

Assessment of the Clinical Outcomes of Tympanostomy Tube Insertion Related to Pediatric Patients with Recurrent Acute Otitis Media

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Abstract: Background: Recurrent acute otitis media (RAOM) is a common disease among children and, in most cases, causes hearing impairment, speech delays, and poor quality of life. **Purpose & Method:** The purpose of the study is to compare clinical, audiometric, and quality-of-life outcomes of TTI in children with RAOM, where a cross-sectional study was carried out among 112 pediatric patients receiving TTI due to RAOM. Patients were divided into two groups: Group A (Success, n=74) and Group B (Recurrence, n=38). The data was gathered in the form of baseline demographics, pre-operative clinical history, surgical information, post-operative complications, audiometric findings, and long-term follow-up outcomes. **Results:** Group A showed much better outcomes, including the lower cases of AOM after the operation (0.6 vs. 3.0), the higher rates of AOM-free in 12 months (75.7% vs. 15.8%), and the higher Pure Tone Average (PTA) hearing thresholds (15.9 dB vs. 10.9 dB). Group B that involved recurrent otorrhea (15.8 vs. 4.1) and a significantly higher rate of reinsertion (42.1 vs. 8.1), had a higher incidence of complications. Recurrence risk factors included the increased frequency of AOM episodes in the pre-operative period, the use of failed antibiotic prophylaxis, or attendance at daycare. **Conclusion:** TTI is very useful in most children with RAOP, which leads to a considerable improvement in hearing and decreased infections. Nonetheless, some patients relapse, and this is more prevalent with increased disease burden pre-operatively and comorbidities.

Keywords: Tympanostomy tubes, Recurrent Acute Otitis Media, Pediatric Otolaryngology, Hearing Loss, Quality of Life, Surgical Outcomes.

INTRODUCTION

Acute otitis media (AOM) has been one of the most prevalent diagnoses of pediatric primary care and the primary cause of antibiotic prescriptions in children across the globe [Sinno, S. *et al.*, 2021]. Although most cases have a spontaneous or medical resolution, a substantial proportion of children come to have recurrent acute otitis media (RAOM), which is often a pattern of three or more episodes in six months or four or more episodes in twelve months [Tran, H. T. *et al.*, 2022; Janky, K. L., & Rodriguez, A. I. 2018]. RAOM is not only associated with significant challenges because of the acute symptoms of pain and fever, but also because of its long-term consequences, such as persistent middle ear effusion, conductive hearing loss, a delay in the development of speech and language, and a reduction in the quality of life related to the health of the child and the family. [Aldè, M. *et al.*, 2024]

Surgical intervention is required when the frequency or severity of infections cannot be controlled using medical management, which should include watchful waiting and antibiotic prophylaxis [Wiener-Vacher, S. R. *et al.*, 2018].

The insertion of tympanostomy tubes (insertion of grommets), or TTI, is the most common ambulatory surgery of children in most developed nations [Brodsky, J. R. *et al.*, 2016]. One of the most common interventions on pediatric patients with recurrent acute otitis media (rAOM), an inflammation of the middle ear with periodic effusion and changing symptoms, is the insertion of a tympanostomy tube [Aldè, M. *et al.*, 2024]. Therefore, a balance between anticipated benefits, including improved middle-ear ventilation, fewer and less severe acute episodes, and fewer effusion days, versus the possible risks of tube placement, including otorrhea, tube obstruction/extrusion, changes in the tympanic membrane, and the necessity of sequelae treatment, is essential in establishing the therapeutic outcomes of tube placement. [Pinninti, S. G. *et al.*, 2024; Rücklová, K. *et al.*, 2023]

Most children have full resolution of symptoms and normalization of hearing, although some have persistence of problems, such as recurrent otorrhea via the tube, premature extrusion, blockage, or recurrence of AOM despite patent tubes [Golz, A.

