



A Study of Surgical Complications of Ventilation Tube Insertion in Children in Central Iran

Mostafa Vahedian ¹, Amrollah Salimi ², Omid Garkaz ³, Seyedeh Tasnim Abdi ², Somayeh Donyadideh ⁴ and Narges Alizadeh ^{2,*}

¹Clinical Research Development Center (CRDC), Qom University of Medical Sciences, Qom, Iran

²Qom University of Medical Sciences, Qom, Iran

³Shahrood University of Medical Sciences, Shahrood, Iran

⁴Social Security Organization, Imam Reza Hospital, Qom, Iran

*Corresponding author: Qom University of Medical Sciences, Qom, Iran. Email: narali360@gmail.com

Received 2020 February 29; Accepted 2020 April 29.

Abstract

Background: Middle ear inflammation and fluid accumulation are one of the most common childhood diseases. Untreated or chronic ear inflammation can lead to more serious complications, including hearing loss, eardrum rupture, adhesive otitis media, tympanosclerosis, temporal bone necrosis, and cholesteatoma. Ventilation tube insertion is one of the best treatments to cure these diseases.

Objectives: This aimed to observe children suffering from ear inflammation who were candidates for VT insertion surgery and study surgical complications.

Methods: A historical cohort study was performed, and 205 VT surgeries were studied. Demographic information of children (like age, sex, and family medical history) was gathered through their medical records and probable complications, including otorrhea, tympanosclerosis, atrophy, and eardrum rupture were noticed through medical examinations and interviews. Data were analyzed using descriptive statistics, chi-square test, independent *t*-test, Fisher's exact, and Mann-Whitney U-test.

Results: The results showed that 57% of surgery cases were boys, and 43% were girls, both having no family medical history. Serous otitis with tonsillar hypertrophy was reported in 200 cases (97.6%), which had concurrent adenoidectomy or adenotonsillectomy. The frequency of otorrhea, tympanosclerosis, atrophy, perforation, and serous otitis recurrence was 2%, 12.2%, 6.8%, 1.5%, and 14.1%, respectively. Serous otitis recurrence was reported in 3.9% of cases with T-tube insertion.

Conclusions: The findings of this study show no significant difference in surgical complications between the two groups of girls and boys. But studying the relationship between the age of patients and the timing of surgery shows that the mean age of girls is significantly higher.

Keywords: Serious Otitis, Ventilation Tube, Otorrhea, Tympanosclerosis, Atrophy

1. Background

Otitis media with effusion (OME) is a collection of fluid in the middle ear space without any acute inflammation symptoms. This disease is common in children at peak ages of two and five years. Furthermore, 80% of children have had at least one episode of OME before the age of ten. By the age of 7-8, about eight percent of children have serious fluid accumulation in the middle ear, with an increase in winter. The serous fluid remains in the middle ear for 6 to 10 weeks. However, in some cases, it may remain more than 3 months, which is called middle ear infection with chronic effusion (COME) (1).

Untreated COME leads to hearing loss, eardrum rup-

ture, adhesive otitis media, tympanosclerosis, temporal bone necrosis, and cholesteatoma. As a result of hearing loss, which is a prominent manifestation of ear infection, the patient may have language, speech, and cognitive development disorders and experience academic failure (2).

Eustachian tube dysfunction is generally considered to be an important factor in the pathogenesis of otitis media, and hypoventilation of the middle ear and serous fluid or mucoid accumulation is the main clinical-pathologic factor in this disease. Eustachian tube dysfunction causes air pressure and fluid build-up in the middle ear and prevents middle ear cleaning and protection; therefore, microorganisms enter the middle ear. In 91% of patients, the causative bacteria are those colonized in the nasopharynx

and adenoid is a reservoir of pathogenic bacteria. Enlarged adenoids can also cause Eustachian dysfunction and otitis media (3, 4).

Ventilation tube is one of the best middle ear effusion (chronic serous otitis) treatments (5). In addition to chronic inflammation of the middle ear along with fluid accumulation, myringotomy surgery and ventilation tube insertion are needed in cases of recurrent acute middle ear infection and severe retraction and atelectasis of the tympanic membrane (6).

Ear ventilation tubes (or vent tube) are very small tubes that are placed in the eardrum and allow air to enter the middle ear. They are also called tympanostomy tubes, ventilation tubes or pressure equalization tubes. There are two basic types of ear tubes: short-term and long-term. Short-term tubes are smaller and typically stay in place for six months to a year before falling out on their own (7).

