

Quality of life improvement in children with otitis media with effusion post ventilation tube insertion

A prospective cohort study

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ABSTRACT

الأهداف: تهدف الدراسة إلى تحديد درجات OM-6 لدى الأطفال السعوديين المصابين بـ OME وتقييم التغيير في جودة الحياة بعد إدخال VT بشكل شخصي. يعد استبيان التهاب الأذن الوسطى 6 (OM-6) مقياساً مستخدماً على نطاق واسع لجودة الحياة (QoL) لدى الأطفال المصابين بالتهاب الأذن الوسطى مع السوائل (OME). تتم الإشارة إلى بضع الطبلية مع إدخال أنبوب التهوية (VT) عندما يستمر OME مع ضعف السمع الموثق سريريًا.

المنهجية: الدراسة الحالية عبارة عن دراسة أترابية مستقبلية تبحث في جودة الحياة للأطفال الذين يعانون من OME باستخدام استبيان OM-6 تم التحقق من صحته. تعرض مقدمو الرعاية لـ 100 طفل للاستبيان قبل الجراحة في الفترة من يناير 2023م إلى ديسمبر 2023م. وخضع جميع المرضى المشمولين ببضع الطبلية الثنائي وإدخال VT مع استئصال الغدانية تحت التخدير العام. طلب من مقدمي الرعاية إكمال استبيان OM-6 بعد ثلاثة أشهر من العمل الجراحي لتقييم التغيير في جودة الحياة.

النتائج: اشتملت هذه الدراسة على 100 طفل. كان متوسط درجة OM-6 هو 16 قبل الجراحة وانخفض إلى 7 بعد الجراحة. هناك انخفاض ذو دلالة إحصائية في النتيجة بعد الجراحة ($p < 0.001$). أثناء النظر في درجة OM-6 بشكل منفصل، يُظهر اختبار التصنيف الموقع ويلكوكسون أن هناك انخفاضاً ملحوظاً إحصائياً في متوسط درجة جميع المتغيرات باستثناء قلق مقدمي الرعاية، والذي ظل كما هو قبل وبعد الجراحة ($p < 0.001$).

الخلاصة: إن جودة الحياة للأطفال الذين يعانون من OME التي تم قياسها بواسطة استبيان OM-6 تحسنت بشكل ملحوظ بعد إدخال VT.

Objectives: To study is to establish the OM-6 scores in Saudi children with OME and subjectively assess the change in QoL following VT insertion. The Otitis Media 6 (OM-6) questionnaire is a widely used measure of the quality of life (QoL) in children with otitis media with effusion (OME). Myringotomy with ventilation tube (VT) insertion is indicated when OME persists with clinically documented hearing impairment.

Methods: The present study is a prospective cohort study investigating the QoL of children with OME using a validated OM-6 questionnaire. The caregivers of 100 children were subjected to the questionnaire

preoperatively from January 2023 to December 2023. All included patients underwent bilateral myringotomy and VT insertion with adenoidectomy under general anaesthesia. Caregivers were asked to complete the OM-6 questionnaire three months postoperatively to assess the change in QoL.

Results: A total of 100 children were enrolled in this study. The average OM-6 score was 16 before surgery and reduced to 7 after surgery. There is a statistically significant reduction in the score after the surgery ($p < 0.001$). While considering the OM-6 score separately, the Wilcoxon signed rank test shows that, there is statistically significant reduction in the average score of all the variables except caregiver concern, which remained the same pre and post-surgery ($p < 0.001$).

Conclusion: The QoL of children with OME measured by OM-6 questionnaire significantly improved following VT insertion.

Keywords: otitis media with effusion, quality of life, ventilation tube, children, hearing loss

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Otitis media with effusion (OME) is a frequently diagnosed condition characterized by accumulation of non-purulent fluid in the middle ear cavity with no signs of an active infectious process.¹ Otitis media with effusion predominantly affects children, with a peak in prevalence at 2 years of age.² It is estimated that up to 90% of children experience at least one episode of OME prior to reaching school age.¹ Both environmental and congenital factors have been reported to play a major role in increasing the risk of developing the condition. Environmental factors such as tobacco smoke exposure, bottle-feeding, day-care attendance, low socioeconomic level, and atopy have been linked to the development of OME.³ Children born with congenital craniofacial malformations such as cleft palate and trisomy 21 are more susceptible to developing OME and are more likely to have recurrent disease.⁴ A large number of OME cases tend to spontaneously resolve within the timeframe of 3 months. However, up to 40% of children experience recurrent episodes, and 10% have episodes which can persist and last up to one year.¹

