Material and Methods
CHAPTER - II
MATERIAL AND METHODS

The clinical significance of otitis media was studied in the backdrop of a highly stratified and diverse North Karnataka city of Hubli. The subjects investigated were drawn in from both in and around the city of Hubli. The high prevalence of the disease in the study area was already known to the researcher. The reason for choosing Hubli as a field area of the study can be attributed to the following factors. Firstly, the cultural diversity of the region proved to be a good raw material to study the incidence, prevalence and the impact of the disease in terms of the various socio-economic parameters considered. Secondly, Hubli being the major industrial centre in the region has its own ecology which includes slum dwellers who are more prone to the disease when compared to others. Thirdly, the area has a well established and technically sound health delivery system in the form of a government medical college and a hospital wherein the patients are diagnosed and treated in separate specialized departments including ENT and finally the fact that the researcher was well acquainted with the language and the settlement pattern of the study area proved to be of great convenience as it solved the problem of accessibility in data collection to a large extent.

The subjects were questioned sitting along side the doctors of the ENT department of the government hospital. The data comprised of 2054 subjects suffering from otitis media. The field work was conducted from the middle of 1999 to the end of 2001. The subjects were interviewed on the basis of a scheduled questionnaire specially designed for the purpose
of the study. The sample spans across a broad spectrum of people with a variety of social, economical and educational background. The following chapter thus tries to describe the overall methodology employed, the format and the contents of the questionnaire used. It also discusses the nature and the purpose of the study involved, the technique and procedure of data collection, and method of analysis.

2.1 METHODOLOGY

As already mentioned the present study is primarily concerned with the incidence and the prevalence of otitis media and the effect of the extrinsic factors on a community level. Thus considering the nature of the study involved and the size of the population to be covered the method of sample survey was deemed appropriate. Apart from this, the literature review (Giebink et al., 1982 and Zakzouk et al., 2002a) of disease in question also revealed the fact that the method of sample survey was more feasible than any other method.

The questionnaire schedule used for this purpose is attached at the end of the thesis. A lot of related literature was analysed to arrive at the questions which would generate required information for this study. The questions were formulated in such a way as to bring to light any possible relation between the clinical aspects of the disease and the socio-economic milieu of the subjects studied. Most of the questions framed were derived from the observations made from the published literature (Moriniere et al., 1998; Teele et al., 1989 and Saim et al., 1997) on the subject.
But the major difficulty was in arriving at a clearly distinguishable classification of stages of infection and the subsequent hearing impairment caused by the disease. However, there exists a direct correlation between infectious nature of the disease and the impairment it causes. This aspect was further used by the researcher to categorise the people in terms of the audibility range and hearing loss.

The disorder which is basically triggered by a microbial infection and which in turn is caused by unhygienic living conditions and lack of proper sanitation, when left untreated would certainly result in deterioration of the middle ear and progressive hearing impairment. Thus, this clinical basis of the disease can be further implied to distinguish different levels of hearing loss. The extent of impairment or handicap is accordingly classified as classroom level, conversational level and severe loss level. Classroom level of impairment denotes a kind of inability wherein a subject finds it difficult to hear within a range of a classroom. The best example is that of a child unable to hear his teacher in a classroom. The conversational level of handicap results when a subject finds it difficult to converse even when he is in face to face with a normal person and finally severe loss means a complete loss of ability to hear anything that is being conveyed to the subject.

2.2 COMPOSITION OF THE QUESTIONNAIRE

The questionnaire analysed the information in nine categories namely, demographic information, socio-economic status, chief complaints of the patients, classification of the disease, cellularity of
mastoid process, family history, extent of hearing handicap, educational impact, socio-cultural impact and other host and environmental factors. Each of these elements of the questionnaire have been discussed below.

2.2.1 Demographic information

The demographic information relating to the patient was elicited through asking questions about his/her sex, age, locality which showed a direct co-relation with the disease. The ethnic components like religion, caste, sub-caste were rather indirectly related when compared to the earlier mentioned ones.

2.2.2 Socio-economic status

The socio-economic status of the subject was ascertained by three parameters namely, education, occupation and income. The information acquired through these heads help to know the financial status of the subject, that is, whether he is dependent or independent and the nature and the working conditions of the employment provided to the subject. This has a direct bearing as far as the accessibility required for the treatment for the disease is concerned. Further, all these three parameters were cross classified in terms of caste and community of the people. The parameter of education was subdivided into three different categories namely, lower, moderate and higher education (Census, 1991). The next parameters of occupation were also sub-divided into three different classes like primary, secondary and tertiary occupations (Census 1991).
Finally, the subject were classified on the basis of the total family income of each subject. They were classified into three income groups according to Karnataka economic survey, they are, the lower, middle and higher income groups.

