

Complications of Shepard tympanostomy tube in children and the effect of adenoidectomy on it

Lana Abdul Razzaq Shahabaddin*

Abstract

Background & objectives: the aim of the study is to evaluate the postoperative complications following tympanostomy tube insertion for children with otitis media with effusion and the effect of adenoidectomy on the complications.

Methods: This is a case series study on 78 patients who underwent Shepard tympanostomy tube insertion, adenoidectomy was done for 52 of them. The operated cases for the period between March 2016 to March 2017 were included in the study, the patients were followed up postoperatively by a thorough otoscopic examination (by microscope or endoscope) at 1 week and at 1 month. Further control examinations were done once in every 3 months for further two years.

Results: Seventy four children enrolled in the study, 43 were male and 31 were female, aged 3-12 years. Early otorrhea occurred in (0.7%), late otorrhea occurred in (4.7%), granulation tissue was seen in (2.0%), early extrusion in (3.4%), plugged tubes in (0.7%), persistent perforation in (1.4%), myringosclerosis in (22.3%), atrophy in (0.7%). In three patients; two complications occurred in the same ear as follows: late otorrhea and myringosclerosis in the same ear in (1.4%), late otorrhea and persistent perforation in (0.7%), early otorrhea and atrophy in (0.7%). In our study medial displacement, retraction and cholesteatoma were not seen.

Conclusions: Shepard tympanostomy tube insertion is an effective and safe procedure; nevertheless, it is associated with complications. Over all complications were less in patients who underwent tympanostomy tube insertion with adenoidectomy, especially late otorrhea

Keywords: Otitis media with effusion; Tympanostomy tube; Grommet.

* Lecturer, M.B.CH.B., Msc, Rizgari Teaching Hospital

Corresponding author: Lana Abdul Razzaq Shahabaddin. lanadabbagh@yahoo.com

Introduction

Otitis media with effusion (OME) is a disease characterized by the presence of fluid in the middle ear cavity behind intact tympanic membrane of different viscosity lasting at least three months¹. It is regarded as a sequel of the inflammation that happens following recurrent attacks of acute otitis media, this fact is established in experimental studies on animals². Otitis media is regarded as a common disease in childhood; nearly 90% of children have experienced at least one attack of otitis media under the age of two years^{3,4}. Appropriate diagnostic measures include children and parent's reports, complete otolaryngological examination focusing on microscopic or ear examination, tympanometry and hearing test¹. Established bilateral OME may lead to ongoing cognitive and language problem in the diseased child^{5,6}. Armstrong in 1954 presented tympanostomy or ventilation tube treatment to resolve otitis media with effusion, reinstate hearing, and avoid language developmental problems⁷. Currently tympanostomy tubes have been considered effectual treatment modality for persistent otitis media with effusion. The routine indications for ventilation tube

insertion are; persistent otitis media with effusion, recurrent acute suppurative otitis media, and chronic hypoventilation of the middle ear⁸. Standard pattern ventilation tubes like Shepard, Shah remain in place for a shorter period than longer- term T-tube designs, but the longer a tube stays in situ, the higher incidence of complications⁹. In United States; tympanostomy tube insertion is one of the most common surgeries in pediatric patients and the main reason a child receives general anesthesia¹⁰. The expected gain from the surgical procedure is the restoration of ventilation of the middle ear, and a fast increase in hearing¹¹. Adenoids have a role in the pathogenesis of OME by mechanical obstruction of the Eustachian tube (Hypertrophy) or functional obstruction due to inflammation (adenoiditis). If ventilation tubes are to be inserted, adenoidectomy is considered effectual adjuvant procedure⁹. Even though tympanostomy tube insertion is considered an easy procedure with significant benefits, complications can occur¹². The chief complications of tympanostomy tubes insertion incorporate; otorrhea, blocked tubes, early extrusion, granulation tissue, myringosclerosis,

perforation of the tympanic membrane, atrophy, retraction, medial displacement of tube and rarely cholesteatoma^{13,14}. Kenna et al added recurrence of effusion, although minor, is regarded as a concern¹⁵. The objective of this study is to determine tympanostomy tube complications in

