

PABINA RAYAMAJHI
 POONAM AGGARWAL
 HEEMPALI DAS DUTTA
 PRASHANT TRIPATHI
 BIJAYA KHAREL
 RABINDRA BHAKTA PRADHANANGA
 YOGESH NEUPANE
 KRIPA DONGOL

Department of ENT and Head-Neck Surgery
 Tribhuvan University Teaching Hospital
 Maharajgunj Medical Campus, Institute of
 Medicine, Kathmandu, Nepal.

Corresponding Author

Dr. Kripa Dongol

Department of ENT and Head-Neck Surgery
 Tribhuvan University Teaching Hospital
 Maharajgunj Medical Campus, Institute of
 Medicine, Kathmandu, Nepal

Email: kripadongol@yahoo.com

BURDEN OF CHRONIC OTITIS MEDIA-MUCOSAL TYPE AND THE IMPACT OF ITS SURGICAL MANAGEMENT IN THE QUALITY OF LIFE OF PATIENTS IN A TERTIARY HOSPITAL

ABSTRACT

Objective:

The objective of this study was to assess the burden of COM-mucosal disease and analyse the general and disease-specific quality of life (QOL) in patients after myringoplasty.

Materials and Methods:

The study was conducted in the department of ENT and Head & Neck Surgery (HNS) from 1st December 2019 to 1st June 2020. The data was collected from the initial three months of the mentioned duration. For the assessment of the burden of COM-mucosal disease in the department all the patients visiting with the aforementioned diagnosis was recorded and compared with the total patient visit in the department in the three months duration. Sixty patients were included in the study for the QOL assessment after myringoplasty. Patients who had undergone myringoplasty filled the quality-of-life questionnaires. The means of the pre and postoperative values were compared and the benefit in their quality of life evaluated.

Results:

The prevalence of COM-mucosal disease among the total new patients visited in the outpatient department of the hospital was 5.4%. Disease-specific QOL in patients with COM improved after myringoplasty in all the scales of the questionnaire. All the activity/lifestyles scores, medical help scores and symptom scores showed statistically significant improvement after surgery.

Conclusion:

There is a high burden of the COM-mucosal disease. Myringoplasty did lead to a significant improvement of disease-specific QOL in patients with COM- mucosal type.

Keywords: COM- mucosal, Myringoplasty, Quality of life (QOL).

INTRODUCTION

Chronic otitis media (COM) is still one of the commonest ear diseases in the developing countries like Nepal. There is a high socio-economic burden of this disease in the patients, being the sufferers as well as to the treating centres for dealing with the massive number of these cases¹. Literatures from the developing countries mention 88% of the patients suffer from social embarrassment from recurrent ear discharge and 71% of the patients suffer from the hearing impairment. The majority of the patients don't get dry ear as surgical management is not prompt too^{2,3}. The scenario is similar in Nepal too with a very high

burden of the disease. The prevalence of COM in Nepal is 7.2% pointing to the high burden of the disease in our country.⁴ Eastern part of Nepal has 7.73% of children suffering COM-mucosal type of disease and 0.45% suffering from COM- squamous type.⁵ Similarly, there is 5.7% prevalence of COM in school-going children in the capital itself.⁶

Among the types of COM, mucosal type is considered the safe type of disease with higher prevalence than the squamous type. The quality of life (QoL) in these patients are affected by discharging ear, hearing loss, tinnitus and other complications. They have the high-cost burden of multiple

hospital visits, discharging ears, use of medications, precaution during bath, surgical treatment etc. Because of the hearing loss and chronically draining ear, patients with this condition frequently become socially withdrawn and professionally inhibited too.^{7,8}

The ultimate management of COM-mucosal type is surgical treatment by myringoplasty. Nowadays apart from the objective audiological improvement more focus is on the subjective benefit perceived by the patients after surgery; thus, focusing on the quality of life. Studies have addressed the changes in quality of life after surgical rehabilitation of the ear diseases using various QoL surveys. Literatures have mentioned the use of QoL measurements like Chronic Ear Survey (CES),^{9,10} Glasgow Benefit Inventory (GBI),¹¹ Chronic Otitis Media Outcome Test-15 (COMOT-15) etc.¹²

Tribhuvan university Teaching Hospital being one of the referral centres has a massive load of patients suffering due to chronic ear diseases. This creates a lot of backlogs and delay in their surgery thus leading to patients being managed at a later-stages and with complications. The earlier treatment of these patients manages the symptoms of the patients, prevents complications and on a long run improves their quality of life.

