



STUDY OF GENERAL QUALITY OF LIFE OUTCOME AFTER SURGICAL INTERVENTION IN PATIENTS WITH CHRONIC SUPPURATIVE OTITIS MEDIA-TERTIARY HOSPITAL BASED STUDY

Otolaryngology

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ABSTRACT

Background: Chronic Suppurative Otitis Media (CSOM) affects approximately 2% of the population, in South East Asia CSOM has a prevalence of approximately 5.2% in the general population. Hearing loss is the world's most common disability, affecting more than 5% of the global population (360 million people), with over half of these patients resident in low- and middle-income nations. Therefore, it is important to have effective measures of quality of life (QoL) and health status to evaluate the burden of disease and effectiveness of treatments.

OBJECTIVE To compare General quality of life in patients with CSOM before and after ear surgery using SF-36 questionnaire.

MATERIALS AND METHODS This prospective study was conducted in the department of Otorhinolaryngology, Head and Neck, Srinagar. All those patients who were treated at the Department and fulfilling the inclusion criteria were included in the study. The measurement of general health-related QOL life was performed using two instruments (1) Short Form 36 (SF-36). Data was collected at three times of measurement (TM): pre-operatively (TM1), 6 months (TM2), and 12 months after surgery (TM3) using SF-36 questionnaire. Tympanoplasty, Canal wall-up, canal wall-down mastoidectomy, and ossicular reconstruction was done.

RESULTS: Our study group comprised of 213 patients with majority of patients 157 (73.70%) were in the age group 18 to 30 years. Of 213 patients 129 (60.56%) were females and 84 (39.43%) were males. General quality of life using SF-36 was seen improved after surgical intervention in all patients with CSOM with total mean (79.51, 83.59, 86.89) preoperatively, at 6 months, at 1 year respectively with p-value <0.001.

CONCLUSION Based on the observations of our study we concluded that General health related quality of life measured with SF-36 improved after surgical intervention at 6 months and 1 year. Comparison of SF-36 questionnaire values (mean) preoperatively, at 6 months and at 1 year was done which showed improvement at 6 months and then at 1 year of follow up between its sub-scales with p-value <0.001.

KEYWORDS

SF-36, CSOM

INTRODUCTION

Chronic Suppurative Otitis Media (CSOM) affects approximately 2% of the population.¹

In South East Asia CSOM has a prevalence of approximately 5.2% in the general population.⁽²⁾ The World Health Organization has indicated that a prevalence rate of CSOM greater than 4% in a defined population of children is indicative of a massive public health problem requiring urgent attention.⁽³⁾ CSOM is more common in areas where overcrowding, poor hygiene, poverty, malnutrition, passive smoking and lack of access to health care are prevalent.^{4,5} Deaf people of working age find difficulty securing employment and that employment is usually lower paid.⁶ Older people with untreated hearing loss have a higher incidence of depression, paranoia, anxiety, insecurity and engage less in social activity.⁷ Ear disease can also cause debilitating physical symptoms such as ear pain and discharge which negatively impacts quality of life (QoL).⁸ Therefore, it is important to have effective measures of quality of life (QoL) and health status to evaluate the burden of disease and effectiveness of treatments.

The importance of measuring subjectively assessed quality of life (QOL) is steadily increasing in clinical medicine. Health-related quality of life (HR-QOL) has an ever increasing importance as an outcome parameter. For the proof of the success of surgical interventions, the evidence of an improvement of HR-QOL in addition to an improvement in objectively measurable parameters is required.⁹ To demonstrate this evidence, the availability of validated disease-specific instruments is an essential prerequisite.¹⁰ So far, studies on HR-QOL with validated instruments have focused on otitis media in children.^{11,12,13} Measurements of all aspects of HR-QOL in patients with CSOM with validated measurement tools were, however, to date, only rarely carried out systematically.¹⁴

AIM AND OBJECTIVE

To compare General quality of life in patients with CSOM before and after ear surgery using SF-36 questionnaire.

