DOI: 10.14260/jemds/2014/2963

REVIEW ARTICLE

A CLINICAL STUDY TO ASSESS THE POST-OPERATIVE OUTCOME IN TYMPANOPLASTY USING COMOT-15 IN INDIAN SCENARIO

M. Mahendra Kumar[1], S. Muneerudin Ahmed[2], B. Harikrishna Kishore[3], Krishna Chaitanya[4], V. Pratapa Reddy[5]

HOW TO CITE THIS ARTICLE:
M. Mahendra Kumar, S. Muneerudin Ahmed, B. Harikrishna Kishore, Krishna Chaitanya, V. Pratapa Reddy. "A Clinical Study to Assess the Post-Operative Outcome in Tympanoplasty using Comot-15 in Indian Scenario". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 28, July 14; Page: 7730-7736, DOI: 10.14260/jemds/2014/2963

ABSTRACT: Functional and subjective evaluation of 96 patients with CSOM following Tympanoplasty was conducted to assess health-related quality of life (HR-QOL). Many instruments are tried by various authors in evaluating relevant dimensions of HR-QOL. A prospective study was conducted to know the patient satisfaction and it is correlated with the Graft healing and audiological measurement.COMOT-15 parameter described by Baumann I, Kurpiers B, Plinkert PK, Praetorius M et al. was used in Indian scenario. It showed good correlation between the subscale hearing function from the COMOT-15 questionnaire and audiological findings. **AIM:** To prospectively evaluate subjective improvement in Health related Quality of Life and Disease specific Quality of Life in patients undergoing surgery for CSOM. To evaluate the relation between audiometric and psychometric measurements in post Tympanoplasty patients. The study also aims to audit the results of surgery in a surgeon's perspective of integration of the graft, prosthesis function and objective audiological improvement. **MATERIALS AND METHODS:** 110 patients who underwent surgery for CSOM at Government General Hospital, Kurnool, attached to Kurnool Medical College, Kurnool, Andhra Pradesh were assessed with Chronic Otitis Media Outcome Test (COMOT-15), Visual Analogue Scale, PTA, Closure of AB gap and otoscopic examination for evidence of graft healing and prosthesis function. The study was conducted between September 2011 and January 2014 and the patients were assessed at 6 months 12 months statistically analyzed to calculate the overall benefit to the patient. **RESULTS**: Use of multiple parameters like COMOT-15, Visual Analogue Scale, PTA and Closure of AB gap in assessing Tympanoplasty patients showed an easy and practicable method of evaluation with reliability. The test reliability coefficients was (all r>0.6). Content validity was determined by a study of the literature. These tests can distinguish CSOM patients from healthy subjects. The responsiveness of the COMOT-15 questionnaire was good since it was translated in their mother tongue TELUGU. **CONCLUSIONS**: A Bidirectional approach to evaluate post-surgery patients for CSOM was a reliable, valid and sensitive with instruments for measurement of HR-QOL of CSOM patients. The results obtained with the questionnaire can be interpreted very well by the investigator. COMOT-15, VAS, PTA and AB gap closure can be used conveniently to audit the otological outcomes of research.

KEYWORDS: Subjective Evaluation, COMOT-15, PTA, Visual Analogue Scale, Tympanoplasty, CSOM, AB gap.

INTRODUCTION: Surgery for Chronic Inflammatory disease of the Middle ear has evolved to a highest standard in the recent past in India. Awareness among the patients and improvement in the Health insurance to the rural population and economically backward classes has resulted increase in

turnout of these patients. Post-operative evaluation of patients subjectively and objectively is increasing in clinical practice.

Pre- operative subjective evaluation of patients with CSOM shows that apart from ear discharge and impaired hearing, complaints of fullness in the ear, tinnitus, headache and vertigo affects the Quality of life. In children in addition, hearing loss causes communication problems, educational problem and social withdrawal. Impaired hearing is expressed in varying grades like the impaired hearing for speech from long distances, difficult to understand spoken voice in a noisy surrounding and difficult to understand speech when people are speaking simultaneously.

Pre-operative clinical examination has Tympanic membrane perforations, Polyps, granulations, mastoiditis and labyrinthitis. Audiological evaluation has Loss of air conduction and AB gap seen often in daily clinical practice. Surgical procedures include Cortical mastoidectomy, Modified Radical Mastoidectomy, Combined approach Tympanoplasty, aim to treat the complications of CSOM. They also aim to reconstruct not only the perforated tympanic membrane but also to explore and recover middle ear function with suitable prosthesis.

