CHAPTER III - MATERIALS AND METHODS

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3.1 Description of the Study Area

Jalgaon district is located in the north-west region of the state of Maharashtra. It receives an average annual rainfall of about 690 mm and the temperature varies from 10 to 48°C. Jalgaon is one of the major cotton growing districts of the state. Jalgaon is rich in volcanic soil which is well suited for cotton production. The existence of favorable factors like availability of raw cotton, cheap labor and means of transport in Jalgaon district gave impetus to the development of the cotton ginning, pressing, spinning and weaving operations. Approximately 15,000 workers are involved in the cotton processing industries in the district. During the process of cotton ginning and pressing, the gin mill workers are exposed to high levels of noise and cotton dust. Most of the ginning has only a day shift that runs for about 12 hrs, and the workers spend 8–12 hrs/day at the workplace. The present study was conducted in 12 ginning industries located in the Chopda and Dharangaon tehsils of Jalgaon district. The ginning and pressing machines are the major source of noise in the ginning industries.

3.2 Workplace Environment Monitoring

3.2.1 Measurement of Workplace Noise

Questionnaire survey, noise level monitoring and audiometric tests of the ginning workers are the important steps of the study. Noise dosimeter (Type 4436; Bruel and Kjear, Denmark) is used for the measurement of cumulative exposure of subjects to noise over a period of time. Noise dose were determined as 90 dBA criteria for 8 hrs, with 3 dB exchange rate. Noise dosimeter was calibrated by using a standard sound level calibrator (Optel, Bombay, India) at 1 kHz calibration frequency for 94 dB before each measurement. The instrument was attached to the body of the subjects during duty hours as per the guidelines provided in the manual of the instrument. Noise dose is measured for all section workers of the ginning industry. It was ensured that factory was all regular operation was in running condition for determining mixed noise dose due to all activities.
3.2.2 Measurement of Microenvironment

Microenvironment plays very important role in dispersion of air pollutant at workplace environment.

Temperature and Humidity

Workplace microenvironment like temperature and humidity were measured using digital temperature and humidity meter during the sampling. The microenvironment plays a vital role in dispersion of pollutants in the workplace area.

3.2.3 Dust Monitoring

The exposure of workers to cotton dust was measured by a portable personal dust sampler (AS2, Technovation Analytical Instruments Pvt. Ltd) over an 8 hrs period. The sampling unit contained an air pump powered by an internally sealed lead acid gel battery. Air was drawn at flow rate between 1.5 to 2.5 liters per minute (LPM) with average of 1.8 LPM. Dust sampling unit was attached to the body of the ginning mill workers during duty period. The dust (PM$_{10}$) was collected by filtration of air through a glass fiber filter (Whatman GF/A Grade, 25 mm diameter). The samples collected were measured by the gravimetric method and expressed as dust in mg/m$^3$.

Concentration of respirable dust in the air is calculated according to a formula:

$$ X = \frac{M_2 - M_1}{V} \times 1000 $$

where:

$X$ – respirable dust concentration [mg/m$^3$]

$M_2$ – filter mass after sampling [mg]

$M_1$ – filter mass before sampling [mg]

$V$ – air sample volume calculated as a product of volumetric intensity of uptaken air flow and sampling time
3.3 Selection of Subjects

Selection of subject for occupational health studies is very important to avoid bias. In any occupational epidemiology study, the first practical task is to select the study participants from the source population (Pearce; 2007).

3.3.1 Selection of Subjects

We selected 304 workers aged between 19 and 55 years who had been working at least for 1 year in the cotton ginning industry. One hundred and fifty other workers who have participated in the study are not considered due to some factors like workplace exposure less than 1 year, previous medical history as mentioned in questionnaire and old age peoples. The average age of the sample was 35 years, and the participation rate of the workers for the study was 90%; others could not be involved in the study even after proper counseling by the authors. As there were female workers rarely involved in this occupation, only male workers are considered as the study subjects. These workers were not using any noise prevention aids for ear protection and respiratory mask to prevent dust exposure. The workers carry out their work for a period of 8–10 hrs daily and for 6–7 days in a week. All the workers in this study are below 55 years of age. Consequently, old workers were not included in the evaluation of hearing loss and respiratory impairment as many studies have reported the effect of aging on hearing thresholds and pulmonary function. Nevertheless, there are some reports that use a limit of 55 years for an onset of detectable age-induced hearing loss (Tunay and Melemez; 2008). The workers were categorized as per exposure duration and age group. For respiratory health study, a group of 97 village people involved in labor work in rural area having same economic status and aged between 21 and 51 years was served as a control group. The average age of the control group was 31 years, with a standard deviation of 8.45. The same group is used for hearing impairment tests.
3.3.2 Audiometric Analysis