Patients and methods

Seventy-eight children scheduled for bilateral tympanostomy tube insertion at Rizgari teaching Hospital with diagnosis of bilateral chronic otitis media with effusion following failure of medical treatment for more than 3 months were enrolled in this study. In 52 patients, in addition to tympanostomy tube insertion adenoidectomy was done. Cases operated between March 2016 to March 2017, all patients followed up regularly for two years. The diagnoses were made by otomicroscopic examination, tympanometry and pure-tone audiometry when it's applicable. Written informed parental consent for participants were obtained, to whom full explanations about the study was given. Surgery was done under general anesthesia. A fluoroplastic ventilation Shepard tube, from Xomed, with 1.14 mm, was used in all cases. Adenoidectomy was done under general anesthesia, patient was

children with chronic otitis media with effusion who were treated with Shepard grommet tympanostomy tube insertion and the effect of adenoidectomy on the rate of complications. This tube type was chosen, as it is the most commonly used one in our hospital.

placed in Rose position using a head light and mouth gag. The adenoid was removed by curette. All cases were examined postoperatively at 1 week and 1 month, then once in every 3 months for two years. Frequency of otorrhea, blocked tubes, granulation tissue, medial displacement, persistent perforations in addition structural tympanic membrane changes after extrusion of tympanostomy tubes like (myringosclerosis, atrophy, retraction) and cholesteatoma were recorded. The exclusion criteria were the existence of myringosclerosis before surgery; patients skipping follow up appointments. Analysis of data done by Statistical Package for the Social Sciences (SPSS) Version 25. For difference T test, and for relation Chi-square test were used. The level of significance adopted was $\alpha = 0.05$. The study was approved by the ethical committee in college of Medicine /Hawler Medical University.

Results

All 78 children included in the study received insertion of tympanostomy tubes bilaterally, totaling 156 operated ears. The children were between 3-12 years of age.

Four patients were excluded because of loss

of follow-up after the first postoperative assessment, 43 (58.1%) were male and 31 (41.9%) were female. Demographic data shown in Table (1).

Table (1): Age Distribution

Age	Frequency	Percent
3	12	16.2
4	12	16.2
5	16	21.6
6	11	14.9
7	13	17.6
8	6	8.1
9	1	1.4
11	1	1.4
12	2	2.7
Total	74	100.0

In 52 (70.27%) cases; adenoidectomy was done with the tympanostomy tube insertion while in 22 patients (29.729%) only the tympanostomy tube insertion was done. Table (2).

Table (2): Gender Distribution according to type of operation.

	Gender		Total
	Male	Female	
Ventilation tube+ Adenoidectomy	26	26	52
Ventilation tube	17	5	22
Total	43	31	74

Complications of Shepard tympanostomy tube in children and the effect of adenoidectomy on it

Among 148 ears; complications were: early otorrhea occurred in 1 (0.7%), late otorrhea occurred in 7 (4.7%), granulation tissue was seen in 3 (2.0%), early extrusion in 5 (3.4%), plugged tubes in 1 (0.7%), persistent perforation in 2(1.4%), myringosclerosis in 33 (22.3%), atrophy in (0.7%), late otorrhea

and myringosclerosis in 2(1.4%), late otorrhea and persistent perforation in 1(0.7%), early otorrhea and atrophy in (0.7%). Medial displacement, retraction and cholesteatoma were not seen as shown in Table (3).

Table (3): Complications of Shepard Tympanostomy tube.

	Frequency	Percent	Type of Operation		p- value
			Ventilation tube + Adenoidectomy	Ventilation tube	
No Complications	91	61.5	70	21	0.015
Early Otorrhea	1	0.7	1	0	
Late Otorrhea	7	4.7	2	5	
Plugged tubes	1	0.7	1	0	
Granulation tissue	3	2.0	1	2	
Early extrusion	5	3.4	2	3	
Myringosclerosis	33	22.3	25	8	
Persistent perforation	2	1.4	1	1	
Atrophy	1	0.7	1	0	
Late Otorrhea and Myringosclerosis	2	1.4	0	2	
Late Otorrhea and Persistent perforation	1	0.7	0	1	
Early Otorrhea and Atrophy	1	0.7	0	1	
Total	148	100.0	104	44	

Complications of Shepard tympanostomy tube in children and the effect of adenoidectomy on it

The most common complications were otorrhea and myringosclerosis. Regarding early otorrhea, p- value was not significant among patients who underwent ventilation tube insertion and those who did ventilation tube insertion and adenoidectomy, but it was

significant in late otorrhea. Regarding myringosclerosis p- value was not significant among patients who underwent ventilation tube insertion and those who did ventilation tube insertion and adenoidectomy, as shown in table(4).

