decreased hearing 36.67% unilateral, 13.33% bilateral followed by an earache 36.67% unilateral, 6.67% bilateral. The less common were nasal discharge, throat pain, vertigo and tinnitus.

OTOSCOPIC EXAMINATION FINDINGS

In our study, the subjects were subjected for Otoscopic examination. In which we assessed the presence of various features such as the presence of dullness over the tympanic membrane, Retracted TM, Air fluid level and Pneumatic otoscopic findings. According to our observations, the majority of the study cases presented with Retracted TM (70.83% Vs 66.67%), followed by dullness over the tympanic membrane (62.5% Vs 70.83%). Air-fluid level and Pneumatic otoscopic findings were rarely observed.

Ajayan PV et al[8]: In their study that he observed that the tympanic movement could be detected only in 17.14% cases and the in rest (82.85%) movement could not be appreciated in pneumatic otoscopy.

DEGREE OF HEARING LOSS

In our study, we analysed that the study subjects according to decreased hearing present in the cases. We observed that most of the cases among both the groups were having a hearing loss between 20-40 dB (66.67% Vs 62.5%).

Ajayan PV et al[8], In their study, found that most of the subject had hearing loss in the range of 31-40 dB with a mean hearing loss of 36.5 dB. The maximum hearing loss was 50 dB while the minimum was 25 dB when both ears were considered together.

LATERALITY OF SOM

In our study, we assessed the laterality of the SOM among study subjects. We observed, both the groups (A and B), the majority of the study subjects presented with bilateral SOM (66.67% Vs 45.83%), followed by right-sided SOM (25% Vs 33.33%) and left-sided SOM (8.33% Vs 20.83%).

TYMPANOMETRY FINDINGS

In our study, we evaluated the study subjects according to their tympanometry findings. Majority of the study subjects in both the groups presented with B type of tympanogram (70.83% in group A and 66.67% in group B), followed by Type C (29.17% in group A and 33.33% in group B).

Wafters GW, Jones JE et al[10] **:** They published in clinical otolaryngology about the predictive values of tympanometry in the diagnosis secretory otitis media. A type B tympanogram has a high sensitivity (0.91) in predicting middle ear effusion with good specificity (0.3) type 'C' indicates that the increases the sensitivity of the predicting dry middle ear to 0.79. In our study, type B curve was found in 77% and type 'C' curve was found in 23%.[10]

AFTER INTERVENTIONS

It has been shown in many studies that the hearing loss in Secretory otitis media shows a wide range with air conduction thresholds averaging 27.5 dB[12] . This wide variation is probably related to the amount and type of fluid, its physical character (serous or mucous) and its exact location within the middle ear.

In our study, cases were evaluated after proposed interventions according to the groups. We observed that percentages of Symptomatic relief (95.83% Vs 58.33%) and Air-bone gap < 10 dB (75% Vs 20.83%) was comparatively found better in group A, as compared to group B.

In our study, we compared the air-bone gaps before and after surgery. We reported that the mean air-bone gap was reduced more among group A as compared B group. The gaps further reduced after 12 weeks of the follow-up.

Gates et al[11] found a significantly better outcome hearing, decreased the duration of the middle ear effusion, longer time to recurrence, and fewer repeat operations in children with Grommet as compared with those undergoing myringotomy and aspiration.

Similar conclusions were reached by Madel, Bluestone, and Paradise et al and others argued that tympanostomy tubes should be used as the initial procedure of choice for patients with persistent OME because tympanostomy tube placement is less involved and less expensive than adenoidectomy. They reserve adenoidectomy for cases with recurrent secretory otitis media.[11]

Ajayan PV et al[8], In their study Tympanogram, was used to verify the significant changes towards a positive prognosis at 6 weeks and 3 months postoperatively. Chi-square statistics revealed a good prognosis at all stages of observation with a p-value<0.01 which was significant. 6 weeks following surgery 55.71% of type B tympanogram changed to type A and 15.7% to type C, while in 28.57% type B persisted. After 3 months 65.71% of tympanogram were type A and 8.57% were type C. In 25.71% of subjects type B tympanogram persisted. He observed that in all those subjects with persistent type B tympanogram, the preoperative hearing loss was higher, that is, between 40-50 dB.

Van den Aardweg et al[11], In their study concluded that, Adenoidectomy in combination with a unilateral tympanostomy tube has a beneficial effect on the resolution of OME (risk difference 22% (95% CI 12% to 32%) and 29% (95% CI 19% to 39%) for the non▪operated ear at six and 12 months, respectively (n = 3 trials)) and a very small (< 5 dB) effect on hearing, compared to a unilateral tympanostomy tube only.

However,**Lildholdt T. Et al**[12], published a preliminary report of the results in 91 children for Unilateral grommet insertion and adenoidectomy in bilateral secretory otitis media. They did not find any statistical significance between the difference between the outcomes following both procedures.

Conclusion : The management of Secretory otitis media in Group A (Adenotonsillectomy with gommet insertion) has shown better results as compared to Group B (Adenotonsillectomy without grommet).

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