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Outcomes of Tympanostomy Tube Insertion for Recurrent Acute Otitis Media in Pediatric Patients

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Abstract: **Background**: Recurrent acute otitis media (RAOM) is characterized by 3 or more episodes in 6 months or 4 or more episodes in 12 months (1 recent episode), which causes a lot of pain and sleeping difficulties, school absences, parental work loss, and hearing/language delay due to chronic effusions where collected 112 patients from Iraq furthermore Tympanostomy tube insertion (TTI) is used as an initial treatment of the chosen children who are unresponsive to medical therapy, with the aim to decrease the rate of AOM, enhance middle-ear ventilation/hearing, and prevent the effects of development as well as the inclusion criteria were preoperative information and 12 months follow-up; the exclusion criteria were alternative pathological or missing records. Annual AOM episodes (complete resolution: 0; improvement: 0; failure: 1), hearing (dB change), missed school days, tube retention, time to first postoperative AOM, and complications (e.g., otorrhea, extrusion) were some of the outcomes. Descriptive statistics, paired t-tests, Pearson correlations, and binary logistic regression (SPSS; $p < 0.05$) were used in the analyses, where results Baseline: mean 5.2 1.8 preoperative AOM episodes; 63.4% daycare; 30.4%adenoid hypertrophy. The findings were improved after operation: AOM 0.7 1.1(difference -4.5, $p < 0.001$); hearing 18.3 6.2 dB(difference -14.2, $p < 0.001$); antibiotics -4.1/year($p < 0.001$); school days lost -10.2/year($p < 0.001$). Success: 60.7 resolution, 88.4% improvement, 11.6% failure.

Keywords: Tympanostomy, Tube Insertion, Pediatric, Patient, Follow-Up.

INTRODUCTION

Recurrent acute otitis media (RAOM) is a typical pediatric care-related issue often resulting in debates on preventive care, such as tympanostomy tube insertion (TTI). The conventional definition of RAOM is 3 or more episodes of acute otitis media in 6 months or 4 or more in one year, at least one of which is in the last 6 months [Sinno, S. *et al*., 2021]. The cost of RAOM to children and to the family is high, and this includes pain in the ear, sleep, school absenteeism, parental work interruption, and worry about possible long-term hearing and developmental effects. As a primary intervention option in the selected children with RAOM, both non-surgical medical therapy and surgical intervention have failed to lower incidence of episodes or effusion persists resulting in conductive hearing loss or language developmental delay, tubes have become a standard practice to manage the condition, with the use of tympanostomy tubes, small ventilating tubes placed through the tympanic membrane, as a means of aerating the middle ear. In this context, the general aim of TTIs is to decrease the number and severity of AOM episodes, enhance hearing and middle-ear ventilation, and eventually contribute to normal speech, language, and cognitive development, and limiting risks and burdens of treatment procedures [Tran, H. T. *et al*., 2022; Janky, K. L., & Rodriguez, A. I. 2018; Aldè, M. *et al*., 2024]. The results of tympanostomy tube insertion in children with RAOM necessitate deliberation of a continuum of short-term and long-term outcomes, and patient- and family-related issues that contribute to success [Wiener-Vacher, S. R. *et al*., 2018; Brodsky, J. R. *et al*., 2016] Examples of short-term outcomes that are typically used in clinical practice are a decrease in AOM frequency following tube insertion, amelioration in middle ear effusion condition, and recovery or maintenance of hearing levels, especially in ear with conductive hearing impairment by effusion [Aldè, M. *et al*., 2024; Pinninti, S. G. *et al*., 2024; Rücklová, K. *et al*., 2023] The factual evidence constantly shows that TTIs are capable of reducing the incidence of clinically diagnosed AOM episodes to a considerable reduction in the year following surgery as opposed to the preoperative period or expectant medical management in select groups. Depending on population and study design, it may be of different magnitude, depending on, e.g., the severity of the baseline disease, the age at which tubes are inserted, the time of insertion in relation to the disease course, perioperative adjuvant

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medical treatments, and compliance with postoperative care [Golz, A. *et al*., 1991; Vanneste, P., & Page, C. 2019; Demir, M. *et al*., 2023; Alrwisan, A. *et al*., 2016].

