Indian Journal of Otolaryngology and Head & Neck Surgery (2023) 75:S97–S102
https://doi.org/10.1007/s12070-022-03278-9

Assessment of Quality of Life After Ventilation Tube Insertion Using Otitis Media 6-Item (OM-6) Questionnaire

Aditiya Saraf1 · Monica Manhas2 · Parmod Kalsotra1

Received: 6 April 2022 / Accepted: 10 November 2022 / Published online: 16 November 2022
© Association of Otolaryngologists of India 2022

Introduction

Otitis media with effusion (OME) is the chronic accumulation of mucus within the middle ear and mastoid air cell system. The time that the fluid has to be present for the condition to be chronic is usually taken as 12 weeks. [1] The prevalence of having at least one episode of OME among children younger than 4 years of age amounts to 90%, whereas this percentage decreases to 3–4% between six and eight years. [2]

Usually, otitis media with effusion resolves spontaneously within first 3 months, but 30–40% of children have recurrent episodes and in some 5–10% children, it lasts longer than 1 year. Risk factors for OME include male gender, recent upper airway infection, allergic rhinitis, bottle feeding, overcrowding, cigarette smoke at home, Down syndrome, Cleft palate and other craniofacial anomalies. [3]

The pathogenesis for development of OME is explained by decreased aeration and poor ventilation of middle ear space as a result of eustachian tube dysfunction. This results in a negative pressure which leads to fluid transudation, and hypoxia and hypercapnia in middle ear mucosa- causing clear cell hypersecretion. The end result is a sterile fluid, which can be secondarily infected.[4] Children with OME present with mild hearing loss, otic fullness/discomfort, delayed/defective speech- resulting in change behaviour and communication skills, hence affecting quality of life of child and the caregiver. [5]

The treatment is based on restoration of adequate middle ear ventilation- either by achieving proper functioning of eustachian tube or by placement of ventilation tube. The first ventilation tube insertion described by Armstrong in the year 1954.[6] According to the guidelines identifying the management of OME, children who have had more than 3 episodes of Acute otitis media in a 6-month period and...
more than 4 episodes in a 1-year period and those who have effusion shown by tympanometry and otoscopy over three months should be considered for insertion of ventilation tube.[7] While the surgical intervention is made according to these criteria, the net effect of ventilation tube insertion can be evaluated with questionnaires assessing impact of otitis media on quality of life.[8, 9]

The Otitis Media 6-Item (OM6) survey, developed by Rosenfeld RM in the year 1997, is one such easy-to-use questionnaire that has been developed for assessing quality of life in children with recurrent acute otitis media and otitis media with effusion. It consists of six domains- physical suffering, hearing loss, speech impairment, emotional distress, activity limitation and caregiver concerns, each of which is addressed by a single question. The question gets a positive response if any one of the listed symptoms is present. Answers are given on a 7-point categorical scale and total score is calculated by taking the mean of the 6 domain scores.[10]

Despite the frequency with which ventilation tube insertion is performed, there have been very limited research work done on the impact of this procedure on the child’s and caregiver’s quality of life using OM-6 questionnaire, especially in our local population. We, with our study, aim to assess the impact of Ventilation tube insertion on the quality of life of children with otitis media with effusion using OM-6 questionnaire.

**Materials and methods**

The present prospective study was conducted in the Department of ENT, SMGS Hospital on 65 children suffering from Otitis Media with Effusion-OME (diagnosed by otoscopy and tympanometry after 3-month follow-up) over a period of 1 year from December 2020 to December 2021.

The study was approved by Institutional Ethics Committee. Written Informed consent was taken from caregivers of all 65 patients in the language they understood. No animals were used in this research.

Relevant clinical history was taken, General physical examination and Local ENT examination was done on all 65 children.

**INCLUSION CRITERIA:**

- Age 5–12 years.
- Who came for follow-up at 6th postoperative week.
- Otitis media with effusion in both ears for more than 3 months (Otoscopic findings- Dull Tympanic membrane with loss of light reflex, restricted mobility of Tympanic membrane and/or fluid level/ air bubbles.
- Child accompanied by a caregiver.
- Child able to complete audiometry testing (Inclusion criteria being B type curve on tympanometry and Hearing loss of 35dB or more).

**EXCLUSION CRITERIA:**

- Tympanic membrane perforation.
- Middle ear pathology other than OME,
- Suspected developmental delay / neurological disorder.

