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

ENT

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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. Ear disease can also cause debilitating physical symptoms such as ear pain and discharge which negatively impacts quality of life (QoL). 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. 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,so this prospective study was conducted in our department with the objective,To compare disease-specific quality of life in patients with CSOM before and after ear surgery using COMOT -15 questionnaire.

METHOD: This prospective study was conducted in 213 patients in the Department of Otorhinolaryngology Head and Neck Surgery, Government Medical College and associated 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. Data was collected at three times of measurement (TM): pre-operatively (TM1), 6 months after surgery (TM2), and 12 months after surgery (TM3) using COMOT-15 questionnaire.Tympanoplasty,Canal wall-up,canal wall-down mastoidectomy ,and ossicular reconstruction was done.

RESULTS: Our study group comprised of total 213 patients with majority of patients 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 . The results of present study using COMOT-15 for Disease specific HR-QOL suggested that patients benefitted from surgery. Total mean **Comot**-15 values were (**43.69, 21.10, 18.99** preoperatively, at 6 months and at 1 year respectively)

Conclusion : By observations of our study we concluded that Disease specific health related quality of life measured with COMOT-15 improved after surgical intervention at 6 months and 1year.

KEYWORDS

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

1. To compare disease-specific quality of life in patients with CSOM before and after ear surgery using COMOT -15 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 after surgery (TM2), and 12 months after surgery (TM3) using COMOT-15. 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. Further data (age, gender, primary or revision surgery, unilateral or bilateral disease) was collected at TM 1. Quality of life questionings was conducted at all three TM. The QOL measurements was executed using validated measurement tool. Measurement of

disease-specific QOL was performed using the Chronic Otitis Media Outcome Test 15 (COMOT-15) Annexure 1[15]. This instrument consists of three subscales called ear symptoms (ES, questions 1-6), hearing function (HF, questions 7-9), and mental health (MH, questions 10-13), which form the overall score (OS, questions 1-13). In addition, one question on the general evaluation of the impact of CSOM on QOL (question 14) and one question to indicate the frequency of doctor visits in the last six months as a result of CSOM (question 15) are asked. The total score and the subscores are transformed to a 0-100 scale by dividing the sum of the raw scores of the items by the sum of spans of the items followed by multiplying by 100.

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 from july 2014 to july 2016.A total of 213 Patients were included with following details

Table 1: Age distribution in relation with gender

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 .

Figure :1

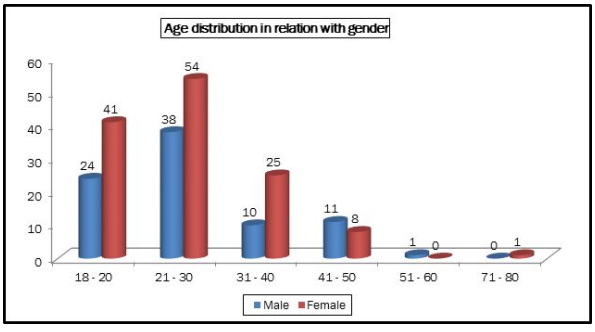

Figure 1 showing that 157 (73.70%) patients were in the age group 18 to 30 years of age.Of 213 patients 129 (60.56%) were females and 84 (39.43) were males .

Table 2: Comparison of COMOT-15 preoperatively, at 6 months and at 1 year

COMOT-15	PRE-OP		6 MONTHS		1 YEAR	
	Mean	SD	Mean	SD	Mean	SD
Q1	54.93	8.721	12.68	12.697	21.69	5.576
Q2	34.93	8.721	.66	3.574	.66	3.574
Q3	45.73	9.063	21.22	15.060	26.29	9.309
Q4	0.00	0.000	5.73	9.063	5.73	9.063
Q5	20.66	14.716	5.54	8.971	5.63	9.018
Q6	74.93	8.721	26.10	9.231	21.03	14.948
Q7	40.66	14.716	14.93	8.721	11.74	9.871
Q8	30.80	9.992	20.00	0.000	14.93	8.721
Q9	30.80	9.992	20.66	14.716	12.39	18.025
Q10	54.93	8.721	25.73	9.063	20.94	4.241
Q11	45.73	9.063	25.73	9.063	15.87	10.179
Q12	34.93	8.721	25.73	9.063	20.94	4.241
Q13	65.73	9.063	45.82	9.107	45.82	9.107
Q14	45.73	9.063	25.73	9.063	20.94	4.241
Q15	74.93	8.721	40.38	2.721	40.38	2.721

Table 2 shows comparison of COMOT-15 PREOPERATIVELY ,at 6 months and at 1 year.overall there was improvement in all the domains of comot-15 except Q -1,Q- 3, Q -13.