Some benefits of ventilation tube insertion include reduction of future ear infections risks, treatment of hearing loss due to middle ear fluid, improvement of speech and balance problems, and improvement of chronic ear infections, which may cause sleeping problems (8).

While the VT insertion surgery can be considered a simple procedure with significant benefits, it can also have adverse effects. Reports show several adverse effects of VT insertion on the tympanic membrane. Some VT insertion surgical complications include otorrhea, tympanosclerosis, eardrum rupture, eardrum stretching, and cholesteatoma. In many cases, it is difficult to distinguish the complications of the disease from the complications that resulted from the treatment (9).

Otorrhea is the most common complication of ventilation tube, which can occur in 3% to 50% of cases (10). Two out of every three children with VT develop otorrhea every year (11). There is no significant evidence that precautions, when exposed to water, can prevent this disease. Otorrhea is related to nasal discharge during an upper respiratory infection. Nasal discharge results from the incompatibility of Eustachian tubes or reaches the middle ear through the external ear canal (12).

Tympanosclerosis is a condition caused by hyalinization and subsequent calcification in the collagen layer of the tympanic membrane, which mostly occurs in patients who underwent VT insertion surgery. Ear injury (trauma), as one of the important factors of tympanosclerosis, is commonly associated with myringotomy and VT insertion. Bleeding inside the eardrum is another pathogenesis of tympanosclerosis. In a meta-analysis performed by Kai et al., the incidence of this complication has been reported to be 32% VT insertion may cause tympanic membrane atro-

phy. Permanent eardrum rupture is another adverse complication of VT insertion (12, 13).

Bingham et al. suggested that eardrum rupture should be diagnosed as a permanent complication if it persisted for one year (14). Wilson also suggested that the rupture of the secondary tympanic membrane caused by VT insertion may be due to the growth of squamous epithelium on the lower surface of the tympanic membrane (15). Barati et al. (14) and Kamrani et al. (4) observed complications of VT insertion in their study.

Patients with exacerbated ear infection symptoms, including earache and symptoms of upper respiratory tract infections, hearing loss, or symptoms of upper airway obstruction, referred to a specialist physician and were diagnosed to have VT surgery. While this is one of the most common children's surgeries requiring general anesthesia, few studies have been done on its long-term complications (16).

2. Objectives

The purpose of this study was to evaluate the complications of VT insertion surgery in children under the age of 10 in the Kamkar Hospital of Qom from 2017 to 2019.

3. Methods

This historical cohort study was carried out on 205 children under the age of 10 who underwent VT insertion surgery in Kamkar Hospital from 2017 to 2019. Demographic questionnaire (including age, sex, family medical history, reasons for surgery, date of surgery) and patient medical records (complications and symptoms) were used for data collection. The inclusion criteria were age (under 10 years old), having serous otitis media, having VT insertion surgery and complete medical records. The exclusion criteria were concurrent diseases that affect the eardrum and having incomplete medical records. To obtain informed consent, the study population was informed about the subject and procedure of study and participants were invited for re-examination and interview. Subsequently, postoperative status and surgery side effects, including otitis media, tympanic membrane atrophy, tympanosclerosis, tympanic membrane perforation, and otorrhea data were recorded using an interview and examination. Descriptive statistics were used to describe the basic features of the data and independent *t*-test, Mann-Whitney U-test, Fisher's exact, and chi-square test were used for analysis. Data were then entered into SPSS 18 software with a significance level of less than 0.05.

4. Results

The results showed that a total of 205 children aged three to 10 years underwent VT insertion surgery in Kamkar Hospital from 2017 to 2019. Moreover, 117 children were boys (57%), and none had a family medical history (Table 1). In many cases, ventilation tube insertion was due to serous otitis with hypotrophy, resulting in 200 (97.6%) operations involving VT with adenoidectomy. The study of surgery complications showed that in 201 (98%) cases, VT insertion resulted in otorrhea. Tympanosclerosis, eardrum atrophy, and perforation cases due to VT insertion were 25 (14.1%), 14 (6.8%), and 3 (1.5%), respectively. Also, serous otitis recurrence was observed in 29 cases (14.1%). Embedded VT was observed and reported in 27 (13.2%) of the examinations. There were also 8 (3.9%) cases of infections and recurrences with T-tube insertion (Table 2).

Table 1. Demographic Characteristics of Children Undergoing VT Insertion Surgery in Kamkar Hospital From 2017 to 2019^a

Variable	Values
Sex	
Male	117 (57.1)
Female	88 (42.9)
Date of surgery	
2017	127 (62)
2018	54 (26.3)
2019	24 (11.7)
Family medical history	
Yes	0 (0)
No	205 (100)

^aValues are expressed as No. (%).