These procedures are indicated if the disease has persisted for more than three months with or without hearing impairment. Post-operative evaluation is possible with patient counseling at 6 monthly intervals for 1 year. It included microscopic examination of the ear, pure tone audiogram, measurement of AB gap, a questionnaire of COMOT-15 and VAS. The present study Included evaluating 96 post-operative Tympanoplasty patients both subjectively and objectively. The Outcome of this study in assessing the health related quality of life (HR-QOL) and disease specific quality of life is reliable valid and convincing.

MATERIALS AND METHODS: The present study is conducted in Government General Hospital attached to Kurnool Medical College, Kurnool, Andhra Pradesh, India, recognized for Health insurance scheme “Arogya sree” run by the Government of Andhra Pradesh for the population of below poverty line from Rural as well as urban areas. It is mandatory on the part of the surgeon to furnish the post-operative assessment in the form of otoscopic examination showing graft integration and functional benefit as recorded in PTA to claim the insurance amount for surgery which will be utilized by the institute.

In addition to pre and post-operative objective assessment with measuring hearing thresholds (PTA) and AB gap, the pre- operative and post- operative assessment (At 6 months, 12 months was dTest-15 (COMOT-15) were done to assess the overall outcome of the surgery. Visual Analogue Scale (VAS) is an instrument for evaluating subjective characteristics or attitudes that cannot be directly measured. When responding to a VAS item, patients specify their level of suffering by referring to a picture shown in a row of pictures starting from very sad to a smiley one.

VAS was used to assess post operatively the symptoms like vertigo, tinnitus, Headache, Fullness in the ear and overall improvement in hearing capability. COMOT -15-test was also used in the present study.[2] The COMOT- 15 was developed by a group of experts, who identified 31 HR-QOL concepts as being relative for CSOM which was reduced to 15 items (COMOT-15) by sequential statistical analysis on the basis of data from 121 consecutive CSOM patients.

In addition to the overall score (GS), three sub-scores (ear symptoms (OS); hearing function (HF); and mental being (PB) were introduced. This instrument consists of three Subscales called ear symptoms (ES, questions 1-6), Hearing function (HF, questions 7-9), Mental health (MH, questions

DOI: 10.14260/jemds/2014/2963

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. Standard statistical methods were used.

The significance of the differences between two groups was evaluated by Student's t test. Differences within groups were tested by a paired t test. Pearson's correlation coefficient was calculated to analyze correlations of the COMOT-15 scales versus pure tone average (air conduction). The significance level for all tests was set at $p < .05$.

110 patients presented with Chronic Suppurative Otitis Media of Tubotympanic type in 61 patients and attico antral type in 35 patients underwent surgery. The period of study was between July 2009 and December 2013. Out of 110 patients 65patients were male and 45 were female, with a median age of 30 years (range 18-50 years) were included.

Sex	n=110
Male	65
Female	45

Table I: Sex Distribution

Age interval	n=96
18-25	24
26-30	32
31-40	22
41-50	18

Table II: Age distribution

All the patients participated in the questioning and examinations and included in the calculation of statistical data. The age distribution is shown in Table II. 32 patients were in the age group of 26-30. 22 patients were in the age group of 31- 40 years. 24 were in the age group of 18 to 25 and 18 were in 41 to 50 years.

Type of CSOM	N=96
Tubo-tympanic	61
Attico-antral	35

Table III: Type of CSOM

Number of patients	Hearing loss in dB
19	46-50
44	41-45
33	35-40

Table IV: Pre-operative functional assessment (PTA): n=96

DOI: 10.14260/jemds/2014/2963

Number of patients	AB gap in dB
18	46-50
26	41-45
52	35-40

Table V: Assessment of AB gap: n=96

Opposite ear normal	70 (80.35%)
Opposite ear diseased	26 (19.64%)

Condition of the opposite Ear: n=96

Prostheses used	Number of patients
PORP	14
TORP	16

Prostheses used: n=96

The Inclusion criteria patients aged 16 or above and having full legal capacity were included. Exclusion criteria were patients aged below 16. All the patients were subjected to examination of the ear under microscope, surgical profile and radiological and audiological investigations before surgery. Pure tone average measurement showed (Table IV) 46 to50 dB losses in 19 Patients, 41 to 45 dB loss in 44 patients and 36 to 40 dB losses were seen in 33 patients. (Table V) AB gap was measured and it was found that 18 patients showed AB gap of 46 to 50 dB, 26 patients showed 41 to 45 dB loss and 52 patients showed 35 to 40 db.