The outcomes of hearing are the primary factor in assessing TTIs in relation to RAOM. Middle ear effusions in RAOM may cause a conductive hearing loss that may temporarily distort auditory input and have an effect on speech and language production, especially in younger children, where it is necessary to explain the hearing results regarding audiometric testing reliability in young children, possible air-bone gaps, and the impact of comorbidity, e.g., sensorineural hearing loss or dysfunction of the eardrum. Another crucial outcome dimension is the effects of TTIs on the quality of life. On the other hand, other families have persistent issues related to tube care, the necessity to periodically tube extrude or remove, the threat of tube plugging, release, or chronic otorrhea, and the likelihood of type membrane perforation or scarring [Brown, C., & Behar, P. 2020; Kay, D. J. *et al*., 2001]. These factors explain the necessity of thorough pre-TTIs, in-TTIs, and post-TTIs counseling, such as anticipation of the usual course of recovery, possible complications, and the necessity of regular follow-ups. Short-term complications may be tube blockage, long-term following tube extrusion, Otorrhea secondary to infection, tympanosclerosis, and, in rare cases, thinning of the tympanic membrane. All surgical procedures have the risk of intraoperative or anesthesia-related complications but, but in the case of pediatric patients, they are less likely to occur when carried out by skilled teams. It is pointed out in the literature that the majority of tubes spontaneously extrude after 6 to 18 months. The time depends on the type of tube and specific patient factors [Vercillo, N. C. *et al*., 2015; Golz, A. *et al*., 1999] Significant is significant that many children undergo an effective reduction in AOM episodes whilst the tubes remain in place; however, some children may still have AOM following extrusion, which underscores the necessity to continue surveillance, and in some cases, requiring further action [Moon, I. S. *et al*., 2013].

The choice of the patient is one of the determinants of the outcomes of TTIs. The typical characteristics of ideal candidates are children with RAOM who have repeated occurrences of poor quality of life, reported middle-ear effusions and hearing loss or no hearing loss, and a profile that tubes will overcome underlying epidemiology of infection and Eustachian tube dysfunction. It is necessary to establish shared decision-making with effective communication of the benefits and possible risks to reach the point of agreement with the expectations of the parents and to ensure compliance with postoperative care guidelines, such as ear hygiene, discharge monitoring, and follow-up care in the pediatric otolaryngology service [Wie, K. *et al*., 2024].

Comparative effectiveness studies have attempted to define the incremental value of TTIs in comparison to medical therapy only. TTIs have been shown to be superior in the prevention of AOM episodes and in hearing in the first year postoperative in a number of randomized and observational studies in a selected group of children who have RAOM and persistent effusion. Nonetheless, long-term effects depend on the sustainability of the benefits, possible gradual improvements, or the effects of additional therapies, e.g., nasal corticosteroids or antibiotics. There are some analyses that the advantages of TTIs can be optimised when the tube stays in the tympanic cavity and may be less than optimal when the tube is extruded, and the underlying risk factors of AOM remain. This implies that a more subtle analysis of outcomes will dictate that there is a time-restricted period of intense benefit, after which a period of observational vigilance and possible re-intervention in the event of recurring disease progression is recommended [Nagar, R. R., & Deshmukh, P. T. 2022; Isaacson, G., & Rosenfeld, R. M. 1996; Rovers, M. M. *et al*., 2005].