et al., 1991]. Moreover, a significant percentage of patients need secondary procedures, including repeat tube insertion or adenoidectomy, which suggests that TTI is not necessarily the cure-all in terms of the underlying pathophysiology [Vanneste, P., & Page, C. 2019]. The literature of the past has found out various possible risk factors of poor outcome, such as young age at the time of insertion, daycare, secondhand smoking, allergic rhinitis, and adenoid hypertrophy. Tubes offer an avenue of pressure equalization as well as drainage of fluids that can help to lower conductive hearing loss and enhance the local antimicrobial atmosphere. [Demir, M. et al., 2023]

PATIENTS & METHOD

Design and Population of the Study

The study was a retrospective cohort study of 112 children who are diagnosed with recurrent acute otitis media (RAOM) and have a bilaterally or unilaterally implanted tympanostomy tube during the years between January 2024 and December 2025. The researchers performed the study at a tertiary care pediatric otolaryngology facility in different hospitals in Iraq. The inclusion criteria were children between 6 months and 12 years of age who had a history of RAOM (3 episodes or 4 episodes, respectively) and had not responded to medical interventions. The exclusion criteria were children who had craniofacial anomalies, cleft palate, immunodeficiency disorders, or previous ear surgery other than myringotomy.

Data Collection

The electronic medical records were used to extract patient data and arrange them in seven categories: baseline demographics, preoperative clinical characteristics, surgical details, postoperative outcomes, complications, audiometric results, and long-term follow-up.

Group Stratification

Patients were categorized into two groups according to the outcomes within a 12 months follow-up after surgery, where group A (Success): Patients who had not gotten AOM or who had made very few episodes (<2) no additional surgical care, while group B (Recurrence): Patients who had recurrent cases of AOM (3 or more), persistent effusion, or who had to reinsert tubes or had further surgical procedures (e.g., adenoidectomy) during the follow-up period.

Statistical Analysis

Mean \pm standard deviation (SD) was used to represent the continuous variables (e.g., age, hearing thresholds), and frequencies and percentages to represent the categorical variables (gender and ethnicity). The independent t-tests of continuous variables and chi-square or Fisher's exact tests of categorical variables were used to compare Group A and Group B. The p-value of less than 0.05 was regarded as statistically significant. And all the analyses were done using SPSS, version 24.0.

RESULTS

Table 1 shows that the two outcome groups were similar in core demographics. The age distribution of the groups was similar (Group A 29.1 months vs. Group B 27.0 months), and the gender balance was similar (males approximately 58.6% in each group). The percentile of weight and BMI was relatively the same, and the percentile rates of daycare attendance and breastfeeding history were fairly similar. Nonetheless, Group B experienced a greater rate of secondhand smoke exposure (36.8% vs. 23.0%), which can be potentially applied to recurrence risk.

Table 1. Baseline the hospitalization and demographic features of 122 patients.

VARIABLE	OVERALL (N=112)	GROUP A: SUCCESS (N=74)	GROUP B: RECURRENCE (N=38)
Age (months), mean \pm SD	28.4 \pm 12.6	29.1 \pm 11.8	27.0 \pm 14.1
Gender, n (%)	—	—	—
Male	67 (59.8)	45 (60.8)	22 (57.9)
Female	45 (40.2)	29 (39.2)	16 (42.1)
Weight (kg), mean \pm SD	13.2 \pm 3.4	13.5 \pm 3.2	12.6 \pm 3.7
BMI percentile, mean \pm SD	62.3 \pm 24.1	63.8 \pm 23.5	59.4 \pm 25.3
Daycare attendance, n (%)	78 (69.6)	49 (66.2)	29 (76.3)
Breastfeeding history, n (%)	64 (57.1)	46 (62.2)	18 (47.4)
Secondhand smoke exposure, n (%)	31 (27.7)	17 (23.0)	14 (36.8)

Table 2 shows that Group B was initially more burdened with disease, especially the frequency and the middle ear effusion being persistent. Group B had an average of more AOM episodes in the last year (6.6 vs 5.4 in Group A), and the last 6 months' episodes were also more (4.3 vs 3.4). Group B had a longer DOM of OME (11.6 weeks

vs 9.5 weeks), indicating more long-term middle ear pathology preceding tube insertion. Broadly similar levels of comorbid conditions, including allergic rhinitis, asthma, and GERD, were present in both groups, but family history of recurrent AOM was significantly greater in Group B (44.7% vs 32.4%).

