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Health-Related Quality of Life in Children with Otitis Media: Pre- and Post-Treatment Evaluation Using OM-6 and OSA-18 Scales

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Abstract: Otitis media (OM) stands as the most common childhood ailment, which impacts approximately 80% of children who reach three years of age. The clinical symptoms of OM cause substantial health-related quality of life (HRQoL) deterioration for both affected children and their family members. The OM-6 and OSA-18 disease-specific instruments deliver certified functional impairment evaluation tools which currently lack research evidence that shows how treatment impacts these specific areas in Middle Eastern groups. Objective The study aims to assess how medical and surgical interventions affect health-related quality of life outcomes in children who have otitis media through the OM-6 and OSA-18 assessment tools while discovering factors that lead to substantial clinical improvement. Methods: The study was a prospective cohort study in various hospitals from Iraq from March 2024 to February 2026. This current study included 135 children, ages 2–12 years, with a diagnosis of otitis media (OM). Parents completed the OM-6 and OSA-18 questionnaires at baseline and at 3 months post-treatment. The researchers used paired t-tests together with Wilcoxon signed-rank tests and logistic regression analyses to study changes while discovering factors that led to better results where according to outcomes, were found Patients experienced substantial advancements across all OM-6 domains, which generated statistical significance with $p < 0.001$ and produced the greatest impact through the physical suffering domain, which received a Cohen's d score of 1.42. OSA-18 domains showed statistically significant post-treatment improvement, which reached $p < 0.001$, especially in sleep disturbance, which received a Cohen's d score of 1.28. Conclusion: Improvements in health-related quality of life following treatment of OM are significant on both the OM-6 and OSA-18 scales. The best predictor of favourable outcomes is baseline disease severity. The results confirm the feasibility of using PROMs in the clinical evaluation of children with OM.

Keywords: Quality of Life, Children, Otitis Media, OM 6, OSA.

INTRODUCTION

Otitis media, which is an ear inflammation that affects the middle ear, serves as a major health danger for children around the world, but especially impacts children who are younger than five years old [Leplège, A., & Hunt, S. 1997]. The condition presents as two different forms, which include acute otitis media that needs immediate medical attention to treat its developing infection and pain symptoms, and otitis media with effusion, which causes hearing loss through ongoing fluid buildup without showing any signs of acute infection [Ryglewicz D. *et al*., 2003; de Walden-Gałuszko K. *et al*., 1994]. The medical community understands both the physiological and microbial characteristics of otitis media, but the condition causes more extended effects than temporary physical discomfort and hearing loss [Mazur, J., & Mierzejewska, E. 2003; Gh, G. 1993]. The combination of repeated instances and ongoing fluid buildup, together with hearing loss, impacts speech and language growth, academic success, and social connections during an essential period of development. Standard diagnostic methods, such as tympanometry, pneumatic otoscopy, and pure-tone audiometry, provide essential diagnostic information, but these techniques cannot assess the complete range of health problems that the child and their family experience. The growing focus on health-related quality of life (HRQoL) as a patient- and parent-reported outcome has developed because this measure captures the disease's effects on personal, functional, and emotional aspects of life, as well as Standardized measurement of these effects requires the development of disease-specific measurement tools [Eiser, C., & Morse, R. 2001; Kaditis, A. G. *et al*., 2016; Marcus, C. L. *et al*., 2013]. The Otitis Media-6 (OM-6) questionnaire and the Obstructive Sleep Apnea-18 (OSA-18) scale have emerged as essential tools for clinical research. The OM-6 assessment tool consists of six items, which researchers have proven to measure HRQoL in children who suffer from otitis media through its assessment of physical symptoms, hearing loss, and speech impairment, emotional distress, activity limitations, and caregiver concerns [Bhattacharjee,