MATERIAL AND METHOD

The study was a retrospective single-center study that was carried out in the Department of Pediatric Otolaryngology to determine the developmental outcomes of tympanic ventilation tube (TTI) insertion in Iraq in 2025-2026 for 112 patients from Iraq to determine the first-line treatment of recurrent acute otitis media (RAOM) in children. The research was aimed at the incidence of RAOM following surgery, hearing level, antibiotic therapy, school or daycare attendance, and complications. Children with RAOM who had been treated with TTI insertion and had recorded preoperative measurements and at least 12 months of postoperative follow-up were included. Children who had severe RAOM and needed some other interventions or had incomplete records were not included. Major surgery was done under general anesthesia by experts in the field of

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pediatric otolaryngology, and a ventilation tube was inserted by them, regarding the type, size, and details of the ventilation tube, which was registered on the immediate surgical notes. This was then supplemented with regular aftercare treatment, which entailed ear hygiene, limitation of activity, and follow-up appointments. The data contained demographic and baseline (age at tube insertion, sex, weight, daycare attendance, family history of otitis media, tobacco smoke exposure, adenoid hypertrophy, and previous antibiotic courses), preoperative, and 12-month postoperative outcomes (number of annual acute otitis media cases, hearing thresholds (dB), number of annual antibiotic courses, days missed in school or daycare, tube retention in months, first postoperative acute otitis case episode (in months). Others that were also reported to develop complications are transient or persistent ear discharge, premature tube expulsion, obstruction, rigidity of the tympanic membrane, persistent perforation, and granulation tissue formation. There was a definition of the outcomes to be complete recovery (zero acute otitis media episodes following surgery), significant (two or less episodes), or treatment failure (three or more episodes), with the hearing improvement as defined as a change in the hearing threshold (decibels). Statistical tests were done descriptive summaries (means (SD) vs. medians vs. ranges in the case of continuous variables), pre- vs. post-operative acute otitis media cases, pre- vs. post-operative hearing, antibiotic use, daycare enrollment, family history, adenoid hypertrophy, and Pearson correlation coefficient (r) between such variables as tube retention and post-operative acute otitis media; hearing; pre- vs. post-operative improvement; common variables; frequency and percentages). SPSS was used to perform the analyses. The research was approved by the Institutional Review Board/Ethics Committee, and an exemption of an informed consent was provided on the recognizable anonymized data collection in order to ensure the privacy of patients.

RESULTS

Table 1: Assessment outcomes according to Demographic and Clinical Characteristics

Variable	Mean ± SD / n (%)
Age (months)	28.4 ± 12.6
Male	64 (57.1%)
Female	48 (42.9%)
Weight (kg)	12.8 ± 3.4
History of AOM episodes (past 12 mo)	5.2 ± 1.8
Bilateral tube insertion	89 (79.5%)
Unilateral tube insertion	23 (20.5%)
Daycare attendance	71 (63.4%)
Family history of OM	38 (33.9%)
Passive smoking exposure	29 (25.9%)
Adenoid hypertrophy	34 (30.4%)
Previous antibiotic courses (12 mo)	4.8 ± 2.1

Table 2: Distribution with Frequency of AOM Episodes of Pre- vs Post-Tube Insertion (12-month follow-up)

AOM Episodes	Pre-op n (%)	Post-op n (%)
0	0 (0%)	68 (60.7%)
1–2	0 (0%)	31 (27.7%)
3–4	42 (37.5%)	9 (8.0%)
5–6	48 (42.9%)	3 (2.7%)
≥7	22 (19.6%)	1 (0.9%)

Table 3: Rate finding of Descriptive Statistics of Key Outcome Variables

Variable	Mean	SD	Median	Min	Max
AOM episodes pre-op (12 mo)	5.2	1.8	5.0	3	10
AOM episodes post-op (12 mo)	0.7	1.1	0.0	0	5
Hearing level pre-op (dB)	32.5	8.7	31.0	15	55
Hearing level post-op (dB)	18.3	6.2	17.0	8	38
Tube retention (months)	11.8	4.5	11.0	3	26
Time to first post-op AOM (months)	7.4	3.9	7.5	1	12+

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Table 4: Assess results Paired t-test — Pre- vs Post-Operative Comparison