In patients with tubotympanic type of CSOM a cortical Mastoidectomy was done to eradicate the disease, to clear the audits and water test was used to confirm the patency. After ossicular chain inspection an underlay temporalis fascia grafting done, the fascia itself was earlier harvested from the same post aural wound.

In patients with Attico Antral disease a modified radical Mastoidectomy was performed with type III Tympanoplasty and underlay fascia graft. Silastic Total Ossicular prosthesis in 14 patients and Partial Ossicular prosthesis in 16 patients was used, where incus necrosis was found in 3 patient's malleus Translocation was done after cutting the tensor tympani tendon and the anterior malleolar ligament to facilitate the handle of the malleus to directly articulate with the stapes superstructure. 96 patients (53 male and 43 females) with a median age of 30 years participated in all questionings and examinations.

Ten patients were lost for follow up and did not turn up to answer the questionnaire. The data of these patients were used for statistical analysis. Among the 96 patients 70 (72.91%) showed healthy ears on the opposite side. 26 patients (27.08%) had opposite ear either operated, But having discharge from the ear or with CSOM per se.

Hearing Results: The Tympanoplasty resulted in a significant improvement in air conduction threshold and a reduction of the air bone gap. The bone conduction threshold remained stable. Pure

DOI: 10.14260/jemds/2014/2963

tone average [dB] calculated from air conduction hearing loss [dB] at 500 Hz, 1K, and 2K (n = 96), COMOT-15 both the overall score and all three sub scores showed significantly better ratings for the second time of measurement, which stayed stable after 12 months, except the mental health scale.

The analysis was correlated between the scales of the COMOT-15 and post- operative results of the audiometry and it was found to have clear associations for Hearing Function and Mental Health. In Patients who were undergoing surgery for the second time in the same ear did not show improvement of hearing and scored badly with COMOT-15. The Pearson correlation analysis between the scale "Hearing Function" and the pure tone average (PTA) for the measurement of air conduction for TM1, TM2 and TM3 revealed significant correlations.

DISCUSSION: In more recent times, health-related quality of life (HRQOL) measurements have formed an important part of assessing the quality of routine care in general practice.[3] The main symptoms of (CSOM) with which the patients present are Hearing impairment, Discharge from the ears, pain in the ear, fullness in the ear, headache and tinnitus. In some situations it leads to depression, anxiety and social withdrawal. It leads to loss of health related Quality of life in social, familial, physical and functional dimensions.[1]

Answering the dimension of the Health related quality of life in the management of diseases is ever increasing in all specialties.[5] By analyzing the complex interdependence between morbidity, health related behaviors the possibility and limitation of HRQOL (Health related quality of Life) measurements at population level can be assessed.[6] It is now being taken as a parameter to express the outcome treatment applied to cure or control the disease. In the present study the proof of the success of surgical interventions, was mandatory to claim the insurance amount for the institute. Hence the evidence of an improvement of HR-QOL in addition to an improvement in objectively measurable parameters is required.

In the State of Andhra Pradesh the “Arogya sree Trust” sends a letter to the beneficiary to get a feedback from the patient regarding cure or control of disease. Hence to show the evidence suitable instruments are required to assess the health related quality of life. Such studies include validated instruments like the Hearing Handicap Inventory for Adults (HHIA) and the (modified) Amsterdam Inventory Auditory Disability and Handicap Score. Measurements of all aspects of HR-QOL in patients with CSOM with validated measurement tools were, however, to date, only rarely carried out systematically as opined by Baumann I, Kurpiers B, Plinkert PK, Praetorius M: Entwicklung et al.[7]

Up to 2009 the Chronic Ear Survey (CES) has been the only validated instrument. As pointed out by them evaluating with CES, the clinical symptoms of CSOM are well represented, whereas functional deficits (e.g. understanding in noisy environment) or psychological impairments (e.g. anxiety, depression) were not represented. COMOT-15 developed by these authors is suitable for the detection of disease-specific QOL in patients with CSOM as experienced and established in the present study.