In childhood, OME is the leading cause of acquired hearing loss.⁵ The development of hearing impairment profoundly impacts children's social and educational outcomes as it can delay the language acquisition process and lead to behavioural disorders.^{6,7} In order to avoid the detrimental effects of chronic OME, timely surgical intervention and placement of a ventilation tube (VT) is warranted. The main indication of VT insertion is the persistence of effusion for more than a three-month duration with clinically documented hearing loss.² A variety of questionnaires were designed to comprehensively evaluate the impact of OME on patients' quality of life (QoL). At present, a total of fifteen validated and reliable QoL questionnaires are referenced in 23 published articles.⁸ The Otitis Media 6-Item (OM-6) questionnaire, developed in 1997 by Rosenfeld, is the most widely applied tool to assess QoL-related issues in children with OME.⁹ The questionnaire consists of six questions that address six functional health status domains. Each question focuses on capturing the severity of symptoms related to physical suffering, hearing difficulties, speech impairment, emotional distress, activity limitations, and caregiver's concern for their child over the past 4 weeks. The responses are provided on a 7-point

categorical scale, and the overall score is calculated by measuring the mean of the 6 domain scores. The caregiver quantifies the severity by scoring from 1-7 with 1 meaning absence of symptoms and a higher score indicating worse symptoms and poorer QoL.

The primary objective of this study was to determine OM-6 scores in a prospective cohort study of Saudi children with OME. The secondary objective was to assess the change in QoL of Saudi children with OME following surgical intervention by comparing the preoperative and postoperative scores.

Methods. We present a prospective cohort study investigating the QoL of children with OME using a validated OM-6 questionnaire. This study was carried out at. Ethical approval was obtained from the Institutional Review Board (IRB) at King Abdullah International Medical Research Center (KAIMRC). We invited all pediatric patients under 14 years of age with an existing diagnosis of OME who underwent myringotomy with VT insertion and adenoidectomy between January 2023 to December 2023 at King Abdullah Specialized Children's Hospital (KASCH), Riyadh, Saudi Arabia to participate in the study. Patients with congenital head and neck and craniofacial anomalies or have had previous VT insertion were excluded from the study. The diagnosis of OME was confirmed based on clinical, tympanometric, and audiological findings. Shah-type fluoroplastics VTs (1.14 cm inner diameter with 1.58 cm interflange distance) were used in all included patients. Prior to participation, the caregivers declared their approval by signing an informed consent form provided by the IRB at KAIMRC. The caregivers of all included 100 children were subjected to the questionnaire 3 months preoperatively. While waiting their child's appointment, the caregivers completed the questionnaire under supervision of an academic otolaryngology resident or a medical intern. Any questions or concerns raised by the parents were acknowledged and answered. All included patients underwent bilateral myringotomy and VT insertion with adenoidectomy under general anesthesia. Three months postoperatively, the caregivers were asked again to complete the OM-6 questionnaire to assess the change in QoL.

The data collection form included a comprehensive set of baseline clinical and demographic characteristics. This included the participants' gender, age, and body mass index (BMI). The data were extracted from medical charts and Hospital Health Information System.

Statistical analysis. Statistical analysis of the data was performed using Statistical Package for the Social

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Sciences, version 25.0 (IBM Corp., Armonk, NY, USA). The categorical data were summarized and reported as frequencies and proportions, while the continuous variables were summarized and reported as means and standard deviations (SD). The normality of the variables were checked by Shapiro Wilk test and they were not normal. Hence non-parametric test was used for the comparison. Wilcoxon Signed Rank Test was used to compare the average OM-6 scores, pre-surgery and post-surgery.

Results. A total of 100 children who fulfilled the inclusion criteria from January 2023 to December 2023 were enrolled in the study. Fifty-two patients were male, while the rest were female (48%). The mean age of presentation was 6 (Table 1).

Otitis media-6 Scores. The overall mean preoperative OM-6 score for 100 children with OME was 16.4 (Table 2).

The highest scores indicating poorest QoL were for hearing loss (4.1) and physical suffering (3.5), while the lowest item score was for caregiver concern (1.1) (Table 3).

Total OM-6 scores pre and post-surgery. The normality of the variables were checked by Shapiro Wilk test and they were not normal. Hence non-parametric test was used for the comparison. The Wilcoxon Signed Rank Test was used to compare the average OM-6 scores, pre-surgery and post-surgery. The average score was 16 before surgery and reduced to 7 after surgery. There is a statistically significant reduction in the score after the surgery ($p < 0.001$) (Table 2).

While considering the OM-6 score separately, the Wilcoxon Signed Rank Test shows that, there is statistically significant reduction in the average score of all the variables except caregiver concern, after surgery

Table 1 - Demographic and clinical characteristics of the participants.

Variables	Mean (SD)	Median (IQR)
Age	6.1 (2.5)	6 (4, 8)
Height (cm)	104 (21.74)	104 (86, 122)
Weight (Kg)	21 (11.43)	19.4 (13.8, 28)
BMI	19.94 (12.01)	15.71 (14, 21.18)

BMI: body mass index

Table 2 - Comparison of total OM-6 scores pre and post-surgery.

Variable		Before surgery	After surgery	P-value
OM-6 score	Median (IQR)	16 (12, 21)	7 (6, 7)	<0.001
	Mean (SD)	16.42 (6.41)	6.87 (1.02)	

OM-6: Otitis Media 6-Item (OM-6) questionnaire, IQR: Interquartile range; SD: Standard deviation

Table 3 - Comparison of OM-6 scores separately pre and post-surgery.

