

Assessment of Quality of Life Issues in Otitis Media Patients: A Prospective Observational Study

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Abstract: *Background:* Middle ear disease (otitis media) is one of the most negligible disease in INDIA. Measuring quality of life in otitis media is of importance in accessing treatment outcomes. We examine trends in antibiotic dispensing. The objective of this work was to collect prospective audiological data and data on general and disease specific quality of life with validated quality of life measurement instruments to assess the impact of disease. *Methods:* 100 patients were included in the study. otitis media and perforation of the tympanic membrane were diagnosed by tympanometry and audiometry, the GHSI questionnaires were filled by the OM patients. Their prescriptions are monitored for antibiotics and other classes of drugs. *Results:* Complete data records from 100 patients were available for statistical analysis. Quality of life has improved due to the treatment. Out of the 100 patients females are the most prone to OM with 62% compared to 38% of males. Among the antibiotics, penicillins antibiotics are mostly prescribed followed by Cephalosporins, Fluoroquinolones and Broad spectrum antibiotics. *Conclusion:* The impact of OM on Quality of life in this population seems substantial and OM affects various aspects of the all the age group patients functioning. Our true knowledge, however of QOL in all OM patients with Acute and Chronic OM is still limited, up to now different instruments were used to assess well-being in all patients population with recurrent otitis media and most of them actually measure GHSI rather the QOL. Furthermore data on reliability and validity of these instruments are insufficient and QOL instruments are not adequate for assessments in individual patients. Use instruments that include emotional and social functioning and add a valuation or effective response in patient functioning.

1. Introduction

Otitis media is inflammation of the middle ear and the tympanic membrane, which often occurs as a result of an acute upper respiratory tract infection. Generally, it is caused by a viral infection that is complicated by a secondary bacterial infection.¹Otitis media covers a spectrum of conditions, of which the most common are acute otitis media and otitis media with effusion(OME).

Otitis media is a common illness in young children and occurs much less frequently in children over six years of age.^{1, 2}In developed countries, Otitis media is the commonest indication for antibiotic prescribing and surgery in young children. In the United States, annual costs were estimated to be US\$3-5 billion in the 1990s.

Otitis media in India

Acute OM incidence rate is 10.85% i.e. 709 million cases each year. Chronic suppurative OM incidence rate is 4.76% i.e. 31 million cases. Each year 21 thousand people die due to complications of OM. India was reported to be associated with the highest prevalence of otitis media with more than 6% experiencing the disorder. Most of the school children in India have been reported to associate with at least one episode of otitis media varying from 10% to 20% of the children.

Acute otitis media

Most children will experience at least one episode of acute otitis media.¹The peak incidence of infection occurs between 6 and 12 months. Although the pathogenesis of this condition is multifactorial both viruses and bacteria are implicated.¹

The pain associated with acute otitis media resolves within 24 hours in around 60% and within three days in around 80% of patients.²young children are less likely to spontaneous resolution.⁴

Complications of acute otitis media include chronic suppurative otitis media, mastoiditis, labyrinthitis, facial palsy, meningitis, intracranial abscess, and lateral sinus thrombosis.⁵Mastoiditis was the most common life-threatening complication in the pre-antibiotic era. It is now rare in developed countries. A small proportion of children with acute otitis media.¹

Otitis media with effusion:

This is the commonest form of otitis media and affects all children but is usually asymptomatic. The point prevalence in screening studies is around 20% in young children.¹ it is more common in aboriginal communities and was detected in over 40% of young children in a recent survey in the Northern Territory.

Otitis media with effusion can occur spontaneously, as part of rhino sinusitis, or following an episode of acute otitis media. The same respiratory bacterial pathogens associated with acute otitis media have been implicated in its pathogenesis.

Most children will improve spontaneously within three months and complications from this illness are uncommon.¹ a small proportion of children who have persistent otitis media with effusion have associated hearing loss. The average hearing loss associated with otitis media with effusion is around 25 decibels.¹Despite large numbers of studies, a causal relationship between otitis media with

effusion and speech and language delay has not been proven.^{5,7}

Chronic suppurative otitis media:

Occasionally, children with acute otitis media with perforation will go on to develop chronic suppurative otitis media. In developed countries, chronic suppurative otitis media is now very uncommon and most often occurs as an impoverished populations including those in developed countries, chronic suppurative otitis media occur as a complication of acute otitis media with perforation. In rural and remote communities in northern Australia, more than 20 % of young children are effected.⁸

