# Original Article

# A systematic review of adenoidectomy in the treatment of otitis media with effusion in children

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Abstract: Object: Systematic reviews and meta-analyses were conducted to assess the efficacy and security of adenoidectomy for otitis media with effusion in children. Method: Based on the principles and methods of Cochrane systematic reviews, Electronic search included PubMed, Medline, Elisevier, Ovid, CBM, CKNI, VIP and Wanfang datebase. Randomized controlled trials about using adenoidectomy to treat otitis media with effusion in children were included. Meta-analysis was performed for the result of homogeneous studies using RevMan 5.2 software. If meta- analysis can't be done, qualitative descriptions were made. Results: Adenoidectomy (with or without myringotomy) in reducing the episode of acute otitis media, removing the middle ear effusion were superior to myringotomy or observation. Adenoidectomy with tympanostomy tube in the removal of the middle ear effusion and improving hearing level were superior to tympanostomy tube. Three trials described postoperative haemorrhage, incipient malignant hyperthermia, postoperative pneumonia, velopharyngeal insufficiency. Conclusions: Our research shows a benefit of adenoidectomy in the removal of middle ear effusion in children with OME. Adenoidectomy combined with tympanostomy tube in improving hearing level was superior to tympanostomy tube. At present, there is no evidence shows adenoidectomy has serious postoperative complications.

Keywords: Adenoidectomy, otitis media effusion, randomized controlled trial, systematic review, meta-analysis

#### Introduction

Otitis media is one of the most common diseases during childhood for which children visit doctors and receive antibiotics before ten years old [1-3]. Otitis media with effusion (OME) is one of the sub-classifications of otitis media, defined as the presence of fluid in the middle ear without symptoms or signs of infection. It is reported that about 80% children under the age of ten had at least one episode of OME [4]. An early childhood history of OME, especially recurrent OME and chronic OME can result in auditory and verbal disabilities that exert influence into late childhood [5]. OME has multiple causes, including environmental and host factors [6, 7]. Adenoids have been associated with the pathogenesis of OME. The adenoids may cause mechanical obstruction of the nasopharynx, play an important role in the pathogenesis of otitis media or become a reservoir for pathogenic bacteria especially resistant bacteria that can cause recurrent infections and greatly affect medical treatments [8]. The role of biofilms in the etiopathogenesis of chronic OME was demonstrated in several studies [9-11].

Adenoidectomy can remove the adenoids-a nasopharyngeal reservoir of potential respiratory pathogens and a physical obstruction of the Eustachian tubes, thereby, restoring mucus drainage and normal pressure in the middle ear affecting the ability of pathogens to invade and reside within the middle ear space. However, at present the effectiveness of adenoidectomy in children with OME remains uncertain and practice is experience-based rather than evidencebased. Practice differed surgeon from surgeon. Some surgeons prefer to perform adenoidectomy in these children, whereas others do not [8]. To obtain a more comprehensive estimate of the adenoidectomy on OME, we conducted the systematic reviews and meta-analyses to assess the efficacy and security of adenoidectomy for otitis media with effusion in children.

	AT/AT	+M	O/M			Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Dempster 1993	9	35	18	37	73.6%	0.37 [0.14, 0.99]	<b></b>
Fiellau-Nikolajsen 1980	15	22	14	20	26.4%	0.92 [0.25, 3.41]	_
Total (95% CI)		57		57	100.0%	0.51 [0.23, 1.12]	•
Total events	24		32				
Heterogeneity: Chi <sup>2</sup> = 1.20			7); I <sup>2</sup> = 179	%		H	1.01 0.1 1 10 100
Test for overall effect: Z =	1.68 (P =	0.09)				0	AT/AT+M O/M

**Figure 1.** Forest plot of comparison: Adenoidectomy (with or without myringotomy) versus observation or myringotomy, outcome: resolution of effusion at 6 months.