Table 2. Distribution of clinical features preoperatively for 112 patients.

VARIABLE	OVERALL (N=112)	GROUP A (N=74)	GROUP B (N=38)
AOM episodes in the past 12 months, mean ± SD	5.8 ± 1.9	5.4 ± 1.7	6.6 ± 2.1
AOM episodes in the past 6 months, mean ± SD	3.7 ± 1.2	3.4 ± 1.1	4.3 ± 1.3
Duration of OME (weeks), mean ± SD	10.2 ± 4.8	9.5 ± 4.3	11.6 ± 5.5
Laterality, n (%)			
Bilateral	82 (73.2)	52 (70.3)	30 (78.9)
Unilateral	30 (26.8)	22 (29.7)	8 (21.1)
Prior antibiotic courses, mean ± SD	6.2 ± 2.8	5.7 ± 2.5	7.2 ± 3.1
Prior failed antibiotic prophylaxis, n (%)	43 (38.4)	25 (33.8)	18 (47.4)
Comorbidities, n (%)			
Allergic rhinitis	34 (30.4)	20 (27.0)	14 (36.8)
Asthma	19 (17.0)	11 (14.9)	8 (21.1)
GERD	14 (12.5)	8 (10.8)	6 (15.8)
Adenoid hypertrophy	28 (25.0)	16 (21.6)	12 (31.6)
Family history of recurrent AOM, n (%)	41 (36.6)	24 (32.4)	17 (44.7)

Table 3 indicates that the surgical method and preoperative intraoperative ear condition were largely similar, indicating that the recurrence rates are probably more of a patient/disease factor than is of great significance in the major difference in procedure. The distributions of tube types were fairly equal, with Armstrong grommets being the most prevalent in both groups (63.5% in Group A vs. 55.3% in Group B), and the p-values do not show any significant evidence of differences in tube choices. There were also no differences in the

type of anesthesia and the duration of the procedure (mainly general anesthesia and minimal differences in the duration of the procedure). Bilateral placement frequency was similar as well. There were no statistically significant differences in the intraoperative characteristics of middle ear effusion: serous, mucoid, purulent, or none/dry, but the proportion of mucoid effusion was numerically higher in Group B (52.6% vs 41.9%), and the proportion of none/dry was a bit more favorable in Group A (2.6% vs 8.1%).

Table 3. Enroll the surgical outcomes of 112 patients.

VARIABLE	OVERALL (N=112)	GROUP A (N=74)	GROUP B (N=38)	P-VALUE
Tube type, n (%)				
Armstrong grommet	68 (60.7)	47 (63.5)	21 (55.3)	0.391
Shepard tube	29 (25.9)	18 (24.3)	11 (28.9)	—
T-tube (long-term)	15 (13.4)	9 (12.2)	6 (15.8)	—
Anesthesia type, n (%)				
General (mask)	98 (87.5)	65 (87.8)	33 (86.8)	0.882
General (IV)	14 (12.5)	9 (12.2)	5 (13.2)	—
Procedure duration (min), mean ± SD	12.4 ± 4.2	12.1 ± 3.9	13.0 ± 4.7	0.296
Bilateral placement, n (%)	82 (73.2)	52 (70.3)	30 (78.9)	0.322
Concurrent adenoidectomy, n (%)	26 (23.2)	15 (20.3)	11 (28.9)	0.299
Middle ear effusion at surgery, n				

(%)				
Serous	42 (37.5)	30 (40.5)	12 (31.6)	0.247
Mucoid	51 (45.5)	31 (41.9)	20 (52.6)	—
Purulent	12 (10.7)	7 (9.5)	5 (13.2)	—
None/Dry	7 (6.3)	6 (8.1)	1 (2.6)	—

Table 4 gives that Group A tended to use tubes more effectively compared to Group B, and that recurrence was correlated with poorer postoperative clinical courses. The decrease in AOM episodes indicates that both groups made positive progress, although Group A made better progress (Group A decrease 4.8 vs Group B decrease 3.6), which supports the notion that

recurrence patients entered into and maintained a more challenging disease. AOM-free status at both time periods greatly favored Group A: 87.8% of Group A were AOM-free at 6 months compared with only 36.8% of Group B; 75.7% of Group A were AOM-free at 12 months versus 15.8% of Group B, as the outcome definition implies.

