



## Original Article

# Evaluation of Children Quality of Life after Serous Otitis Media Surgery

Yalda Jabbari Moghaddam<sup>1\*</sup> , Alireza Mirghaffari<sup>2</sup> <sup>1</sup>Department of Otolaryngology, Faculty of Medicine, Tabriz University of Medical Sciences, Pediatric Health Research Center, Tabriz, Iran<sup>2</sup>Department of General Medicine, Faculty of Medicine, Islamic Azad University, Tabriz Branch, Tabriz, Iran**ARTICLE INFO**

## Article History:

Received: 5 Sep. 2017

Accepted: 11 Jul. 2018

ePublished: 1 Sep. 2018

## Keywords:

Quality of life, Otitis media, Children

## \*Corresponding Author:

Otolaryngologist, Email: Yj\_moghaddam@yahoo.com

**ABSTRACT****Introduction:** Otitis media with effusion is a common childhood disease diagnosed with the accumulation of serous fluid or mucous in the middle ear. If not treated, the sustainable effusion leads to change and destruction of middle ear structures. One of the most successful treatment methods is myringotomy and ventilation tube insertion, which leads to improvement of patients' quality of life. The aim of this study was to evaluate children's quality of life after inserting ventilation tubes.**Methods:** This prospective cross-sectional study examined the quality of life of the children suffering from otitis media with sustainable effusion, who were candidates for ventilation tube insertion. Otitis Media Outcome-22 (OMO -22) questionnaire, was used to record the patients' problems in a 12-week period before and after surgery.**Results:** In this study, 70 patients, including 43 (61.4%) boys and 27 (38.6%) girls (1y-13y), who completed the questionnaire, were studied. Treatment with ventilation tubes improved many physical symptoms of the hearing loss along with speech and behavioral symptoms. A significant reduction was observed in the number of physician visits and the use of antibiotics for ear problems.**Conclusion:** Ventilation tube insertion not only reduced the symptoms of otitis media with effusion, but also improved the children's quality of life.**Citation:** Jabbari Moghaddam Y, Mirghaffari A. Evaluation of children quality of life after serous otitis media surgery. J Car Sci 2018; 7 (3): 131-5. doi:10.15171/jcs.2018.021.**Introduction**

Otitis media with effusion is a common childhood disease characterized by the accumulation of fluid in the middle ear. Without infective sign or symptoms, this is serous or mucus fluid, but usually not purulent. Otitis media with effusion can occur following acute otitis media resulting in Eustachian tube dysfunction.<sup>1</sup> The prevalence of serous otitis media predisposing factors with effusion can vary depending on age, sex, nutrition and different seasons, so that the incidence usually peaks at the second year of a child's life in the winter, and it is more frequently observed in boys or in children who were not breast fed.<sup>2,3</sup> Thirty million physician visits are done for the treatment of acute otitis media and its complications in children in the United States annually, which costs over one billion dollars;<sup>4</sup> however, there are no exact statistics available in our country.

Not treating the sustainable cases of the disease may lead to hearing loss, chronic infection of the middle ear, change and destruction of structures in the middle ear, serious intracranial complications such as meningitis and cholesteatoma, speech and behavioral disorders and can significantly affect the children's quality of life.<sup>1,2,5,6</sup>

One of the most successful therapeutic techniques is myringotomy and ventilation tube insertion, described by Dr. Armstrong for the first time in 1954.<sup>2,7</sup> There are studies in the field suggesting that timely ventilation tube insertion can prevent irreversible complications of the disease and improve the children's quality of life.<sup>8-13</sup>

The examination of the evolution of complications in chronic middle ear disease in the areas of cognition,

speech and language, along with social and psychological developments showed that early insertion of VT had no significant change in improvement of the prognosis evolution in children less than 3 years with sustainable effusion in the middle ear.<sup>14</sup> In a study conducted on 187 children with sustainable effusion for 4 to 6 months, 93 patients underwent VT insertion and 94 were considered for watchful waiting treatment. The quality of life improved after 6 and 12 months in both groups.<sup>15</sup> and the Otitis media-6 (OM-6) questionnaire was the best available tool to assess the functional healthy status in children with otitis media.<sup>16</sup>

Different predisposing factors could affect serous otitis media treatment outcomes especially geographic, genetic and socioeconomic factors; however, relatively scant attention has been paid to the variations in children's post-surgery life quality, and that's what we set out to achieve in the present study. The aim of our prospective cross-sectional study was to examine the changes in the children's quality of life following serous otitis surgery.