	AT/AT	+M	O/M	I		Odds Ratio	Odds Ratio				
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI		M-H, Fixe	ed, 95%	CI	
Dempster 1993	20	37	13	37	55.2%	2.17 [0.85, 5.53]					
Widemar 1985	13	24	13	35	44.8%	2.00 [0.70, 5.75]		_			
Total (95% CI)		61		72	100.0%	2.09 [1.04, 4.22]			<b>•</b>		
Total events	33		26								
Heterogeneity: Chi <sup>2</sup> = 0 Test for overall effect:		0.01	0.1 AT/AT+M	1 O/M	10	100					

**Figure 2.** Forest plot of comparison: Adenoidectomy (with or without myringotomy) versus observation or myringotomy, outcome: resolution of effusion at 12-24 months.

#### Methods

#### Search strategy

We carried out a systematic search based on the principles and methods of Cochrane systematic reviews. We carried out the electronic search of PubMed, Medline, Elisevier, Ovid, CBM, CKNI, VIP and Wanfang datebases. The date of the last search was December 2014. Randomized controlled trials about using adenoidectomy to treat otitis media with effusion in children were included. The following key words were used in our search strategies: ('otitis media' OR 'otitis media with effusion' OR 'glue ear' OR 'secretory otitis media') AND ('adenoidectomy' OR 'surgery') and ('Randomized controlled trials'). We restricted the search to human studies. No language restrictions were imposed. The objects were diagnosed OME and their age ranged from 1 year old to 15 years old. The intervention is defined as adenoidectomy alone, or in combination with other routine therapies (including observation, myringotomy, tympanostomy tube) in the treatment groups. The control groups received routine therapies. The outcome measures included the proportion of time with effusion, the improvement of hearing level, the average number of episodes, as well as incidence of adverse events after adenoidectomy. The follow-up time is more than 6 months.

### Data extraction and management

Two authors (X-Y Tian and M-Q Wang) independently assessed all studies for quality using the Cochrane bias risk assessment tools, which allowed a total score from 0 to 6 points (6 reflecting the highest quality). We defined above 3 points as the high quality. We extracted the following data from each study: total number of children in each trial, description of participants (mean age, inclusion and exclusion criteria), follow-up time in months, description of intervention and control therapy, number of patients per intervention group, the outcomes, the complications of adenoidectomy and the authors' conclusion.

#### Statistical methods

For the meta- analysis, outcome measures were assessed by RevMan software version 5.2. For continuous outcomes, we compare outcome measures using the means difference

	AT+T	Т	П			Odds Ratio	Odds Ratio					
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl	M-H, Fixed, 95% CI					
Liu2012	41	45	31	43	45.0%	3.97 [1.17, 13.49]						
Maw 1986	25	36	13	47	55.0%	5.94 [2.29, 15.44]	-					
Total (95% CI)		81		90	100.0%	5.05 [2.38, 10.75]	•					
Total events	66		44									
Heterogeneity: Chi <sup>2</sup> = 0 Test for overall effect: 2					0.01 0.1 1 10 100							
rest for overall effect.	Z = 4.Z1 (I	` 0.0	001)			AT+TT TT						

**Figure 3.** Forest plot of comparison: Adenoidectomy with tympanostomy tube vs tympanostomy tube, outcome: resolution of effusion at 12 months.

	Α		TT		Mean Difference			Mean Difference					
Study or Subgroup	Mean	SD	Total	Mean	SD	<b>Total</b>	Weight	IV, Random, 95% CI		IV, Ra	ndom, 9	95% CI	
Hammare' n-Malmi 2005	1.7	1.8	102	1.4	1.5	96	53.9%	0.30 [-0.16, 0.76]					
Paradise 1990	1.09	1.2	45	1.67	1.5	27	46.1%	-0.58 [-1.25, 0.09]			•		
Total (95% CI)			147			123	100.0%	-0.11 [-0.97, 0.75]					
Heterogeneity: $Tau^2 = 0.30$ ; $Chi^2 = 4.54$ , $df = 1$ ( $P = 0.03$ ); $I^2 = 78\%$ Test for overall effect: $Z = 0.24$ ( $P = 0.81$ )									-100	-50	0	50	100

**Figure 4.** Forest plot of comparison: Adenoidectomy with tympanostomy tube vs tympanostomy tube, outcome: mean episodes of otitis media at 24 months.