Caregivers of all 65 children were subjected to Otitis Media 6-Item (OM-6) questionnaire (Table 1) at the time of admission (preoperative). All 65 children were subjected to ventilation tube insertion (Shephard Grommet) under general anaesthesia via Myringotomy in antero-inferior quadrant of tympanic membrane of both ears.

Post-operatively at 6 weeks of ventilation tube insertion, caregivers were again asked to fill OM-6 questionnaire. The six items on OM-6 questionnaire (Table 1) were graded by caregiver on a seven-point scale where 1 indicates no problem and 7 indicates extreme problem. The individual scores were summed up and divided by 6 to get an overall mean score.

All study data was entered in Microsoft Excel Spreadsheet and analysed/compared using the Statistical Package for Social Sciences (SPSS) software (version 21 for windows). Appropriate statistical tests were used as advised by statistician.

**Results**

A total of 84 children with otitis media with effusion were enrolled in our study. However, due to COVID-19 pandemic related restrictions in our region, out of 84, 65 children came for follow-up at 6th postoperative week. We in our study results included these 65 children as 19 children were lost to follow-up. The mean age of presentation was 8.02 ± 1.66 years, with majority of children (57.7%) in the age group of 7–10 years [Table 2]. Out of 65 children, 38 were males (58.4%) and 27 were females (41.5%), male to female ratio being 1.8:1. The most common presenting complaint was hearing impairment in all 65 patients (100%), ear fullness in 39 patients, itching ear in 11 patients and delayed speech in 07 patients. Out of 65 patients, 34 children had bilateral disease while 31 children had unilateral disease (17- left ear, 14- right ear).

The mean pre-operative overall OM6 score was 4.59 ± 1.02 and mean postoperative overall OM6 score was 2.22 ± 0.83, the difference being statistically significant (p < 0.05) [Table 3].
Table 1  Otitis media 6 item (OM-6) Questionnaire

A) PHYSICAL SUFFERING: Ear pain, Ear discomfort, Ear discharge, Ruptured Ear Drum, High Fever, Poor Balance. How much of a problem for your child during the past 4 weeks?

- Not present/ no problem: 1
- Hardly a problem at all: 2
- Somewhat of a problem: 3
- Moderate problem: 4
- Quite a bit of problem: 5
- Very much of a problem: 6
- Extreme problem: 7

B) HEARING LOSS: Difficulty hearing, questions must be repeated, frequently says “what” or television is excessively loud. How much of a problem for your child during the past 4 weeks?

- Not present/ no problem: 1
- Hardly a problem at all: 2
- Somewhat of a problem: 3
- Moderate problem: 4
- Quite a bit of problem: 5
- Very much of a problem: 6
- Extreme problem: 7

C) SPEECH IMPAIRMENT: Delayed speech, poor pronunciation, difficult to understand or unable to repeat words clearly. How much of a problem for your child during the past 4 weeks?

- Not present/ no problem: 1
- Hardly a problem at all: 2
- Somewhat of a problem: 3
- Moderate problem: 4
- Quite a bit of problem: 5
- Very much of a problem: 6
- Extreme problem: 7

D) EMOTIONAL DISTRESS: Irritable, frustrated, sad, restless or poor appetite. How much of a problem for your child during the past 4 weeks as a result of ear infections or fluid?

- Not present/ no problem: 1
- Hardly a problem at all: 2
- Somewhat of a problem: 3
- Moderate problem: 4
- Quite a bit of problem: 5
- Very much of a problem: 6
- Extreme problem: 7

E) ACTIVITY LIMITATIONS: Playing, Sleeping, doing things with friends/family, attending school or day-care. How limited have your child’s activities been during the past 4 weeks because of ear infections/ fluid?

- Not present/ no problem: 1
- Hardly a problem at all: 2
- Somewhat of a problem: 3
- Moderate problem: 4
- Quite a bit of problem: 5
- Very much of a problem: 6
- Extreme problem: 7

F) CAREGIVER CONCERNS: How often have you, as a caregiver, been worried, concerned or inconvenienced because of your child’s ear infections or fluid over the past 4 weeks?