Initially, two groups of boys and girls were compared in terms of how long ago surgery was performed. Since time distribution was not normal in these two groups, Mann-Whitney U-test was used for comparison, which showed no significant difference between the two groups in terms of elapsed time after surgery (P value = 0.84) (Table 3). The comparison of the age of the patients who underwent surgery showed a difference between the two groups where the mean age of the girls was significantly higher than that of the boys. The girls in the sample seemed to need surgery at an average age of 6.7 years, which was one year later than the boys (Table 4).

The results also showed that boys were more at risk of getting serious otitis, but no significant difference was observed between boys and girls (P value > 0.05). In the case of tympanosclerosis, girls were more at risk. In cases

Table 2. VT Insertion Surgery Complications in Children Under the Age of 10 in Kamkar Hospital From 2017 to 2019^a

Variable	Values
Otorrhea	
Yes	4 (2)
No	201 (98)
Eardrum atrophy	
Yes	14 (6.8)
No	191 (93.2)
Perforation	
Yes	3 (1.5)
No	202 (98.5)
Serous otitis	
Yes	29 (14.1)
No	176 (85.9)
Adenoidectomy	
Yes	200 (97.6)
No	5 (2.4)
Tympanosclerosis	
Yes	25 (12.2)
No	180 (87.8)
Observing VT during the examination	
Yes	27 (13.2)
No	178 (86.8)
T-tube insertion	
Yes	8 (3.9)
No	198 (96.1)
Surgery	
Serous otitis with tonsillar hypertrophy	200 (97.6)
Serous otitis without tonsillar hypertrophy	5 (2.4)

^aValues are expressed as No. (%).

of eardrum atrophy, VT observation, and T-tube there was no significant difference between boys and girls (P value > 0.05). In the case of T-tube, one of the cells in the table had a frequency of less than 5, so Fisher's exact test was used. Based on Fisher's exact test there was no significant difference in the frequency of two sexes and values were mostly close to each other (P value > 0.05) (Table 5).

5. Discussion

This study was carried out on 205 children under the age of 10 who underwent VT insertion surgery in Kamkar

Table 3. Mann-Whitney Test Results in Two Groups of Boys and Girls About the Elapsed Time After the Surgery

Sex	Number	Mean, mo	Mean Rank	Sum of Rank	Mann-Whitney U	P Value
Boy	117	26.78	103.7	12133	5066	0.84
Girl	88	26.82	102.07	8982		
Total	205	-	-	-	-	-

Table 4. Mann-Whitney U-test Results in the Two Groups of Boys and Girls About the Age of the Surgery

Sex	Number	Mean, mo	Mean Rank	Sum of Rank	Mann-Whitney U	P Value
Boy	117	5.6	89.53	10475	3572	0.001
Girl	88	6.7	120.91	10640		
Total	205					

Table 5. Chi-Square Test in Studying the Complications of VT Insertion Surgery and Patient's Sex^a

Type of Complication	Status	Values		Chi-Square	df	P Value
		Boy	Girl			
Tympanosclerosis	Yes	11 (9.4)	15 (15.9)	1.986	1	0.16
	No	106 (90.6)	74 (84.1)			
Eardrum atrophy	Yes	8 (6.8)	6 (6.8)	0	1	0.99
	No	109 (93.2)	82 (93.2)			
Serous otitis	Yes	19 (16.2)	10 (11.4)	0.983	1	0.32
	No	98 (83.8)	78 (88.6)			
Observing VT during the examination	Yes	15 (12.8)	12 (13.6)	0.029	1	0.86
	No	102 (87.2)	88 (86.4)			
T-tube	Yes	6 (5.1)	2 (2.3)	-	-	0.47 ^b
	No	111 (94.9)	86 (97.7)			

^aValues are expressed as No. (%).

^bFisher's exact test.

Hospital from 2017 to 2019. As studies show, there were 127 (62%) surgeries in 2017, 54 (26.3%) surgeries in 2018, and 24 (11.7%) surgeries in 2019. Moreover, 117 surgeries (approximately 57%) were performed on boys and the rest were performed on girls, which is inconsistent with the study by Khalili et al. (17) and Karimi et al. (18). Some studies have shown that complications of VT insertion are higher in females; however, this issue was not proven in our study, which can be due to the non-normal distribution of gender variables in the patients under study. Also, no positive family history was recorded for any of the children in this study.