Table 4. Determining the outcomes of postoperative outcomes into 112 patients.

VARIABLE	OVERALL (N=112)	GROUP A (N=74)	GROUP B (N=38)	P-VALUE
AOM episodes post-tube (12 months), mean \pm SD	1.4 \pm 1.6	0.6 \pm 0.8	3.0 \pm 1.4	<0.001
Reduction in AOM episodes, mean \pm SD	4.4 \pm 2.1	4.8 \pm 1.8	3.6 \pm 2.4	0.004
AOM-free at 6 months, n (%)	79 (70.5)	65 (87.8)	14 (36.8)	<0.001
AOM-free at 12 months, n (%)	62 (55.4)	56 (75.7)	6 (15.8)	<0.001
Time to first post-op AOM (months), mean \pm SD	7.2 \pm 4.1	9.8 \pm 3.2	3.1 \pm 2.0	<0.001
Hearing improvement reported, n (%)	94 (83.9)	68 (91.9)	26 (68.4)	0.001
Speech/language improvement, n (%)	72 (64.3)	53 (71.6)	19 (50.0)	0.023
Parental satisfaction (1-10), mean \pm SD	7.8 \pm 1.9	8.6 \pm 1.3	6.2 \pm 2.1	<0.001
Antibiotic courses post-tube (12 months), mean \pm SD	1.8 \pm 1.9	0.9 \pm 1.1	3.5 \pm 2.0	<0.001
ER visits for ear-related issues, mean \pm SD	0.8 \pm 1.1	0.4 \pm 0.7	1.6 \pm 1.3	<0.001

In the entire group of 112 children, 38/112 (33.9) had any complication in the post-operative period. This rate was significantly lower in Group A (20/74; 27.0%) than in Group B (18/38; 47.4%), with a p-value of 0.030. Looking at specific complications, tube otorrhea was observed in 24/112 (21.4%) overall, occurring in 17.6% (13/74) of Group A and 28.9% (11/38) of Group B. For recurrent otorrhea (≥ 3 episodes), the overall frequency was 9/112 (8.0%), with 4.1% (3/74) in Group A versus 15.8% (6/38) in Group B, showing a significant between-group difference (p = 0.028).

Other surgical/structural complications were usually rare and indicated no statistically significant differences between groups and included premature tube extrusion (<6 months) (12.5% overall; p = 0.172), tube blockage (7.1% overall; p = 0.315), persistent perforation (>6 months post-extrusion) (4.5% overall; p = 0.210). Similarly, no significant difference was found in granulation tissue (5.4% overall; p = 0.389), cholesteatoma (0.9% overall; p = 0.339) and medial tube displacement (1.8% overall; p = 0.614).

Table 5. Prevalence of the outcomes of complications in the post-operative period.

COMPLICATIONS	OVERALL (N=112)	GROUP A (N=74)	GROUP B (N=38)	P-VALUE
Any complication, n (%)	38 (33.9)	20 (27.0)	18 (47.4)	0.030
Tube otorrhea, n (%)	24 (21.4)	13 (17.6)	11 (28.9)	0.159
Recurrent otorrhea (≥ 3 episodes), n (%)	9 (8.0)	3 (4.1)	6 (15.8)	0.028
Premature tube extrusion (<6 months), n (%)	14 (12.5)	7 (9.5)	7 (18.4)	0.172
Tube blockage, n (%)	8 (7.1)	4 (5.4)	4 (10.5)	0.315
Persistent perforation (>6 months post-extrusion), n (%)	5 (4.5)	2 (2.7)	3 (7.9)	0.210

Tympanosclerosis, n (%)	18 (16.1)	11 (14.9)	7 (18.4)	0.627
Granulation tissue, n (%)	6 (5.4)	3 (4.1)	3 (7.9)	0.389
Cholesteatoma, n (%)	1 (0.9)	0 (0.0)	1 (2.6)	0.339
Medial displacement of tube, n (%)	2 (1.8)	1 (1.4)	1 (2.6)	0.614

Table 6. Assessment of audiometric outcomes of patients in comparison between pre-operatives versus post-operative.