The aim of our study is to study the prevalence of the COM-mucosal type of the disease in the outpatient department of ENT and Head & Neck Surgery and to assess the post-operative QoL in a population of patients who had undergone myringoplasty. Measurement of disease-specific QoL was performed using the questions from Chronic Ear Survey (CES) and Chronic Otitis Media Outcome Test 15 (COMOT-15) based questionnaire with some additional questionnaires to suit the local population of patients.

MATERIALS AND METHODS

This retrospective, observational, monocentric study was conducted in the department of ENT and Head & Neck Surgery, Tribhuvan University Teaching hospital from 1st December 2019 to 1st June 2020. The patients record was kept in the initial three months i.e., from 1st December 2019 to 1st March 2020. The study was approved by the Institutional Research Committee of the institution. Regarding the prevalence of COM-mucosal type; hospital data record of the patients visiting ENT OPD with the same diagnosis was

retrieved in the above-mentioned duration and used for the calculation.

For the study of the quality of life in patients with COM-mucosal type who had undergone myringoplasty, random allocation was done using the lottery method. Informed consent was taken from all the patients. The sample size was calculated using the sample size calculator. The sample size for study came out to be 60. The inclusion criteria for the QOL assessment were, age 15 or above, all genders who had undergone myringoplasty surgery in the same centre at least six months before. The patients irrespective of their graft material and ossiculoplasty done during the surgery were included. The exclusion criteria were: multiple comorbidities and profound hearing loss.

Patients coming for follow up after myringoplasty surgery in ENT OPD after minimum of six months of their myringoplasty surgery and fulfilling the inclusion criteria were randomly selected by lottery method. Clinical examinations were done. Both the pre and postoperative audiological tests were evaluated. Further data (age, gender, primary or revision surgery, unilateral or bilateral disease) were collected. After explaining the details and implications of study in the language that the patient could understand, a written informed consent was taken from each participant by principal investigator. No information shall be withheld from the participant at the time of getting informed consent. Then the patients were asked to either fill up the quality of life (QOL) questionnaire on their own or they were interviewed with the clinician filling up the forms. The QOL measurements were executed using validated measurement tools.

Measurement of disease-specific QOL was performed using the Chronic Ear Survey (CES) and Chronic Otitis Media Outcome Test 15 (COMOT-15) based questionnaire with some modifications to suit the local population of the patient and their social habits. This instrument consisted of questions with three subscales called activities or lifestyle (questions 1-7), medical help (questions 8-10) and ear symptoms (questions 11-15). Each question had five choices in hierarchical basis from 1 to 5 with 5 having the worst symptom and 1 with the best symptom score. Comparison is done in the preoperative and postoperative mean scores. Less the score better was the outcome of the surgery. Average from all patients of each question was taken and was also compared be-

tween the preoperative and postoperative status. Statistical evaluation was carried out using SPSS version 21. For comparison of the mean values student t test was applied and p value < 0.05 was taken to be significant.

RESULTS

The total number of patients with COM-mucosal disease in the outpatient department in our tertiary hospital in the three months were 474 out of total of 8700 new patients in the department. Thus, approximately the prevalence of COM-mucosal disease was 5.4% in our tertiary hospital.

Total numbers of sixty patients were evaluated for the study. The age distribution was as shown in figure I with the majority of the patients in the age between 30-44 years of age. There are very few numbers of patients going for surgery after 45 years of age.

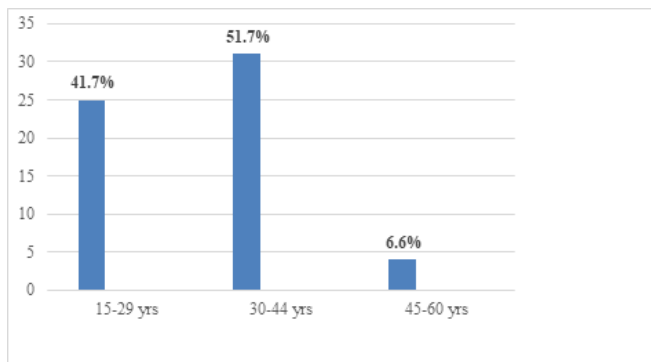


Figure I. Age distribution of the patients (n=60)

The gender distribution was with male: female ratio as 1.3:1 with slight male predominance. The largest volume of patients came at the follow up at the seventh month followed by those patients coming at the sixth and eighth month. There was fewer number of patients coming for follow up towards or at the end of one-year period as shown in figure II.