Table (4): Type of operation, relation to otorrhea and myringosclerosis.

	Type of operation		Total	p- value
	Ventilation tube+ Adenoidectomy	Ventilation tube		
Non - Early Otorrhea	103	44	147	0.514
Early Otorrhea	1	0	1	
Non - Late Otorrhea	102	39	141	0.013
Late Otorrhea	2	5	7	
Non-Myringosclerosis	79	36	115	0.434
Myringosclerosis	25	8	33	
Total	104	44	148	

Discussion

Tympanostomy tube insertion is a common surgical procedure performed for children in otolaryngology practice. Otorrhea is one of the most frequent complications of this procedure. The incidence ranges from 0.8 to 83%^{8,16}. Early otorrhea occurs within 2–4 weeks postoperatively, and delayed otorrhea seems more common after first month postoperatively¹⁷. Otorrhoea in association with a ventilation tube in situ may occur

after an acute upper respiratory tract infection or can be the result of a chronic biofilm infection of the tube itself⁹. In this study early otorrhea within the first four weeks postoperatively was (0.7%), late otorrhea occurred in (4.7%), they were treated with systemic antibiotic and topical antibiotic/corticosteroid drugs. Kay et al in his meta-analysis study, had found early otorrhea in 16% of patients and delayed

otorrhea in 26% of patients¹³. Higher occurrence of otorrhea is reported in long-term tubes like T-tubes (32.5%) than short term tubes like Shepard and Shah (14.8%)¹³. In other studies; otorrhea rates were (5.3%), (8.2%) and (47.3%) respectively¹⁸⁻²⁰. Klopp-Dutote²¹ and Yaman²² who used (Shepard grommet-type) otorrhoea occurred in (4.6%), (5.6%) respectively. The results in these two studies are nearest to our results, as they used Shepard ventilation tubes. In the literature; several factors were mentioned contributing for the occurrence of otorrhea such as younger age, external auditory canal contamination during surgery, upper respiratory tract infection, mucoid or purulent middle ear effusions^{8,23}. Otorrhea is not serious in most cases. In our study; it was less than in many other studies we mentioned because in all our cases we used topical antibiotics (ciprofloxacin) 3 times a day for 3 days postoperatively. In this study, granulation tissue was seen in three ears (2.0%), which was accompanied by otorrhea. In meta-analysis by Kay; the mean incidence of granulation tissue occurring after tympanostomy tube insertion was less than 5%¹³. This complication rate was 0.3% for Shepard tubes, and 13% for T-tubes⁸.

Yaman et al reported granulation tissue as (1.2%)²², which is similar to our results. We treated our cases of granulation tissue with topical antibiotic–steroid ear drops. Plugged tubes occurred in one ear (0.7%) in our study and we treated it by a simple suction, while in a study by Ragab et al was (6.3 %) ¹⁸. Erdogljia and Kay reported early extrusion of tube in (3.9%) of their cases^{1,13}. While in a study by Ragab et al the result was (2.1%)¹⁸. This result is similar to our results (3.4%). Possible causes of early extrusion are otorrhoea, quadrant of insertion of tube, large myringotomy and the character of the fluid^{1,18}. In Our study persistent perforation was found in (1.4%). Klopp-Dutote reported perforation of the tympanic membrane in (6.5%)²¹. Yaman et al reported persistent perforation in (5.6%), several types of patching materials including paper, absorbable gelatin film, and fat plug was used to treat persistent perforation after tube removal²². Brown et al reported the rate of persistent perforation with short-term tubes and long-term tubes was significantly different (6.6% and 20% respectively)²³. These results are in accordance to our results regarding short term tubes, we didn't use paper patching for the persistent perforation, and follow up of these patients is necessary

to ensure that the eustachian function is good before closing the perforation.

