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Original Article

Efficacy and safety of tympanostomy tube insertion combined with adenoidectomy in children with recurrent otitis media: impact on effusion clearance time, otitis media recurrence rate, and hearing improvement

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Abstract: Objective: To investigate whether adenoidectomy (Ad) combined with tympanostomy tube insertion (TTI) would provide additional benefits for children with recurrent otitis media (ROM). Methods: We analyzed the medical records of 160 children aged 3 to 10 years who underwent ROM surgery at Guangdong Medical University Panyu He Xian Memorial Hospital between December 2019 and December 2024. These children were divided into two groups according to their treatment regimen: TTI only group (n=64) and TTI + Ad group (n=96). Clinical measures, including tympanic membrane healing, middle ear effusion clearance, as well as complications and recurrent otitis media, were compared between the two groups. Pure tone audiometry and tympanogram were performed at 2 weeks and 6 months postoperatively. Results: The TTI + Ad group demonstrated significantly faster middle ear effusion clearance, lower recurrence rate of otitis media, and better improvement in hearing at speech frequency range, compared with the TTI only group. Postoperatively, the tympanogram of TTI + Ad group showed a higher proportion of type A curve, suggesting better middle ear function recovery. Multivariate logistic regression analysis further confirmed that TTI + Ad was a protective factor for treatment failure (OR=0.267) and disease recurrence (OR=0.275). Conclusion: The combination of TTI and Ad is more effective than TTI alone in treating ROM. This combined surgical approach not only facilitates faster clearance of middle ear effusion and reduces the risk of recurrence but also contributes to better recovery of the child's hearing.

Keywords: Tympanostomy tube insertion, adenoidectomy, recurrent otitis media, efficacy, safety

Introduction

Recurrent otitis media (ROM) is a common health problem in children. The disease is characterized by repeated inflammation and fluid buildup in the middle ear. Not only will the child experience ear discomfort, but it may also affect daily life and learning due to hearing loss [1]. It is currently believed that the occurrence of the disease is related to a variety of factors, which influence each other and together lead to recurrent fluid buildup and infection in the middle ear [2]. Despite recent advances in drug therapies, many children continue to experience symptoms and even develop complications. Therefore, for these children, surgical intervention has become one of the important treatments [3].

For ROM, the central goal of surgery is to prevent recurrence. Tympanostomy tube insertion (TTI) is currently the most common method of treating effusion in the middle ear. It reduces the episodes of acute infections and improves hearing in affected children by inserting a catheter to drain effusion and maintain ventilation [4-6]. However, it should be recognized that although TTI can effectively remove fluid, it has a limited effect on potential causes such as adenoid hypertrophy. These factors, if left unad-

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dressed, can still lead to continued inflammation and infection, which can affect the overall efficacy of treatment.

Adenoidectomy (Ad) is mainly used to solve the problem of obstruction or recurrent infection due to adenoid hypertrophy. Because the surface of adenoids easily retain pathogens and inflammatory substances, chronic inflammation and even biofilms are often formed, affecting normal function of the eustachian tube. Ad helps restore patency of the eustachian tube, thereby reducing the risk of ROM [7, 8]. Previous studies have shown that even Ad alone has a positive effect on middle ear condition, suggesting that it may lead to better clinical outcomes when combined with TTI [9]. However, the specific effects of TTI combined with Ad on effusion clearance, recurrence of disease, and hearing improvement have not been fully evaluated and verified.

In evaluating the effect of surgical treatment on ROM, the duration of removal of the effusion, the recurrence rate and the degree of hearing improvement are three key factors. If the effusion in the middle ear persists, it will significantly slow down the recovery process and restrict the improvement of hearing. Typically, the quicker the effusion is cleared, the better the treatment and the fewer complications that may follow [10]. Higher recurrence rates requires more frequent clinic visits and even a secondary surgery. This not only increases the medical burden but also affects the quality of life of the child and his family. Prolonged fluid buildup may cause further hearing loss, in turn impairing language development, learning ability, and social performance. Therefore, a successful procedure should aim to restore stability to the child's hearing and effectively prevent further hearing damage [11].

Pediatric surgery places particular emphasis on safety, especially when involving general anesthesia. Among common surgical procedures, TTI and Ad have fewer complications and relatively higher safety. Clarifying the safety level of combined surgical procedures has reference significance for developing clinical plans. Possible complications include otorrhea, middle ear infection, tympanosclerosis, and persistent tympanic membrane perforation. Systematic assessment of the above risks can help doctors better select surgical patients and improve perioperative management measures [12, 13].

The combination of TTI and Ad provides a promising solution for achieving treatment goals. This study aims to provide a reference for cognitive accumulation in this field by systematically analyzing the impact of combined surgery on the main clinical outcomes.

