

Long Term Follow Up of Audiological Evaluation of Standalone Adenoidectomy versus Adenoidectomy with Grommet Insertion in Children with AOM with Effusion

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Abstract:

Background: Acute Otitis media (AOM) is defined as an infection of the middle ear cleft and commonly seen as a pediatric emergency. AOM can occur at any age, but most frequently observed in children between 05 and 11 years. Nearly 80% of all children will experience minimum one incidence of AOM during their lifetime. Among them nearly 70% to 85% will have AOM with effusion before reaching the teen age. The present study was directed to reviews the epidemiology, etiology, evaluation, and management of AOM with effusion with an emphasis on the role of Adenoidectomy alone or in combination with Grommet insertion in its management.

Aim of the Study: To study the epidemiology, etiology, evaluation, and management of AOM with effusion with an emphasis on the role of Adenoidectomy alone or in combination with Grommet insertion in its management.

Materials: A prospective analytical study was conducted at Shadan Institute of Medical Sciences, Hyderabad to study the incidence, clinical signs and symptoms, final outcomes of treatment of AOM with Adenoidectomy alone (Group A) and Adenoidectomy in combination with Grommet insertion (Group B) in children over a period of 02 years. Mini AOM questionnaire containing AOM-10 Questionnaire which classified hearing loss, behavioral changes, school performance, sleep habits, and frequency of upper respiratory infections were used with 2 points for each of the queries graded on a Likert scale 1 to 10. Tympanic membrane findings were also graded as 3 categories- normal tympanic membrane, dull looking tympanic membrane with straw colored fluid with or without air bubbles in the middle ear, and Thick and grossly dull, retracted, or bulging, lusterless tympanic membrane. Data was analysed to compare and correlate the final outcome measured in terms of auditory gain and relief from symptoms using chi square and t test.

Results: The demographic data showed a mean age of 8.3 ± 1.4 years in Group A and 7.3 ± 1.7 years for Group B. 59 male patients and 25 females in Group A and 57 children were males and 27 children were females in Group B were included. There was no statistical difference between the two groups in terms of age and gender. The statistical significance was indicated by a p-value of 0.0001. The mean auditory gain after 18 months in Group A children was 14.85 ± 2.15 dB and in Group B it was 19.75 ± 3.10 dB which was significant statistically with p value 0.001.

Conclusions: Acute Otitis Media with effusion is a common entity and frequently reported in children and results in pain in the ear and loss of hearing. Eustachian tubal occlusion due to large adenoid masses was the true cause for AOM with effusion. Surgical treatment either with Adenoidectomy alone or in combination with Grommet insertion is the choicest management. Combined surgical treatment of Adenoidectomy and Grommet insertion demonstrated greater efficacy and statistically significant auditory gain when compared to Adenoidectomy alone.

Keywords: Acute Otitis Media, PTA, Glue ear, Adenoids, Tubal block and audiometry.

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Introduction

Acute otitis media (AOM) is an infection of the middle ear space and encompasses a range of conditions, including AOM, chronic suppurative otitis media (CSOM), and otitis media with effusion (OME). [1] It is the second most common pediatric diagnosis in emergency departments, following upper respiratory infections. [2] While otitis media can affect individuals of any age, it is most prevalent among children aged 02 and 12 years. [3] Infections in the middle ear are caused by viruses, bacteria, or a combination of both. The most frequently identified bacterial pathogens include *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*. [4] Common viral pathogens include respiratory syncytial virus (RSV), coronaviruses, influenza viruses, adenoviruses, human metapneumovirus, and picornaviruses. [5] Diagnosis of otitis media is primarily clinical, relying on physical examination findings (otoscopy) along with the patient's history and symptoms. Several diagnostic tools, such as pneumatic otoscopes, tympanometry, and acoustic reflectometry, can assist in confirming the diagnosis. [6]

Among these, pneumatic otoscopy is the most reliable, offering greater sensitivity and specificity than standard otoscopy, though tympanometry and other methods can be helpful when pneumatic otoscopy is not available. [7] The role of antibiotics for the treatment of AOM was a subject of debate and varies by subtype. Without appropriate treatment, effusion of fluid or glue like material fills the middle ear cleft resulting in loss of hearing and speech development delays. [8] In the United States, high-dose amoxicillin is the primary treatment for diagnosed AOM, particularly effective in children under two years old. [9] In contrast, countries like the Netherlands often adopt a watchful waiting approach, resorting to antibiotics only if symptoms persist. [10] Analgesics, such as non-steroidal anti-inflammatory drugs like ibuprofen, can be utilized alone or in combination to effectively manage pain in patients with AOM. [10]