Audiometry is the measurement of hearing sensitivity. Audiometer tests the hearing sensitivity of the auditory system by presenting pure tone signals to the ear through earphones and varying the intensity of the signals until the level is identified at which the person is just able to hear the sound. This level is known as the person's threshold; clinically, threshold is usually defined as the level at which the subject will be able to detect the signal 50 percent of the times that it is presented. Pure tones are presented at frequencies across the range of human hearing. Because the tones are presented at the external ear, and processing of those signals through the auditory nervous system is necessary in order for the subject to be aware and respond that the signal was heard, this type of testing evaluates the auditory system as a whole, and is capable of identifying hearing problems at almost any level within the auditory system (NHANES; 2003).

All the subjects from the target and control group were tested for audiometric analysis in the morning, ensuring that subjects were not exposed to any type of high noise levels before the test. Audiometric analysis was conducted after collecting information by questionnaire. As per response to the SAAST survey, workers with a history of treatment with ototoxic drugs and trauma infection were excluded from the samples (Sindhusake et al; 2001). All the subjects tested for the frequency range from 0.25 kHz to 8 kHz.

3.3.3 Lung Function Testing (LFT)

All the participated subjects were also tested for lung function impairment. These workers were not using respiratory mask to prevent dust exposure. The workers above 55 years of age were excluded from the study. Same control group as mentioned in point 3.3.1 is considered for the lung function test. All the subjects from the target and control group were tested in the morning after their weekly off, ensuring that subjects were not exposed to any type of high dust levels before 24 hrs of the test. As per response to the questionnaire survey, workers with a history of treatment with heart, asthma,
pulmonary operations and chain smokers, drinkers were excluded from study. Only 303 workers were considered out of 490 workers who have attended questionnaire survey due to exclusion criteria.

The cotton ginning workers categorized into four groups as per the period of exposure to the cotton dust. Years of employment was taken as criteria for the exposure of the workers. Among the total 303 workers involved in the study 85 workers had been working from less than 3 years, 90 workers had been working for 4 to 6 years, 63 workers had been working from 7 to 9 years and remaining workers had been working more than 10 years in the cotton ginning industries. It was ensured that the control group is not exposed to excessive air pollution and these subjects are non-smoker with no previous history of respiratory diseases. This study includes workers working in ginning and pressing room as the dust emissions are high in these units of mills. It was confirmed that all study subjects are non-smokers and none of the subjects had respiratory tract symptoms such as cold or dry cough during the spirometric testing. Lung function test was conducted among the selected workers as well as in the control group. Lung function test was performed in assistance with medical team.

3.4 Health Survey

3.4.1 Self-Administered Audiometric Screening Test (SAAST)

A self-administered audiometric screening test (SAAST) survey among the subjects is most frequently used to assess health perceptions in epidemiological research. Sindhusake et al (2001) reported that the questionnaire survey about hearing appeared to be sufficiently sensitive and specific to provide reasonable estimates of hearing loss prevalence among the workers. In the present study, a standard questionnaire administered by a team of trained interviewers was used for collection of data on hearing status of the subjects. The questionnaire was provided to the subjects in order to collect the information on work, age, time of work, any other job with high noise levels, any injury/trauma to the ears, exposure to ototoxic drugs or
solvents for a long duration, etc. The questionnaire used for the study is attached in Annexure I.

3.4.2 OSHA, Respirator Medical Evaluation Questionnaire

Questionnaire survey among the subjects is most frequently used to assess health perceptions in epidemiological research (Kumar; 2003). The questionnaire survey is the efficient and fast method to evaluate self reported physiological response of the subjects. In the present study, a standard questionnaire administered by a team of trained interviewers was used for collection of data on respiratory status of the subjects. The questionnaire was provided to the subjects in order to collect the information on work, age, their time of work, any previous job with high dust levels, difficulty in respiration, chest pain and frequent coughing. Questions like health history, previous case of asthma in the family of subject and habits like smoking and tobacco are also included in questionnaire for detail data collection. The questionnaire used for the study is attached in Annexure II.