2. Review of literature

Taketo Osaka, Osama vitamin et al. Department of otolaryngology, have performed sado otitis media study in Japan, titled "*Incidence survey of Acute otitis media 'in children insado island'*", Japan and it was published in PLOS ONE in 2013 july,vol8,issue7,e68711.Study was conducted in a closed population, in each month, one week was assigned as surveillance week. In total 8283 clinic visits were conducted and 354 episodes among 312 children were diagnosed as acute otitis media. The incidence of AOM was highest in children of 1year of age. Serotype coverage of 7 and 13 valet pharmacoccal conjugate vaccines in this study were 38% and 62.8% respectively. A high proportion of s.pneumoniae isolates showed resistance to penicillin. Approximately 4-5% of paediatric outpatients, even without AOM-related symptoms, had AOM in this study.

Virginia Pate, Leah J.mcgrathetal. Department of Epidemiology, have performed acute otitis media study ,titled "*Trends in Antibiotic Treatment of Acute Otitis Media and Treatment Failure in Children 2000-2011*",and it was published in PLOS ONE in 2013 December ,vol8 ,issue12 , e81210.The study was conducted in children aged 3 months to 12 years with an AOM diagnosed between 2000-2011.We analyzed trends in antibiotic use and failure by class of antibiotic and year. They identified over 4 million children less than 13 years with AOM. Cephalosporin's prescriptions increased by 41.5 % over eleven years. Antibiotic failure decreased slightly and macrolides had the lowest proportion of failures, while all other classes had failure rates around 10%.Overprescription at antibiotics and use of non-penicillin therapy for AOM treatment could lead to the development of antibiotic-resistant infections.

Ingo Baumann, Bianca Gerendas et al. Department of Otorhinolaryngology, have performed study on chronic suppurative otitis media titled "*General and disease specific quality of life in patients with chronic suppurative otitis media-a prospective study*", and it was published in Biomed Central in 2011 June. The study was conducted in 121 patients .Patients was clinically examined in the hospital before and 6 months after surgery including audio logical testing. They filled the quality of life questionnaires SF-36 and Chronic Otitis Media Outcome Test 15 pre-operatively and 6 and 12 months operatively, respectively. Disease specific HR-QOL in patients with CSOM improved after tympanoplasty in all the scales of the COMOT-15.General HR-QOL measured with the SF-36 was not significantly

changed by tympanoplasty.Very well correlations were found between the subscale hearing function from the COMOT-15 questionnaire and audio logical findings. Revision surgery seems to be a predictor for a worst outcome.

Katsuhisalkeda, shigek Misawa et al. Department of Otorhinolaryngology, have performed study on chronic suppurative otitis media titled "*Comparative bactericidal activity of four fluoroquinolones against Pseudomonas aeruginosa isolated from chronic suppurative otitis media*", and it was published in Biomed Central .They collected P.aeruginosa isolated from clinical specimens taken from the middle ear perforation under a microscope in patients with CSOM at the department of Otorhinolaryngology, juntendo university hospital from January in 2010 to march 2013.They examined bactericidal activity of four types of fluoroquinolones, garenoxacin, levofloxacin, ciprofloxacin and sitafloxacin against current isolates of P.aeruginosa. Sitafloxacin exhibited the most potent activity of both MIC50 and MIC90, followed by ciprofloxacin, levofloxacin and garenoxacin. The number of garenoxacin resistant strains was significantly greater than those of levofloxacin, ciprofloxacin and sitafloxacin, suggesting that the clinical application of topical sitafloxacin would be useful to prevent the emergence of resistant mutants of P.aeruginosa.

Amanda J Leach, Peter S Morris et al, have performed study on otitis media with effusion and otitis media with perforation titled "*Compared to placebo, long term antibiotics resolve otitis media with effusion and prevent acute otitis media with perforation in high risk population: A randomized controlled trial*".103 Aboriginal infants with first detection of OME were randomized to receive either amoxicillin or placebo for 24 weeks. Five of 52 infants in the amoxicillin group and none of 51 infants in the placebo group achieved success at the end of therapy. During therapy the proportion of examinations with penicillin non-susceptible pneumococcal was not significantly different between the amoxicillin group and the placebo group. Beta lactamase positive non-capsular H.influenzae was uncommon during therapy but more frequent in the amoxicillin group than placebo. There was no significant increase in resistant pneumococci or NCHi in amoxicillin children compared to placebo children who received regular paediatric care and antibiotic treatment for symptomatic illness.