Materials and methods

Study population

We reviewed and analyzed the medical records of 160 children with ROM who underwent surgical treatment at Guangdong Medical University Panyu He Xian Memorial Hospital from December 2019 to December 2024. The analysis included their medical records, clinical examination data, and postoperative follow-up data.

Inclusion criteria: ① Age 3-10 years, no gender restriction; ② Conformity to the diagnostic criteria for pediatric ROM as outlined in the "Guidelines for Diagnosis and Treatment of Otitis Media in Children (Draft)" [14]; ③ Adenoid hypertrophy confirmed by electronic nasopharyngoscopy or lateral nasopharyngeal X-ray (adenoids/nasopharyngeal cavity [A/N] ratio ≥0.6%); ④ Complete medical, clinical, and follow-up data.

Exclusion criteria: ① Congenital cleft lip and palate, congenital ciliary body dysfunction syndrome, congenital middle ear or inner ear malformations; ② Immunodeficiency and allergy-related diseases; ③ History of chronic suppurative otitis media, history of ototoxic drug use, family history of deafness, long-term noise exposure, and other underlying ear diseases; ④ Psychiatric history, cognitive impairment, severe liver and kidney dysfunction.

Ethics statement

The study protocol was reviewed and approved by the Medical Ethics Committee of Guangdong Medical University Panyu He Xian Memorial Hospital. As this is a retrospective study, all data were extracted from the hospital's electronic medical record system and clinical databases, thus waiving the need for informed consent from the children and their families.

Study grouping

The 160 children were defined into two groups based on the surgical procedures they actually received: the Tympanostomy Tube Insertion (TTI) group (n=64) and the combined with Adenoidectomy (TTI + Ad) group (n=96). Children in the TTI group suffered from middle ear effusion and associated hearing loss; although they had adenoid hypertrophy, they did not exhibit significant clinical symptoms and thus only underwent TTI. In contrast, children in the TTI + Ad group exhibited symptoms related to both middle ear effusion and adenoid hypertrophy and therefore received TTI + Ad. For all children, the assessment of adenoid hypertrophy and related symptoms primarily relied on the OSA-18 scale, which evaluates the impact of obstructive sleep apnea hypopnea syndrome (OSAHS) on the quality of life in children. A score of less than 60 was considered indicative of no significant clinical symptoms.

Preoperative standardized drug treatment

Prior to considering surgical intervention, all pediatric patients received a standardized 4-week non-surgical treatment regimen strictly in accordance with the recommendations of the "Guidelines for the Diagnosis and Treatment of Otitis in Children" [14]. The specific medications included Amoxicillin-Clavulanate Potassium (approval number: H10920034, North China Pharmaceutical Co., Ltd., Hebei Province) (dose: 45 mg/kg per dose, twice daily) and Mometasone Furoate Nasal Spray (approval number: H20113481, Zhejiang Xianju Pharmaceutical Co., Ltd., Zhejiang Province) (one spray per nostril daily, each spray containing 50 μg). An efficacy assessment was conducted after the 4-week drug treatment period. Indications for surgical intervention were defined as inadequate response to standardized medical treatment, meeting at least one of the following criteria: ① Persistent symptoms: no significant improvement in subjective symptoms such as hearing loss and ear fullness; ② No improvement on otoscopic examination: tympanic membrane still amber or orange-red, disappearance of light reflex, presence of fluid level or air bubbles; ③ Audiological tests not returning to normal: re-examination of tympanometry still showing type B or C tympanograms; pure-tone audiometry indicating that air-conduction thresholds had not returned to within normal range (>25 dB HL). After evaluation, all 160 children in this study met the above criteria for 'inadequate response to medical treatment' and thus underwent surgical treatment.

Surgical procedures

All patients were placed in a supine position and underwent tracheal intubation for general anesthesia, followed by routine disinfection and sterile draping. In the TTI group, under ear endoscopy, the disinfectant in the external auditory canal was completely aspirated, and after ensuring a clear view of the intact tympanic membrane, an incision was made in the anteroinferior part of the tympanic membrane. The effusion in the middle ear cavity was aspirated, and a T-shaped silicone ventilation tube was inserted. Specifically, under ear endoscopy, a radial incision of approximately 2 millimeters in length was made in the anterior-inferior quadrant of the tympanic membrane. The wing of a T-tube ventilating tube (model: Shepard tube, inner diameter 1.14 mm, length 4.76 mm) was carefully inserted into the incision to ensure it was securely embedded within the tympanic membrane. In the TTI + Ad group, tympanic tube insertion was completed first. Subsequently, a nasal tube was used to elevate the soft palate, thereby clearly exposing the nasal pharyngeal cavity. Under the guidance of the 70° sinus endoscopic video system inserted orally, the Ad was performed using a low-temperature plasma knife. The surgery was performed using the EVac 70 Xtra plasma surgical system (AR-5000, American ArthroCare Company) and the Reflex 55 electrode. The energy parameters were set to the cutting mode with 7 settings and the coagulation mode with 4 settings. Throughout the procedure, the electrode maintained a gentle contact with the tissue. A method of layer-by-layer ablation from the outside inward was employed, ensuring that the cutting depth was strictly controlled at 2-3 mm below the mucosal layer to avoid thermal damage to deeper tissues. Bleeding points were treated using a point-contact coagulation method, which helped maintain a clear surgical field. The extent of the resection was guided by the anatomical landmarks of fully exposing the posterior nasal margin and the pharyngotympanic tube prominence. This app-