**Materials and methods**

The aim of this prospective cross-sectional study was to examine the changes in the children's quality of life after serous otitis surgery. This prospective cross sectional study was carried out from 2015 -2016 in ENT department of Tabriz children Hospital. The inclusion criteria were chronic bilateral serous otitis over 16 weeks, tympanometry type B, negative pressure more than 200 db and air bone gap more than 35 db, and the exclusion criteria were any underlying diseases including a variety

of syndromes and brain and behavioral disorders.

The OMO-22 questionnaire was used in this 2-year study. The questionnaire included 31 questions, with the last 22 questions developed form of the OM-6 questionnaire, which evaluates the quality of life in ear-related problems in terms of physical health, emotional health, hearing loss and speech symptoms. The questions were scored based on a 7-point Likert scale and it also included demographic questions whose validity and reliability were examined in the conducted studies. First, the questionnaire was translated into Farsi, 24 key questions related to the quality of life were selected and its validity and reliability were evaluated in a separate statistical study. The opinions of 10 faculty members who was experts in the fields of medical statistics and epidemiology and ENT were applied to determine the content validity. These experts were asked to judge and comment on the validity of each question in the questionnaire on a scale of 10 degrees (maximum 10 and minimum 1). Content validity criterion for each question was scoring a minimum of 70% based on faculty members' comments. Finally, if all questions acquired more than 70% of the total score, it was determined that the questionnaire had the required validity.

A total of 30 questionnaires were completed by parents. Cronbach's alpha calculating method was used to evaluate the reliability. A confidence coefficient of 95% and significance level of  $P < 0.05$  were considered in all calculations. Cronbach's alpha coefficient is the most common method of calculating the internal consistency of the questions in a questionnaire. Based on this method, when Cronbach's alpha coefficient is greater than or equal to 0.7, the tool will have an appropriate reliability.

The study was initiated after the validity and reliability of the questionnaire had been evaluated and the necessary standards obtained. Having signed their written consent forms to participate in this study, the parents and caregivers of children were given questionnaires before and after surgery. They reported the child's symptom process during the past 12 weeks, and they completed the questionnaire again 12 weeks after surgery. This study was approved by Tabriz Azad University ethics committee, Ethical code: IR.IAU.TABRIZ.REC.1397.108. All patients were recruited with informed consent. The study was conducted on patients who were candidates for the surgery.

## Results

There were 76 participants in this prospective study; however, as 6 subjects left during the study, the data obtained from the remaining 70 patients were analyzed.

The average age of the 70 patients was 4.3 (2.66) years, with a range of 1 to 12 years. The average weight of the studied patients was 20.64 (7.84) kg, (min = 10, max = 40). Of the 70 patients, 27 (38.6%) were girl and 43 (61.4%) were boy.

**1. The incidence of middle ear infections:** In a period of 12 weeks before the surgery, 22.9% of patients had no infection, while in the same period after surgery the figure rose to 65.7%, with 32.9% of the patients having infection only once or twice. Sixty-nine patients (98.6%)

had no infection or they only had one once or twice. None of the patients had infection more than 4 times after surgery. The number of ear infection cases was significantly reduced after surgery compared to before surgery ( $P < 0.01$ ).

**2. The antibiotic use associated with ear infections:** In total, 67.1% patients received no antibiotic during the 12 weeks after surgery, which increased significantly compared with before surgery. After surgery, 31.4% of the patients received antibiotic once or twice and 1.4% did three or four times. The rate of antibiotics received due to ear infection was significantly reduced after surgery compared to before surgery ( $P < 0.01$ ).