- Not present/ no problem: 1
- Hardly a problem at all: 2
- Somewhat of a problem: 3
- Moderate problem: 4
- Quite a bit of problem: 5
- Very much of a problem: 6
- Extreme problem: 7
The mean preoperative physical suffering score was 4.66 and mean postoperative score was 2.11, the difference being statistically significant (p < 0.05). For hearing loss, the mean preoperative score was 4.92 and mean postoperative score was 2.76, the difference being statistically significant (p < 0.05). The mean preoperative speech impairment score was 4.43 and mean postoperative score was 3.55, the difference being statistically significant (p < 0.05). The mean preoperative emotional distress score was 4.39 and mean postoperative score was 2.12, the difference being statistically significant (p < 0.05). The mean preoperative activity limitation score was 4.26 and mean postoperative score was 2.40, the difference being statistically significant (p < 0.05). The mean preoperative caregiver concern score was 4.73 and mean postoperative score was 1.97, the difference being statistically significant (p < 0.05). [Table 4]

Out of the six domains, the highest mean preoperative-postoperative difference was seen in Caregiver Concern (2.76), followed by Physical suffering (2.55). The least mean preoperative-postoperative difference was seen in Speech impairment (0.88). [Figure 1]

**Discussion**

Quality of life (QOL) of Children having otitis media with effusion is poorer than healthy children of similar age group, thus, resulting in behavioural changes and poor school performance. While traditional outcome measures like recurrence rates of disease, status of tympanic membrane and hearing impairment, there is more and more utility of patient-based quality of life assessments in children.

![Fig. 1 Mean OM6 Domain-wise Preoperative-Postoperative Difference](image)
having otitis media with effusion. Chronic OME leads to complications such as tympanic membrane perforation and cholesteatoma, which can be avoided by inserting a ventilation tube. [11]

Quality of life assessment is also important to see up to what extent the surgical procedure affects the patients, as the interventions that lead to improved quality of life, are more widely accepted to clinicians and patients. The disease specific QOL questionnaire OM-6 is a reliable, rapid and valid survey for assessing functional health status children having OME and is free from many potential biases. This questionnaire not only encompasses physical and emotional concerns of child and caregiver, but also includes a measure of global health related to child quality of life. [10]

In our study, the mean age of presentation was 8.02 ± 1.66 years, with majority of children (57.7%) in the age group of 7–10 years [Table 2]. This finding was consistent with study conducted by Chow Y et al. (2007) [11] and Yazici A & Coskun ME (2018) [12]. Out of 65 children, 38 were males (58.4%) and 27 were females (41.5%), male to female ratio being 1.8:1. Similar male predominance was observed in their study by Heidemann CH et al. (2013) [9] and, Moghaddam YJ & Mirghaffari A (2018) [13]. In our study, the most common presenting complaint was hearing impairment in all 65 patients (100%), ear fullness in 39 patients, itching ear in 11 patients and delayed speech in 07 patients. Out of 65 patients, 34 children in our study had bilateral disease while 31 children had unilateral disease (17- left ear, 14- right ear).

The mean pre-operative overall OM6 score was 4.59 ± 1.02 and mean postoperative overall OM6 score was 2.22 ± 0.83, the difference being statistically significant (p < 0.05). Similar finding was seen by Chow Y et al. (2007) [11], who showed mean pre-operative OM6 score of 3.43 and mean postoperative score of 2.07, difference being statistically significant. Similar post-surgical improvement in quality of life was also observed in their study by Moghadam YJ & Mirghaffari A (2018) [13]. In our study, the reason for improved quality of life post-surgery could be due to reduction in number of symptomatic episodes of otitis media and lesser use of antibiotic for middle ear infections. However, Kujala T et al. (2014) [14] suggested that quality of life in such children would improve gradually over time with age and not post-ventilation tube surgery. However, their study had long follow-up and since ventilation tube benefits are for short term, the quality of life may fluctuate in affected children after 9 months.

Coming to domain-wise OM6 survey changes, the mean preoperative physical suffering score was 4.66 and mean postoperative score was 2.11, the difference being statistically significant (p < 0.05). For hearing loss, the mean preoperative score was 4.92 and mean postoperative score was 2.76, the difference being statistically significant (p < 0.05). The mean preoperative speech impairment score was 4.43 and mean postoperative score was 3.55, the difference being statistically significant (p < 0.05). The mean preoperative emotional distress score was 4.39 and mean postoperative score was 2.12, the difference being statistically significant (p < 0.05). The mean preoperative activity limitation score was 4.26 and mean postoperative score was 2.40, the difference being statistically significant (p < 0.05). The mean preoperative caregiver concern score was 4.73 and mean postoperative score was 1.97, the difference being statistically significant (p < 0.05). Out of the six domains, the highest mean preoperative-postoperative difference was seen in Caregiver Concern (2.76), followed by Physical suffering (2.55). The least mean preoperative-postoperative difference was seen in Speech impairment (0.88). Caregiver concern showed highest improvement post-surgery due to the relief of anxiety/stress due to admitting their child in hospital during COVID-19 pandemic and also, due to complications associated with subjecting their child to a surgical procedure under general anaesthesia. Also, caregiver concern might be associated with high physical suffering, as ear pain/fever experienced by child directly affects the caregiver as well. However, Yazici A et al. (2018) [12], Mui S et al. (2005) [15] and Richards M et al. (2002) [16] in their study showed maximum improvement in hearing loss domain. We in our study did not use any objective audiological test to assess postoperative hearing threshold, but we used OM6 questionnaire-based caregiver evaluation which showed statistically significant hearing improvement (p < 0.05). The least mean postoperative improvement was seen in speech impairment, the finding being consistent with Rosenfeld RM et al. (2000) [3]. The reason for least improvement in speech impairment could be due to the short follow-up period of 6 weeks in our study.