roach allowed for the complete removal of the adenoid tissue while effectively protecting the surrounding normal structures.

Postoperatively, all children received routine anti-infection treatment for one week. Weekly follow-ups were conducted to check for displacement, detachment, or blockage of the ventilation tubes, with instructions given to parents to observe any fluid discharge from the operated ear. The time from the end of surgery until no fluid flow was defined as the effusion clearance time. Two weeks postoperatively, pure-tone average (PTA) at speech frequencies was reassessed, and six months postoperatively, tympanometry and otoscopic examination were performed to determine whether there was recurrence of effusion or purulent discharge due to middle ear infection.

Observation indicators

(1) Clinical indicators, including tympanic membrane healing and effusion clearance time [14].

(2) Safety indicators, including the recurrence rate of otitis media and the incidence of postoperative complications. According to the "Guidelines for Diagnosis and Treatment of Otitis Media in Children (Draft)" [14], during the 6-month postoperative follow-up period, any of the following manifestations would be considered as a recurrence of otitis media: ① Hearing loss and ear blockage sensation in the child; ② Otoscopic examination showing tympanic membrane retraction, appearing yellow or amber; ③ Tympanometry indicating middle ear pressure <-200 mm H_2O. Complications primarily included otorrhea, middle ear infection, tympanosclerosis, and non-healing tympanic membrane perforation [15]. To more precisely assess the safety of the surgery, we categorized complications based on their impact on the child's health, the difficulty of treatment, and long-term prognosis into mild, moderate, and severe levels. Specifically, otorrhea was classified as mild, middle ear infections and tympanosclerosis as moderate, and non-healing tympanic membrane perforations as severe.

(3) Hearing improvement, including preoperative and postoperative PTA at speech frequencies and tympanometry [16, 17]. One week before surgery and two weeks after surgery, pure tone audiometry (OB992, Madsen Audio, Denmark) was used to assess the children's hearing thresholds. The test frequencies included 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz. Each frequency started at 10 dB above the hearing threshold and utilized a descending 10 dB and ascending 5 dB step method to determine the threshold: the sound intensity was gradually decreased until the sound was no longer heard, then increased again until it was heard, repeating this process three times. The lowest consistent intensity value at which the sound was heard twice was recorded as the hearing threshold for that frequency. The PTA at speech frequencies was calculated from the air conduction thresholds at 500 Hz, 1000 Hz, and 2000 Hz. One week before surgery and six months after surgery, middle ear analyzer (AT235h, Grason-Stadler Inc., USA) was used to measure the children's tympanic pressure and acoustic admittance values. The tympanograms were classified into types A, B, and C based on the shape of the tympanogram curves.

(4) Clinical efficacy: Six months postoperatively, clinical efficacy was classified into three levels - full recovery, effective, and invalid - based on improvements in symptoms, hearing restoration, and middle ear function. Full recovery was defined as a tympanogram returning to type A, complete disappearance of clinical symptoms (tinnitus, ear fullness), and normalization of hearing and tympanic membrane appearance. Effective was defined as a tympanogram changing from type B to type C or from type C to type A, significant improvement in clinical symptoms, a reduction in hearing thresholds by 10-15 dB, and no significant tympanic membrane retraction. Invalid was defined as no change in the tympanogram, with no significant improvement in clinical symptoms, hearing, or tympanic membrane appearance. The total efficacy of the treatment 6 months after surgery was calculated as follows: Total effective rate = (full recovery + effective) × total cases/100% [18].