Myringosclerosis is a pathological condition that occurs when tissue restoration happens, wherein high amounts of collagenic tissue are accumulated in the lamina propria that covers the ossicles, the walls of the middle ear cavity and the medial layer of the tympanic membrane. Clinically it is important if it affects the hearing through interfering with sound transmission through middle ear structures²⁴. In a study by Yaman et al²², myringosclerosis was the most common late complication of tympanostomy tube insertion; the incidence rate was of 34.6%. The occurrence of this complication was similar to what is reported by Kay et al. and Johnston et al.^{13,25}, in which this complication was seen in 32% and 40.4% respectively. It was usually situated on the inferior quadrants of eardrum. Klopp - Dutote et al in his last follow-up, had found that the most common complications were tympanosclerosis (6.9%)²¹. Ragab et al reported myringosclerosis in (1.6%) ears¹⁸. Saki et al reported myringosclerosis in (37.9%)¹⁹. In a study by Branco et al myringosclerosis was identified in (35.4%) of the operated ears²⁴. Myringosclerosis was observed in 22.3% in our study. Again we can see discrepancy in results of

different studies because of different materials and types of tube used and the duration of follow up. Serious complications may be due to atrophy like spontaneous perforations. Segmental atrophy seems to be produced by the tube insertion where as thickening and minor atrophic scars are more related to middle ear diseases¹⁸. Yaman et al reported atrophy of tympanic membrane in (23.5%) without hearing loss²². Ragab et al found atrophy in (0.5%) of ears that had been operated on, with no effect on hearing¹⁸. In our study atrophy was (0.7%). We think that the variability in the results due to the variable tube types and relatively short follow up period postoperatively. Yaman et al reported retraction of tympanic membrane in (16.7%) with maximum follow up of 66 months²². No retraction was found in our study, probably because of the short duration of the follow up comparing to the mentioned studies. Medial displacement of tympanostomy tubes are very rare¹³. We didn't have this complication in our study. Cholesteatoma as a sequel to tympanostomy tube insertion is very rare, but it is the most serious complication after tympanostomy tube insertion, for short-term tubes, the incidence is 0.8%^{13,17}. However we didn't have cholesteatoma in our study. We suspect that

cholesteatoma in the reported cases is related to disease process and not to tube insertion as both diseases usually occur because of poor Eustachian tube function.

Regarding late otorrhea, p-value was significant (0.013) among patients who underwent ventilation tube insertion and those who did ventilation tube insertion and adenoidectomy. Children operated for ventilation tube placement with adenoidectomy presented a significantly smaller number of otorrhea episodes

Conclusions

There are considerable complications associated with tympanostomy tube insertion, which are nearly similar to what are reported in other centers worldwide.

Complication rates are less when

Conflict of interests

The authors recorded no conflict of interests.

References

1.Erdogljija M, Sotirović J, Baletić N. Early postoperative complications in children with secretory otitis media after tympanostomy tube insertion in the Military Medical Academy during 2000-2009. *Vojnosanit Pregl.* 2012;69(5):409-13.
2.Giebink GS. Progress in understanding the pathophysiology of otitis media. *Pediatr Rev* 1989; 11:133-8.

($P=0.02$)²⁰. Hao et al in his study found that adenoidectomy was a preventive factor for upper respiratory tract infection²⁵. In the Meta-analysis by Samantha and Matthew, Ten studies ($n=71\,353$) reported that primary adenoidectomy with tympanostomy tube insertion decreased the risk of recurrent acute otitis media or otorrhea compared with only tympanostomy tube insertion, while Four studies ($n=538$) reported no such a difference²⁶.

adenoidectomy done in addition to tympanostomy tube insertion. Physicians should explain the possible post-operative complications to patient's parents.

3.Keyhani S, Kleinman L, Rothschild M et al. Clinical characteristics of New York children who received tympanostomy tubes in 2002. *Pediatrics.* 2008; 12(1):24-33.
4.Schraff SA. Contemporary indications for the ventilation tube placement. *Curr Opin Otolaryngol Head Neck Surg.* 2008; 16(5):406-11.