All these patients in our study had myringoplasty for the perforation in the pars tensa. Out of them four patients had revision surgery and three of the total patients had some sort of hearing reconstruction like one had partial ossicular replacement surgery (PORP), one had augmented type

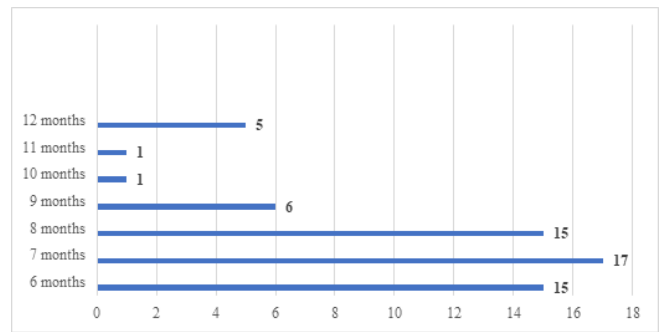


Figure II: Time at follow up after surgery (n=60)

III tympanoplasty and one had incus interposition ossiculoplasty with myringoplasty. Thus, total of 53 (88%) patients had myringoplasty, 4 had revision myringoplasty and remaining 3 had myringoplasty with some form of hearing reconstruction procedures as shown in figure III.

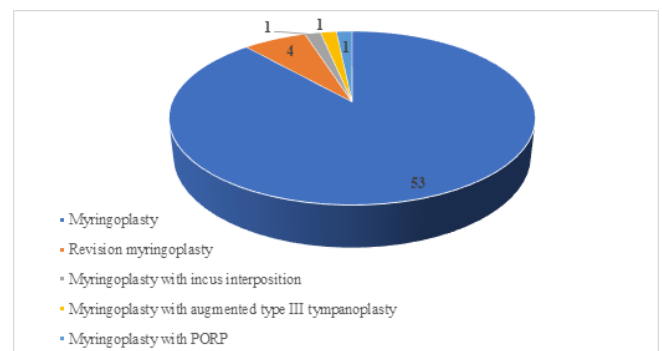


Figure III: Surgical details of the patients (n=60)

All of the patients filled up the fifteen questionnaires with pre and postoperative experiences of the patients. The answers were graded from 1 to 5 with 1 having the best remarks and 5 having the worst remarks. The average mean of each of the symptoms were tabulated as in Table 1 and evaluated. Similarly, the activities score, medical help scores and symptom scores were evaluated both pre and postoperatively. Each of the scores was evaluated and all showed betterment after the surgery as shown in figure IV. The maximum benefit was seen in the symptom score and then the activities score. Overall, all the patients had improvement in all the activities score, medical help scores and symptoms scores. Student t test was applied which showed the difference to be significant.

Table 1. Pre and postoperative mean scores

	Question pair	Preop mean	Postop mean	SD	P value
I. Activities or lifestyle scores	1. hamper swimming or shower	3.3	1.8	1.06	<0.00
	2. optimism about future	3.5	2	1.07	
	3. feeling about oneself	4	2	1.36	
	4. does it make oneself depressive?	3	2	0.7	
	5. participation in activities	3	2	0.7	
	6. skipped work?	4	2	0.7	
	7. recommend surgery to others?	3	3	0.35	
II. Medical help scores	8. visit to doctors for ear problem	3.4	2.5	0.3	
	9. use of oral antibiotics	3.5	3.1	0.3	
	10. use of ear drops	3.5	3.2	0.2	
III. Symptom scores	11. earache	2.5	1.6	0.63	
	12. hearing loss	2.4	1.7	0.49	
	13. ear discharge	3.3	1.2	1.49	
	14. odour from ear	2.8	2.1	0.48	
	15. frequency of ear discharge	3.7	1.7	1.4	