Peter S Morris, Amanda J Leach et al, have performed study on otitis media titled "*Otitis media in young Aboriginal children from remote communities in Northern and Central Australia: a cross-sectional survey*".709 Aboriginal children aged 6-30 months living in 29 communities from 4 health regions participated in the study between May and November 2001.Otitis media affected nearly all children .Overall prevalence estimates adjusted for clustering by community were:10%(95%CL8,12) for unilateral otitis media with effusion(OME);31%(95%CL 27,34) for bilateral OME;26%(95%CL 23,30) for acute otitis media without perforation(AOM/woP);7%(95%CL 11,19) for chronic suppurative otitis media. The perforation prevalence ranged from 0-60% between communities and from 19-33% between regions. Perforations of the tympanic membrane

affected 40% of children in their first 18 months of life. In this high risk population, high rates of tympanic perforation were associated with high rates of bulging of the tympanic membrane.

Martha F. Mushy, Alfred E. Mwalutende et al. Department of Microbiology and Immunology has performed a study on chronic suppurative otitis media titled "*Predictors of disease complications and treatment outcome among patients with chronic suppurative otitis media attending a tertiary hospital, Kwanza Tanzania*". This was a prospective hospital based cross sectional study involving 301 patients attending ENT clinics at Bugando Medical Centre between October 2013 and March 2014. Out of 301 patients with CSOM; 187 had positive aerobic culture within 48 h of incubation. Disease complications and poor treatment outcome were observed in 114 and 46 patients respectively. Both disease complications and poor treatment outcome were otalgia, being infected by multi drug resistant bacteria and being HIV positive. Prolonged illness duration before seeking medical attention was found to be associated with disease complications. This study suggests that urgent preventive measures and laboratory guided early treatment are necessary to reduce complications associated with CSOM.

Marie Mortensen, Ricky Beck Nielsfisker et al. Department of clinical Epidemiology have performed a study on otitis media titled "*Hospitalization with otitis media in early childhood and cognitive function in young adult life: a prevalence study among Danish conscripts*". It was conducted on Danish men born between 1977 and 1983. Cognitive function was measured by the Boerge Prien validated group intelligence test. Of the 18412 eligible conscripts aged 18-25 years, 1000 had been hospitalized with OM before age 8. Compared with conscripts without such a record, the adjustment prevalence ratio for a BPP score in the bottom quartile was 1.20. There was no major difference in the proportion of men with a GCSE and those without among those hospitalized with OM in early childhood. Among men with severe hearing impairment, the proportion with a BPP score in the bottom quartile did not differ between those with and without an OM hospitalization. Overall we found that hospitalization with OM in early childhood was associated with a slightly lower cognitive function in early adulthood.

Heidi Smith-Vaughan, Roy Byun et al, have performed a study on Otitis media titled "*Measuring nasal bacterial load and its association with otitis media*". Quantitative measures of the respiratory pathogens *s.pneumoniae*, *h.influenzae* and *m.catarrhalis* and total bacterial load were analysed in nasal swabs from Aboriginal children from remote communities and non-Aboriginal children attending urban child care centres. In both populations, nearly all swabs were positive for at least one of these respiratory pathogens. Using either quantification method, positive correlations between bacterial load and ear state were observed. This relationship held for single and combined bacterial respiratory pathogens, total bacterial load and the proportion of respiratory pathogens to total bacterial load. The increased bacterial load despite similar clinical condition may predict persistence of middle ear effusions and progression to

suppurative OM in the Aboriginal population. Nasal bacterial load was significantly higher among original children and may explain their increased risk of suppurative OM.

Christian Hamilton Heinemann, Christian Godballe et al. Department of ENT, have performed a study on Otitis media titled "*The Otitis Media-6 questionnaire: psychometric properties with emphasis on factor structure and interpretability*". Children and their families were consecutively enrolled in the study from 13 private ENTs from February 15th 2011 to February 28th 2012 as a part of cohort study. Analyses of structural validity and internal consistency indicated that parent appraisal of hearing and speech problems may be problematic. Cut off values of 16.7 and 30.0 were found to represent minimal important change for the patients. This study sheds light on possible weakness of the instrument that needs to be acknowledged in the utilization of the instrument. Furthermore indications of values representing minimal important change as perceived by the respondent are presented.