AUDIOMETRIC MEASURE	OVERALL (N=112)	GROUP A (N=74)	GROUP B (N=38)
Pre-operative PTA (dB), mean \pm SD	32.6 \pm 8.4	31.8 \pm 7.9	34.2 \pm 9.2
Post-operative PTA (dB), mean \pm SD	18.4 \pm 7.2	15.9 \pm 5.8	23.3 \pm 7.6
PTA improvement (dB), mean \pm SD	14.2 \pm 6.8	15.9 \pm 6.1	10.9 \pm 7.1
Pre-operative ABG (dB), mean \pm SD	18.7 \pm 6.9	18.2 \pm 6.5	19.7 \pm 7.6
Post-operative ABG (dB), mean \pm SD	7.3 \pm 5.1	5.6 \pm 3.8	10.6 \pm 5.9
ABG closure (dB), mean \pm SD	11.4 \pm 5.6	12.6 \pm 5.1	9.1 \pm 6.0
Achieved normal hearing (PTA \leq 20 dB), n (%)	76 (67.9)	60 (81.1)	16 (42.1)
Pre-op tympanometry Type B, n (%)	89 (79.5)	57 (77.0)	32 (84.2)
Post-op tympanometry Type A, n (%)	82 (73.2)	62 (83.8)	20 (52.6)
Speech Reception Threshold improvement (dB), mean \pm SD	12.8 \pm 6.2	14.3 \pm 5.7	9.9 \pm 6.5

Both groups showed improvements in Audiometric performance post-surgery, but the extent of improvement was larger in Group A as compared to Group B, with the mean of the PTA (pure-tone average) standing at 32.6 \pm 8.4 dB pre-operative and 31.8 \pm 7.9 dB post-operative, respectively. Postoperative PTA had deteriorated to 18.417.2 dB with a total PTA of 14.216.8 dB. Group A had a PTA of 15.9615.9 dB hearing improvement, and Group B had 10.9710.9 dB hearing improvement. Pre-operative ABG (air-bone gap) averaged 18.7 \pm 6.9 dB overall, with 18.2 \pm 6.5 dB in Group A and 19.7 \pm 7.6 dB in Group B. Post-operatively, ABG reduced to 7.3 \pm 5.1 dB overall, reaching 5.6 \pm 3.8

dB in Group A and 10.6 \pm 5.9 dB in Group B. Correspondingly, the ABG closure averaged 11.4 \pm 5.6 dB overall, with 12.6 \pm 5.1 dB in Group A and 9.1 \pm 6.0 dB in Group B. Functional hearing outcomes also differed: achieved normal hearing (PTA \leq 20 dB) occurred in 76/112 (67.9%) overall, but this was higher in Group A (60/74; 81.1%) than in Group B (16/38; 42.1%). Tympanometry status had changed to pre-op dysfunction to post-op improvement with pre-op tympanometry Type B being present in 89/112 (79.5) overall (77.0 in Group A vs 52.6 in Group B), and post-op Type A in 82/112 (73.2) overall (83.8 in Group A vs 52.

Table 7. Assessment of clinical characteristics of patients during follow-up and long-term outcomes.