**3. The number of physician visits associated with ears:** Almost all patients had at least one visit during the 12 weeks before surgery, with 2 patients having more than 8 visits. The maximum number of visits during 12 weeks after surgery was 5-6 times. Fifty percent of the patients visited physicians once or twice after surgery and 40% visited three or four times, which was because of the control and follow-up after surgery and the normal treatment process. Visits due to ear problems were reduced after surgery compared to before surgery ( $P < 0.01$ ).

**4. Hearing loss:** Almost 75% of the patients had no hearing problems and about 18% rarely mentioned a problem related to hearing. In fact, more than 90% of the patients either had no problems in hearing or problems were rare and insignificant. None of the parents recorded more than a score of 3 (medium difficulty) in hearing problems of their child, except 2 of them. Hearing loss after surgery was significantly reduced compared to before surgery ( $P < 0.01$ ).

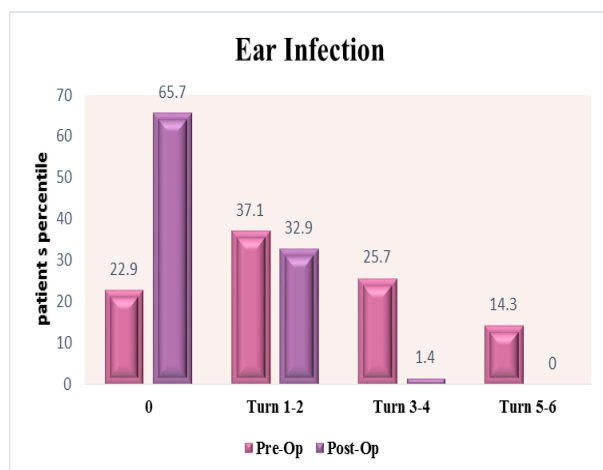
**5. Dysarthria (speech disorder):** Twenty-one patients (30%) had speech disorders before surgery, and 12 weeks after surgery, 13 (61.9%) parents reported symptoms of speech improvement in their children, but the problem was not completely resolved, which was statistically significant ( $P < 0.01$ ).

**6. Earache:** In total, 65.7% (46) of the patients had no earache, 21.4% rarely did and 11.4% had minor problems; 98.6% of the patients had no serious ear problems and the earache score was 2 or less. Earache was significantly reduced after surgery compared to before surgery ( $P < 0.01$ ).

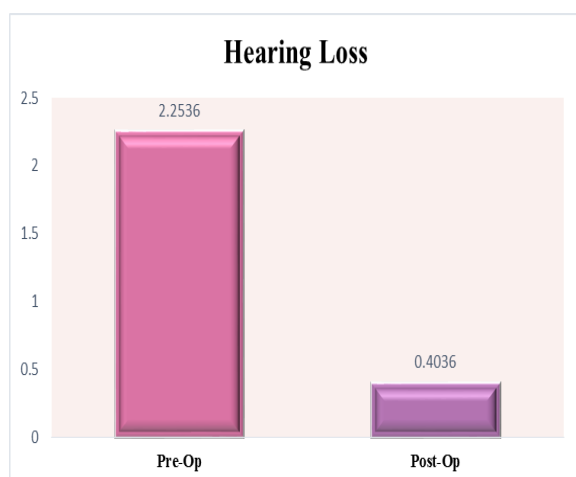
**7. Irritability and aggression:** About one-fifth of the patients (21.4%) had no problem with irritability before surgery, and the rest had trouble to some degree. The percentage of patients without problems after surgery was 40. Irritability and aggression were reduced after surgery compared to before surgery ( $P < 0.01$ ).

**8. Sleep disorders:** A total of 22.9% of patients were suffering from sleep disorders before surgery. However, 88.6% of patients had no problem in this regard. Sleep disorders were reduced after surgery compared to before surgery ( $P < 0.001$ ).

