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OTOLOGY

Compare two surgical interventions for otitis media with effusion in young children

Jinsheng Hao[1,2,3] · Min Chen[1,2,3] · Bing Liu[1,2,3] · Yang Yang[1,2,3] · Wei Liu[1,2,3] · Ning Ma[1,2,3] · Yang Han[1,2,3] · Qiaoyin Liu[1,2,3] · Xin Ni[1,2,3] · Jie Zhang[1,2,3]

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Abstract

Objective To prospectively evaluate the effect of tympanostomy tubes combined with adenoidectomy and tube insertion on treatment for otitis media with effusion in young children, and to analyze the related factors of prognosis and recurrence of the disease.

Methods The clinical and follow-up data of 184 children with otitis media with effusion who were treated in the department of Otolaryngology, Head and Neck Surgery, Beijing Children's Hospital, Capital Medical University from September 2013 to January 2015, were reviewed systematically. According to different surgical methods, they were randomly divided into the observation group in which patients were treated with tube insertion combined with adenoidectomy, and control group in which the rest underwent simple tube insertion. The curative effect, changes of air conduction hearing threshold before and after surgery, the healing time of tympanic membrane and recurrence of middle ear effusion were compared between the two groups. Influencing factors of recurrence of otitis media with effusion were analyzed, and the effect of healing time on tympanic membrane after tube removal was observed.

Results The total effective rate of treatment in the observation group was higher than that in the control group (91.84% vs 80.23%, $P<0.05$), and the air conduction hearing thresholds in two groups were decreased significantly at 3 months and 6 months after surgery, respectively ($P<0.05$). The total effective rate of children under 4 years old in the observation group was also higher than that in the control group. The duration of middle ear effusion and the recurrence rate in the observation group were shorter/lower than those in the control group ($P<0.05$). Analysis showed that recurrent respiratory tract infection before surgery and retention time of ventilating tube shorter than 12 months were risk factors for recurrence of otitis media with effusion, while adenoidectomy was a protective factor. Besides, the tympanic membrane healing time of the tympanic membrane tube for 1 years was shorter than that of the tympanic membrane tube for more than one year ($P<0.05$). The persisted perforation rate is 3.57% in less 12 months of tube, as opposed to it was 12% in more 12 months of tube ($P<0.05$).

Conclusions Tube insertion combined with adenoidectomy is more effective than tympanostomy tubes in the treatment of young children with OME, and the same results were found for children under four years of age. It can significantly shorten the duration of middle ear effusion and reduce the recurrence rate after surgery. For 3–6 year-old children, the upper respiratory tract infection and short ventilation tube indwelling time increase the possibility of OME recurrence, it is recommended that the ventilation tube should be retained for at least 12 months.

Keywords Young children · Otitis media with effusion · Tube insertion · Adenoidectomy · Risk factor for recurrence

✉ Xin Ni
nixin@bch.com.cn

✉ Jie Zhang
stzhangj@263.net

[1] National Center for children's Health, Beijing, People's Republic of China

[2] Department of Otolaryngology, Head and Neck Surgery, Beijing Children's Hospital, Capital Medical University, Beijing 100045, People's Republic of China

[3] Beijing Key Laboratory for Pediatric Diseases of Otolaryngology, Head and Neck Surgery, Beijing Pediatric Research Institute, Beijing Children's Hospital, Capital Medical University, Beijing, People's Republic of China

Introduction

Otitis media with effusion (OME) is a common disease in department of E.N.T, which occurs mostly in children. About 90% of children have OME before school age [1] It is characterized by middle ear effusion and conductive hearing loss, and it has certain effect on children's language and intelligence development [2]. Tympanostomy tubes insertion is a common treatment for OME, and it can maintain balance the middle ear pressure, reducing the proliferation of glands and goblet cells, and suppressing excessive fluid production [3]. However, many children with OME are accompanied by adenoidal hypertrophy, and whether adenoidectomy is performed at the same time with tube insertion needs further study. It was found that the recurrence rate for OME was as high as 20–25% in children [4], the study of risk factors for recurrence in OME has clinical significance. In this paper, a prospective study on the treatment of OME by tympanostomy tubes combined with adenoidectomy and the risk factors of recurrence was discussed, so as to provide evidence and strategy for clinical treatment of OME in young children.

Materials and methods

Definition

The presence of fluid in the middle ear without signs or symptoms of acute ear infection [4].