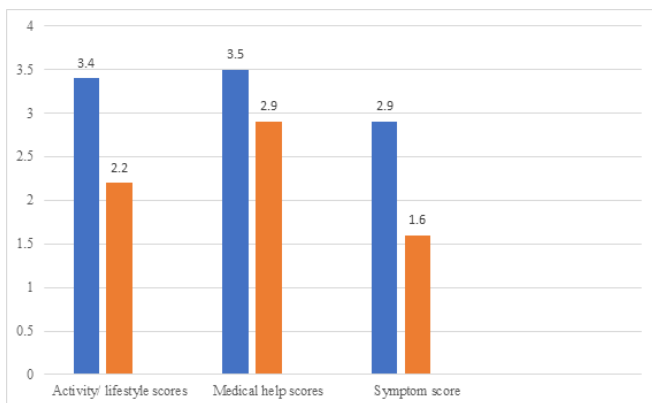


Figure IV. Pre and postop mean overall score comparison (P value=0.03)

DISCUSSION

The chronic otitis media is still one of the commonest ear diseases in the developing countries. Among the two forms of COM, mucosal type has more incidence than squamous type. In Nepal with the prevalence of 7.2%⁴ the burden of the disease is high. The three months data of our hospital also denotes high prevalence in the tertiary hospital in the capital city of Nepal. Similar high burden of the disease is seen in Nigeria too as mentioned by Orji et al.¹ Globally also it affects 2-3% of the population.⁹

Chronic otitis media (COM) is characterized by the clinical symptoms of hearing loss, otorrhea, fullness of the ears, earache and tinnitus. In ad-

dition, there is usually a restriction on the ability to communicate, difficulty in noisy environment, difficulty in understanding speech etc. This can secondarily cause depression, anxiety and social withdrawal too. Ultimately, this leads to a reduced health-related QOL in different dimensions like physical, functional, social, psychological and familial¹³. Health-related quality of life (HR-QOL) is gaining increasing importance as an outcome parameter. For the proof of the success of any medical or surgical interventions, the evidence of an improvement of HR-QOL would help in addition to an objective improvement.¹³

To demonstrate this evidence of subjective improvement of quality of life, the availability of validated disease-specific instruments is an essential prerequisite. Over the past thirty years, the concept of health-related quality of life has gradually gained large consensus to evaluate post-operative results in most fields of otolaryngology¹⁴. There are various QOL index developed being used. But disease specific instruments have always proven to be superior to the general QOL instruments.¹⁵

It is seen that until 2009 the Chronic Ear Survey (CES) was the only validated instrument for measuring QoL in ear diseases. Evaluating the CES, it deals more with the symptoms whereas functional deficits like understanding in noisy environment

or psychological impairments like anxiety, depression are not represented.^{10,12} Bakir et al¹⁶ have shown a high prevalence of psychiatric symptoms such as depression, anxiety, phobia and somatization in a population of patients affected by COM. COMOT-15 represents a useful tool in assessment of quality of life in patients affected by COM, with focus on symptom severity, mental health and ease of administration. COMOT-15 scores have individual entries have 5 answer options each whereas answer options vary from 4 to 6 in CES. In our present study we have done some modifications in the questions and their grading of CES and COMOT-15 and made our set of fifteen questions. This was to make it easier to answer and grade the questions as well as to suit the local population.

Literatures around the world also modified the QOL indexes and validated into their respective languages to make it more practical in their part of the world^{17,18}. Aldriweesh et al¹⁷ have mentioned that the Arabic GBI questionnaire is suitable to be used in the Arab speaking population to assess their benefits. Shrestha et al¹⁹ in their studies have done assessment of health-related quality of life by COMOT-15 in patients with cartilage myringoplasty showed relief from the ear symptoms and improvement in hearing but no significant improvement in the mental health. Philips et al²⁰ have put forward single time based QOL assessment after intervention to cut down the difficulty of multiple visits to the hospital.

Our study was a retrospective assessment of the patient's improvement after the surgery and the sample size is relatively low. The study showed significant improvement in the postoperative scores of the patients in all scores as in previously stated literatures. The benefit was more in the lifestyle/ activity score and symptom score than the medical help score. This maybe due to the reason of the patient's multiple visit to the hospital after operation too for the follow-up thus making them feel that they have similar hospital visits.

Our study thus showed that patients QoL also improves after the surgical management in COM-mucosal diseases. The limitation of the study was the small sample size, multiple surgeons and shorter duration of follow-up. The future recommendation could be the larger sample size with longer duration of surgery and comparison with the audiometric benefit as well.

CONCLUSION

The burden of chronic otitis media- mucosal type visiting ENT OPD as new patients in three months of study duration was 472 patients among the total new patients of 8700 thus the prevalence was 5.4% in our hospital setting. Myringoplasty is a useful surgery to be performed in cases of chronic otitis media- mucosal type not only for the objective improvement but also for the subjective improvement in relation to the quality of life. Patients have more improvement in the lifestyle and symptom scores than the need of medical help scores.