K. Leskinen and L. Jerohave done a study on otitis media titled "*Acute complications of otitis media in adults*". Volume 30, issue 6, December 2005. It is a retrospective chart review with a sent questionnaire. It is to establish the incidence, current treatment and outcomes of adult patients with acute intratemporal and intracranial complications of otitis media. The annual age adjusted of acute intratemporal and intracranial complications was 0.32/100 000. Forty one of the complications were intratemporal and nine were intracranial. The ear disease behind the acute complication was acute otitis media in 80%, chronic otitis media in 12% and COM with cholesteatoma in 8%. The study suggests that the commonest cause is AOM rather than COM. Complications of OM are still associated with considerable morbidity, and early recognition is most likely to form the basis for effective treatment.

Aims & Objectives

Aim

To assess the Quality of life issues in otitis media done by the Pharm- D students in secondary care hospital for 6 months period.

Objectives

- To make provide Quality of life services for the OM patients visiting the clinic.
- To examine trends in antibiotic dispensing patterns to treat OM.
- To collect prospective audio logical data to assess the impact of disease on health related quality of life.

Materials

- QOL Questionnaire
- Patient medication chart
- Case History Form
- Pure Tone Audiogram

Methods

It is a prospective observational study which was done at Swetha ENT hospital, Anantapuramu. we are included all the patients visiting the clinic with OM.

3. Results

The study was carried out for a period of six months at an ENT hospital. A total of 92 patients were included in the study. Out of these 92 patients, males were 41.3% and females were 58.69%. Out of the 92 patients otitis media male patients were suffering with acute (55.26%) and chronic (44.73%), otitis media female patients were suffering with acute (64.81%) and chronic (35.18%).

In our study we categorized the patients suffering with both ears discharge on males (15.78%) and female (5.55%) the patients who are suffering with single ear males (84.20%) and females (94.44%) as shown in figure 1

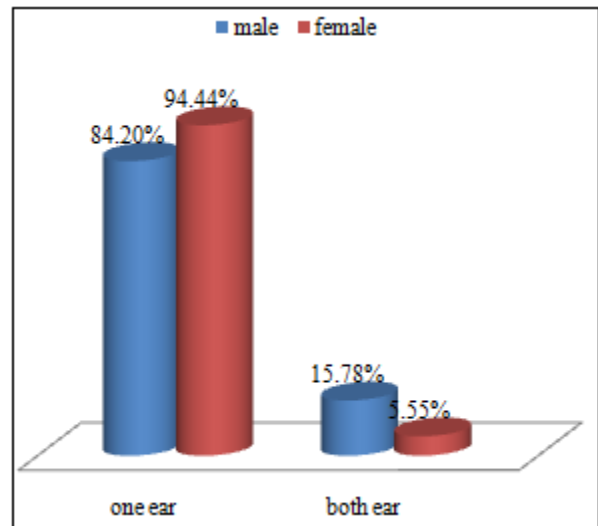


Figure 1: Representing ear discharge on males and females.

Different classes of drugs are prescribed in the prescription those data are represented in the below figure – 7.4.

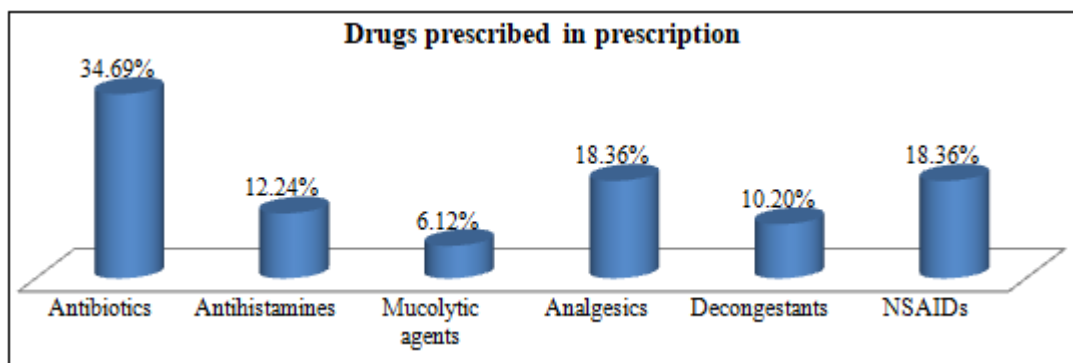


Figure: 7.4 Representing different classes of drugs prescribed in prescription.