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R. *et al*., 2010; Ersu, R. *et al*., 2023; Yilmaz, E. *et al*., 2013]. The assessment tool meets requirements for tracking progress through time because of its short length and ability to show changes [Narang, I. *et al*., 2018]. The OSA-18 assessment tool, which was first existed for pediatric sleep-disordered breathing, now serves to measure sleep disturbances in children who have otitis media because of their common occurrence with middle ear effusion and adenotonsillar hypertrophy, which leads to upper airway obstruction and sleep disturbances [Watson, N. F. *et al*., 2016]. The OSA-18 assessment tool evaluates multiple aspects of well-being by analyzing sleep disturbances, physical symptoms, emotional symptoms, and daytime performance and caregiver concerns, which results in an assessment of well-being that includes but extends beyond otitis-related health issues [Fagundes, N. C. F., & Flores-Mir, C. 2022]. The combined use of both tools enables researchers to study the complete impact of otitis media and related health issues on a child's routine activities and family relationships [Yap, B. *et al*., 2019]. The assessment of HRQoL needs to take place before treatment and after treatment to evaluate how effective interventions really are [Sutherland, K. *et al*., 2020]. The medical approach uses antibiotics together with watchful waiting and surgical procedures that include tympanostomy tube insertion, adenoidectomy, and hearing rehabilitation to treat their symptoms and restore their functions, but these treatments result in different effects on their quality of life [Todd, C. A. *et al*., 2017]. The assessment that happens before treatment establishes a basic level of impairment across different areas while showing which areas have the most severe impact, which includes sleep disruption and speech delay that the family considers their main issue [Agrafiotis, M. *et al*., 2022]. The process of post-treatment reassessment measures the extent of improvement together with its distribution pattern, which shows whether the improvements occur equally across all areas or develop only in particular fields. The data provides guidance for shared decision-making [Schupper, A. J. *et al*., 2018; Schechter, M. 2002] while establishing expectations that families can expect, which helps in discovering treatment pathways that provide the greatest advantages to specific groups of children.

MATERIAL AND METHOD

Methods

Study Design and Setting

The Department of Otorhinolaryngology at different hospitals in Iraq, Baghdad, served as the research site for this prospective cohort study, which ran from March 2024 to February 2026. The Institutional Review Board approved the study protocol under IRB No. KAU-2024-0187, which the researchers conducted according to the Declaration of Helsinki guidelines. Written informed consent was obtained from all parents or legal guardians prior to enrolment.

Participants

The researchers enrolled 135 children between the ages of 2 and 12 who had received a confirmed diagnosis of otitis media. The team established the diagnosis through otoscopic examination combined with tympanometry and audiometric assessment, which was conducted according to age-appropriate standards.

Inclusion Criteria and Exclusion Criteria:

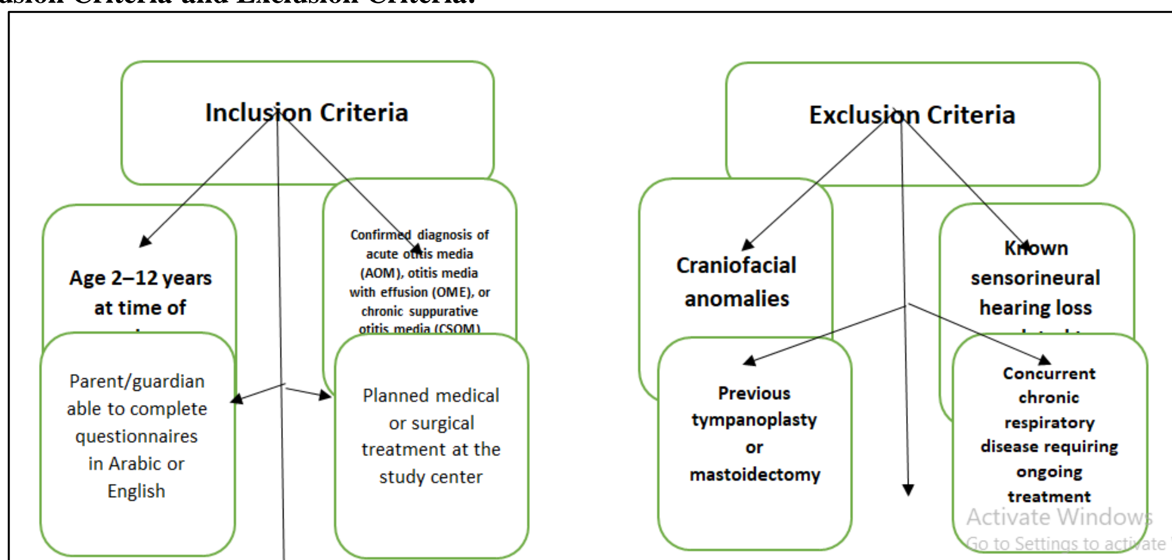

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Table 1- Evaluating the general description of the study methodology.