3.5 Health Impact Assessment

3.5.1 Hearing Impairment

The hearing threshold levels of the subjects were determined by using the clinical pure tone audiometer (EDA-3N3 Mille; Elkon Pvt. Ltd., Mumbai, India) by wearing headphone (ELEGA, dynamic receiver, DR-59). The hearing threshold levels were measured by the ascending procedure at 250, 500, 1000, 1500, 2000, 3000, 4000, 6000 and 8000 Hz. Three successive tests were conducted subsequently on the same day for each subject and the best result was used for this study. The audiometric test was conducted in separate cabin to avoid effect of surrounding noise. The response of the subject is noted in result sheet. Using a cut-off >25 dB, hearing threshold averages were calculated as the binaural at low (250, 500, 1000 and 1500 Hz), the binaural mid (1500, 2000, 3000 and 4000 Hz) and binaural high (3000, 4000, 6000 and 8000 Hz) frequencies.
Calculation of Monaural and Binaural Hearing Impairment

Monaural and binaural hearing impairment is expressed in terms of percentage by using threshold average of frequencies 1000, 2000, 3000 and 4000 Hz. Hearing impairment was defined as a threshold average greater than 25 dB hearing level.

Monaural Hearing Impairment

Percentage of monaural hearing impairment was calculated as follows:

a. From the audiometric results, the average of thresholds of hearing for frequencies of 1000, 2000, 3000 and 4000 Hz was calculated.
b. Deduct from it 25 dB (as there is no impairment up to 25 dB).
c. Multiply it by 1.5. Formula for monaural hearing impairment is given below:

\[
\frac{(1000 \text{ Hz} + 2000 \text{ Hz} + 3000 \text{ Hz} + 4000 \text{ Hz})}{4} - 25 \times 1.5 = \% \text{ monaural hearing loss.}
\]

Binaural Hearing Impairment

a. From the percentage monaural impairment, multiply the percent of better ear by 5.
b. To this, add the percent of worse ear.
c. Divide it by 6. Formula for binaural hearing impairment is as follows:

\[
\frac{[\% \text{ better ear} \times 5] + [\% \text{ worse ear}]}{6} = \% \text{ binaural hearing loss.}
\]

Percentage of hearing impairment in different age groups was calculated by the National Institute of Occupational Safety and Health (NIOSH) handicap equation 1997 available online at [www.occupationalhearingloss.com](http://www.occupationalhearingloss.com). It detects early effects of noise on function of inner ear with respect to age and sex of an individual.

Degree of Hearing Impairment

The criterion of Clarke (1981) was used for classification of degree of hearing loss as shown below in Table 3.1. Audiometric values at 500, 1000, 2000 and 4000 Hz were averaged to determine the degree of hearing impairment.
Table 3.1 – Classification of Degree of Hearing Loss (dB)

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Degree of Hearing Loss</th>
<th>Hearing loss (dB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Normal</td>
<td>&lt;25</td>
</tr>
<tr>
<td>2</td>
<td>Mild</td>
<td>26–40</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
<td>41–55</td>
</tr>
<tr>
<td>4</td>
<td>Moderately severe</td>
<td>56–70</td>
</tr>
<tr>
<td>5</td>
<td>Severe</td>
<td>71–90</td>
</tr>
<tr>
<td>6</td>
<td>Profound</td>
<td>91+</td>
</tr>
</tbody>
</table>

“Source: Clarke (1981)”

3.5.2 Blood Pressure –

The blood pressure of the workers is measured using a manual blood pressure apparatus, sphygmomanometer (Diamond, India make) with a team which includes medical practitioners. The monitoring of blood pressure of the ginning workers was conducted before stating the shift and after completion of the shift. Control group was tested at morning and evening. The subject under test was asked to relax for ten minutes before the measurement. The cuff of sphygmomanometer was fastened on bare upper arm of the subject under test. The bulb of the apparatus was squeezed to inflate the cuff quickly to raise the mercury level reading to about 180 mm or above. The stethoscope diaphragm was placed over the middle bend of the arm just below the edge of cuff. Slowly the valve of the bulb was opened to release the air. The pulse sound was carefully heard through the earpiece of stethoscope. The higher number reading when the first sound heard was recorded as systolic blood pressure and the lower number reading when the last sound heard was recorded as diastolic blood pressure (Singh et al 1982, 1986; Iorio, 1999)