Criteria

Inclusion criteria: (1) according with the diagnostic criteria for OME, (2) age between 3 and 6 years old, (3) with surgical indications after conservative treatment failure, (4) family members were fully informed of the study and signed informed consent. Exclusion criteria: (1) children with mixed deafness, (2) children with craniofacial deformities, (3) children not between 3 and 6 years old, (4) children with incomplete clinical follow-up data. (5) In follow-up, due to various reasons the ventilation tube indwelling time less than 6 month.

Grouping

All patients were randomly divided into the observation group (group A) and the control group (group B) according to different surgical methods. The group A was treated by tube insertion and adenoidectomy. The group B was treated by tympanostomy tubes insertion. Patients younger than 4 years old in group A and group B were divided into group A1 and group B1, respectively.

Treatment methods

The group B was treated by tympanostomy tubes insertion. After satisfying general anesthesia, the tympanic membrane was incised at anterior inferior or posterior inferior quadrant under endoscope at 0°, and fluid in the tympanic cavity was cleared. For jelly-like substance which was difficult to clear, dexamethasone was used for rinse and then the substance was extracted. The T-silicone ventilation tube was correctly placed in the tympanic membrane, and it was adjusted properly if necessary. The group A was treated by tube insertion and adenoidectomy. Tube insertion was the same as that of control group. Steps of adenoidectomy were as follows, the endoscope at 0° was put into the choana through nasal cavity. The adenoid tissues were resected with high-speed micro-power cutting aspirator through mouth under high-definition monitor. The bilateral pharyngeal ostia and tori were protected during surgery, and the depth of surgery was basically parallel to the posterior pharyngeal wall.

Evaluation of curative effect

Clinical curative effect included recovery (complete disappearance of clinical symptoms and middle ear effusion, hearing recovering), effective (relief of clinical symptoms, decrease of middle ear effusion, improvement of hearing but not returning to baseline level) and ineffective (no relief of clinical symptoms or middle ear effusion or improvement of hearing level). The total effective was the sum of cure rate and effective rate.

Follow-up

These patients were followed up for one and a half years to three and a half years. The tube should be taken at least 6 months and extended to 2 years after surgery. After the removal of tube, the patients were followed up for 1 years to see if there was recurrence, reoperation and recovery. The curative effect, preoperative air conduction hearing threshold and at 3 and 6 months postoperatively were compared between the two groups. The healing time of tympanic membrane after tube removal and recurrence rate were recorded.

Statistical analysis of data

The measurement data were expressed by the average number ± standard deviation ($\bar{x} \pm \mathrm{sd}$), t test was used for analysis, the enumeration data were analyzed by x^2 test analysis,

Logistic regression analysis was used for multivariate analysis, and difference analysis of data was performed by SPSS 20.0 software. $P < 0.05$ indicates that the difference was statistically significant.

Results

The clinical and follow-up data of 184 children with OME who were treated in the department of otorhinolaryngology head and neck surgery of Beijing Children's Hospital, Capital Medical University from September 2013 to January 2015 were reviewed systematically. General data was show in the Table 1. There was no statistically significant difference between the two groups.

Comparison of clinical curative effect between the two groups

The total effective rate of treatment in the group A was 91.84%, and was higher than that in the group B, with a statistically significant difference (to see Table 2, $P < 0.05$). In addition, in group A and group B, there was no statistically significant difference in the efficacy of patients who had adenoidal hypertrophy with I, II and III degrees ($P > 0.05$).

Comparison of preoperative and postoperative air conduction hearing threshold between the two groups

The air conduction hearing thresholds were decreased at 3 and 6 months after surgery compared with preoperative

Table 1 General data

	Group A	Group B	*P* value
Male	63 (121 ears)	55 cases (106 ears)	> 0.05
Female	35 cases (67 ears)	31 cases (60 ears)	> 0.05
Age	5.03 ± 0.95 years	5.21 ± 1.02 years	> 0.05
Course of disease	11.44 ± 6.41 months	13.56 ± 6.84 months	> 0.05
Adenoid hypertrophy with grade I	20 cases	17 cases	> 0.05
Adenoid hypertrophy with grade II	33 cases	27 cases	
Adenoid hypertrophy with grade III	45 cases	42 cases	
Tympanometry with "B" type	149 ears	139 ears	> 0.05
Tympanometry with "C" type	39 ears	27 ears	