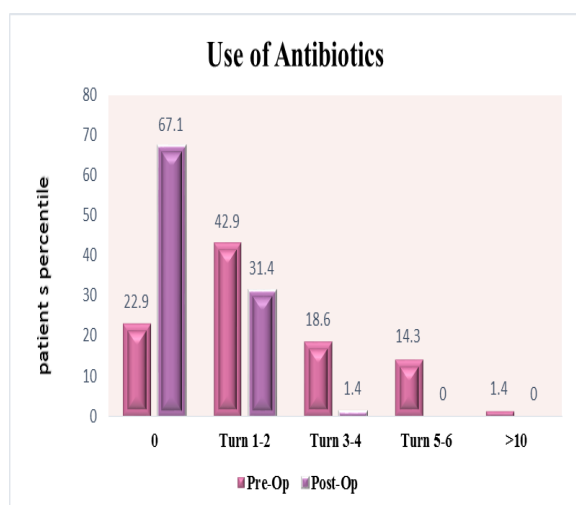
**9. Anorexia:** In total, 44.3% of the patients were suffering from anorexia before surgery, which reached 50% after surgery. There was no significant difference in anorexia before and after surgery ( $P = 0.78$ ). Please notice Figure 1-4.



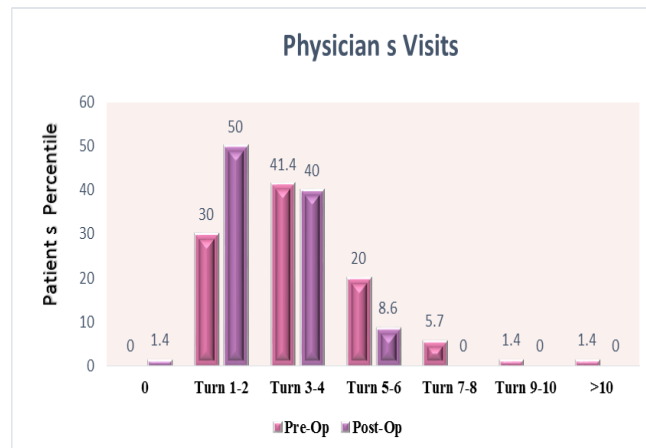
**Figure 1.** Comparison of the Frequency of Ear Infection before and After Surgery



**Figure 2.** Comparison of the frequencies of problems resulted from hearing loss before and after surgery



**Figure 3.** Comparison of the frequency of antibiotics use before and after surgery



**Figure 4.** Comparison between the frequency of the number of medical appointment before and after surgery

### Discussion

Nowadays, the quality of life has an important place in many medical treatments and receives particular attention in treatment-oriented programs. This is especially true in aggressive and surgical treatments in order to see to what extent the invasive procedure affects patients, as some of the expenses and potential physical and emotional difficulties imposed on the sick will affect the quality of life. Meanwhile, treatments and interventions that lead to improvement of life quality are more widely accepted among doctors and patients. Several parameters for evaluating the quality of life should be considered in order to encompass most aspects of life. However, given the high cost of large-scale and time-consuming research, researchers always attempt to identify and select the most important effective parameters.<sup>16</sup> Insertion of tympanostomy tubes is the most common ambulatory surgery performed on children in the United States. Children with recurrent acute otitis media may have fewer episodes after tympanostomy tube placement; surgical treatment with ventilation tubes is widespread but controversial. Some studies recommend that clinicians insert a ventilation tube if they obtained a hearing test and serous otitis media was permanent for longer than 3 months or a significant hearing loss was detected, structural problems of the tympanic membrane or middle ear were suspected or a child was at increased risk for speech, language, or learning problems from chronic OME because of baseline sensory, physical, cognitive, or behavioral factors, ventilation tube insertion.<sup>17-22</sup> A significant reduction was observed in the number of physician visits associated with the ear and the use of antibiotics for middle ear infections in our study, which was consistent with the results obtained in the study of Mui et al.<sup>9</sup> According to recent studies, four spectrums of problems, including physical, hearing, speech and behavior, make up the most important problems in patients with chronic middle ear diseases.<sup>10,16</sup> In this study, we essentially focused on evaluating the problems. In terms of hearing loss, which is one of the most influential problem in the patients' life,

our study showed that more than 74% of patients had no problem with hearing loss during the 12 weeks after surgery, while the statistic was about 17% before surgery.