VARIABLE	OVERALL (N=112)	GROUP A (N=74)	GROUP B (N=38)
Follow-up duration (months), mean \pm SD	18.6 \pm 6.4	19.2 \pm 6.1	17.4 \pm 6.8
Tube duration in situ (months), mean \pm SD	11.8 \pm 4.6	12.4 \pm 4.3	10.6 \pm 5.0
Spontaneous tube extrusion, n (%)	91 (81.3)	63 (85.1)	28 (73.7)
Required tube removal, n (%)	16 (14.3)	8 (10.8)	8 (21.1)
Tube still in situ at last follow-up, n (%)	5 (4.5)	3 (4.1)	2 (5.3)
Need for reinsertion, n (%)	22 (19.6)	6 (8.1)	16 (42.1)
Time to reinsertion (months), mean \pm SD	14.2 \pm 5.8	16.8 \pm 4.9	12.6 \pm 5.9
Resolution of middle ear effusion, n (%)	89 (79.5)	66 (89.2)	23 (60.5)
Pre-op QoL score (OM-6), mean \pm SD	4.8 \pm 1.2	4.7 \pm 1.1	5.0 \pm 1.3
Post-op QoL score (OM-6), mean \pm SD	2.4 \pm 1.1	2.0 \pm 0.8	3.2 \pm 1.2
QoL improvement, mean \pm SD	2.4 \pm 1.3	2.7 \pm 1.2	1.8 \pm 1.4
Adenoidectomy during follow-up, n (%)	18 (16.1)	8 (10.8)	10 (26.3)
No further ear interventions needed, n (%)	72 (64.3)	58 (78.4)	14 (36.8)

DISCUSSION

The findings of the study emphasize the effectiveness of the overall use of tympanostomy

tube insertion in the treatment of pediatric RAOM, along with specific peculiarities of the failure or recurrence of the treatment. We find that our

findings are in line with the existing literature that TTI can greatly lower the burden of disease, increase hearing, and improve the quality of life. [Golz, A. et al., 1991; Vanneste, P., & Page, C. 2019; Demir, M. et al., 2023]

In line with Asian studies, our cohort showed a significant decrease in the number of AOM episodes after surgery. The general average decrease was 4.4 episodes annually. The improvements in audiometry were significant, and the improvement in the mean Pure Tone Average (PTA) was 14.2 dB, where group A had almost normal hearing thresholds (mean post-op PTA 15.9 dB), but Group B had a slight conductive loss (mean post-op PTA 23.3 dB). TTI is effective in overcoming the mechanical blockage of effusion, but the recurrence group may still be affected by underlying mucosal disease or dysfunction of the Eustachian tube, which restricts complete auditory recovery. [Alrwisan, A. et al., 2016; Brown, C., & Behar, P. 2020]

These results are in line with those of the Welsh paper that found out that hearing gains universally, but the extent of gain depends on the degree of pre-operative effusion and duration of disease [Kay, D. J. et al., 2001]. Our data has revealed a number of predictors of recurrence [Vercillo, N. C. et al., 2015; Golz, A. et al., 1999]. Group B experienced many more AOM episodes before operation (6.6 vs 5.4) and the rate of failure of antibiotic prophylaxis was high (47.4 vs. 33.8). As well as environmental influences contributed to it; the incidence of daycare attendance was greater in Group B (76.3% vs. 66.2%), and the exposure to secondhand smoke was almost twice in the recurrence group (36.8% vs. 23.0%).

In particular, recurrent otorrhea was a significant distinguishing factor, 15.8% in Group B and 4.1% in Group A. This implies that children with recurrence tendencies also seem to respond inflammationally or harboring of bacteria in a way that predisposes them to tube-related infections. As a result, Group B had a significantly greater need for reinsertion (42.1) than Group A (8.1%). This recurrence group reoperation rate indicates the financial and mental strain on families in which maximization of initial management is required.

In contrast to other studies in Britain, which established no significant difference in outcome according to adenoid status, our data established that adenoid hypertrophy was more common in Group B (31.6% vs. 21.6%), and adenoidectomy at

follow-up was significantly more common in this group (26.3% vs. 10.8%). [Moon, I. S. et al., 2013; Wie, K. et al., 2024; Nagar, R. R., & Deshmukh, P. T. 2022]

CONCLUSION

Tympanostomy tube placement is a proven and most effective intervention in the treatment of pediatric recurrent acute otitis media, with a high level of success in the improvement of hearing, decrease in frequency and quality of infections, and quality of life in most patients. Yet, around one-third of patients in this cohort had recurrence or complications, which were defined by the increased pre-operative disease burden, environmental risk factors, including daycare attendance and smoke exposure, and anatomical factors, including adenoid hypertrophy.

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