Table 2 Comparition of clinical curative effect between the two groups [*n* (%)]

Groups	*n*	Cured *n* (%)	Effective *n* (%)	Ineffective *n* (%)	Total effective rate *n* (%)
Group A	98	52 (53.06)	38 (38.78)	8 (8.16)	90 (91.84)
Group B	86	42 (48.84)	27 (31.40)	17 (19.77)	69 (80.23)
χ^2					5.253
P					0.022

Table 3 Comparison of preoperative and postoperative air conduction hearing threshold between the two groups ($\bar{x} \pm$ sd, dB HL)

Groups	Air conduction hearing threshold		
	Before surgery	3 months after operation	6 months after operation
Group A	34.84 ± 12.93	15.54 ± 5.70* 15.54 ± 5.70	14.52 ± 5.42*
Group B	34.56 ± 12.88	16.32 ± 5.94$^{\Delta}$	15.28 ± 5.27$^{\Delta}$
t	0.147	0.908	0.961
P	0.883	0.365	0.388
*t**		13.211	14.055
*P**		0.000	0.000
t^{Δ}		11.433	12.271
P^{Δ}		0.000	0.000

Compared with the same group before surgery, $P^{*} < 0.05$, $P^{\Delta} < 0.05$

air conduction hearing thresholds, respectively, in two groups ($P < 0.05$), without statistically significant difference between groups at the same time point ($P > 0.05$, To see Table 3).

Comparison of middle ear effusion, tympanic membrane healing time and recurrence between the two groups

The duration of middle ear effusion was shorter and the recurrence rate was lower in the group A than group B ($P < 0.05$), but there was no significant difference in tympanic membrane healing time between the two groups ($P > 0.05$, to see Table 4).

Univariate analysis of factors affecting the recurrence of OME

There were a total of 184 cases in the two groups, with a total of 354 ears, and there were 23 cases (12.50%) of recurrence after surgery, a total of 42 ears (11.86%).

Table 4 Comparison of middle ear effusion, tympanic membrane healing time and recurrence between the two groups

Groups	*n*	Healing time of tympanic membrane (days)	Recurrence rate [*n* (%)]
Group A	98	24.38 ± 5.94	6 (6.12)
Group B	86	24.87 ± 6.08	17 (19.77)
T or χ^2		0.552	7.797
P		0.582	0.005

Univariate analysis showed that there were statistically significant differences between the recurrence of disease and allergic rhinitis, recurrent respiratory tract infections and retention time of tube < 6 months ($P < 0.05$, , to see Table 5.

Multivariate analysis of factors affecting the recurrence of OME

Multivariate logistic regression analysis showed that recurrent respiratory tract infection ($P = 0.002$), retention time of tube shorter than 6 months ($P = 0.010$) and adjuvant adenoidectomy were risk factors for recurrence of OME, while adenoidectomy was a protective factor ($P = 0.003$) (to see Table 6).

The total effective rate of treatment in the group A1 was 94.60%, and was higher than that in the group B1, with a statistically significant difference ($P < 0.05$), see Table 7.

The tympanic membrane healing time after shorter than 6 months of tube placement was (2.14 ± 1.53) weeks, while the tympanic membrane healing time after longer than 6 months was (3.05 ± 2.78) weeks, with a statistically significant difference ($P < 0.05$). Our overall rate of persistent tympanic membrane perforation in patients who underwent tympanostomy tubes removal was 8.15%. 3 (3.57%) cases in less 6 months of tube, as opposed to those was 12 (12%) in more 6 months of tube. There was a statistically significant difference in two groups ($P = 0.037$).

Table 5 Univariate analysis of factors affecting the recurrence of OME

Factors	Recurrence (23 cases)	Non-recurrence (161 cases)	*T* or χ^2	*P*
Gender (male/female)	16/7	102/59	0.338	0.561
Course of disease (months)	15.43 ± 11.24	13.49 ± 9.91	1.871	0.063
Adjuvant adenoidectomy [*n* (%)]	6 (26.09)	92 (57.14)	7.801	0.005
Allergic rhinitis [*n* (%)]	18 (78.26)	90 (55.90)	4.150	0.042
Recurrent respiratory tract infection [*n* (%)]	10 (43.48)	27 (16.77)	8.936	0.003
Tube retention time < 12 months [*n* (%)]	16 (69.57)	68 (42.24)	6.058	0.014
With history of tube placed	3 (13.04)	20 (12.42)	0.007	0.933