The analysis of the observations in the present study shows that the patients with CSOM benefit from Tympanoplasty in both the subjective and audiological evaluation. The questionnaire related to disease-specific QOL pertaining to "Ear Symptoms" and "Hearing Function" were answered in affirmative and statistically significant (p=.001). These patients remained affirmative in responding to these questions over the entire period of study. Thus, the results of a study by Baumann I, Kurpiers B, Plinkert PK, Praetorius M: Entwicklung was confirmed. Disease-specific

questions when compared to the questions related to general health are superior, but cannot be ignored. General instruments are essential to capture the impact of specific diseases on general health.[4,8]

The post-operative audiological evaluation in these patients showed no deterioration in hearing and a significant mean reduction in the air bone gap by 9.6 dB and also a significant improvement in mean air conduction by 16.8db. A good correlation was seen between the audiological measured acoustic function and the subjectively evaluated hearing function.

The influence on the evaluation of disease-specific QOL was more significant with Tubo-tympanic type of CSOM than attico-antral type in the present study.[9] This is in contrast with the study of Ingo bauman; "The type of CSOM (mesotympanic versus epitympanic) had no influence on the evaluation of disease-specific QOL". The outcome of untreated epitympanic CSOM is more uncertain and may end in serious complications than the natural history of Tubo-tympanic CSOM. The unsatisfactory evaluation of subjective QOL by patients with revision surgery and bilateral disease as compared to the primary surgery patients can possibly be explained by the prolonged course and associated higher burden of the disease, and absence of stereophonic hearing. [4,10]

CONCLUSIONS: Tympanoplasty did lead to a significant improvement of disease-specific HR-QOL in patients with CSOM while general HR-QOL did not change. Very well correlations were found between 19 the subscale hearing function from the COMOT-15 questionnaire and Audiological findings. Revision surgery seems to be a predictor for a worse outcome.

REFERENCES:

1. Nadol JB Jr, Staecker H, Gliklich RE: Outcomes assessment for chronic otitis media: the Chronic Ear Survey. Laryngoscope 2000, 110:32-35. PubMed Abstract | Publisher Full Text.
2. Baumann I, Kurpiers B, Plinkert PK, Praetorius M: Entwicklung und Validierung des Chronic Otitis Media Outcome Test 15 (COMOT-15) zur Messung der gesundheitsbezogenen Lebensqualitätbeichronischer Otitis media. HNO 2009, 57:889-895. PubMed Abstract | Publisher Full Text.
3. Gliklich RE, Metson R: Effect of sinus surgery on quality of life. Otolaryngol Head Neck Surg 1995, 117:12-17.
4. Bluestone CD, Gates GA, Klein JO, Lim DJ, Mogi G, Ogra PL, Pararella MM, Paradise JL, Tos M: Recent advances in otitis media. 1. Definitions, terminology, and classification of otitis media. Ann Otol Rhinol Laryngol 2002, 111:8-18. PubMed Abstract.
5. 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. PubMed Abstract | Publisher Full Text.
6. Bullinger M, Kirchberger I; Handanweisungzum Fragebogen. Hogrefe, Göttingen; The SF-36 questionnaire and its usefulness in population studies: Results of the German Health Interview and Examination Survey 1998. A text book; conclusion.
7. 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. PubMed Abstract | Publisher Full Text.

DOI: 10.14260/jemds/2014/2963

8. 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. PubMed Abstract | Publisher Full Text.
9. Ingo Baumann**,** Bianca Gerendas**,** Peter K Plinkert and Mark Praetorius, Health and Quality of Life Outcomes. 2011, 9:p 48.
10. 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. PubMed Abstract | Publisher Full Text.

AUTHORS:

1. M. Mahendra Kumar
2. S. Muneerudin Ahmed
3. B. Harikrishna Kishore
4. Krishna Chaitanya
5. V. Pratapa Reddy

PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of ENT, Kurnool Medical College, Kurnool, A. P.
2. Professor and HOD, Department of ENT, Viswabharathi Medical College, Kurnool, A.P.
3. Assistant Professor, Department of ENT, Viswabharathi Medical College, Kurnool, A.P.
4. Assistant Professor, Department of ENT, Viswabharathi Medical College, Kurnool, A.P.
5. Senior Resident, Department of ENT, Kurnool Medical College, Kurnool, A. P.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. M. Mahendra Kumar,
Government General Hospital,
Attached to Kurnool Medical College,
Kurnool, A. P,
Door No. 49/50-A-46A,
Sreeramanagar,
Kurnool-518002, A.P.
Email: maimal@rediffmail.com

Date of Submission: 21/06/2014.
Date of Peer Review: 22/06/2014.
Date of Acceptance: 26/06/2014.
Date of Publishing: 09/07/2014.