REFERENCES

1. Adoga A, Nimkur T, Silas O. Chronic suppurative otitis media: Socio-economic implications in a tertiary hospital in Northern Nigeria. *Pan Afr Med J*. 2010;4:3.
2. Orji FT. A Survey of the Burden of Management of Chronic Suppurative Otitis Media in a Developing Country. *Annals of Medical and Health Sciences Research*. 2013; 3(4): 598-601
3. Acquin J. Chronic suppurative otitis media, burden of illness and management options. World Health Organization, Geneva, Switzerland, 2004.
4. Little P, Bridges A, Guragain R, Friedman D, Prasad R, Weir N. Hearing impairment and ear pathology in Nepal. *J Laryngol Otol*. 1993; 107: 395-400.
5. Thakur SK, Acharya R, Singh SK, Ghimire N. Ear diseases in school going children of Sunsari and Morang districts of Nepal. *Journal of Chitwan Medical College*. 2017; 7(19): 16-19.
6. Adhikari P, Sinha BK, Pokharel NR, Kharel B, Aryal R, Ma J. Prevalence of chronic suppurative otitis media in school children of Kathmandu district. *Journal of Institute of Medicine*. 2007;29(3);10-12.
7. Maile EJ, Youngs R. Quality of life measures in otitis media. *The Journal of Laryngology & Otology*. 2013;127: 442-447.
8. Maile EJ, Tharu PB, Blanchford HLK, Edmiston R, Youngs R. Quality of life of Nepali patients with ear disease before and after corrective surgery. *Tropical Medicine and International Health*. 2015; 20 (8): 1041-1047.
9. Nadol JB Jr, Staecker H, Gliklich RE. Outcomes assessment for chronic otitis media: the chronic ear survey. *Laryngoscope*. 2000;110: 32-5.
10. Choi SY, Cho YS, Lee NJ, Lee J, Chung W, Hong SH. Factors associated with quality of life after ear surgery in patients with chronic otitis media. *Arch Otolaryngol Head Neck Surg*. 2012;138(9):840-845.

11. Dutt SN, McDermott AL, Jelbert A, Reid AP, Proops DW. The Glasgow benefit inventory in the evaluation of patient satisfaction with the bone-anchored hearing aid: quality of life issues. *The Journal of Laryngology & Otology*. 2002;116;7-14.
12. Baumann I, Gerendas B, Plinkert PK, et al. General and disease specific quality of life in patients with chronic suppurative otitis media - a prospective study. *Health Qual Life Outcomes*. 2011; 9:48.
13. Koller M and Lorenz W. Survival of the quality of life concept. *Br. J. Surg*. 2003;90 (10):1175-1177.
14. Lucidi D, De Corso E, Paludetti G, Sergi B. Quality of life and functional results in canal wall down vs canal wall up mastoidectomy. *Acta Otorhinolaryngol. Ital*. 2019; 39:53-60.
15. Bhattacharyya N. Outcomes research in otology. *ORL J. Oto-Rhino-Laryngol*. 2004;66(4):214-220.
16. Bakir S, Kinis V, Bez Y et al. Mental health and quality of life in patients with chronic otitis. *Eur Arch Otorhinolaryngol*. 2013; 270:521-526.
17. Aldriweesh B, Alharbi M, Alkhatib A, Almomen A, Alzahrani M. Reliability of the Arabic Glasgow benefit inventory after otolaryngology interventions. *Eur Arch Otorhinolaryngol* 2017; 274:2029-203.
18. Ralli G, Milella C, Ralli M, Fusconi M, Torre GL. Quality of life measurements for patients with chronic suppurative otitis media: Italian adaptation of 'Chronic Ear Survey'. *Acta Otorhinolaryngol. Ital*. 2017;37 (1):51-57.
19. Shrestha B, Amatya RCM, Dhakal A, Pradhan A, Rajbhandari P. Comparison between pre- and post-operative chronic otitis media outcome (COMOT-15) in patients who underwent cartilage myringoplasty in Kathmandu University Hospital: The Nepal scenario. *Int J Sci Rep*. 2017;3(4):90-94.
20. Phillips J, Yung MW. A Systematic Review of Patient-Reported Outcome Measures for Chronic Suppurative Otitis Media. *Laryngoscope*. 2016; 126:1458-1463.