OM-6 score	Before surgery	After surgery	P-value
<i>Physical</i>			
Median (IQR)	3 (2, 5)	1 (1, 1)	<0.001
Mean (SD)	3.54±1.86	1.13±0.33	
<i>Hearing</i>			
Median (IQR)	4.5 (2, 6)	1 (1, 1)	<0.001
Mean (SD)	4.12±2.03	1.21±0.48	
<i>Speech</i>			
Median (IQR)	1 (1, 3)	1 (1, 1)	<0.001
Mean (SD)	2.24±1.80	1.15±0.35	
<i>Emotional</i>			
Median (IQR)	1 (1, 5)	1 (1, 1)	<0.001
Mean (SD)	2.78±2.24	1.05±0.22	
<i>Activity</i>			
Median (IQR)	1 (1, 4)	1 (1, 1)	<0.001
Mean (SD)	2.55±1.92	1.14±0.35	
<i>Caregiver</i>			
Median (IQR)	1 (1, 1)	1 (1, 1)	-----
Mean (SD)	1.19±0.44	1.19±0.44	

OM-6: Otitis Media 6-Item (OM-6) questionnaire, IQR: interquartile range, SD: standard deviation

($p < 0.001$). The average score of caregiver concern remains the same pre and post-surgery (Table 3).

Discussion. Myringotomy and VT tube insertion is the most frequently performed surgical procedure on children.² The efficacy and benefits of the procedure as assessed by outcome measures such as disease recurrence rates, status of the tympanic membrane, and audiometric results have consistently been reported. Unlike traditional outcome measures, quality of life assessment provides insight on the impact of the disease and benefit of treatment as perceived by the patient or caregiver. Compared to other QoL questionnaires, the OM-6 is found to be the most inclusive of all disease aspects by addressing the child's physical symptoms, emotional well-being, and parental concerns.⁸ A number of papers have evaluated the subjective impact of myringotomy and VT tube insertion on children's QoL.¹⁰⁻¹⁴

In our population, the individual OM-6 domain scores are high, indicating poor QoL in children with OME, similar to other published articles. Improvements in scores following surgery were noted in each individual QoL domain. In a study by Chow et al¹⁴ investigating QoL outcomes following VT insertion in an Australian population, the highest domain score was for caregiver concern (3.81 +- 1.95) which reduced to (1.90 +- 1.53) postoperatively. Similarly, Rosenfeld et al¹¹ assessed the impact of tympanostomy tube insertion on QoL and the highest domain score was caregiver concern (4.9).

Similar findings were reported by Saraf et al¹² with the highest mean preoperative-postoperative score difference (2.76) observed in the caregiver concern domain. Furthermore, a recently published article by Boyle et al¹³ reported the greatest caregiver concern domain score of 5.1 which reduced to 1.7 at 3 months postoperatively. Caregiver perception of the impact of OME on children's QoL significantly improved following VT insertion. In contrast, our results reveal that caregiver concern scored the lowest out of all domains (1.19) and did not change postoperatively.

In the present study, the domain with the highest score was hearing loss, with a mean preoperative score of (4.12) and a mean postoperative score of (1.21). Since parental assessment of hearing impairment may correlate poorly with audiometric results, documentation of baseline hearing status prior to VT insertion could facilitate assessing the objective improvement. As for the overall mean OM-6 score, a statistically significant reduction after the surgery was noted. The overall mean OM-6 score in this study was 16.42 and reduced to 6.87 ($p < 0.001$) after VT insertion. This finding is consistent with the results reported in other studies. Chow et al,¹² Saraf et al,¹³ and Boyle et al¹⁴ all documented substantial post-surgical improvement in the overall mean OM-6 scores. Preoperatively, Saraf et al. reported a mean overall OM-6 score of 4.59 ± 1.02 which improved to 2.22 ± 0.83 at the 6-week postoperatively, the difference being statistically significant ($p < 0.05$).¹² Similarly, the preoperative mean OM-6 score found by Boyle et al¹³ was 4.5 and reduced to 1.35 at 3 months following VT placement.

The benefits of VT insertion in children are well documented in the literature. This study uniquely contributes by being the first to assess the subjective effect of VT insertion on children's QoL in Saudi Arabia. Our findings demonstrate a significant improvement in the QoL of children with OME, as measured by the OM-6 questionnaire, following VT insertion. While the caregiver concern domain did not change postoperatively, significant improvements were observed in all other QoL domains.

Study limitations. This study has potential limitations. Comprehensive assessment of a child with OME includes an evaluation of clinical status, tympanometric examination, and audiological hearing threshold. This study did not incorporate objective hearing tests to measure postoperative improvement, this may have introduced a degree of overestimation of the clinical severity as it is solely based on parental input. In addition, we did not investigate the influence

of the parents' cultural, socioeconomic, and educational backgrounds on the obtained scores.

In conclusion, our study reveals a statistically significant improvement in the QoL of Saudi children with OME following VT insertion. Notable improvements were observed in each of the OM-6 questionnaire domains post-surgery, except for the caregiver concern domain, which remained unchanged.

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