5. Roark R, Petrofski J, Berson E, Berman S. Practice variations among pediatricians and family physicians in the management of otitis media. *Arch Pediatr Adolesc Med* 1995; 149 :839-44.
6. Bluestone CD, Swartz JD. Human evolutionary history: consequences for the pathogenesis of otitis media. *Otolaryngol Head Neck Surg* 2010; 143 :739-44.
7. Armstrong BW. A new treatment for chronic secretory otitis media. *Arch Otolaryngol*. 1954; 59:653-4.
8. Kalcıoglu MT, Cokkeser Y, Kizilay A, Ozturan O. Follow-up of 366 ears after tympanostomy tube insertion: why is it draining? *Otolaryngol Head Neck Surg*. 2003;128(4):560-4.
9. Peter R., Ian W. Otitis media with effusion. *Scott-Brown's Otolaryng*. 8th ed. CRC Press. 2018; 115-7.
10. Vital and Health Statistics: Ambulatory and inpatient procedures in the United States, 1996. Series 13: Data from the National Health Care Survey No. 139. US Department of Health and Human Services. Hyattsville, MD, November 1998, DHHS Publication.
https://www.cdc.gov/nchs/data/series/sr_13/sr13_139.pdf
11. Schwartz RH, Linde RE. Iatrogenic implantation cholesteatoma: an unusual complication of tympanostomy tubes. *J Pediatr* 1979; 94:432-3.
12. de Carvalho Leal M, Ferreira Bento R, da Silva Caldas et al. Influence of hypercalcemia in the formation of tympanosclerosis in rats. *Otol Neurotol*. 2006;27(1):27–32.
13. Kay DJ, Nelson M, Rosenfeld RM. Meta-analysis of tympanostomy tube sequelae. *Otolaryngol Head Neck Surg*. 2001; 124:374–80.
14. Hellström S, Groth A, Jörgensen F et al. Ventilation tube treatment: a systematic review of the literature. *Otolaryngol Head Neck Surg*. 2011;145(3):383-95.
15. Kenna MA. Diagnosis and management of acute otitis media and otitis media with effusion. In: Wetmore RF, Muntz HR, McGill TJ, Postic WP, Healy GB, Lusk RP, editors. *Pediatric otolaryngology: Principles and practice pathways*. New York: Thieme; 2000. pp. 272-7.
16. Ah-Tye C, Paradise JL, Colborn DK. Otorrhea in young children after tympanostomy-tube placement for persistent middle-ear effusion: prevalence, incidence, and duration. *Pediatrics*. 2001;107(6):1251-8.
17. Vlastarakos PV, Nikolopoulos TP, Korres S, Tavoulari E, Tzagaroulakis A, Ferekidis E. Grommets in otitis media with

effusion: the most frequent operation in children. But is it associated with significant complications? *Eur J Pediatr.* 2007; 166:385– 91

18. Ragab A, Mohammed A, Abdel-Fattah A, Afifi A. Prevalence of complications associated with tympanostomy tube insertion. *Menoufia Med J.* 2015; 28(4): 918-22.

19. Saki N, Nikakhlagh S, Salehe F, Darabifard A. Incidence of Complications Developed after the Insertion of Ventilation Tube in Children under 6 years old in 2008-2009. *Iran J Otorhinolaryngol.* 2012; 1(24), 15-8.

20. Pereira MB, Pereira DR, Costa SS. Tympanostomy tube sequelae in children with otitis media with effusion: a three-year follow-up study. *Braz J Otorhinolaryngol.* 2005;71(4):415-20.

21. Klopp-Dutote N, Kolski C, Strunski V, Page C. Tympanostomy tubes for serous otitis media and risk of recurrences. *Int J Pediatr Otorhinolaryngol.* 2018; 106:105-9.

22. Yaman H, Yilmaz S, Alkan N, Subasi B, Guclu E, Ozturk O. Shepard grommet

tympanostomy tube complications in children with chronic otitis media with effusion. *Eur Arch Otorhinolaryngol* (2010) 267:1221–4.

23. Brown C, Behar P. Factors affecting persistent tympanic membrane perforation after tympanostomy tube removal in children. *Int J Pediatr Otorhinolaryngol.* 2020; 130:109779.

24. Branco C, Monteiro D, Paço J. Predictive factors for the appearance of myringosclerosis after myringotomy with ventilation tube placement: randomized study. *Eur Arch Otorhinolaryngol.* 2017;274(1):79-84.

25. Hao J, Chen M, Liu B et al. Compare two surgical interventions for otitis media with effusion in young children. *Eur Arch Otorhinolaryngol.* 2019; 276(8):2125-31.

26. Samantha M, Matthew B. Adenoidectomy as an Adjuvant to Primary Tympanostomy Tube Placement. *JAMA Otolaryngol Head Neck Surg.* 2014;140(2):95-10