Statistical analysis

Statistical analyses were performed using SPSS statistical software (version 29.0; developed by SPSS Inc., Chicago, IL, USA). Continuous variables, after being tested for normal distribution using the Shapiro-Wilk test, were expressed as means ± standard deviations (M ± SD) and compared between groups using inde-

Table 1. Comparison of general data between the two groups

Parameters	TTI group (n=64)	TTI + Ad group (n=96)	t/χ^2	P
Age (years)	6.23 ± 1.38	6.59 ± 1.45	1.574	0.117
Gender [n (%)]			0.004	0.948
Male	35 (54.69%)	52 (54.17%)		
Female	29 (45.31%)	44 (45.83%)		
Disease duration (months)	11.64 ± 1.41	11.43 ± 1.43	0.898	0.371
Affected ear [n (%)]			0.004	0.947
Binaural	39 (60.94%)	58 (60.42%)		
Monaural	25 (39.06%)	38 (39.58%)		
A/N [n (%)]			0.158	0.691
>0.7%	38 (59.38%)	60 (62.50%)		
0.6-0.7%	26 (40.62%)	36 (37.50%)		
Clinical symptoms				
Hearing loss [n (%)]	64 (100.00%)	96 (100.00%)	-	-
Aural fullness [n (%)]	52 (81.25%)	84 (87.50%)	1.176	0.278
Otalgia [n (%)]	32 (50.00%)	52 (54.17%)	0.267	0.605
Comorbidities				
Recurrent sinusitis [n (%)]	12 (18.75%)	20 (20.83%)	0.104	0.747
Tonsillitis [n (%)]	10 (15.62%)	14 (14.58%)	0.033	0.857

Abbreviations: TTI, tympanostomy tube insertion; TTI + Ad, tympanostomy tube insertion combined with adenoidectomy; A/N, adenoids/nasopharyngeal cavity.

pendent samples t-tests. Categorical variables were expressed as frequencies and percentages [n (%)] and compared between groups using the χ^2 test. A *p*-value less than 0.05 was considered indicative of statistically significant differences. To further explore risk factors affecting the efficacy and safety in children with ROM at 6 months after surgery, univariate and multivariate logistic regression analyses were conducted. The dependent variables were "clinical efficacy at 6 months postoperatively (invalid =1, effective + full recovery =0)", "recurrence of otitis media at 6 months postoperatively (recurrence =1, no recurrence =0)" and complication occurrence at 6 months postoperatively (occurrence =1, no occurrence =0). Potential influencing factors (TTI + Ad, age, male gender, duration of illness, A/N >0.7%, binaural involvement, preoperative PTA at speech frequencies) were included as independent variables.

Results

General data

Table 1 compares general data between the TTI group (n=64) and the TTI + Ad group (n=96). No significant differences were noted in age (P=0.117), gender (P=0.948), disease duration (P=0.371), affected ear (P=0.947), A/N ratio (P=0.691), or clinical symptoms including aural fullness (P=0.278) and otalgia (P=0.605). Similarly, comorbidities such as recurrent sinusitis (P=0.747) and tonsillitis (P=0.857) showed no significant differences between groups.

Clinical indicators

Figure 1 provides a comparison of eardrum healing time and effusion clearance time between the TTI group and the TTI + Ad group. Eardrum healing time did not differ significantly between the groups (P=0.921). In contrast, the TTI + Ad group experienced a significantly shorter effusion clearance time (7.19 ± 1.12 vs 7.72 ± 1.35, t=2.718, P=0.007).

Safety indicators

Table 2 compares the incidence of otitis media recurrence and complications between the TTI group and the TTI + Ad group. The otitis media recurrence rate was significantly lower in the TTI + Ad group (4.17% vs 14.06%, χ^2=5.038, P=0.025). No significant difference was noted in the overall complications rate (P=0.180). Specifically, the TTI + Ad group showed a 2.08% incidence of severe complications, indicating good safety. Although there was no significant difference in the overall complication rate, the stratified data provided more detailed risk information for clinicians.

Hearing improvement

Figure 2 compares PTA at speech frequencies between the TTI group and the TTI + Ad group. Preoperative PTA values did not differ significantly (P=0.979). However, postoperative PTA values at 2 weeks were significantly lower in the TTI + Ad group (19.11 ± 6.36 vs 21.86 ± 6.92, t=2.581, P=0.011).