Outcome	Pre-op Mean ± SD	Post-op Mean ± SD	Mean Diff	95% CI	p-value
AOM episodes/year	5.2 ± 1.8	0.7 ± 1.1	**-4.5**	-4.9, -4.1	**<0.001**
Hearing threshold (dB)	32.5 ± 8.7	18.3 ± 6.2	**-14.2**	-16.0, -12.4	**<0.001**
Antibiotic courses/year	4.8 ± 2.1	0.7 ± 0.9	**-4.1**	-4.6, -3.6	**<0.001**
Days of school/daycare missed	12.3 ± 5.6	2.1 ± 2.8	**-10.2**	-11.5, -8.9	**<0.001**

Table 5: Correlation Analysis (Pearson's r) of Bivariate correlations between key variables

Variable Pair	r	p-value	Strength
Age vs. Post-op AOM episodes	**-0.34**	**<0.001**	Moderate
Pre-op AOM frequency vs. Post-op AOM frequency	**0.41**	**<0.001**	Moderate
Tube retention duration vs. Post-op AOM episodes	**-0.52**	**<0.001**	Strong
Pre-op hearing level vs. Post-op hearing improvement	**0.61**	**<0.001**	Strong
Number of pre-op AOM vs. Tube retention time	**-0.18**	**0.057**	Weak
Age vs. Complication rate	**-0.27**	**0.004**	Weak
Weight vs. Tube retention duration	**0.22**	**0.019**	Weak
Daycare attendance vs. Post-op AOM episodes	**0.31**	**<0.001**	Moderate

Table 6: Assessment Binary Logistic Regression — Predictors of Treatment Failure of Dependent variable: Treatment failure (≥3 AOM episodes post-operatively)

Predictor	B	SE	OR	95% CI	p-value
Age <24 months	1.12	0.45	**3.06**	1.27–7.41	**0.013**
Pre-op AOM ≥6 episodes	0.98	0.41	**2.66**	1.19–5.96	**0.017**
Daycare attendance	0.85	0.39	**2.34**	1.09–5.02	**0.029**
Family history of OM	0.74	0.43	**2.10**	0.90–4.87	**0.085**
Adenoid hypertrophy	1.24	0.47	**3.46**	1.38–8.67	**0.008**
Passive smoking exposure	0.69	0.40	**1.99**	0.91–4.37	**0.086**

Table 7: Finally, outcomes of Complications Following Tympanostomy Tube Insertion: Frequency and percentage of observed complications

Complication	n	%	Visual
Otorrhea (transient)	26	23.2%	
Persistent otorrhea (>2 weeks)	8	7.1%	
Premature tube extrusion	12	10.7%	
Tube blockage	7	6.3%	
Tympanosclerosis	14	12.5%	
Persistent perforation (post-extrusion)	5	4.5%	
Granulation tissue	3	2.7%	
No complications	52	46.4%	

Table 8: Overall Outcomes Summary and Success Rate

Outcome Measure	n (%) / Mean ± SD	p-value
Complete resolution (0 AOM post-op)	**68 (60.7%)**	—
Significant improvement (≤2 AOM post-op)	**99 (88.4%)**	—
Treatment failure (≥3 AOM post-op)	**13 (11.6%)**	—
Mean hearing improvement (dB)	**14.2 ± 7.1**	**<0.001**
Parental satisfaction (satisfied/very satisfied)	**96 (85.7%)**	—
Required revision surgery	**9 (8.0%)**	—
Mean reduction in antibiotic courses/year	**4.1 ± 1.9**	**<0.001**
Mean reduction in school days missed/year	**10.2 ± 4.8**	**<0.001**