Table 6 Multivariate analysis of factors affecting the recurrence of OME

Factors	*B*	Wald	*P*	OR	95% CI
Adjuvant adenoidectomy	− 1.145	8.709	0.003	3.142	1.469–6.723
Allergic rhinitis	0.172	1.185	0.277	1.188	0.871–1.619
Recurrent respiratory tract infection	1.089	10.113	0.002	2.987	1.515–5.334
Retention time of tube < 12 months	0.812	6.648	0.010	2.245	1.207–4.093

Table 7 Comparison of clinical curative effect between the A1 and B1 groups [*n* (%)]

Groups	*n*	Cured *n* (%)	Effective *n* (%)	Ineffective *n* (%)	Total effective rate *n* (%)
Group A1	37	25 (67.57)	10 (27.02)	2 (5.4)	35 (94.6)
Group B1	32	18 (56.25)	6 (18.75)	8 (25)	24 (75)
χ^2					5.32
P					0.037

Discussion

Surgical treatment is required for children who are unable to recover from the disease and undergo medical treatment failure. Tube insertion is an effective method for the clinical treatment of OME in children [5]. Related research shows that adenoid hypertrophy is also one of the important reasons causing OME in children. The increase of adenoid hypertrophy cells can promote the expression of inflammatory factors and enhance local inflammation, resulting in abnormal physiological function of Eustachian tube and middle ear effusion. At the same time, it is found that there are many pathogenic microorganisms in the middle ear effusion which are similar to the pathogenic bacteria in adenoid tissues of children. Further studies showed that the immune response induced by infection of adenoids can cause effusion middle ear effusion through ascending pathway [6, 7]. In addition, the adenoid hypertrophy blocking the Eustachian tube could affect the swallowing function of children, and the reflux of the secretion would further aggravate the condition [8]. However, adenoid is one of the human immune organs. There is still controversy about removal the adenoid at the same time of tube insertion for children with OME [9, 10]. In this study (To see Table 2), the clinical data of children with OME were analyzed. The results showed that the total effective rate of the Group A was significantly higher than that of the group B (91.84% vs 80.23%), suggesting that effects of tube insertion combined with adenoidectomy were better than tube insertion alone in improving clinical symptoms and signs. Recent research has concluded that adenoidectomy has a long-lasting beneficial clinical effect for at least 2 years [11, 12]. Furthermore, there was no statistically significant difference in the total effect of patients who had adenoidal hypertrophy with I, II and III degrees in groups A and B. It is more believed that adenoids trigger nasopharyngeal inflammatory response, which affects the function of Eustachian and eventually leads to OME. In addition, it may be that the adenoids cause focal infections that resulted in dysfunction of the Eustachian.

The postoperative air conduction hearing thresholds of the two groups decreased significantly at 3 months postop and 6 months, compared with those before surgery. However, there was no significant difference of the air conduction hearing threshold between the two groups at the same time point, suggesting that the two surgeries can effectively improve the postoperative hearing level in children. Compared with tube insertion, tube insertion combined with adenoidectomy had no obvious advantage on hearing improvement (To see Table 3). The reason may be that the observation time is too short.

The recurrence rate in the Group A was significantly lower than that in the Group B (6.12% vs 19.77%), which indicated that combined surgery could decrease the recurrence rate of OME (To see Table 4). It was also found that adenoidectomy reduced the risk of OME recurrence requiring renewed ventilation tubes [13].The effusion could be cleared through the tube, which, it could not completely eliminate infection and promotes the recovery of Eustachian tube function. Therefore, the recurrence rate after simple tube insertion was significantly higher [14].

Although surgical treatment can obviously shorten the duration of effusion and reduce the recurrence rate, there is still recurrence of OME in children after the exfoliation of the ventilating tube. Results of this study showed that in 184 cases, 23 cases were recurrent, and the recurrence rate was 12.50% within 1 year. Univariate and multivariate analyses showed that recurrent respiratory tract infection and retention time of tube shorter than 12 months were the risk factors for recurrence of the disease, except for surgical procedure (Table 5). The absence of a significant association between gender, course of disease, history of tube insertion and allergic rhinitis and the recurrence of OME, respectively, in our study. Recurrent respiratory tract infection plays a key role in the recurrence of OME,according to multivariate analysis eventually. Nasopharyngeal edema induced by recurrence respiratory tract infection can lead to abnormal patency of Eustachian tube and mucociliary transport system, and OME was likely to be the sequela of middle ear infection [15]. Moreover, the development of the immune system is not perfect and the immunity is poor in underage children. The enclosed space of the kindergarten provides a favorable environment for the transmission of respiratory tract infection [16]. Therefore, recurrent respiratory tract infection is a risk factor for the recurrence of OME in under-age children. It is generally believed that retention time of ventilation tube was negatively related to the recurrence rate of OME [17].