(MD) with 95% confidence intervals (CI). For dichotomous outcomes, the odds ratio (OR) with 95% CI was used. After heterogeneity test, date without heterogeneity could be using fixed effect model. Date with heterogeneity could be using randomized effect model estimated. If meta- analysis can't be done, qualitative descriptions were made.

#### Results

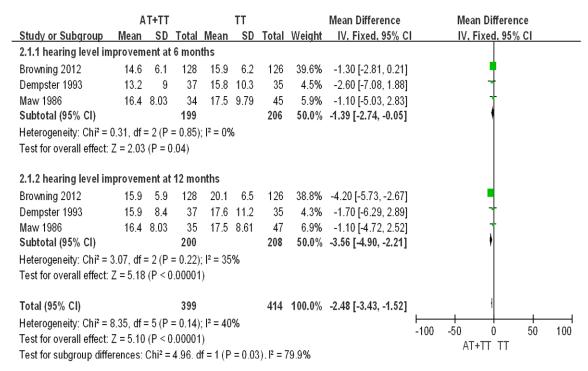
We retrieved a total of 213 articles. We first sifted the articles by title or abstract and this left us 34 articles to read in full text. A total of 12 studies [12-23] (n=2007 children) were included in this review. 9 studies [13-18, 20-22] explicitly described the randomized methods, of which 3 studies [15, 16, 22] used the random number table system, 6 studies [13, 14, 17, 18, 20, 21] used the distribution of computer center.8 studies [13-16, 18, 20-22] described allocation concealments, of which 2 studies [15, 18] randomly allocated by a the sealed envelope system, 6 studies [13, 14, 16, 20-22] used center random methods. 2 studies [18, 20] adopt blind methods. 8 studies [12, 14, 16, 17, 19-21, 23] addressed complete outcome data. 9 studies [13, 15-19, 21-23] had nonselective outcome reporting complete result report. We assessed the 12 studies with the cochrane bias risk assessment tools. There are 3 studies [12, 19, 23] got 2 points, which were defined as low quality. The rest of studies [13-18, 20-22] got 3 to 5 points, which were defined as high quality.

Adenoidectomy (with or without myringotomy) versus observation or myringotomy

*Meta-analysis:* Analysis 1 shows no heterogeneity ( $I^2$  value 17%, P=0.27) between the two studies [18, 19] when resolution of effusion is considered at 6 months. The overall odds ratio is 0.51 (95% CI, 0.23 to 1.12) (**Figure 1**).

According to Analysis 2 there is no heterogeneity ( $I^2$  value 0%, P=0.85) between studies [18, 23] when resolution of effusion is considered at 12-24 months. The overall mean difference is 2.09 (95% CI, 1.04 to 4.22) (**Figure 2**).

Description analysis: Paradise [13] reported on 304 children aged 3 to 15 years with recurrent acute otitis media or persistent otitis media with effusion. They were randomly allocated to



**Figure 5.** Forest plot of comparison: Adenoidectomy with tympanostomy tube vs tympanostomy tube, outcome: hearing level at 6 months and 12 months respectively.

1) adenoidectomy (n=100), 2) adenotonsillectomy (n=103), 3) the control group (n=101). He reported that the mean rate of AOM episodes (> 10 days) during the first year was 1.8 per subject in the adenoidectomy group and 2.1 per subject in the control group. After two and three years the episode rates were 1.7 versus 1.2 and 1.3 versus 1.5, respectively. The difference between the mean rate of AOM episodes (> 10 days) during the first year was significant.