**Conclusion**

Very few studies have been conducted on assessment of quality of life in children having otitis media with effusion, in this area of our country. According to our study, there is statistically significant improvement in quality of life in children with OME, after insertion of ventilation tube. Each domain of OM-6 questionnaire showed significant improvement post-ventilation tube insertion- with greatest improvement in caregiver concern and least in speech impairment.

**Funding sponsorship** NIL.

**Declarations**

**Conflict of interest** NIL.
References

1. Rosenfeld RM, Shin JJ, Schwartz SR et al (2016) Clinical practice Guideline: Otitis Media with Effusion Executive Summary (Update). Otolaryngol Head Neck Surg 154:201–214
2. Tos M (1984) Epidemiology and natural history of secretory otitis. Am J Otol 5:459–462
3. Rosenfeld RM, Bhaya MH, Bower CM et al (2000) Impact of tympanostomy tubes on child quality of life. Arch Otolaryngol Head Neck Surg 126(5):585–592
4. Surgical Management of Otitis Media with Effusion in Children (2008) National Collaborating Center for Women's and Children's Health. National Institute for Health and Clinical Excellence, London.
5. Rosenfeld RM, Goldsmith AJ, Madell JR (1998) How accurate is parent rating of hearing for children with otitis media. Arch Otolaryngol Head Neck Surg 124(9):989–992
6. Lous J, Ryborg CT, Thomsen JL (2011) A systematic review of the effect of tympanostomy tubes in children with recurrent acute otitis media. Int J Pediatr Otorhinolaryngol 75(9):1058–1061
7. Lieberthal AS, Carroll AE, Chonmaitree T et al (2013) The diagnosis and management of acute otitis media. Pediatrics 131:964–999
8. Fang TY, Rafai E, Wang PC et al (2016) Pediatric otitis media in Fiji: Survey findings. Int J Pediatr Otorhinolaryngol 85:50–55
9. Heidemann CH, Lauridsen HH, Kjeldsen AD et al (2015) Quality of life differences among diagnostic subgroups of children receiving ventilating tubes for otitis media. Otolaryngol Head Neck Surg 153:636–643
10. Rosenfeld RM, Goldsmith AJ, Tetuš A et al (1997) Quality of life for children with otitis media. Arch Otolaryngol Head Neck Surg 123(10):1049–1054
11. Chow Y, Wabnitz DAM, Ling J (2007) Quality of life outcomes after ventilating tube insertion for otitis media in an Australian population. Int J Ped Otorhinolaryngol 71:1543–1547
12. Yazici A, Coskun ME (2018) The effect of ventilation tube insertion to the health related quality of life in a group of children in Southeast Asia. Clin Otolaryngol 43(6):1578–1582
13. Moghaddam YJ, Mirghaffari A (2018) Evaluation of children quality of life after serous otitis media surgery. J Caring Sci 7(3):131–135
14. Kujala T, Alho OP, Luotonen J et al (2012) Tympanostomy with and without adenoidectomy for prevention of recurrences of acute otitis media: a randomised controlled trial. Pediatr Infect Dis J 31(6):565–569
15. Mui S, Rasgon BM, Hilsinger RL Jr et al (2005) Tympanostomy tubes for otitis media: quality of life improvement for children and parents. ENT- Ear Nose and Throat Journal 84(7):418–424
16. Richards M, Giannoni C (2002) Quality of life outcomes after surgical intervention for otitis media. Arch Otolaryngol Head Neck Surg 128(7):776–782

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Springer Nature or its licensor (e.g. a society or other partner) holds exclusive rights to this article under a publishing agreement with the author(s) or other rightsholder(s); author self-archiving of the accepted manuscript version of this article is solely governed by the terms of such publishing agreement and applicable law.