The traditional Patho-physiology used to explain the middle ear effusion was that dysfunction of the Eustachian tube was a prerequisite precursor. [11] But the newer models suggested that an already existing inflammation of the middle ear mucosa due to a reaction to bacteria was producing the fluid in the middle ear. [12] Bluestone and others have shown, using radiographic evidence, that reflux of swallowed liquids up the Eustachian tube was in children prone to AOM. [13] Crapko et al. [14] discovered pepsin in the middle ear space of 60% of children with AOM thought eh reflux occurred also in the healthy children. [15] Parents seek the advice mainly due to the pain and loss off hearing in their children. [16]

There is lack of uniform approach and following a definite protocol in the management of AOM with effusion in different countries all over the world. [17]. Possible interventions practiced are Myringotomy with or without ventilation tube insertion, either alone or in conjunction with adenoidectomy, and occasionally tonsillectomy. Establishing evidence based correct diagnosis, choosing the appropriate surgical treatment and explaining the parents about its necessity is further complicated by the incidence of potential complications associated with each procedure. [18] This study aims to study the epidemiology, etiology, evaluation, and management of AOM with effusion with an emphasis on the role of Adenoidectomy alone or in combination with Grommet insertion in its management.

Materials:

Type of Study: A prospective analytical study.

Duration of Study: 1 year- From October 2023 to September 2024.

Institute of Study: Shadan Institute of Medical Sciences, Hyderabad, Telangana.

This study was conducted in the Department of ENT, Shadan Institute of Medical Sciences, Hyderabad, and Telangana. 84 children diagnosed with AOM with middle ear effusion and adenoids enlargement and aged between 02 and 12 years were included. An Institution ethics committee was obtained before the study and an ethics committee approved consent form was used.

Inclusion Criteria: Children aged between 02 and 12 years were included. Children with adenoid hypertrophy (grades 3 or 4) were included. Children with complaints of loss of hearing were included. Children who showed Type B Tympanogram were included. Children of both the genders were included. Parents of the children who were consenting to join the study were included.

Exclusion Criteria: Children aged below 02 years and above 12 years were excluded. Children with history of Acute Suppurative Otitis media, CSOM with perforation of Tympanic membrane were excluded. Children with sensorineural hearing loss were excluded. A detailed epidemiological data, clinical history was taken from the parents of the children.

A mini AOM questionnaire was prepared out of AOM 10 Questionnaire was used which included the aspects such as hearing loss, behavioral changes, school performance, sleep habits, and frequency of upper respiratory infections were included (2 points for each of the queries graded on a Likert scale). Co-existing medical and surgical conditions were ruled out and excluded from the study.

Children were subjected to otoendoscopy and pneumatic otoscopy, and Tympanic membrane findings were graded as 3 categories: 1) normal tympanic membrane, 2) Dull looking tympanic membrane with straw colored fluid with or without air bubbles in the middle ear, and 3) Thick and grossly dull, retracted, or bulging, lusterless tympanic membrane. Diagnostic nasal endoscopy was performed to assess the grade of Adenoids were graded as degree of obstruction to the posterior choanae: Grade I – adenoid tissue obstructs 0% to 25% of posterior choanae; Grade II – adenoid tissue obstructs 26% to 50% of posterior choanae; Grade III – adenoid tissue obstructs 51% to 75% of posterior choanae; and Grade IV – adenoid tissue obstructs 76% to 100% of posterior choanae. The complete examination of the throat was also done to note the tonsillar enlargement. Tuning fork tests were conducted, and all children underwent pure-tone audiometry and tympanometry to document the type and degree of hearing loss, as well as the tympanogram curve. Radiological investigations included a soft tissue lateral view X-ray of the neck to evaluate adenoid hypertrophy and any airway compromise. The 84 children were divided into 2 groups: Group A, children were managed with adenoidectomy alone, and Group B, were treated with adenoidectomy combined with myringotomy and grommet insertion. Each group was followed up once weekly, with otoendoscopy, pure-tone audio-

gram, and tympanometry findings documented at the first, third, and sixth months were also recorded. During these follow-ups, symptomatic improvement and postoperative hearing enhancement were recorded.