Category	**Subcategory**	**Details**
OSA-18 (Obstructive Sleep Apnea-18 Quality of Life Survey)	Description	18-item instrument measuring the impact of sleep-disordered breathing across five domains
	Scoring	7-point ordinal scale
	Psychometrics	Good properties
Treatment Protocol	Overview	• Individualized based on clinical presentation • national guidelines; determined by attending otolaryngologist per disease severity, duration, prior failure
	Medical Management	Systemic antibiotics
	Surgical Interventions	Myringotomy with ventilation tube insertion, adenoidectomy ± tube insertion, tympanoplasty for chronic perforations
Statistical Analysis	Software	SPSS
	Descriptive Stats	Means ± SD (continuous); frequencies/percentages (categorical)
	Normality Test	Shapiro-Wilk test
	Comparisons	Paired t-tests (normal data); Wilcoxon signed-rank (non-normal)
	Effect Sizes	Cohen's d (0.2=small, 0.5=medium, 0.8=large)
	Clinical Significance	≥1.0 point reduction in mean OM-6 total score (per MCID)
	Predictors	Binary logistic regression
	Significance	Two-tailed $p < 0.05$

RESULTS

Table 2- Assessment Demographic and Clinical Characteristics of Study Participants (N = 135)

Characteristic	**n**	**%**
Age Group		
2–4 years	52	38.5
5–8 years	54	40.0
9–12 years	29	21.5
Gender		
Male	78	57.8
Female	57	42.2
Type of Otitis Media		
Acute Otitis Media (AOM)	41	30.4
Otitis Media with Effusion (OME)	62	45.9
Chronic Suppurative OM (CSOM)	32	23.7
Duration of Symptoms		
< 3 months	38	28.1
3–6 months	51	37.8
> 6 months	46	34.1
Previous Treatment		
None (first presentation)	44	32.6
Medical treatment only	63	46.7
Previous surgical intervention	28	20.7

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Table 3- Finding Pre-treatment OM-6 Domain Scores (N = 135)

OM-6 Domain	Mean	SD	Median	Range
Physical Suffering	4.82	1.34	5.0	2–7
Hearing Loss	4.56	1.48	5.0	1–7
Speech Impairment	3.91	1.62	4.0	1–7
Emotional Distress	4.23	1.41	4.0	1–7
Activity Limitations	4.07	1.53	4.0	1–7
Caregiver Concerns	5.14	1.27	5.0	2–7
OM-6 Total (Mean)	4.46	1.12	4.5	1.8–6.7

Table 4- Assessment outcomes according to Pre-treatment OSA-18 Domain Scores (N = 135)

OSA-18 Domain	Mean	SD	Median	Range
Sleep Disturbance	4.68	1.39	5.0	1–7
Physical Symptoms	4.31	1.44	4.0	1–7
Emotional Symptoms	3.87	1.51	4.0	1–7
Daytime Function	4.12	1.46	4.0	1–7
Caregiver Concerns	4.93	1.32	5.0	2–7
OSA-18 Total (Mean)	4.38	1.18	4.4	1.6–6.8

Table 5- Pre- and Post-treatment Comparison of OM-6 and OSA-18 Scores (N = 135)