MATERIALS AND METHODS

This prospective hospital based study was conducted in the

Department of Department of Otorhinolaryngology, Head and Neck, SMHS Hospital Srinagar. All those patients who were treated at the Department of Otorhinolaryngology, Head and Neck Surgery at SMHS hospital Srinagar and fulfilling the inclusion criteria were included in the study.

INCLUSION CRITERIA

- CSOM. All patient with age group 18 or above Having full legal capacity.

EXCLUSION CRITERIA

- Age below 18, Loss of full legal capacity, Gravidity
- Medical or surgical treatments or conditions having the potential to influence the outcome of the study.

Data was collected at three times of measurement (TM): pre-operatively (TM1), 6 months (TM2), and 12 months after surgery (TM3) using SF-36 questionnaire. Tympanoplasty was performed in all patients. In most of the cases a retroauricular incision with a tympanomeatal flap was made. In cholesteatoma cases canal wall up and canal wall down procedures were performed according to the extension of the disease. For reconstruction of the tympanic membrane, temporalis fascia was used mostly in primary surgery cases with inactive CSOM. In cases with active disease and in revision surgery compound grafts from cartilage and perichondrium or perichondrium alone harvested from the tragus were used. For ossicular reconstruction was done using incus interpositioning or titanium made total and partial ossicular replacement prostheses (TORP and PORP). In the latter cases a cartilage sheet of a size just a bit larger than the prosthesis head to overlap it was prepared and put on top to prevent migration of the prosthesis through the tympanic membrane. The measurement of general health-related QOL life was performed using the instrument (1) **Short Form 36 Health Survey (SF-36)**¹⁵ Annexure 1. The SF-36 Health Survey consists of a questionnaire with 36 items organized into several subject areas. Each item represents a scale in itself or part of a scale. The SF-36 Health Survey records eight aspects of subjective health, using different item numbers: Physical Functioning (PF, 10 items), Role-Functioning Physical (RP, items), Bodily Pain (BP, 2 items), General Health (GH, 5

items), Vitality (VT, 4 items), Social Functioning (SF, 2 items), Role-Functioning Emotional (RE, 3 items), and Mental Health (MH, 5 items).

Statistical Analysis

Data was entered in a Microsoft excel spreadsheet. Categorical variables were summarized as frequency and percentage. Continuous variables were summarized as mean and standard deviation. Relationship between two continuous variables was evaluated using Pearson's correlation coefficient. Paired samples t-test was used to compare GBI score at 6 months versus 1 year. To compare SF-36 scores at baseline, 6 months and 1 year, repeated measures ANOVA was used. Two-sided p-values were reported and a p-value of <0.05 was considered statistically significant.

OBSERVATIONS AND RESULTS

This prospective hospital based study was conducted in the Department of Otorhinolaryngology, Head and Neck, Government Medical College and Associated SMHS Hospital Srinagar. A total of 213 patients were included with following details.

Age Group (years)	Male	Female
18 - 20	24	41
21 - 30	38	54
31 - 40	10	25
41 - 50	11	8
51 - 60	1	0
71 - 80	0	1

Table 1 showing that 157 (73.70%) patients were in the age group 18 to 30 years of age. Of 213 patients 129 (60.56%) were females and 84 (39.43) were males.

Sf36	PRE-OP		6 MONTHS		1 YEAR		p-value*
	Mean	SD	Mean	SD	Mean	SD	
Physical Function	98.03	2.45	100.00	0.00	100.00	0.00	<0.001
Role function physical	100.00	0.00	100.00	0.00	100.00	0.00	—
Bodily Pain	89.66	9.66	97.45	4.37	100.00	0.00	<0.001
General Health	46.57	11.03	62.41	7.67	68.40	5.71	<0.001
Vitality	66.71	2.38	66.79	6.57	70.56	6.33	<0.001
Social Function	78.63	11.02	80.64	15.24	91.08	5.66	<0.001
Role Functional emotional	100.00	0.00	100.00	0.00	100.00	0.00	—
Mental Health	59.15	5.30	64.79	7.38	72.88	4.49	<0.001
TOTAL	79.51	2.91	83.59	2.26	86.89	0.96	<0.001