Results:

This study was a prospective analytical nature calculating the incidence, clinical signs and symptoms, final outcomes of treatment over a period of 02 years. The demographic data showed that the youngest child was aged 02 years and the eldest child was aged 12 years with a mean age of 8.3 ± 1.4 years in Group A and 7.3 ± 1.7 years for Group B.

There were 59 male patients and 25 females in Group A and 57 children were males and 27 children were females in Group B. 17 (20.23%) children in Group A belonged to low income group, 11 (13.09%) belonged to middle income group and 16 (19.04%) children belonged to high income group. In Group B 16 (219.04%) children belonged to low income group, 13 (15.47%) belonged to middle income group and 11 (13.09%) children belonged to high income group. There was no statistical difference between the two groups in terms of age and gender and socio economic groups to which they belonged. (Table 1)

Table 1: Showing the age, gender and social groups of the children in the study (n- Group A- 44 and Group B-40)

Observation	Number		P value
	Group A- 44	Group B-40	
Age in Years			
02 to 05	11 (13.09%)	10 (11.90%)	0.132
06 to 09	14 (16.66%)	15 (17.85%)	
10 to 12	19 (22.61%)	15 (17.85%)	
Gender			
Male	29 (34.52%)	27 (22.14%)	0.167
Female	15 (17.85%)	13 (15.47%)	
Socio-economic groups			
Low	17 (20.23%)	16 (19.04%)	0.211
Middle	11 (13.09%)	13 (15.47%)	
High	16 (19.04%)	11 (13.09%)	

Pre-operative symptoms were found in right ear in 27 (36.90%) of the Group A and 24 (34.52%) of the Group B children. The Left ear was affected in 13 (15.47%) of the Group A and 11 (13.09%) of the Group B children. Both ears were affected in 04 (04.76%) of the Group and 05 (05.95%) of the Group B children. Pain in the ear was the main complaint in 38 (45.29%) of the Group A children and 36 (42.85%) of the Group B children.

Loss of Hearing was noted in 37 (44.04%) of the Group A children and 36 (40.47%) of the Group B children. Type 1 otoendoscopy was noted in 09 (10.71%), Type 2 otoendoscopy was noted in 23

(27.38%), Type 3 otoendoscopy was noted in 12 (14.28%) children of Group A. In Group B children Type 1 otoendoscopy was noted in 11 (13.09%), Type 2 otoendoscopy was noted in 15 (17.85%), Type 3 otoendoscopy was noted in 14 (16.66%) children. Pre-operative Audiometry showed PTA values with 15 to 20 dB loss in 10 (11.90%), 20 to 25 dB loss in 19 (22.61%) and 25 to 30 dB loss in 15 (17.85%) among the Group A subjects. In Group B children, PTA values were 15 to 20 dB loss in 12 (14.28%), 20 to 25 dB loss in 18 (21.42%) and 25 to 30 dB loss in 11 (13.09%) children. Tympanogram studies showed Type B

curve in 42 (50%) of the children of Group A and 39 (46.42%) of the Group B children. Grading of Adenoid mass on DNE was Grade I in 08 (09.52%), Grade II in 09 (10.71%), Grade III in 12 (14.28%) and Grade IV in 15 (17.85%) of the children of Group A.

In Group B, Grade I was found in 06 (07.14%), Grade II in 07 (08.33%), Grade III in 13 (14.47%) and Grade IV in 14 (16.66%) of the children of Group B children. (Table 2) Mini AOM Questionnaire on Likert scale score was 0 to 02 in 01 (01.19%), 03 to 05 in 04 (04.76%), 06 to 08 in

18 (21.42%) and 08 to 10 in 21 (25%) children of Group A. In Group B the score was 0 to 02 in 0 (0%), 03 to 05 in 03 (03.75%), 06 to 08 in 18 (21.42%) and 08 to 10 in 19 (22.61%) children. (Table 2) There was no statistical difference in terms of Laterality of the condition, pain in the ear, loss of hearing, otoendoscopy and PTA values on audiometry in both groups (p value >0.05). But there was statistical significant difference in terms of Tympanogram type, Mini AOM questionnaire and grading of adenoid mass. The p value was 0.0001 (p significant at <0.05), (Table 2)