3.5.3 Pulmonary Function Test

The spirometry is the most common of the pulmonary function tests (PFTs), measuring lung function, specifically the measurement of the amount
of volume and/or speed (Flow) of the air that can be inhaled or exhaled by human being. Glady et al. (2003) performed pulmonary function tests in order to diagnose and classify disease processes that impair lung function. Impairment in lung function can be broadly classified as those resulting in airflow obstruction, volume restriction and combination of obstructive and restrictive defects (Ries; 1989).

The pulmonary function test was performed among the workers and control subjects under study. Before the test age, height, and weight of the subjects were entered in the spirometer (Medspiror, Recorder and Medicare Systems, India). The spirometer gives two values: one is expected value and the other is the actual value. The expected value is based on the height, age, and weight of the subjects. Medspiror software calculates the expected values for the adults using a set of prediction equation. The results of spirometry were assessed according to the criteria given in the manual of the Medspiror.

The actual values of FVC, FEV\textsubscript{1} and PEFR are based on the maximal inspiration and expiration of the subjects. The pulmonary function test was conducted by sitting the subjects comfortably in a chair. Three tests were performed and the subjects were assisted to improve their efforts. Pierce and Johnes (2004) reported that at least three technically acceptable maneuvers should be obtained, ideally with less than 0.2L variability for FVC, FEV\textsubscript{1} and PEFR between highest and second highest result. Regular sterilization of mouthpieces was done before each test. The best of the three performances of FVC, FEV\textsubscript{1} and PEFR were considered for further analysis.

The results of the spirometry tests were assessed according to the criteria given in the Medspiror manual. The test was performed for comparison of observed values of pulmonary function test in target and control groups. The ventilatory impairment of the subjects was analyzed using the lung parameters FVC, FEV\textsubscript{1}/FVC, and PEFR. The percentages of the normal, mild, moderate and severe impairment of subjects in the number of samples were specified in ventilatory impairment.
The prediction equations were as follows –

\[
\begin{align*}
\text{FVC} (\text{L}) & = 0.050H - 0.014A - 4.49 \\
\text{FEV}_1 (\text{L}) & = 0.040H - 0.021A - 3.13 \\
\text{PEFR} (\text{L/Sec}) & = 0.071H - 0.035A - 1.82
\end{align*}
\]

Where, \(H\): is height in cms and \(A\): is age in years.

During inspiration air is inhaled into the lungs and during expiration air is exhaled out of the lungs. Depending on these phases of respiration and effort, the quantity of air ventilated or contained in the lungs is divided into the following types –

a) Total Lung Capacity (TLC) is the volume of air in the lungs following a maximal inspiration (Normal Range=5 to 6L).
b) Total Volume (TV) is the volume of air that enters and leaves the lungs during normal breathing (Normal=500ml).
c) Inspiratory Reserve Volume (IRV) is the maximal amount of air that can be inhaled from at the end of a normal inspiration (Normal=2 to 3.3L).
d) Residual Volume (RV) is the volume of air remaining in the lungs following a maximal expiratory effort (Normal=1.2L).
e) Expiratory Reserve Volume (ERV) is the maximal amount of air that can be exhaled from the end of a normal expiration (Normal=1L).
f) Functional Residual Capacity (FRC) is the volume of air with the lungs at the end of a normal expiration. FRC is composed of two primary lung volumes, expiratory lung volume (ERV) and residual volume (Normal=2.5 to 3L).
g) Inspiratory Vital Capacity (IVC) is the maximum volume of air inhaled after full expiration.
h) Inspiratory Capacity (IC) is the volume of air taken during maximal inspiratory effort from the end of normal expiration (Normal=3.5L).
3.5.4 Biochemical Analysis of Blood

A health check-up campaign was organized at ginning industries. The authors were assisted by pathological and medical experts. Blood sample from each worker is collected by venipuncture technique. Blood samples were analysed at pathology laboratory for Eosinophils, ESR, WBCs count and other hematological parameters for detail study. Only 200 subjects and 50 control subjects undergone for the blood test. There was hesitation and fear observed among the workers regarding blood testing. In spite of maximum efforts of the team only 200 subjects participated in the blood testing camp.