Thus, the socio-economic status of the subjects affected by the disease were analysed by studying the impact of factors like education, occupation and income by cross classifying them with caste, community and gender.

2.2.3 Chief complaints of the patient

This question-head was taken into consideration in order to analyse the symptoms of the disease. This was useful in measuring the degree of severity of the disease.

2.2.4 History of cold/URTI

Otitis media being a disorder, which is basically induced by microbial infection, it was felt necessary that the concurrence of the disease with that of any infection in the related areas has to be investigated in all its details. One such infection which showed a lot of linkage was cold or upper respiratory tract infection – URTI. This kind of linkage denotes that the infection which occurs in our respiratory tract more often than not results in otitis media. Thus, it may be inferred that the respiratory infections which carry to our ears cause otitis media. This fact was further validated by the data collected.
2.2.5 Past history of similar episodes

The past history of the individuals refers to the number of times or episodes of the disease that has occurred in his life span. The past history also denotes the various factors which lead to the recurrence of the disease. A constant exposure to unhealthy and unclean environment may result in an increased frequency of recurrence of disease.

2.2.6 Types of otitis media

Based on the clinical features the subject expressed the type of the otitis media which was determined as acute, chronic, specific and adhesive otitis media. These types actually refer to a typical set of symptoms which are derived using clinical techniques as far as acute and chronic otitis media are concerned, they refer to two different types of the middle ear infections, that is, acute otitis media is characterized by short duration and sudden onset while chronic otitis media is a condition wherein the disease shows prolonged duration with gradual onset. Thus, on the whole, the classification of the disease was done by ENT specialists taking into account the combination of factors like duration, mode of onset and clinical features.

2.2.7 Cellularity of mastoid process (as seen on x-ray)

The pneumatization or the cellularity of the mastoid process can be classified into three types based on the development of the air cells as cellular, diploetic and acellular. Cellular type of mastoid process indicates a well developed and well pneumatized mastoid air cells. Diploetic
mastoid consists of few air cells. Acellular mastoid shows no cells. As poorly pneumatized middle ears cells are taken as a possible cause in the increase in infection, the level of cellularity was taken as the indicator of the study.

2.2.8 Family history

Family history of the subject refers to the occurrence of the disease in the family of the subject both from his parent generation and sibling generation. By taking into account the number of affected subjects and their relationship to the person being interviewed a pedigree of all the relationships in the family was prepared. Thus, through these pedigrees a pattern in which the disease occurred in a family, that is, successive generation of affected individuals could be traced. This further prompted the researcher to explore a possible genetic hypothesis based on the available information. Here a link was being tried to establish between the patterned occurrence of the disease in the family to that of a possible genetic inheritance. Thus, the questionhead relating to the family history was included in the questionnaire with an intention to draw conclusions regarding the pattern of inheritance of the disease.

2.2.9 Levels of hearing loss

Physiological impairment caused by the continued infection results in different degrees of hearing loss on the part of the subject. There are three different levels in which the handicap occurs. They are, classroom level, conversational level and severe loss. In classroom level the subject is unable to hear and therefore react to whatever occurs within a limit of
the classroom, conversational level refers to an inability to converse even when he is in face to face with a normal person. And severe loss is a condition wherein the subject is completely incapable of hearing anything that is conveyed to him. The information gathered helped the researcher to classify the given subject interns of the severity of the hearing loss which has a direct relationship with the level of infection in the middle ear and to some extent the severity of the disease also.

2.2.10 Educational impact

Individuals suffering form otitis media, especially children, have to face a lot of perception related practical problems. The school going children have to put up with handicap resulting from the disease and therefore have to put additional efforts in order to reach expected level of performance. It may also happen that in some serious instances of the disease the children may drop out of the school creating problems both to the teachers and the family. Thus in order to access the level of impact of the disease on the normal mental growth of the individual, this particular aspect of the questionnaire was included.

2.2.11 Socio-cultural impact

The socio-cultural impact was accessed by taking into account various combination of factors like parental reaction, sib relation, adult life of the subject and reactions of neighbours, friends and other relatives.
**Reaction of the parents about the disease**

This question was added in the questionnaire in order to grade the various possible reactions from the parents when they came to know about the disease affecting the child. Similarly, the different types of reactions were classified as shock, lack of acceptance, anger, acceptance. The information gathered through this question denoted the acceptance level of the disease from the sociological point of view.