Table 2: Showing the clinical signs and symptoms in the study on both the groups (n- Group A- 44 and Group B-40)

Clinical Symptoms and signs	Group A	Group B	P Value
	Number (%)	Number (%)	
Laterality			
Unilateral			0.245
Right	27(36.90%)	24 (34.52%)	
Left	13 (15.47%)	11 (13.09%)	
Bilateral	04 (04.76%)	05 (05.95%)	
Pain in the ear	38 (45.29%)	36 (42.85%)	0.102
Loss of Hearing	37 (44.04%)	34 (40.47%)	0.207
Otoendoscopy			
Type 1	09 (10.71%)	11 (13.09%)	0.311
Type 2	23 (27.38%)	15 (17.85%)	
Type 3	12 (14.28%)	14 (16.66%)	
Audiometry- PTA			
15 to 20 dB loss	10 (11.90%)	12 (14.28%)	0.421
20 to 25 dB loss	19 (22.61%)	18 (21.42%)	
25 to 30 dB loss	15 (17.85%)	11 (13.09%)	
Tympanogram			
Type B	42 (50%)	39 (46.42%)	0.0001
Type A	01 (01.19%)	0 (0%)	
Type C	01 (01.19%)	01 (01.19%)	
DNS findings- Adenoid mass			
Grade I	08 (09.52%)	06 (07.14%)	0.0001
Grade II	09 (10.71%)	07 (08.33%)	
Grade III	12 (14.28%)	13 (15.47%)	
Grade IV	15 (17.85%)	14 (16.66%)	
Mini AOM Questionnaire on Likert scale score			
0 to 02	01 (01.19%)	00 (0%)	0.001
03 to 05	04 (04.76%)	03 (03.57%)	
06 to 08	18 (21.42%)	18 (21.42%)	
08 to 10	21 (25%)	19 (22.61%)	

Post-operative follow-ups were conducted every three months using the Mini AOM questionnaire to assess improvements in symptoms and signs of AOM with effusion. The results revealed a significant reduction in scores among a greater number of patients within six months in terms of auditory gain on measuring the PTA and Mini AOM Questionnaire, indicating more substantial

improvement in Group B compared to Group A. (Table 3). The statistical significance was indicated by a p-value of 0.0001. The mean auditory gain after 18 months in Group A children was 14.85±2.15 dB and in Group B it was 19.75±3.10 dB which was significant statistically with p value 0.001. (Table 3)

Table 3: Showing the Post-operative follow up results for 18 months in the study (n- Group A- 44 and Group B-40)

Observation	0 to 03 months		04 to 06 months		06 to 09 months		10 to 18 months	
	Group A-44	Group B-40	Group A-44	Group B-40	Group A-44	Group B-40	Group A-44	Group B-40
Audiometry- PTA								
15 to 20 dB loss	06	02	03	01	01	0	00	01
20 to 25 dB loss	09	04	05	03	03	02	02	0
25 to 30 dB loss	07	01	04	02	03	02	01	0
Mini AOM Questionnaire on Likert scale score		0	0	0	0	0		
0 to 02	01	02	01	0	01	0	0	0
03 to 05	02	14	06	02	03	0	0	0
06 to 08	10	17	04	02	03	0	02	0
08 to 10	13						01	0
Mean Auditory Gain	--	--	--	--		----	14.85±2.15	19.75±3.10

(p- Value at 0.0001)

Discussion

The present study was conducted with an aim to study the epidemiology, etiology, evaluation, and management of AOM with effusion with an emphasis on the role of Adenoidectomy alone or in combination with Grommet insertion in its management. The age group selected was between 02 and 12 years. Age is a key risk factor for otitis media with effusion (OME). Zielhuis et al. [19] identified two peaks in prevalence: one around age 2 and another around age 5. Although OME typically decreases after age 5, it remains common among school-age children. In the present study a bimodal age distribution was found, with a mean age of 7.3± 1.7 years. There was a gender preference among the male children in the present study; 59 male patients and 25 females in Group A and 57 children were males and 27 children were females in Group B.