In this study, more surgical complications, including otorrhea, eardrum atrophy, perforation, serous otitis, and tympanosclerosis were observed, which was consistent with similar studies (10, 14, 18-20). In fact, these results indicate the need to look after children to prevent such complications. According to the analysis, there was no signifi-

cant relationship between the two groups of boys and girls in terms of elapsed time after the surgery and insertion of VT in different years, which was inconsistent with similar studies (20). The reason for this disagreement could be different study locations and different disease distribution in these two studies. Studying the relationship between age and time of surgery showed a significant difference where the mean age of girls was significantly higher, and the girls needed surgery later than the boys. These results were consistent with similar studies (18).

This study showed girls experience tympanosclerosis complications more than boys, but there was no significant difference between the two groups. These results were in agreement with the study of Barati et al. (14) and Klopp-Dutote et al. (21). But not consistent with the study by Hassmann-Poznanska et al. (22), and Yaman et al. (23). This inconsistency may be due to the geographical location of the study. Also, 6.8% of children found to have eardrum at-

rophy after VT insertion surgery that was consistent with the studies of Banan et al. (20) and Zielnik-Jurkiewicz et al. (24). Moreover, the incidence rate was the same in both groups. There was no difference in the incidence to show a reduction of eardrum atrophy after VT insertion surgery.

Serous otitis was 14.1%, although the results show boys are more at risk, there was no significant difference, which was consistent with Jelinek et al. study (24). In fact, one could argue that the longer the time elapsed after surgery, the more likely it is to have serious otitis. So, timing plays an important role in the probability of this complication. Less than 5% of boys and girls needed T-tube insertion, but there was no significant relationship between the two groups of boys and girls.

The limitations of this study included incomplete records, patients' and parent's refusal to cooperate, and coexisting infections and middle ear diseases. It is also suggested to conduct studies to identify the risk factors and their effects, the effects of VT insertion on hearing and quality of life, and long-term complications.

5.1. Conclusions

The findings of the current study show no significant difference in surgical complications between the two groups of boys and girls. The mean age of girls was significantly higher only in studying the relationship between the age of the patients and the time of need for surgery.

Acknowledgments

We appreciate the financial support of the Vice-Chancellor of Qom University of Medical Sciences, medical records staff of Kamkar Hospital of Qom, doctors, and all those who helped us with this project.

Footnotes

Authors' Contribution: All authors contributed equally to the preparation of the manuscript.

Conflict of Interests: There is no conflict of interest.

Ethical Approval: This study is a doctoral thesis approved by Qom University of Medical Sciences and Ethics Committee with code IR.MUCH.REC.1398.019, which is approved by the Research Vice-Chancellor of Qom University of Medical Sciences.

Funding/Support: This study received the funding from the Vice-Chancellor for Research and Technology of Qom University of Medical Sciences.