Gates [16] reported on 491 children aged 4 to 8 years with chronic effusion. They were randomly allocated to 1) bilateral myringotomy (n=107), 2) bilateral tympanostomy tubes (n=129), 3) adenoidectomy and bilateral myringotomy (n=130) and 4) adenoidectomy and bilateral tympanostomy tubes (n=125). He reported that the meantime with effusion (± SD) in the myringotomy with adenoidectomy group was 0.302 (± 0.250) and in the myringotomy group 0.491 (± 0.252). The corresponding standardised mean difference (SMD) is -0.76 (95% CI, -1.02 to -0.49). The meantime with hearing loss > 20 dB (SD) for the better ear was 0.078 (± 0.131) in the myringotomy with adenoidectomy group and 0.186 (± 0.195) in the myringotomy group. The standardized mean difference (SMD) is -0.66 (95% CI, -0.93 to -0.40). For the poorer ear these numbers were 0.220 (± 0.239) and 0.375 (± 0.253), respectively. The standardized mean difference (SMD) is -0.65 (95% CI, -0.91 to -0.39).

Adenoidectomy with tympanostomy tube versus tympanostomy tube

*Meta-analysis:* Analysis 3 shows no heterogeneity ( $I^2$  value 0%, P=0.61) between the two studies [12, 22] when resolution of effusion is considered at 12 months. The overall odds ratio is 5.05 (95% CI, 2.38 to 10.75) (**Figure 3**).

Analysis 4 shows heterogeneity ( $I^2$  value 78%, P=0.03) between the two studies [14, 21] when mean episodes of otitis media is considered at 24 months. The overall mean difference is -0.11 (95% CI, -0.97 to 0.75) (**Figure 4**).

According to Analysis 5 there is no heterogeneity (I² value 0%, P=0.85) between studies [18, 20, 22] when hearing level of OME measured by pure tone audiometry is considered at 6 months. The overall mean difference is -1.39 (95% CI, -2.74 to -0.05). There is still no heterogeneity (I² value 35%, P=0.22) between studies [18, 20, 22]. When hearing level of OME mea-

sured by pure tone audiometry is considered at 12 months. The overall mean difference is -3.56 (95% CI, -4.90 to -2.21) (**Figure 5**).

Description analysis: Gates [16] reported on 491 children aged 4 to 8 years with chronic effusion. They were randomly allocated to 1) bilateral myringotomy (n=107), 2) bilateral tympanostomy tubes (n=129), 3) adenoidectomy and bilateral myringotomy (n=130) and 4) adenoidectomy and bilateral tympanostomy tubes (n=125). He reported the mean time with effusion (± SD) in the tympanostomy tubes with adenoidectomy group was 0.258 (± 0.212) and in the tympanostomy tubes group 0.349 (± 0.235). The corresponding standardized mean difference (SMD) is -0.40 (95% CI, -0.65 to -0.15). The mean time with hearing loss > 20 dB (± SD) for the better ear was 0.065 (± 0.116) in the tympanostomy tubes with adenoidectomy group and 0.101 (± 0.141) in the tympanostomy tubes group. The standardised mean difference (SMD) is -0.23 (95% CI, -0.48 to 0.02). For the poorer ear these numbers were 0.224 (± 0.221) and 0.304 (± 0.227), respectively. The standardised mean difference (SMD) is -0.35 (95% CI, -0.60 to -0.11).

Black [15] reported on 149 children aged 4 to 9 years with bilateral otitis media with effusion. All children were randomly assigned to 1) adenoidectomy with bilateral myringotomy and unilateral tympanostomy tube insertion (n=37), 2) adenoidectomy with unilateral tympanostomy tube insertion (n=38), 3) bilateral myringotomy and unilateral tympanostomy tube insertion (n=37) and 4) unilateral tympanostomy tube insertion (n=37). He reported only treatment group comparisons of change in mean audiometry scores (dB). Differences of 2.1 dB (95% CI, -2.6 to 6.8), 2.4 dB (95% CI, -2.7 to 7.6) and 6.9 dB (95% CI, 0.3 to 13.7) were found between the group with adenoidectomy and the group without adenoidectomy after 6, 12 and 24 months, respectively.