**Sibling relationship to the subject**

This question tries to describe the nature of the sibling relationship to the subject. The subjects who were affected by the disease had to bare with the range of emotions from their siblings which was more aimed at the disease than the individual. The question thus tried to know the reasons behind this kind of treatment. On a whole the behaviour of the siblings towards the subject was classified as either acceptance or aversion.

**Family life of adult patient**

This particular question tried to go into the details of the factors which cause or further aggravate the disease in case of adults. In order to simplify the given situation the conflicts arising because of the disease; firstly, in the case of adult males the reaction of the opposite sex that is female adults were taken into account. While the second case dealt with the female point of view wherein the reaction of males was considered. Thus, this part of the questionnaire tried to identify the possible similarities or differences between the male and female behaviour towards their affected spouse.
Reaction of neighbours, friends and relatives

This particular aspect of questionnaire though dealing with the same type of behaviour tried to explain the condition from the point of view of three different groups of people who come in contact with the subject other than the parents, siblings and the relationship between husband and wife. They are neighbours, friends and other relatives. The intention being the same that is, to gauge the reaction of above given groups on the subject.

Self impact of the disease

This question tried to measure the acceptance level or the way the subject tried to cope with the situation when he himself was affected by the disease. It enabled to reveal the type of relationship the subject tries to establish with himself when he is confronted with the handicap and hearing loss caused by the disease. The pain and discharge which the subject had to put up with was as much a matter of concern to his friends and relatives as it was to himself. So this question was included to understand the factors which go into the measuring of the capability of the subject in times of crisis which in this case is the disease.

2.2. 12 Other host and environmental factors

Number of members in the household

This question relates to the basic information regarding number of people present in each family household of a given affected subject. As there exists a direct relationship between the number of people in the
family and the occurrence of the disease (Zinkus, 1980 and Visscher, 1984), it follows that whenever a household is overcrowded with people, more often than not results in quick spreading of the infection and the final occurrence of the disease in its full form.

**Duration of breast feeding**

Duration of breast feeding refers to month-wise classification of the period in which the mother breast feeds her infant. This aspect was taken into account to explore the possibility of the relationship between duration of breast feeding and otitis media. Generally the infants who are breast fed are immune to any kind of infection and therefore resistant to the disease resulting out of such an infection. Thus, a relationship was tried to establish between the period of breast feeding and the disease vis-à-vis immunity. That is, as the total number of months of breast feeding went on increasing, there was a progressive decrease in the disease causing infection. This question was included on the basis of various studies (Teele, 1989; Sassen *et al.*, 1994a and Shaaban *et al.*, 1993) conducted to know the role played by the breast feeding as a factor determining the occurrence of the disease. Thus the question tested the effect of breast feeding as one of the factors which goes a long way in determining the extent to which individual is prone to the disease both in infants and children.

**Smoking during pregnancy**

The question was framed in order to gather information regarding any possible cases of smoking during pregnancy. It was again an
outcome of similar researches conducted about the question (Van Cauwenberge, 1986).

**Chewing of tobacco during pregnancy**

This question tried to gather the information about the females who had the habit of chewing tobacco and whether their progeny showed the occurrence of otitis media. The question once again tried to test the fact whether chewing of tobacco during pregnancy causes any impact on the vulnerability to the disease.

**Any member smoking in the house**

This question gathered information regarding smoking habits of the members of the house irrespective of their sex. It was done with an intention to know the immediate impact of smoking on the occurrence of the disease which was shown in some studies (Iversen, 1985; Hinton, 1989; Kraemer et al., 1983).

**Visiting day care centres**

Children who are regularly sent to day care centres showed a lot of vulnerability to the disease (Marx, 1995; Danic, 1990; Henderson et al., 1986). This is assuming the fact that the type of crowding and congestion created a negative effect on the child as far as infection was concerned. Thus, this question tried to explain the influence of such centres where there was over crowding of children.
2.2.13 Statistical methods used in the study

Incidence and prevalence rates

Incidence rate was calculated by dividing the new cases of the disease by the population at risk.

\[
\text{Incidence} = \frac{\text{New cases}}{\text{Population at risk}}
\]

Prevalence rate was calculated by dividing the existing cases of the disease by the population at risk.

\[
\text{Prevalence} = \frac{\text{Existing cases}}{\text{Population at risk}}
\]

Chi-square test

Chi-square was applied to the tables wherever necessary. Chi-square was calculated by the formula

\[
\chi^2 = \frac{(\text{Observed} - \text{Expected})^2}{\text{Expected}}
\]

Genetic basis of otitis media

The genetic basis of otitis media was studied by using the dominant and recessive hypotheses proposed by Meglioli (1965).