Results of this study also showed that 19.05% (16/84) of children had recurrence for the retention time of tube shorter than 12 months, while only 7% (7/100) of the children had recurrence for retention time of tube longer than 12 months (To see Table 6, $P=0.014$), which suggested that the prolonged retention time of ventilation tube could decreased the recurrence rate of OME. Theoretically, the longer retention time of tube is, the better recovery of middle ear mucosa function is, and the lower recurrence rate is [18]. Multivariate analysis showed that adjuvant adenoidectomy was a protective factor for the recurrence of otitis media with effusion, further confirming that adenoidectomy was the key to the recurrence of otitis media with effusion.

According Clinical Practice Guideline: Otitis Media with Effusion (Update), Adenoidectomy is not recommended as a routine treatment for OME in children younger than 4 years of age unless the patient has clear symptoms such as nasal obstruction or snoring [4]. However, in this study, we found that for children younger than 4 years of age, the combined Surgery is still significantly better than the simple tympanostomy tubes on total effective rate of treatment (Table 7, $P<0.05$). Consideration should be given to the fact that adenoidal hypertrophy has a greater impact on the physiological function of the Eustachian tube in children under 4 years of age.

In clinical practice, long-term retention time of ventilation tube might cause complications, such as otorrhea, tympanosclerosis, middle ear infection, cholesteatoma and perforation. The data found there was not significant difference on the healing time of the tympanic membrane in observation (24.38 ± 5.94 days) and control groups (24.87 ± 6.08 days) (Table 4 $P>0.05$). The healing time of the tympanic membrane was 3.05 ± 2.78 weeks in tube removed > 6 months after placement, and it was 2.14 ± 1.53 weeks in tube removed < 6 months. The former was significantly longer than the latter ($P=0.008$). Usually, the longer the ventilation tube is kept, the longer the healing time of tympanic membrane is, and the higher rate of persistent perforation is [19]. There were 15 cases (8.15%) of persisted perforation in all patients. It was known that 3 patients suffered from persisted perforation (3/84, 3.57%) in less 6 months of tube, as opposed to those was 12 (12/100, 12%) in more 6 months of tube. There was a statistically significant difference in two groups ($P=0.037$). The post-tympanostomy tubes sequela likely to require intervention is persistent perforation, which occurs in about 2–3% of children [4]. The perforation rate is higher with the use of T type tube for consideration. The perforation risk from T-tubes is high, reaching 16% in one meta-analysis [20]. The high incidence suggests a need for ongoing otologic surveillance of all patients with indwelling tubes and for a reasonable time period after tube extrusion. Long-term tubes should be used on a selective and individualized basis. To reduce persistent perforation rate, short-term tube is considered instead. Thus, it is necessary to find the appropriate retention time to decrease the recurrence of OME and the perforation of the tympanic membrane after removing the tube meantime.

In conclusion, tube insertion combined with adenoidectomy is more effective than tympanostomy tubes in the treatment of young children with OME, and the same results were found for children under 4 years old. Compared with simple tube insertion, tympanostomy tubes combined with adenoidectomy can effectively shorten the duration of middle ear effusion, reduce the recurrence rate and improve the curative effect, but it has no obvious advantage in improving the postoperative hearing level. Preoperative recurrent respiratory tract infection, ventilation retention time of tube shorter than 12 months are risk factors for the recurrence of OME. To reduce the recurrence rate, it is recommended that the ventilation tube of young children be kept for more than 1 years. But the influence of prolonging time of tube on tympanic membrane healing should also be taken into consideration. Even it increased the risk of persistent perforation of tympanic membrane after extubation.

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Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest whatsoever arising out of the publication of this manuscript.

Ethical standards There is compliance with ethical standard in the research.

Informed consent Informed consent was obtained from all individual participants included in the study.

Human and animal rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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