3.6 Statistical Analysis

3.6.1 Risk Assessment for Hearing Impairment-

The symptoms like hearing loss, unilateral hearing trouble and bilateral hearing trouble, reported by the subjects during the questionnaire survey, were considered for risk assessment. The risk was calculated among the exposed (workers) and unexposed (control) subjects. The odds ratio is calculated by setting a simple 2 x 2 matrix such that the rows divide the subjects according to those who had been exposed (cotton ginning workers) and those who had not been exposed (control) to the risk factor.

**Sensitivity and Specificity**

The agreement between self-reported hearing loss and audiometric analysis was tested by sensitivity and specificity. These are statistical measures of the performance of a binary classification test. Sensitivity is the ability of self-report to detect the presence of hearing loss when detected by audiometry. Specificity is the ability of self-report to detect the absence of hearing loss when it is absent in audiometry. Sensitivity and specificity for different exposure groups is calculated considering the exposure group as predictor and hearing impairment as the outcome. Specificity measures the proportion of negatives that are correctly identified (e.g., the percentage of normal) from the total number of samples.
Analysis of Variance

The audiometric results in dB in each category were used for Analysis of Variance (ANOVA) using Microsoft Excel. The positive predictive value (PPV) of a test is the probability that the question would correctly identify a person having hearing impairment. The negative predictive value (NPV) of a test is the probability that the question would correctly identify a person whose hearing is not affected. PPV and NPV were calculated to determine accuracy of the hearing test. The data on percent of hearing impairment of the different exposure and age group was processed for mean, standard deviation and one-way ANOVA using Microsoft Excel.

3.6.2 Risk Assessment for Respiratory Impairment

The data on the health status of the study group was collected by a standard respirator medical evaluation questionnaire (OSHA; 1998). The questionnaire was modified according to local language and conditions at the workplace. The symptoms of frequent coughing, difficulty in respiration and other information on the health of the target group were collected. PPV and NPV were calculated to determine accuracy of the respiratory test. The data on percent of respiratory impairment of the different exposure groups was processed for mean, standard deviation and one-way ANOVA using Microsoft Excel. Sackett et al. (2000) reported that the attributable risk is a measure of excess risk accounted by exposure to a particular factor whereas relative risk measures strength of an exposure to the risk factor. The data of FVC, FEV$_1$ and PEFR was processed for mean, standard deviation and one way ANOVA using Microsoft Excel.

3.7 Noise Exposure Control Model for Ginning Industry

In ginning industries workers can be used for various works. Ginning unit workers can perform other unit of ginning industries because no technical skill is required for ginning industries. Therefore workers can handle any activity of this industry except few electrical and maintenance
work. Considering this fact we have developed simple excel based model for ginning administrators to decide distribution of work hours in different activities of ginning industry.

3.7.1 Development of strategic Model to Reduce Noise Dose and TWA noise levels

Time Weighted Average (TWA) noise levels and noise dose are the important monitoring parameters to study and decide action to be taken to reduce exposure. The TWA shows a worker's daily exposure to occupational noise, taking into account the average levels of noise and the time spent in each area.

In present study noise dose and TWA are calculated based Occupational Safety & Health Adm. (OSHA) occupational noise exposure computation Standards 29 CFR Part 62 and 29 CFR 1910.95 App-A. We have calculated noise dose and TWA based on present daily working hours of ginning workers in different units of the industry. In the excel model we have recommenced distribution of working hours of ginning and pressing unit working considering their exposure to high noise. We calculated noise dose for 9 hour and 12 hours shift as per present practice of ginning industries of the study area. We have used following equations –

\[
\text{Noise Dose} = 100 \times (C1/T1 + C2/T2 + C3/T3 + ... + Cn/Tn)
\]

Where,
\( C_n \) = time spent at each noise level,
\( T_n \) = Standard exposure limit in hours.

\[
\text{TWA} = 16.61 \log_{10} \left( \frac{D}{100} \right) + 90
\]

Where,
\( \text{TWA} \) is the 8-hour Time Weighted Average Sound Level,
\( D \) is the Dose % as calculated above (or measured with a dosimeter) and \( \log_{10} \) is the Logarithm to base 10.