The results of our study indicated a significant improvement in hearing loss, which is similar to the results of the studies conducted by Michele Richards *et al.* and Mui *et al.*<sup>9,10</sup> One of the important results of this study was the beginning of the recovery process in the patients' speech disorders, which was statistically significant so that 61.9% of the patients with speech disorders had shown improvement in speech in the 12 weeks after surgery. The noteworthy thing in the situation of these patients was that the patients were under 4 years of age and bilateral ventilation tube had been inserted. This result should be taken as an important reminder that if sustainable effusion in the middle ear or serous otitis were bilateral and occurred at young ages, it could make more speech problems. Thus, early diagnosis and treatment can resolve or reduce side effects of the problem. The other aspect of the present study is the reduction in costs.

A significant reduction in the number of physician visits and antibiotic consumption was observed in this study. Thus, it can be concluded that the timely diagnosis and treatment of otitis media with sustainable effusion can prevent the additional costs imposed on patients. Physical and emotional problems are undeniable in quality of life as well. In this study, physical symptoms such as earache due to effusion and infection and emotional symptoms such as irritability and aggression were significantly decreased, and problems caused by sleep disorders were significantly reduced, as well. The use of online internet information may prove helpful for the parent's decision making and understanding their children problems.<sup>23</sup>

## Conclusion

Timely ventilation tube insertion in children with chronic otitis media with effusion or serous otitis improved the children's quality of life.

## Acknowledgments

The researchers would like to thanks to the audiometrists Ms. Aida Ariaifar and Mr. Naser Shadi for their cooperation in this study

## Ethical issues

None to be declared.

## Conflict of interest

The authors declare no conflict of interest in this study.

## References

1. Rosenfeld RM, Schwartz SR, Pynnonen MA, Tunkel DE, Hussey HM, Fichera JS, *et al.* Clinical practice guideline: tympanostomy tubes in children. *Otolaryngology—Head*