*Repeated Measures ANOVA

Table 2 is a comparison table of SF-36 between preoperative, at 6 months and at 1 year. All the values shows improvement at 6months and at 1 year with p-value <0.001. SF-36 values preoperatively- total as well as sub-scale wise, Role function physical and Role functional emotional showing 100 % preoperative value. At 6 months- total as well as sub-scale wise. There was mean value of 100 for sub – scale; physical function, role function physical and role functional emotional, rest all sub-scales showed improvement, at 1 year- total as well as sub-scale wise. There was mean value of 100 for sub-scale; physical function, role function physical, bodily pain and role functional emotional, rest all sub-scales showed improvement. In the present study General quality of life using SF -36 was seen improved after surgical intervention in all patients with CSOM with total mean (79.51, 83.59, 86.89 preoperatively, at 6 months, at 1 year respectively) with p-value <0.001

Discussion

Chronic suppurative otitis media (CSOM) is characterized by the clinical symptoms of hearing loss, otorrhea, fullness of the ears, ear pain, headaches, and often tinnitus. In addition, there is usually a restriction on the ability to communicate because of the hearing loss. This often causes depression, anxiety and social withdrawal^[16].

This leads to a reduced health-related quality of life (QOL) in different dimensions (physical, functional, social, psychological, familial)^[17,18]. In more recent times, health-related quality of life (HR-QOL) measurements have formed an important part of assessing the quality of routine care in general practice¹⁹. It leads to loss of health related Quality of life in social, familial, physical and functional dimensions². There is general consensus among ENT specialists that surgical intervention should be judged not only on quantitative measures such as graft failure, disease recurrence, post-operative infections and audiological thresholds, but also by assessing patients, subsequent quality of life²⁰.

In the present study the measurement of General health-related quality of life (QOL) life was performed using the Short Form 36 Health Survey (SF-36)¹⁵. The SF-36 Health Survey consists of a questionnaire with 36 items organized into several subject areas. Each item represents a scale in itself or part of a scale. The SF-36 Health Survey records eight aspects of subjective health, using different item numbers: Physical Functioning (PF, 10 items), Role-Functioning Physical (RP, 4 items), Bodily Pain (BP, 2 items), General Health (GH, 5 items), Vitality (VT, 4 items), Social Functioning (SF, 2 items), Role-Functioning Emotional (RE, 3 items), and Mental Health (MH, 5 items) In the present study General quality of life using SF -36 was seen improved after surgical intervention in all patients with CSOM with total mean (79.51, 83.59, 86.89 preoperatively, at 6 months, at 1 year respectively) with p-value <0.001, **Morzaria et al**²¹ also showed in their study that the quality of life increased after surgery using SF-36 questionnaire. **Ingo Baumann et al**²² found in their study that total general HR-QOL measured with SF -36 was not significantly changed by tympanoplasty, but some individual sub – scales like vitality, general health, mental health) do show improvement with p-value <0.001. In the present study, general HR-QOL Using SF-36 showed maximum improvement in sub-scales, in **General health** with preoperative value of 46.57 to postoperative value of 68.4 at 1 year, in **Social function** with pre-operative value of 78.63 to postoperative value of 91.08 at 1 year and in **Mental Health** with preoperative Value of 59.15 to postoperative value of 72.88.

Conclusion

Based on the observations of our study we concluded that General health related quality of life measured with SF-36 improved after surgical intervention at 6 months and 1 year. Comparison of SF-36 questionnaire values (mean) preoperatively, at 6 months and at 1 year was done. All the values showed improvement at 6 months and then at 1 year of follow up between its sub-scales with p-value <0.001.