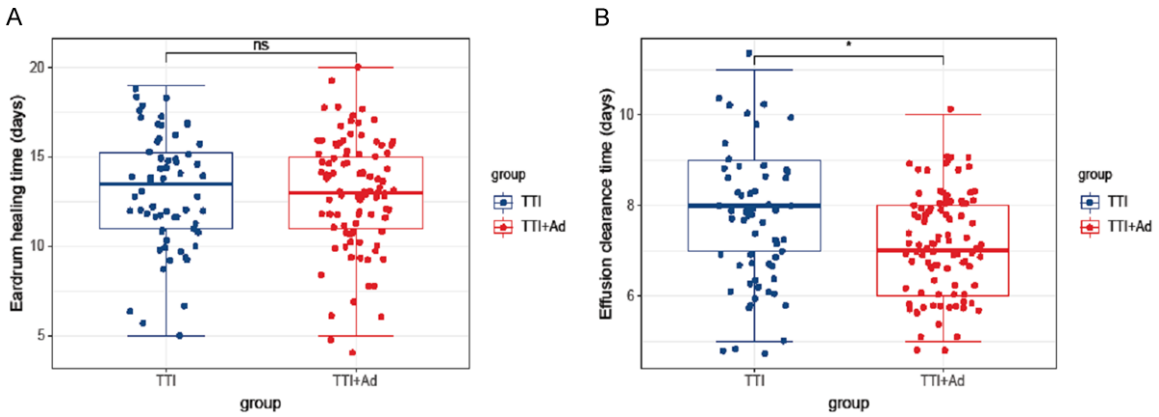

Figure 1. Comparison of eardrum healing and effusion clearance time between two groups. A. Eardrum healing time; B. Effusion clearance time. ns: no significant difference; *: P<0.05. Abbreviations: TTI, tympanostomy tube insertion; TTI + Ad, tympanostomy tube insertion combined with adenoidectomy.

Table 2. Comparison of otitis media recurrence and complication rates between the two groups [n (%)]

Parameters	TTI group (n=64)	TTI + Ad group (n=96)	χ^2	P
Otitis media recurrence rate	9 (14.06%)	4 (4.17%)	5.038	0.025
Complications rate	7 (10.94%)	4 (4.17%)	1.794	0.180
Otorrhea	4 (6.25%)	3 (3.12%)		
Middle ear infection	3 (4.69%)	2 (2.08%)		
Tympanosclerosis	2 (3.12%)	0 (0.00%)		
Non-healing of tympanic membrane perforation	1 (1.56%)	2 (2.08%)		
Severity of complications [n (%)]	10 (15.62%)	7 (7.29%)	2.808	0.094
Mild	4 (6.25%)	3 (3.12%)		
Moderate	5 (7.81%)	2 (2.08%)		
Severe	1 (1.56%)	2 (2.08%)		

Abbreviations: TTI, tympanostomy tube insertion; TTI + Ad, tympanostomy tube insertion combined with adenoidectomy.

Table 3 provides a comparison of tympanogram types between the TTI group and the TTI + Ad group. Preoperative tympanogram types did not differ significantly (P=0.734). In contrast, significant differences were observed at 6 months postoperatively (χ^2=11.786, P=0.003). The TTI + Ad group showed a higher rate of Type A tympanograms (93.75% vs 78.12%) and lower rates of Type B (6.25% vs 12.50%) and Type C (0.00% vs 9.38%) tympanograms compared to the TTI group.

Clinical efficacy

Table 4 shows the total treatment efficacy 6 months after surgery between the TTI group and the TTI + Ad group. The total effective rate was significantly higher in the TTI + Ad group compared with the TTI monotherapy group (93.75% vs 81.25%, χ^2=6.009, P=0.014).

Univariate and multivariate logistic regression analysis

Table 5 shows the univariate and multivariate logistic regression analysis of risk factors for invalid efficacy in children with ROM at 6 months post-surgery. The TTI + Ad method was a significant protective factor in both univariate (P=0.014, OR=0.250, 95% CI=0.083-0.753) and multivariate analyses (P=0.018, OR=0.267, 95% CI=0.087-0.821). Other factors, such as age, gender, disease duration, A/N ratio, binaural involvement, and preoperative PTA, showed no significant associations (all P>0.05). These results suggested that the TTI + Ad approach significantly decreased the risk of ineffective treatment.

Table 6 presents the univariate and multivariate logistic regression analysis for risk factors

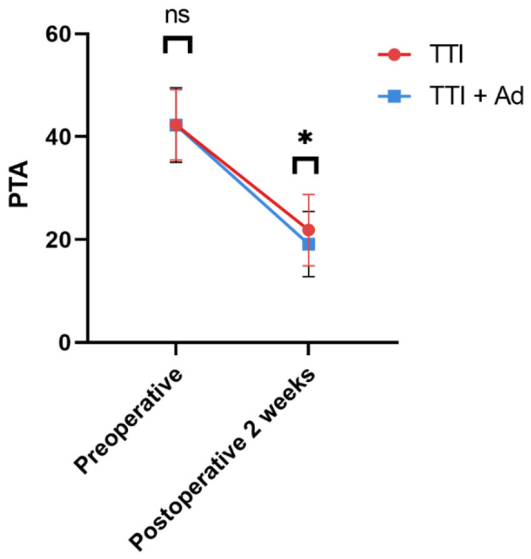

Figure 2. Comparison of PTA at speech frequencies between two groups. (dB HL). ns: no significant difference; *: P<0.05. Abbreviations: PTA, pure-tone average; TTI, tympanostomy tube insertion; TTI + Ad, tympanostomy tube insertion combined with adenoidectomy.

affecting otitis media recurrence in children with ROM 6 months after surgery. Only the TTI + Ad method was a significant protective factor in both univariate (P=0.025, OR=0.267, 95% CI=0.080-0.892) and multivariate analyses (P=0.031, OR=0.275, 95% CI=0.082-0.923). Other parameters, including age, gender, disease duration, A/N ratio, binaural involvement, and preoperative PTA, were not significantly associated with recurrence (all P> 0.05). Overall, these data indicated that the TTI + Ad approach significantly reduced the risk of otitis media recurrence.

