**Proposed Title of the Thesis**

**Occupational Exposure to Silica Dust and its Association with COPD**

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**Introduction**

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) has defined Chronic obstructive pulmonary disease (COPD) is a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases.

chronic airflow limitation that is characteristic of COPD is caused by a mixture of small airways disease and parenchymal destruction the relative contributions of which vary from person to person(GOLD,2018). COPD includes emphysema and chronic bronchitis (john et al.,2011).

COPD is a global health concern and a major causes of chronic morbidity and mortality throughout the world. The Global Burden of Disease Study has projected that COPD, which ranked sixth as the cause of death in 1990, will become the third leading cause of death (Dhadke et al.,2015) and 5th common cause of morbidity all over the world by the year of 2020 (Helvaci et al.,2012).

The main risk factor for COPD is cigarette smoking .Other risk factors have also been implicated including exposure to industrial dust and fumes, outdoor air pollution (Blanc PD et al.,2009) second hand smoke & biomass smoke ( Blum A. et al.,2011) An estimated 15-30% of COPD cases are attributable to occupational exposures(Toren and Jarvholm, 2014).

Increased COPD risk has been associated with some specific occupational exposure agents, including : Silica (Tse et al., 2007; Dement et al., 2010), coal dust (Coggon and Newman Taylor, 1998), asbestos (Dement et al., 2010), Cement dust(Fell et al.,2010), diesel exhausts(Hart et al., 2009).

There is increasing evidence that lung function development is influenced both in utero and in the early years of life by factors such as maternal smoking, low birth weight, diet and nutrition (Boots A.W. et al.,2003).

Although tobacco smoking is the major risk factor for COPD with an estimated fraction of 80–90% (ATS, 1995a), only 15–20% of smokers develop COPD (Barr et al., 2002; Mannino et al., 2002). A significant fraction of all COPD cases and COPD-related mortality occurs among nonsmokers (Eisner et al., 2010).

According to the updates of the Global Initiative for Chronic Obstructive Lung Disease (GOLD),occupational exposure is one of the two most important risk factors for COPD (GOLD,2010). In developing countries such as India COPD due to non-smoking causes account to 30-50% of all COPD cases (Salvi & Barnes,2009).

Crystalline silica is found in stone, rock, sand, gravel and clay, as well as products such as bricks, tiles, concrete, artificial stone benchtops and some plastic materials .When these materials are worked on, the silica is released as a fine dust. This dust is respirable crystalline silica commonly called silica dust( Carey R.N. et al.,2014).

It has been found that crystalline silica is more dangerous because of its needle like structure which is cytotoxic and produce highly reactive surface radicals after grinding which favours the adsorption of surface materials. The severity of diseases depends upon the size, shape, concentration of particles and duration of exposure(Bushra Iftikhar et al.,2009).

The workers of stone quarry are exposed to silica dust of different concentration and particulate size. Average dust levels vary from about 0.5mg/m3 to over 10mg/m3. The studies suggest that loss of lung function occurs with exposures to silica dust at concentration of between 0.1 and 0.2mg/m3(Lesley R.,2007).

Inhalation of silica dust for long periods can causes focal and interstitial fibrosis, centrilobular emphysema and progressive massive fibrosis of lungs (Ralston et al., 2018).

It is also possible that workers exposed to silica have an increased risk of chronic bronchitis as a consequence of non-specific effects of dust (Seaton et al., 2000).

People with COPD suffering from chronic respiratory symptoms such as cough,sputum production and shortness of breath. They may also experience more systemic symptoms such as fatigue, weight loss, muscle weakness and anorexia. Depression and anxiety are also common and contribute to comorbidity (Stuart H,2018).Lung function decline, reduction in muscle strength, and reduced exercise capacity all contribute to increasing disability.

The most widely recommended diagnostic criteria for COPD used in clinical practice requires the presence of relevant symptoms and a compatible clinical history (history of smoking or other noxious exposures) together with objective measures of airflow obstruction as defined by a post-bronchodilator forced expiratory volume in one second (FEV1) to forced vital capacity (FVC) ratio of less than 0.7(Benfield T.et al.,2008)

A study was conducted in Peshaware, Pakistan on 160 workers of dust generating industries having exposure to silica dust for 5 years or more. The result showed, 56(35%) people were suffering from COPD among them 48 were smoker and 8 were non smoker(Bushra iftikhar et al.,2009).

Another study was conducted in Welsh, UK. In that study 1255 men participated among them 726 were slate miners expose to respirable crystaline silica and 529 were unexposed non miners. Result shows COPD was more common in miners(n=213,33%) than non miners(n=120,26%). After adjustment for smoking slate miners were associated with reduction of FEV1 and FVC and increase risk of COPD which is independent of smoking status(C.J.Reynolds et al., 2016).

Stone quarry is an important one among the industries that make the workers more prone to silica exposure. There are more than eight hundred stone quarries in Sylhet, mainly distributed in Bholaganj of Companiganj upazilla and Jaflong of Gowainghat upazilla which roughly employ more than one lac workers (Selim and Ali,2017).