There was no statistical difference between the two groups in terms of age and gender, similar to the study by Kiris et al. and Engel et al. [20, 21] According to Tos et al., [22] any gender differences in Otitis media with effusion are mainly influenced by cultural factors. In the present study Tympanogram studies showed Type B curve in 42 (50%) of the children of Group A and 39 (46.42%) of the Group B children. Khurshid Anwar et al. and Saeed Khan et al. [23] reported that a type B tympanogram with a flat curve was observed in 71.4% of ears. In their study they observed that Tympanometry showed a sensitivity of 85.85%, specificity of 72.22%, positive predictive value of 94.44%, negative predictive value of 48.14%, and overall accuracy of 83.76%.

The present study showed positive predictive value of 92.4% in the Group A and 93.25% in the Group B. In this study Type 1 otoendoscopy was noted in

09 (10.71%), Type 2 otoendoscopy was noted in 23 (27.38%), Type 3 otoendoscopy was noted in 12 (14.28%) children of Group A. In Group B children Type 1 otoendoscopy was noted in 11 (13.09%), Type 2 otoendoscopy was noted in 15 (17.85%), Type 3 otoendoscopy was noted in 14 (16.66%) children. In a similar study by Tian et al. and Liu et al. [24,25], they observed similar results. Pre-operative Audiometry showed PTA values with 15 to 20 dB loss in 10 (11.90%), 20 to 25 dB loss in 19 (22.61%) and 25 to 30 dB loss in 15 (17.85%) among the Group A subjects. In Group B children, PTA values were 15 to 20 dB loss in 12 (14.28%), 20 to 25 dB loss in 18 (21.42%) and 25 to 30 dB loss in 11 (13.09%) children. Tympanogram studies showed Type B curve in 42 (50%) of the children of Group A and 39 (46.42%) of the Group B children.

In a similar study by Khurshid Anwar et al. and Saeed Khan et al. [23] the conductive deafness noted was between 25 and 30 dB in nearly 85.7% of the children with other children having lesser hearing loss on PTA. Grading of Adenoid mass on DNE was Grade I in 08 (09.52%), Grade II in 09 (10.71%), Grade III in 12 (14.28%) and Grade IV in 15 (17.85%) of the children of Group A. In Group B, Grade I was found in 06 (07.14%), Grade II in 07 (08.33%), Grade III in 13 (14.54%) and Grade IV in 14 (16.66%) of the children of Group B children. (Table 2) Tian et al. and Liu et al. and Marchisio P, Bellussi L et al [24, 25] indicated that adenoidectomy was more effective than non-surgical treatments in reducing acute otitis media incidence and clearing middle ear effusion. Additionally, adenoidectomy combined with tympanostomy tubes was found to be superior to tympanostomy tubes alone for both effusion removal and hearing improvement.

The findings of this study corroborate this, showing Post-operative follow-ups conducted every three months using the Mini AOM questionnaire to assess improvements in symptoms and signs of AOM with effusion, the results revealed a significant reduction in scores among a greater number of patients within six months, indicating more substantial improvement in Group B compared to Group A. (Table 3). The statistical significance was indicated by a p-value of 0.0001.

The mean auditory gain after 18 months in Group A children was 16.85 ± 2.15 dB and in Group B it was 19.75 ± 3.10 dB which was significant statistically with p value 0.001. (Table 3) A randomized controlled trial by N.A. Black et al. and C.F.B. Sanderson et al. found that myringotomy with grommet insertion resulted in significant hearing improvements lasting six to twelve months. While adenoidectomy provided only modest hearing improvements, it appeared to offer longer-lasting benefits compared to grommet insertion alone.

Limitations to the study: Potential limitations of this IPD meta-analysis include the selection of studies, the number of subgroup analyses conducted, the diversity of interventions, and the lack of uniformity in outcomes across the original studies.

This necessitated the aggregation of outcomes into a composite primary measure—failure at 12 months. However, sensitivity analyses using alternative definitions of "failure" yielded consistent results.

Conclusion

Acute Otitis Media with effusion is a common entity and frequently reported in children and results in pain in the ear and loss of hearing. Eustachian tubal occlusion due to large adenoid masses was the true cause for AOM with effusion. Surgical treatment either with Adenoidectomy alone or in combination with Grommet insertion is the choicest management. Combined surgical treatment of Adenoidectomy and Grommet insertion demonstrated greater efficacy and statistically significant auditory gain when compared to Adenoidectomy alone.

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