Table 7 presents the results of univariate and multivariate logistic regression analysis to explore factors associated with complications in ROM children 6 months after surgery. In the multivariate analysis, age was a significant protective factor (P=0.043, OR=0.723, 95% CI= 0.528-0.989), while bilateral ear involvement (P=0.012, OR=2.815, 95% CI=1.256-6.308) and disease duration (P=0.028, OR=1.324, 95% CI=1.031-1.701) were significant risk factors. The TTI + Ad surgical approach demonstrated a trend towards reduced risk of complications but this difference did not reach statistical significance (P=0.180).

Discussion

The study focused on the time taken to clear the effusion as the primary outcome measure to evaluate the efficacy of TTI and Ad. The results indicated that the combination of TTI and Ad led to a faster clearance of middle ear effusion compared to the use of TTI alone. This result is similar to the report by Weng et al. [4]. This study also found that combined surgery could clear effusion clearance more quickly. One possible explanation is Ad not only removes a mechanical blockage in the eustachian tube orifice [19] but more importantly removes adenoid tissue harboring bacterial biofilms [10, 20]. Such chronic biofilm infections continuously release inflammatory mediators, causing edema and impaired function in the eustachian tube mucosa [21]. By eliminating this persistent source of inflammation, Ad helps to reduce the inflammatory load and restore mucosal function. This thereby improves middle ear ventilation and drainage [22]. This view is similar to that of Fang et al. [19]. The emphasis on simultaneous processing of obstruction and inflammation is consistent.

This study found that combined surgery can significantly reduce the recurrence rate of otitis media. For ROM patients with adenoid hypertrophy, this advantage highlights the importance of addressing nasopharyngeal etiologies. Rasheed et al. [8] also showed that combined surgery can help prevent the effusion recurrence. This is consistent with the results of this study. The mechanism mainly includes two aspects. Ad fundamentally improves the opening function of the Eustachian tube and reduces the risk of middle ear negative pressure and effusion formation [23, 24]. In addition, as pointed out in the systematic review by Elzayat et al. [10], the presence of bacterial biofilms on the surface of adenoids is a key factor in the sustained existence of ROM. Simple TTI can treat middle ear effusion but it does not eliminate the source of infection in the nasopharynx, Ad directly removed this lesion. This significantly reduces the chances of pathogen recolonization and ascending infection [25]. MacKeith et al.'s [9] Cochrane review also points out that the benefits of Ad in preventing the recurrence of otitis media with effusion (OME) may stem from this.

Table 3. Comparison of tympanograms between the two groups [n (%)]

Parameters	TTI group (n=64)	TTI + Ad group (n=96)	χ^2	P
Preoperative			0.115	0.734
Type B	52 (81.25%)	80 (83.33%)		
Type C	12 (18.75%)	16 (16.67%)		
Postoperative 6 months			11.786	0.003
Type A	50 (78.12%)	90 (93.75%)		
Type B	8 (12.50%)	6 (6.25%)		
Type C	6 (9.38%)	0 (0.00%)		

Abbreviations: TTI, tympanostomy tube insertion; TTI + Ad, tympanostomy tube insertion combined with adenoidectomy.

Table 4. Comparison of overall treatment efficacy between the two groups at 6 months after surgery [n (%)]

Parameters	TTI group (n=64)	TTI + Ad group (n=96)	χ^2	P
Total effective rate	52 (81.25%)	90 (93.75%)	6.009	0.014
Full recovery	28 (43.75%)	59 (61.46%)		
Effective	24 (37.50%)	31 (32.29%)		
Invalid	12 (18.75%)	6 (6.25%)		

Abbreviations: TTI, tympanostomy tube insertion; TTI + Ad, tympanostomy tube insertion combined with adenoidectomy.

Hearing improvement is an important evaluation goal for pediatric otolaryngology surgery. The data showed that the combined surgery resulted in more significant hearing improvement than TTI alone. This advantage can be explained from many perspectives. Timely removal of effusion in the middle ear can help to reduce conductive hearing loss, and effusion is a common cause of such problems [26]. When the adenoids are removed, the eustachian tube function improves, which supports better middle ear ventilation and pressure regulation, which in turn improves hearing sensitivity [24, 27]. The study also found that the TTI + Ad group had a higher rate of type A tympanogram, which suggested that the physiological state of the middle ear was better. Tympanogram A usually reflects the state of health with normal middle ear ventilation, while tympanogram B and C indicate effusion or negative pressure, respectively [28]. The increased proportion of A-shaped curve in this study indicates that combined surgery is more effective in restoring the state of health of the middle ear. This is the same as the report by Turaki et al. [7], whose study also showed that Ad significantly improved tympanogram results. Combined surgery can help establish a more stable state of health of the middle ear by rapidly removing the effusion and reducing the likelihood of recurrence, thus promoting a lasting and more complete recovery of hearing [29]. Yousefi et al. [22] has also been shown that when the function of the middle ear is restored to normal, the related auditory function problems can be effectively solved.