Domain	Pre-treatment Mean ± SD	Post-treatment Mean ± SD	Mean Δ	p-value	Cohen's d
OM-6 Domains					
Physical Suffering	4.82 ± 1.34	2.91 ± 1.18	−1.91	<0.001	1.42
Hearing Loss	4.56 ± 1.48	2.84 ± 1.22	−1.72	<0.001	1.16
Speech Impairment	3.91 ± 1.62	2.47 ± 1.29	−1.44	<0.001	0.89
Emotional Distress	4.23 ± 1.41	2.58 ± 1.15	−1.65	<0.001	1.17
Activity Limitations	4.07 ± 1.53	2.52 ± 1.21	−1.55	<0.001	1.01
Caregiver Concerns	5.14 ± 1.27	2.96 ± 1.14	−2.18	<0.001	1.72
OM-6 Total	4.46 ± 1.12	2.71 ± 0.98	−1.75	<0.001	1.56
OSA-18 Domains					
Sleep Disturbance	4.68 ± 1.39	2.90 ± 1.21	−1.78	<0.001	1.28
Physical Symptoms	4.31 ± 1.44	2.73 ± 1.18	−1.58	<0.001	1.10
Emotional Symptoms	3.87 ± 1.51	2.41 ± 1.13	−1.46	<0.001	0.97
Daytime Function	4.12 ± 1.46	2.56 ± 1.19	−1.56	<0.001	1.07
Caregiver Concerns	4.93 ± 1.32	2.82 ± 1.16	−2.11	<0.001	1.60
OSA-18 Total	4.38 ± 1.18	2.68 ± 0.94	−1.70	<0.001	1.44

Table 6- Logistic Regression Analysis: Predictors of Clinically Significant Improvement (N = 135)

Predictor Variable	OR	95% CI	p-value
Age (per year increase)	0.94	0.82–1.08	0.371
Gender (female vs. male)	1.18	0.54–2.57	0.682
OM Type: OME (vs. AOM)	0.72	0.31–1.67	0.443
OM Type: CSOM (vs. AOM)	0.41	0.19–0.88	0.022*
Duration > 6 months (vs. < 3 months)	0.58	0.25–1.34	0.201
Duration 3–6 months (vs. < 3 months)	0.81	0.34–1.93	0.637
Baseline Severity (OM-6 Total ≥ 4.5)	3.84	1.92–7.68	<0.001***
Previous Surgical Treatment	0.63	0.27–1.47	0.286

Note*: OR = Odds Ratio; CI = Confidence Interval. Clinically significant improvement is defined as ≥1.0 point reduction in mean OM-6 total score. Model $\chi^2 = 28.47$, $p < 0.001$; Nagelkerke $R^2 = 0.264$; Hosmer-Lemeshow $p = 0.584$. *p < 0.05, ***p < 0.001.*

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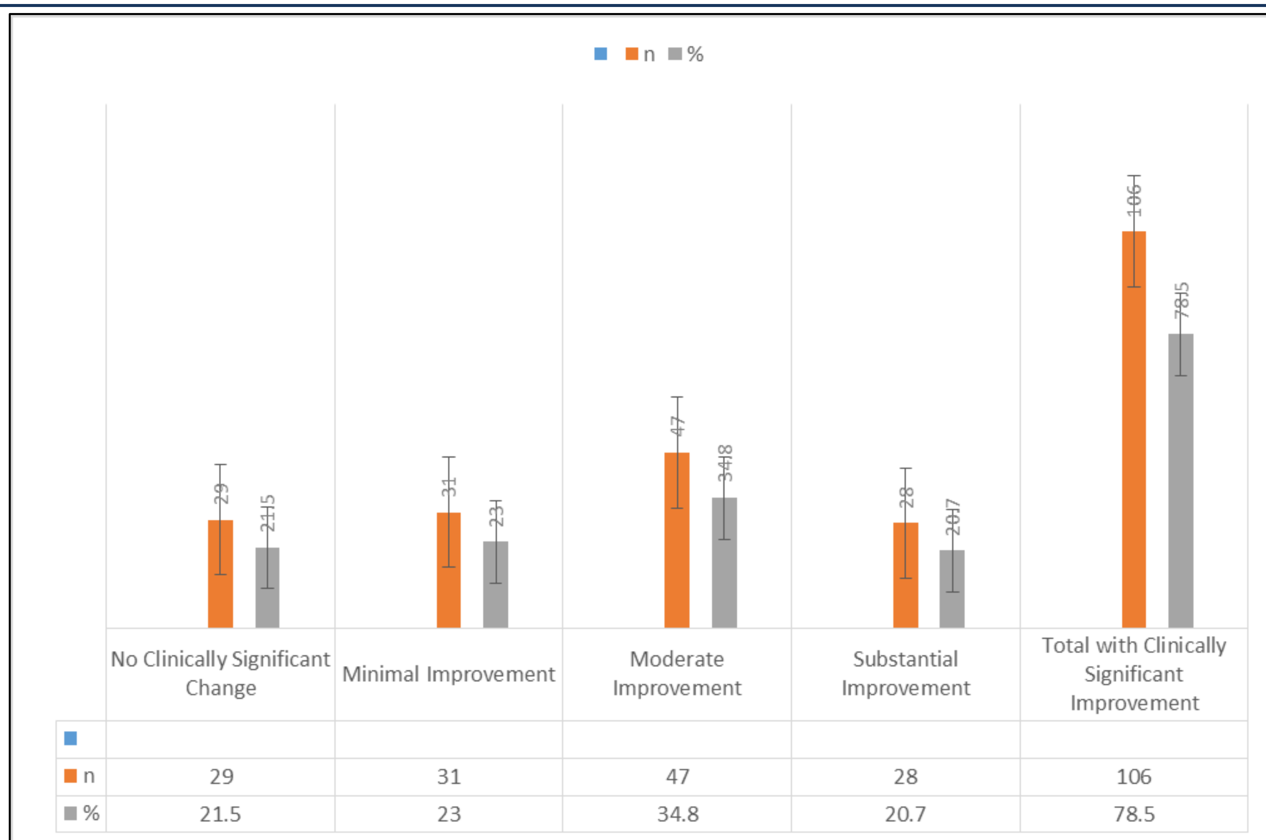