- and Neck Surgery 2013; 149 (1\_suppl): S1-35. doi: 10.1177/0194599813487302.
2. Lous J, Ryborg CT, Thomsen JL. A systematic review of the effect of tympanostomy tubes in children with recurrent acute otitis media. *Int J Pediatr Otorhinolaryngol* 2011; 75 (9): 1058-61. doi: 10.1016/j.ijporl.2011.05.009.
3. Kiris M, Muderris T, Kara T, Bercin S, Cankaya H, Sevil E. Prevalence and risk factors of otitis media with effusion in school children in Eastern Anatolia. *Int J Pediatrics Otorhinolaryngology* 2012; 76 (7): 1030-5. doi: 10.1016/j.ijporl.2012.03.027.
4. Kirchner JA. Current Concepts in Otolaryngology Epistaxis. *N Engl J Med* 1982; 307: 1126-8. doi: 10.1056/NEJM1982.10283071805
5. Hellström S, Groth A, Jörgensen F, Pettersson A, Ryding M, Uhlén I, *et al.* Ventilation tube treatment: a systematic review of the literature. *Otolaryngol Head Neck Surg* 2011; 145 (3): 383-95. doi: 10.1177/0194599811409862.
6. Heidemann CH, Godballe C, Kjeldsen AD, Johansen EC, Faber CE, Lauridsen HH. The Otitis Media-6 questionnaire: psychometric properties with emphasis on factor structure and interpretability. *Health Quality of Life Outcomes* 2013; 11 (1): 201. doi: 10.1186/1477-7525-11-201.
7. Shakurnia AH, Fakoor M, Elhampour H, Taherzadeh M. Evaluation of validity and reliability of the questionnaire of student evaluation of teaching. *Jundishapur Scientific Medical Journal* 2011; 10 (6): 583-93. (Persian)
8. Chow Y, Wabnitz DA, Ling J. Quality of life outcomes after ventilating tube insertion for otitis media in an Australian population. *Int J Pediatrics Otorhinolaryngology* 2007; 71 (10): 1543-7. doi: 10.1016/j.ijporl.2007.06.001.
9. Mui S, Rasgon BM, Hilsinger Jr RL, Lewis B, Lactao G. Tympanostomy tubes for otitis media: quality-of-life improvement for children and parents. *ENT-Ear, Nose & Throat Journal* 2005; 84 (7): 418-24.
10. Richards M, Giannoni C. Quality-of-life outcomes after surgical intervention for otitis media. *Arch Otolaryngology Head Neck Surg* 2002; 128 (7): 776-82.
11. Rosenfeld RM, Bhaya MH, Bower CM, Brook Houser PE, Casselbrant ML, Chan KH, *et al.* Impact of tympanostomy tubes on child quality of life. *Arch Otolaryngology Head Neck Surg* 2000; 126 (5): 585-92.
12. Facione N. Quality of life issues in chronic otitis media with effusion: parameters for future study. *Int J Pediatrics Otorhinolaryngology* 1991; 22 (2): 167-79. doi: 10.1016/0165-5876(91)90036-B.
13. Paradise JL, Feldman HM, Campbell TF, Dollaghan CA, Colborn DK, Bernard BS, *et al.* Effect of early or delayed insertion of tympanostomy tubes for persistent otitis media on developmental outcomes at the age of three years. *N Engl J Med* 2001; 344 (16): 1179-87.
14. Fekete-Szabó G, Kiss F, Rovó L. Long-term follow-up after tympanostomy tube insertion in children with serous otitis media. *Orv Hetil* 2015; 156 (46): 1859-64. doi: 10.1556/650.2015.30291.
15. Rovers MM, Krabbe PF, Straatman HM, Ingels KJ, van Der Wilt GJ, Zielhuis GA. Randomised controlled trial of the effect of ventilation tubes (grommets) on quality of life at age 1–2 years. *Arch Dis Child* 2001; 84 (1): 45-9. doi: 10.1136/adc.84.1.45.
16. Brouwer CN, Maillé AR, Rovers MM, Grobbee DE, Sanders EA, Schilder AG. Health-related quality of life in children with otitis media. *Int J Pediatrics Otorhinolaryngology* 2005; 69 (8): 1031-41. doi: 10.1016/j.ijporl.2005.03.013.



17. Rosenfeld RM, Schwartz SR, Pynnonen MA, Tunkel DE, Hussey HM, Fichera JS, et al. Clinical practice guideline: Tympanostomy tubes in children. *Otolaryngol Head Neck Surg* 2013; 149 (1 Suppl): S1-35. doi: 10.1177/0194 59 9813487302.
18. Browning GG, Rovers MM, Williamson I, Lous J, Burton MJ. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database Syst Rev* 2010; (10): CD001801. doi: 10.1002/14651858.CD001801.
19. Whittemore KR Jr. Tympanostomy tubes: patient selection and special considerations. *Pediatric Health Med Ther* 2015; 6: 41-43. doi: 10.2147/PHMT.S61938. eCollection 2015.
20. 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). Pii: e20170125. doi: 10.1542/peds.2017-0125.
21. Demant MN, Jensen RG, Jakobsen JC, Gluud C, Homøe P. The effects of ventilation tubes versus no ventilation tubes for recurrent acute otitis media or chronic otitis media with effusion in 9 to 36 month old Greenlandic children, the SIUTIT trial: study protocol for a randomized controlled trial. *Trials* 2017; 18 (1): 30. doi: 10.1186/s13063-016-1770-x.
22. Hassmann-Poznańska E, Goździewski A, Piszcz M, Skotnicka B. Long term sequelae of otitis media with effusion during childhood. *Otolaryngol Pol* 2010; 64 (4): 234-9. doi: 10.1016/S0030-6657(10)70022-6.
23. Harris VC, Links AR, Hong P, Walsh J, Schoo DP, Tunkel DE, et al. Consulting Dr. Google: quality of online resources about tympanostomy tube placement. *The Laryngoscope* 2018; 128 (2): 496-501. doi: 10.1002/lary.26824.