Compared with TTI alone, combined surgery showed better overall outcomes. This advantage may be due to the simultaneous processing of mechanical obstruction and middle ear effusion caused by adenoidal hypertrophy. Another possible explanation is that TTI + Ad reduces inflammatory mediators and pathogens in the nasopharynx. These mediators are important in sustaining the cycle of inflammation and infection, and Ad can interrupt this process. As a result, the middle ear environment becomes more favorable for tissue recovery and the maintenance of a healthy state [30, 31]. Research has indicated that hypertrophic adenoid tissue is a critical site for the sustained activation of the NF-κB signaling pathway. Bacterial biofilms attached to its surface, such as those of Streptococcus pneumoniae and Haemophilus influenzae, can release pathogen-associated molecular patterns (PAMPs), which activate the NF-κB pathway through Toll-like receptors (TLRs), subsequently promoting the overexpression of pro-inflammatory cytokines like IL-6 and IL-8 [32]. Ad surgery eliminates this inflammatory signal source by removing the adenoid tissue. This thus inhibits the activation of the NF-κB pathway and reduces the dissemination of cytokines such as IL-6 and IL-8 to the eustachian tube and middle ear mucosa. This mechanism helps alleviate mucosal edema, decrease vascular permeability, and accelerate the absorption and clearance of effusion [33]. In addition to regulating

Table 5. Univariate and multivariate logistic regression analysis of risk factors affecting the invalid efficacy in children with ROM 6 months after surgery

Parameters	Univariate analysis			Multivariate analysis		
	P	OR	95% CI	P	OR	95% CI
TTI + Ad	0.014	0.250	0.083-0.753	0.018	0.267	0.087-0.821
Age	0.342	0.867	0.653-1.151	0.401	0.885	0.662-1.183
Male	0.857	0.933	0.452-1.925	0.901	0.956	0.456-2.003
Disease duration	0.371	1.112	0.882-1.402	0.423	1.098	0.869-1.387
A/N >0.7%	0.691	1.158	0.564-2.377	0.735	1.132	0.550-2.331
Binaural affected	0.947	0.981	0.476-2.023	0.962	0.985	0.477-2.035
Preoperative PTA at speech frequencies	0.979	1.003	0.937-1.073	0.988	1.001	0.935-1.072

Abbreviations: ROM, recurrent otitis media; TTI + Ad, tympanostomy tube insertion combined with adenoidectomy; A/N, adenoids/nasopharyngeal cavity; PTA, pure-tone average; OR, odds ratio; CI, confidence interval.

Table 6. Univariate and multivariate logistic regression analysis of risk factors affecting the recurrence of otitis media in children with ROM 6 months after surgery

Parameters	Univariate analysis			Multivariate analysis		
	P	OR	95% CI	P	OR	95% CI
TTI + Ad	0.025	0.267	0.080-0.892	0.031	0.275	0.082-0.923
Age	0.117	0.794	0.593-1.063	0.145	0.812	0.605-1.089
Male	0.948	0.981	0.456-2.109	0.972	0.990	0.459-2.136
Disease duration	0.371	1.112	0.882-1.402	0.388	1.125	0.870-1.455
A/N >0.7%	0.691	1.158	0.564-2.377	0.702	1.172	0.530-2.592
Binaural affected	0.947	0.981	0.476-2.023	0.955	0.983	0.476-2.031
Preoperative PTA at speech frequencies	0.979	1.003	0.937-1.073	0.981	1.002	0.936-1.073

Abbreviations: ROM, recurrent otitis media; TTI + Ad, tympanostomy tube insertion combined with adenoidectomy; A/N, adenoids/nasopharyngeal cavity; PTA, pure-tone average; OR, odds ratio; CI, confidence interval.