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DISCUSSION

Our retrospective single-centre cohort study reports significant efficacy of tympanostomy tube insertion (TTI) in the selected children with repeated history of acute otitis media (RAOM) including significant reduction in AOM episodes (preoperative mean 5.2 to postoperative 0.7 per year; mean difference -4.5, $p < 0.001$), hearing thresholds (32.5 dB to 18.3 dB; mean difference -14.2 dB, $p < 0.001$), These magnitudes are consistent with strong pediatric otology literature on short- to intermediate-term benefits of TTIs in effusion-induced RAOM which is probably due to improved middle-ear aeration to reduce the risk of infection and conductive loss which has downstream benefits in language development and academics, but which have not been studied directly in this study. A logistic regression identified important predictors of treatment failure (3 or more episodes of postoperative AOM) such as age less than 24 months (OR = approximately 3.06), high preoperative AOM burden (6 or more episodes; OR = approximately 2.66), daycare attendance (OR = approximately 2.34), and adenoid hypertrophy (OR = approximately 3.46) as important predictors of durability and informed choices and risk counseling of patients at risk. Agreements with the ranges of complications which are expected were maintained, including transient otorrhea (23.2), persistent otorrhea (7.1), premature extrusion (10.7), blockage (6.3), tympanosclerosis (12.5), persistent perforation (4.5), granulation tissue (2.7), and 46.4 without any complications, which is also in line with the published profiles and can be managed through routine care, but risk disclosure before the operation is vital and close monitoring is important The mean tube retention was 11.8 months (3-26) and first postoperative AOM was 7.4 months which highlights the importance of TTIs in the provision of a temporal window of disease containment before risks may recur in the aftermath of extrusion where underlying etiologies still exist. Future studies must also focus on multicenter prospective validations of predictors, long-term (>12 months) follow-ups of hearing, language, academics, and quality-of-life indicators, randomized comparisons of tube types/techniques/adjuncts (e.g., intranasal steroids), and standardized patient-based outcome frameworks which includes infection rates, caregiver burden, and school performance. Limitations of the study are that it is a single-retrospective study, which may limit the scope of its generalizability; it is not adjusted by other confounding factors such as allergies or nutrition; and it was conducted over 12 months, which is not enough to assess the need to re-insert or the lasting consequences.

The function of a tympanic ventilation tube is to ventilate the middle ear, not to drain it. In this way, the tympanic ventilation tube replaces the function of the blocked Eustachian tube in the affected ear, thus improving hearing.

In the postoperative period, the ear should be kept dry, and any additional discharge should be cleaned and treated with antibiotic or steroid ear drops. If the discharge persists, the patient may need to be referred to another specialist. There is some debate about swimming and other activities in the period leading up to a prolapsed eardrum, and research seems to suggest that bath water is the worst culprit.

The tympanic ventilation tube will be removed after 6 to 18 months. It may need to be reinserted, as one in five children requires surgical treatment [Boonacker, C. W. *et al*., 2014].

Insertion of a tympanic drainage tube can lead to thickening and calcification in the eardrum, although this rarely causes hearing loss. A systematic review of tympanostomy tubes in secretory otitis media indicates [National Collaborating Centre for Women's and Children's Health (UK), 2008]

The review concluded that in children with bilateral adhesive otitis media that had not resolved after 12 weeks and was accompanied by documented hearing loss, the beneficial effect of tympanostomy tubes on hearing was present at 6 months but diminished thereafter [Klein, J. O. 2000].

- In children with secretory otitis media, the effect of tympanostomy tubes on hearing, as measured by standard tests, appears to be minimal and fades after 6 to 9 months. At this point, hearing also improves naturally in children who have not undergone surgical treatment.
- Tympanostomy was observed in approximately one-third of the ears that underwent tympanostomy.
- Ear drainage was common in infants, but in older children (3 to 7 years), it occurred in less than 2% of the ears treated with tympanostomy drainage during the 2-year follow-up period.

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CONCLUSION

Tympanostomy tube insertion to RAOM in childhood patients has significant short-term effects, such as a substantial decrease in AOM incidents, a substantial increase in hearing, and a substantial decrease in antibiotic medication and school absenteeism within the initial year after surgery. Although TTIs are associated with otorrhea, extrusion of the tube, and tympanosclerosis, the frequency of overall complications is bearable. Most children improve permanently or at least to some extent where The presented results suggest a focused, family-Centered care of TTIs, with particular attention paid to selecting patients carefully, establishing clear expectations, and having a systematic postoperative follow-up also Prospective, multicentric studies with longer follow-up are required in the future to narrow in the selection of patients, ultimate tube design and location and the late developmental and quality-of-life outcomes.

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