References

1. Khanna R, Lakhnpaul M, Bull PD; Guideline Development Group. Surgical management of otitis media with effusion in children: summary of NICE guidance. *Clinical Otolaryngology*. 2008;**33**(6):600-5. [PubMed: [19126137](#)].
2. da Costa Monsanto R, Erdil M, Pauna HF, Kwon G, Schachern PA, Tsuprun V, et al. Pathologic changes of the peripheral vestibular system secondary to chronic otitis media. *Otolaryngology-Head and Neck Surgery*. 2016;**155**(3):494-500. [PubMed: [27165677](#)].
3. Shaffer AD, Ford MD, Choi SS, Jabbour N. Should children with cleft palate receive early long-term tympanostomy tubes: one institution's experience. *The Cleft Palate-Craniofacial Journal*. 2018;**55**(3):389-95. [PubMed: [29437502](#)].
4. Kamrani K, Nasiri Kalmarzi K, Naseri N, Stodeh K. Effects of surfactant on mortality and complications of respiratory distress syndrome in neonates. *Iranian Journal of Pediatric Diseases*. 2008;**18**(1):65-70.
5. Yang FF, McPherson B, Shu H. Evaluation of an auditory assessment protocol for Chinese infants with nonsyndromic cleft lip and/or palate. *The Cleft palate-craniofacial journal*. 2012;**49**(5):566-73. [PubMed: [23030790](#)].
6. Steele DW, Adam GP, Di M, Halladay CH, Balk EM, Trikalinos TA. Effectiveness of tympanostomy tubes for otitis media: a meta-analysis. *Pediatrics*. 2017;**139**(6). e20170125. [PubMed: [28562283](#)].
7. Heidemann CH. Child and Caregiver Quality of Life in Relation to Ventilating Tube Treatment. *Semantic Scholar*. 2015.
8. Subramaniam V, Manuprasad S, Hebin HK, Vijay Kumar K. Otolological and audiological manifestations in cleft lip and cleft palate children: A clinical study. *Int J Otorhinolaryngol Head Neck Surg*. 2015;**1**:7-10. doi: [10.18203/issn.2454-5929.ijohns20150579](#).
9. Faccini VCG, Lavinsky L. *Quinta, 16 de Outubro de 2014*. 2014.
10. van Dongen TM, Schilder AG, Venekamp RP, De Wit GA, Van Der Heijden GJ. Cost-effectiveness of treatment of acute otorrhea in children with tympanostomy tubes. *Pediatrics*. 2015;**135**(5):e1182-9. [PubMed: [25896832](#)].
11. Simon F, Haggard M, Rosenfeld RM, Jia H, Peer S, Calmels M-N, et al. International consensus (ICON) on management of otitis media with effusion in children. *European annals of otorhinolaryngology, head and neck diseases*. 2018;**135**(1):S33-9. [PubMed: [29398506](#)].
12. Nogan S, Phillips K, Grischkan J. The treatment of otorrhea in children with cleft palate: an institutional review. *Ear, Nose & Throat Journal*. 2017;**96**(4/5):164.
13. Branco C, Monteiro D, Paço J. Predictive factors for the appearance of myringosclerosis after myringotomy with ventilation tube placement: randomized study. *European Archives of Oto-Rhino-Laryngology*. 2017;**274**(1):79-84. [PubMed: [27395069](#)].
14. Barati B, Hashemi SM, Tabrizi AG. Otolological findings ten years after myringotomy with tympanostomy tube insertion. *Iranian journal of otorhinolaryngology*. 2012;**24**(69):181.
15. Teh BM, Marano RJ, Shen Y, Friedland PL, Dilley RJ, Atlas MD. Tissue engineering of the tympanic membrane. *Tissue Engineering Part B: Reviews*. 2013;**19**(2):116-32. [PubMed: [23031158](#)].
16. Heidemann CH, Lous J, Berg J, Christensen JJ, Håkonsen SJ, Jakobsen M, et al. Danish guidelines on management of otitis media in preschool children. *International journal of pediatric otorhinolaryngology*. 2016;**87**:154-63.
17. Khalili GR, Sajedi P, Heydari SM, Najmi S. Risk factors of re-intubation of patients in intensive care units. *J Isfahan Med Sci*. 2007;**25**(85):87-94. [PubMed: [27368465](#)].
18. Karimi Q, Hatefi H. Evaluation of Ventilation Tube Disposal Time and Complications in Children with Serous Otitis. *J Shahid Sadoughi Cli Univ Med Sci*. 2009;**9**(4):43-7.

19. van Dongen TM, van der Heijden GJ, Freling HG, Venekamp RP, Schilder AG. Parent-reported otorrhea in children with tympanostomy tubes: incidence and predictors. *PLoS One*. 2013;**8**(7). [PubMed: [23874870](https://pubmed.ncbi.nlm.nih.gov/23874870/)].
20. Banan M, Mousavi Seyed R, Rahmani A. Effect of suctioning of middle ear discharge before ventilation tube on hearing status of patients with otitis media with effusion. *J Guilan Univ Med Sci*. 2002;**10**:79–82.
21. Klopp-Dutote N, Kolski C, Strunski V, Page C. Tympanostomy tubes for serous otitis media and risk of recurrences. *International journal of pediatric otorhinolaryngology*. 2018;**106**:105–9.
22. Hassmann-Poznanska E, Gozdziwski A, Piszcz M, Skotnicka B. Long term sequelae of otitis media with effusion during childhood. *Otolaryngologia polska, The Polish otolaryngology*. 2010;**64**(4):234–9. doi: [10.1016/S0030-6657\(10\)70022-6](https://doi.org/10.1016/S0030-6657(10)70022-6).
23. 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. *European archives of oto-rhinolaryngology*. 2010;**267**(8):1221–4. [PubMed: [20204390](https://pubmed.ncbi.nlm.nih.gov/20204390/)].
24. Zielnik-Jurkiewicz B, Olszewska-Sosinska O, Rakowska M. Results of treatment with tympanostomy tubes in children with otitis media with effusion. *Otolaryngologia polska, The Polish otolaryngology*. 2006;**60**(2):181–5.