Table 7. Univariate and multivariate logistic regression analysis of risk factors affecting the occurrence of complications in children with ROM 6 months after surgery

Parameters	Univariate analysis			Multivariate analysis		
	P	OR	95% CI	P	OR	95% CI
TTI + Ad	0.165	0.342	0.095-1.231	0.180	0.356	0.102-1.241
Age	0.038	0.715	0.521-0.981	0.043	0.723	0.528-0.989
Male	0.791	1.124	0.478-2.642	0.825	1.087	0.512-2.308
Disease duration	0.025	1.351	1.038-1.758	0.028	1.324	1.031-1.701
A/N >0.7%	0.298	1.487	0.705-3.136	0.315	1.452	0.702-3.004
Binaural affected	0.009	2.964	1.308-6.718	0.012	2.815	1.256-6.308
Preoperative PTA at speech frequencies	0.062	1.135	0.994-1.297	0.067	1.128	0.991-1.284

Abbreviations: ROM, recurrent otitis media; TTI + Ad, tympanostomy tube insertion combined with adenoidectomy; A/N, adenoids/nasopharyngeal cavity; PTA, pure-tone average; OR, odds ratio; CI, confidence interval.

inflammatory pathways, Ad also exerts long-term therapeutic effects by reshaping the local immune microenvironment [34]. Bacterial biofilms on the surface of adenoid tissue can recruit a large number of neutrophils and induce M1 macrophage polarization. This creates an immune environment dominated by pro-inflammatory responses. After Ad surgery, with the clearance of biofilms, the pattern of local immune cell infiltration changes: the proportion of M2 macrophages significantly increases, while neutrophil infiltration decreases. M2 macrophages are characterized by the secretion of anti-inflammatory cytokines such as

IL-10 and TGF-β, which promote tissue repair and immune regulation, thereby improving ciliary function of the Eustachian tube mucosa and middle ear ventilation. Furthermore, the removal of biofilm-associated antigens reduces their continuous stimulation of local immune cells, facilitating the restoration of immune homeostasis.

According to the results of univariate and multivariate logistic regression analysis, TTI + Ad has been confirmed to be an important protective factor that can significantly reduce the risk of treatment failure and recurrence of otitis media. This discovery further confirms that combined surgery has better therapeutic effects compared to TTI alone. The reason why Ad can have a protective effect is that it helps improve the function of the Eustachian tube, reduce biofilm formation, and promote mucosal ciliary clearance ability [35, 36].

The baseline characteristics of the two groups of patients in terms of age, gender, disease duration, affected ear side, A/N ratio, as well as clinical symptoms such as ear tightness and pain, remained balanced and comparable. Therefore, the observed differences in results are mainly due to differences in treatment methods, rather than the influence of individual patient characteristics. The two groups did not show significant differences in comorbidities such as recurrent sinusitis and tonsillitis, which further supports the above conclusion and ensures that the research results are not affected by these factors and have good reliability.

This study has yielded encouraging results, yet several limitations remain. The retrospective design may limit causal inference. Future prospective randomized controlled trials could offer stronger evidence regarding the benefits of combined surgery. Although this study evaluated multiple efficacy indicators, there are still some factors that could potentially impact the treatment outcomes and safety that have not been included in the analysis. Further studies should incorporate more comprehensive variables and longer follow-up periods to strengthen the evidence base. In addition, this study did not use multi-channel sleep monitoring or standardized sleep questionnaires to objectively evaluate the postoperative sleep improvement of pediatric patients Although children who undergo TTI combined with adenoidectomy undergo surgery for symptoms related to adenoid hypertrophy, such as sleep snoring, we have reason to believe that their sleep quality should be significantly improved. However, due to the lack of specific sleep data collection, it is still difficult to fully demonstrate the comprehensive effect of this surgery in improving the sleep structure of OSA children. Future prospective studies should consider incorporating such important patient reported outcomes into the core evaluation system. Another limitation of this study is the lack of standardized assessment of postoperative language development in pediatric patients. Although we confirm that combined surgery can more effectively restore auditory pathway function, a six-month follow-up period and a single audiometric measurement are still insufficient to directly evaluate its long-term impact on language acquisition. Improving hearing is indeed an important foundation for language development, but language development itself is also influenced by various factors such as cognition and environment. Therefore, future research should extend the follow-up period to one year or longer and introduce standardized language assessment tools such as the Peabody Picture Vocabulary Test (PPVT), which will help to more fully reveal the true effect of surgery on the long-term quality of life of children with ROM.

Future studies should explore the long-term influence of combined surgery on quality of life and learning ability in children with ROM. Further exploring the impact of these treatment methods on the field of overall health could help optimize clinical strategies. Additionally, analyzing the cytokine profiles and characteristics of microbial communities may shed light on the mechanisms of action of Ad. This can provide insights for identifying new therapeutic targets and develop personalized treatment plans.

Conclusion

TTI combined with Ad is more effective than TTI alone for ROM. Combined surgery not only helps to clear the middle ear effusion faster, but also effectively reduces the risk of recurrence of otitis media, and shows a more significant effect in terms of hearing improvement. The improved tympanogram types also confirms that the recovery of the middle ear function is more desirable in the TTI + Ad group. The

decline in the rate of recurrence and the magnitude of hearing improvement may be related to the effect of Ad. This surgery helps to reduce the localized chronic inflammatory state while improving eustachian tube function.

Disclosure of conflict of interest

None.

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