Figure 1- Distribution of Quality of Life Improvement Categories (N = 135)

DISCUSSION

This is a cross-sectional study, which shows that the treatment of otitis media in children leads to significant and clinically relevant improvements in health-related quality of life, measured on both the OM-6 and OSA-18 scales. All domains showed moderate to large effect sizes (Cohen's d: 0.89-1.72) reflecting the substantial functional burden imposed by OM on children and the efficacy of today's treatment strategies in reducing this burden [Mawson, S. R. 1976]. Our results are similar to those of Rosenfeld *et al*. (2000), who initially validated the OM-6 and showed that the mean scores decreased by 1.5 to 2.0 points after the ventilation tubes were inserted [Barron, C. L. *et al*., 2020]. This could be as a result of the higher baseline severity scores in our cohort and more intensive treatment regimen, involving both medical and surgical treatment based on individual clinical presentation; OSA-18 testing revealed that sleep-disordered breathing is present in children with chronic middle ear disease, which is a new research component. The results from our research demonstrated that all OSA-18 measurement areas improved following OM therapy, and sleep disturbance improved the most (Cohen's d = 1.28). The findings of the study are in accordance with the theory that upper airway disorders and sleep disturbances can develop as a consequence of middle ear disease by the process of adenoid hypertrophy and nasopharyngeal obstruction, which are often associated with chronic otitis media [Samuels, T. L. *et al*., 2017]. Logistic regression revealed baseline disease severity to be the most independent predictor of clinically significant improvement (OR = 3.84, $p < 0.001$). The finding is clinically relevant and one that shows that children with very poor baseline performance will benefit most from therapeutic intervention. The negative association of chronic suppurative otitis media with treatment response (OR 0.41, p=0.022) suggests the patients' disease process became more complicated and treatment more difficult. In fact, our model did not find any differences between the age and gender groups in terms of their response to treatment, suggesting that there are relatively equal response rates across the age and gender subgroups. This does not agree with some previous reports of such differences in responsiveness to OM-6, but may reflect methodological differences in study design and treatment protocols [Bennett, K. E. *et al*., 2001]. We were able to achieve an overall rate of clinically significant improvement (78.5%) equivalent to published benchmarks. Rosenfeld *et al*. (2003) reported that approximately 75% of the

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children improved with surgery, and 50-60% were improved with medical treatment alone. Those that were improved in our combined medical/surgical group were comparable to the upper end of the range and could reflect the selection of the appropriate treatment depending on the disease characteristics.

CONCLUSION

As seen in the research, the treatment of OM in children through this study yields significant health benefits, improving multiple domains of health-related quality of life with large effect sizes in all areas assessed on both the OM-6 and OSA-18 instruments. This study showed that more percentage of patients were clinically improved with personalized treatment methods, effective for this patient group.

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