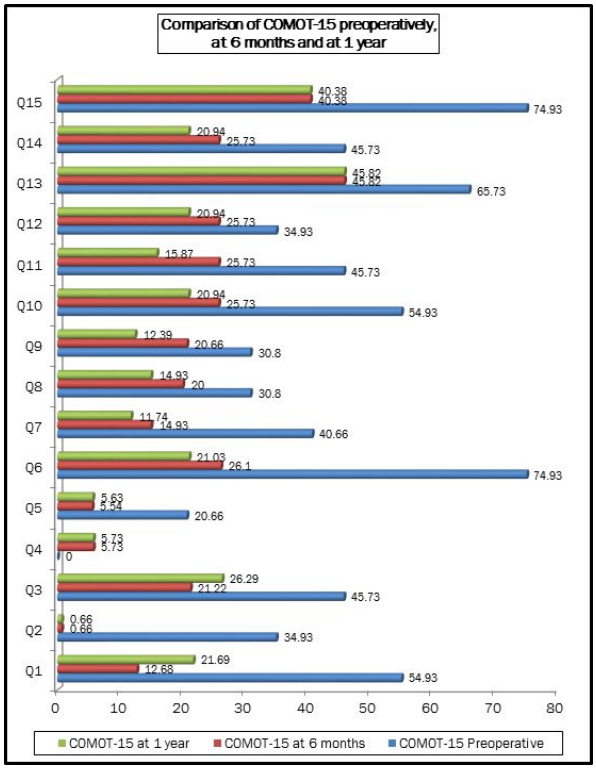

Figure 2 shows comparison of COMOT-15 PREOPERATIVELY ,at 6 months and at 1 year.overall there was improvement in all the domains of comot-15 except Q -1,Q- 3,Q -13.

Discussion

Chronic suppurative otitis media (CSOM) is characterized by the clinical symptoms of hearing loss, otorrhoea, 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 practice.[19] It leads to loss of health related Quality of life in social, familial, physical and functional dimensions[1] 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 life[20].

The results of present study using COMOT-15 for Disease specific HR-QOL suggested that patients benefitted from surgery. Total mean **Comot**-15 values were (**43.69, 21.10, 18.99** preoperatively, at 6 months and at 1 year respectively) . All the questions of **Comot** -15 showed improvement from pre-operative values upto 1 year.Q 13(scared that my ear problems will increase in the future),Q-15(Frequency of doctor visits for problems with my ears) in these two domains the improvement was not that good. This may be because majority of our patients were females (60.56%) and there is always an element of anxity after surgery..For Q 13 COMOT -15 values are (65.73 ,45.82 ,45.82 -Pre-operative ,at 6 month , at 1 year respectively).For Q 15 COMOT-15 values are (74.93, 40.38, 40.38 - Pre-operative ,at 6 month , at 1 year respectively). **INGO BAUMANN et al**[21] found in their study that disease specific HR-QOL measured with COMOT-15 in patients with csom improved after tympanoplasty in all the scales of the COMOT-15. There was no difference in HR-QOL assessment between patients with mesotympanic respectively epitympanic CSOM. However, Ingo Baumann et al did find the outcome to be worse in patients who received revision surgery compared with those receiving primary surgery. .**M.Mahendra Kumar *et al*** [22], In their study found that the patients with CSOM benefit from Tympanoplasty in both the subjective and audiological evaluation. **Khyati Bhatia *et al* (2016)**[23],conducted an analysis of the

impact of the surgery on the patient subjectively using com-5 and its correlation with objective outcomes. Patients were followed up for a period of 6 months and those with an intact graft after 6 months were included in the study. These patients were again made to fill the questionnaire and undergo pure tone audiometry postoperatively. Marked improvement was observed in subjective scores as documented by the questionnaire, pre- and postoperatively with the mean improvement in total scores being 7.89 ± 4.81 on a Visual Analogue Scale. Significant correlation was found between subjective and objective scores in most patients.

Conclusion

By observations of our study we concluded that Disease specific health related quality of life measured with COMOT-15 improved after surgical intervention at 6 months and 1year.

ANNEURE -1

CHRONIC OTITIS MEDIA OUTCOME TEST-15 (COMOT-15)

Following you will find a list of symptoms and social/emotional effects of your *CSOM*. We would like to know more about these issues and would appreciate your answers of these questions to the best of your knowledge. There are no right or false answers, and only you can provide us this information. Please rate your problems as they have been over the past six months. Thank you for your participation. Please do not hesitate to ask any of us for assistance if necessary.

Considering how severe the issue is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale:	No issue at all	Very mild issue	Mild or slight issue	Moderate issue	Severe issue	Problem as bad as it can be
1. Discharge from the ear	0	1	2	3	4	5
2. Earache	0	1	2	3	4	5
3. Ear pressure / fullness of the ear	0	1	2	3	4	5
4. Tinnitus (ringing in the ear)	0	1	2	3	4	5
5. Headache	0	1	2	3	4	5
6. Hearing loss	0	1	2	3	4	5
7. I have difficulties to understand someone speaking from a larger distance	0	1	2	3	4	5
8. I have difficulties to understand something in a noisy surrounding area	0	1	2	3	4	5
9. I have difficulties to understand when people are speaking simultaneously	0	1	2	3	4	5
10. My Hearing loss makes me feel depressive / sad	0	1	2	3	4	5
11. Because of my hearing loss I fear to misunderstand other people	0	1	2	3	4	5
12. My hearing loss does cause embarrassing situations	0	1	2	3	4	5
13. I am scared that my ear problems will increase in the future	0	1	2	3	4	5
14. Overall assessment of the impact of the ear disease on quality of life	0	1	2	3	4	5
For question 15 please notice that we would like to know the number of your visits to the doctor concerning you ears during the last six months	**None**	**One visit**	**Two visits**	**Three visits**	**Four visits**	**More than four visits**
15. Frequency of doctor visits for problems with my ear(s)	0	1	2	3	4	5

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