Table :1.2 Representing different age group patients their QOL score card among females

Age group (in years)	General Subscale Score	Social Support Score	Physical Health Score	Total score
1 – 10	49.03	50.0	65.96	53.24
11 – 20	50.56	62.87	46.20	50.87
21 – 30	52.54	46.01	51.80	51.55
31 – 40	53.46	57.40	55.78	55.33
41 – 50	52.08	58.33	61.66	55.55
51 – 60	51.78	54.76	58.92	52.97
61 – 70	49.30	61.10	63.88	53.7
71 – 80	48.95	41.66	24.99	41.66

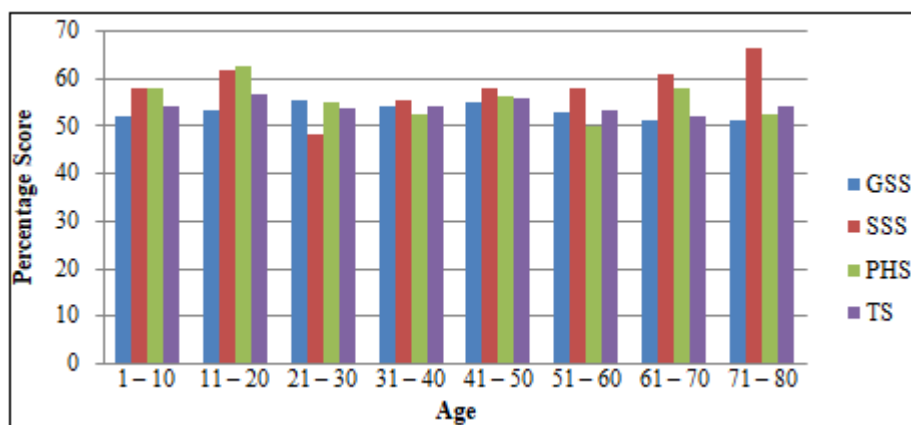


Figure :1.2 Representing different age group patients their QOL score card among females

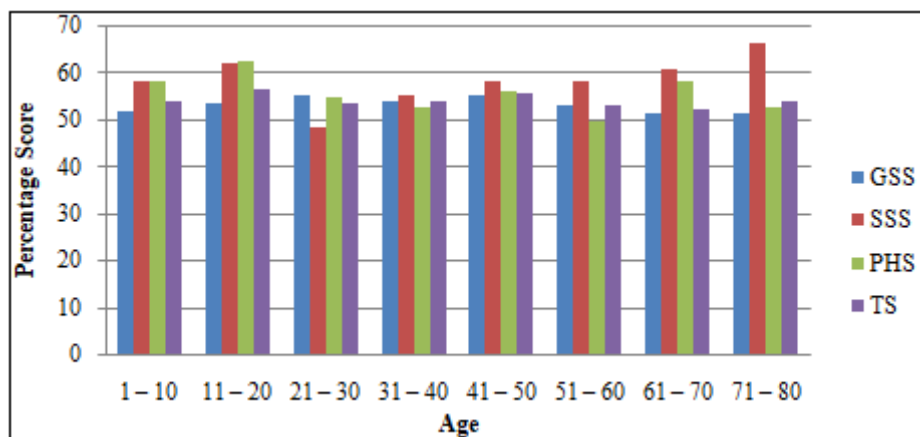


Figure: 1.2 Representing different age group patients there QOL score card among males.

4. Conclusion

The impact of OM on Quality of life in this population seems substantial and OM affects various aspects of the all the age group patients functioning. Our true knowledge, however of QOL in all OM patients with Acute and Chronic OM is still limited, up to now different instruments were used to assess well-being in all patients population with recurrent otitis media and most of them actually measure GHSI rather the QOL. Furthermore data on reliability and validity of these instruments are insufficient and QOL instruments are not adequate for assessments in individual patients. Use instruments that include emotional and social functioning and add a valuation or effective response in patient functioning

5. Recommendations

Further studies on cost analysis, cost effectiveness for patient's treatment depending on their economic status. Assessing the quality of life after surgery or use of grommets in patients following their improvements after using tympanometric tubes or differentiating the causative organism of otitis media or type of bacteria or virus involved (streptococcus, influenza) using the ear discharge from the laboratory data should be done. Patients with otitis media are sensitive so it's better sometimes filling the QOL questionnaires from the guardian. If more than one aspect of a concept is being measured, use a separate sheet of paper for each aspect separately. One rating should not be a reference point for the next rating. Use a computer generated or has the QOL questionnaires, patient audio logical data printed.

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