Casselbrant [17] reported on 98 children aged 24 to 47 months with bilateral or unilateral middle ear effusion. They were randomly assigned to 1) myringotomy and tympanostomy tube insertion (n=32), 2) adenoidectomy with myringotomy and tympanostomy tube insertion (n=32) or 3) adenoidectomy with myringotomy alone (n=34). He reported the percentage of time with middle ear effusion of 18.12% in the

adenoidectomy group and 11.91% in the control group during the first 18 months. After three years this was 20.59% and 18.64%, respectively. Differences of 6.21% (95% CI, -2.91% to 15.33%) and 1.95% (95% CI -5.68 to 9.58) were found between the group with adenoidectomy and the control group after 18 and 36 months, respectively. After 18 months, the number of episodes of AOM was seven and six in the adenoidectomy group and the control group, respectively.

# Complications and adverse effects

Five studies [13, 16, 18, 20, 23] reported information about postoperative complications. In the studies [18, 23] no complications occurred. 2 studies [16, 20] reported on one child with recurring haemorrhage respectively. Paradise [13] reported on one patient with incipient malignant hyperthermia, one with postoperative pneumonia and two with transient postoperative velopharyngeal insufficiency, and no haemorrhage occurred.

#### Discussion

OME is one of the most common diseases in children causing hearing loss and affecting language development during the first 3 years of life [24, 25]. The treatments for OME include watchful waiting or observation, myringotomy, tympanostomy tube and adenoidectomy. However, opinions regarding the risks and benefits of adenoidectomy vary and the management of OME remains controversial. In some studies, adenoidectomy has been proved to be effective in preventing recurrence of OME, recurrent AOM, or the need for repeated tympanostomy tubes [26, 27].

Wallace's meta-analyses indicated that adenoidectomy alone, as an adjunct to myringotomy, or combined with tubes, reduced OME and improved hearing in comparison with either myringotomy or watchful waiting. And his research showed that tubes and adenoidectomy reduce time with OME and improve hearing in the short-term [28]. Wang Mao-Che found that adenoidectomy has protective effect in preventing tympanostomy tube re-insertions compared to tympanostomy tubes alone, especially for children older than 4 years old and who needed tubes for the first time [29]. These studies support that adenoidectomy is effective.

Our research also shows a benefit of adenoidectomy in the removal of middle ear effusion in children with OME. Adenoidectomy combined with tympanostomy tube in improving hearing level was superior to tympanostomy tube. However, it does appear that in children younger than 4 years, adenoidectomy may not provide the same protective effect as in older children. There were 3 prospective randomized clinical trials showing no difference between adjuvant adenoidectomy with primary TT and primary TT alone include the study with age range below age 2 years [31], both studies with age ranges below age 4 years [17, 21]. The randomized clinical trials containing younger subjects disproportionately support the hypothesis that there is no difference. One plausible explanation may be that children who have persistent ear disease at an older age may have a more complex process of eustachian tube dysfunction that leads to recalcitrant disease, possibly leading to more benefit gained by the addition of adenoidectomy to TT. Another plausible explanation may be that adenoid tissue is most active in children between age 4 and 10 years before their involution during puberty, possibly attributing more to the pathophysiology of eustachian tube dysfunction in children of that age [30]. At present, there is no evidence shows adenoidectomy has serious postoperative complications.

To efficiently assess the efficacy and security of adenoidectomy for otitis media with effusion in children, future research is needed.

## Conclusion

Our systematic review and meta-analysis found a benefit of adenoidectomy in the removal of improving hearing level was superior to tympanostomy tube. At present, there is no evidence shows adenoidectomy has serious postoperative complications. In the future, we hope that we can collect more large and high quality RCT trials to date on the efficacy of adenoidectomy in children with otitis media with effusion.

#### Disclosure of conflict of interest

None.

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