REFERENCES

- Nadol JB Jr, Staecker H, Gliklich RE. Outcomes assessment for Chronic Otitis Media: the Chronic Ear Survey. *Laryngoscope* 2000; 110: 32-35.
- Prevention and causes of deafness and hearing impairment in the South East Asia Region. State of Hearing and Ear care in the South East Asia Region. WHO Regional Office for SE Asia, 2004:9-10.
- WHO/CIBA Foundation Workshop. Prevention of hearing impairment from chronic otitis media. London, CIBA Foundation. WHO/PDH/98.4. 1996.
- Bluestone CD. Epidemiology and pathogenesis of chronic suppurative otitis media: implications for prevention and treatment. *Int J Pediatr Otorhinolaryngol* 1998; 42: 207-223.
- WHO/CIBA Foundation Workshop. Prevention of Hearing Impairment from chronic otitis media. 1996.
- Winn S. Employment outcomes for people in Australia who are congenitally deaf: has anything changed? *Am Ann Deaf* 2007; 152: 382-390.
- A Seniors Research Group. The consequences of untreated hearing loss in older persons. *ORL Head Neck Nurs* 2000; 18: 12-16.
- Rosenfeld RM, Goldsmith AJ, Tetlus L. Quality of life for children with otitis media. *Arch Otolaryngol Head Neck Surg* 1997; 123: 1049-1054.
- Koller M, Lorenz W. Survival of the quality of life concept. *Br J Surg* 2003; 90: 1175-7.
- Fitzpatrick R, Davey C, Buxton MJ, Jones DR. Evaluating patient-based outcome measures for use in clinical trials. *Health Technol Assessment* 1998; 2: 14.
- Lee JL, Witsell DL, Dolor RJ, Stinnett S, Hamley M. Quality of life of patients with otitis media and caregivers: a multicenter study. *Laryngoscope* 2006; 116: 1798-1804.
- Richards M, Giannoni C. Quality-of-life outcomes after surgical intervention for otitis media. *Arch Otolaryngol Head Neck Surg* 2002; 128: 776-782.
- Rosenfeld RM, Goldsmith AJ, Tetlus L. Quality of life for children with otitis media. *Arch Otolaryngol Head Neck Surg* 1997; 123: 1049-1054.
- Bhattacharyya N. Outcomes research in otology. *ORL J Otorhinolaryngol Relat Spec* 2004; 66: 214-220.
- Ware JE, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36). I Conceptual framework and item selection. *Med Care* 1992; 30: 473-483.
- Newman CW, Weinstein BE, Jacobson GP, Hug GA. The hearing handicap inventory for adults: psychometric adequacy and audiometric correlates. *Ear Hear* 1990; 11: 430-433.
- Meijer AGW, Wit HP, Albers FWJ. Relation between change of hearing and (modified) Amsterdam Inventory for Auditory Disability and Handicap Score. *Clin Otolaryngol* 2004; 29: 565-570.
- Korsten-Meijer AGW, Wit HP, Albers FWJ. Evaluation of the relation between audiometric and psychometric measures of hearing after tympanoplasty. *Eur Arch Otorhinolaryngol* 2006; 263: 256-262.
- Gliklich RE, Metson R. Effect of sinus surgery on quality of life. *Otolaryngol Head Neck Surg* 1995; 117: 12-17.

20. Edward John Maile, Puran Bahadur Tharu, Hannah L. K. Blanchford, Rachel Edmiston and Robin Youngs. Quality of life of Nepali patients with ear disease before and after corrective surgery. *Tropical Medicine and International Health* 2015 Aug; Volume 20, No 8: pp 1041–1047.
21. Morzaria Sanjay, Westerberg Brian D, Anzarut Alex. Quality of life following ear surgery measured by the 36-item Short Form Health Survey and the Glasgow Benefit Inventory. *Journal of Otolaryngology*. Sep/Oct 2003; Vol. 32, Issue 5: p323-327.
22. Ingo Baumann, Bianca Gerendas, Peter K Plinkert and Mark Praetorius. Health and Quality of Life Outcomes 2011, 9:48