But even with such large number of employees, stone quarrying remains an unorganized sector of industry.

Considering the fact that quarry industry has become one of the major employers of labour in Bholaganj and Jaflong, this study aims to determine the association of occupational exposure to silica dust with COPD among stone quarry workers of that area.

This study will also document the availability of health care facilities and safety measures at the site as ways of minimizing occupational health hazards associated with stone quarrying.

**Rationale**

Rapid industrialization, requiring heavy supplies of construction material like stones, bricks, cement producing silica dust in health endangering amounts. Cigarette smoking, lack of protective measures against silica dust inhalation and long hours of daily exposure are all adding significantly to the problem.

The workplace health hazard are an important public health issue and are avoidable through preventable intervention in the workplace. Although the developed nations have taken few steps forward to ensure safe and healthful working conditions by setting and enforcing standards, Bangladesh is still lagging behind.

Despite the fact that stone quarry industry has been the main way of earning livelihood for thousands of people in Sylhet, the occupation quite understandably posing some health risks too for the employees working there. Silica dust, being the most abundant particulate substance in the air of quarry areas, is likely to causing the chronic obstructive pulmonary diseases.

The purpose of this study is to ascertain the association between prolonged exposure to silica dust and COPD among the stone quarry workers of sylhet. The findings of this study will be beneficial in policy making and enforcing proper legislative measures, so that the health hazards of the quarry workers can be minimized in the future.

**Research Question**

Is silica dust responsible for COPD irrespective of smoking?

**Hypothesis**

* COPD can be caused by silica dust only irrespective of smoking.
* Silica dust act synergistically with smoking causing the chronic obstructive pulmonary diseases(COPD).

**Objectives**

**General Objective:**

To see the association between silica dust exposure and COPD among the stone quarry workers of sylhet.

**Specific Objectives:**

To establish the diagnosis of COPD by compitable history and spirometry.

To see the prevelance of COPD among the non smokers exposed to silica dust.

To see the prevelance of COPD among the smokers exposed to silica dust .

To assess the severity of COPD by GOLD severity scale 2008.

**Methodology**

**Study setting / place of study:**

The stone quarries of Companiganj and Gowainghat upazilla, Sylhet.

**Study period:**

one year after acceptance of the protocol.

**Study design:**

Cross sectional observational study

**Target population**: All stone quarry workers of sylhet.

**Study population**: Target population fulfilling the inclusion criteria within the study period.

**Sampling method:**

Convenient sampling.

Sample size is calculated using Cochran's formula considering 5% level of significance, 5% precision level (permissible error) and prevalence of chronic obstructive pulmonary diseases among stone quarry workers 13.7% (john dement et al., 2015).

The formula is: **n = Z2 pq / d2**

Where, n = estimated sample size

Z = 1.96 (in 95% Confidence Interval)

p = prevalence, 13.7% (0.137),

q = 1- 0.12 = 0.88,

d = permissible error, 5% (0.05)

(1.96)2 x 0.137 x 0.88

So,sample size (n) = -------------------------

(  0.05)2

= 184

Calculated sample size is 184 but in this study 200 samples will be taken.

**Inclusion criteria**

* Workers in the age range of 25 years to 60 years.
* Workers who have been working for at least five years in the quarry.

**Exclusion criteria**

* Workers with history of lung disease even before they started working at the quarry.
* Workers who are not interested to participate in the study.

**Variables**

* Main outcome variable:

association of silica dust with COPD.

* Confounding variables:

1. Duration of Smoking

2. Length of service

3. Use of biomass fuel in cooking

4. low birth weight

5. low soscioeconomic condition.

**Procedures of data collection**

* This study will be conducted on the stone quarries of sylhet, specifically on the quarries that have stone crusher machines.
* Total 10 visits will be made. On each visit, data will be collected from 20 respondents.
* Prior to each day of data collection an advocacy meeting will be arranged with the local elites and the respective industry owner. They’ll be informed in detail about the study and permission will be taken. An announcement will also be made on the day before data collection in the quarry area.
* After relevant history taking ,workers fulfilling the inclusion criteria will be informed about the study goals. Among them who’ll agree to participate voluntarily, will be taken as samples.
* Informed written consent will be taken from the respondents.
* Study population will be divided into two group: smoker and non smoker.
* Workers will be interviewed face to face using the semi-structured questionnaire.
* Baseline spirometry were performed for all the participants of the study. Spirometry will be carried out using a calibrated portable spirometer.
* Spirometry will be done with participants sitting at ambient temperature and after atleast 10 minutes of rest. The subjects will be asked to exhale into the spirometer as forcefully as possible after maximum inspiration.
* The parameters measured will be forced vital capacity (FVC) and forced expiratory volume in one second (FEV**1**). FEV**1**/FVC ratio will be calculated from the measured data.
* Study participants with value of FEV1/FVC of less than 0.7 were examined with post-bronchodilator test, which was performed according to the ATS / ERS guideline, 15 minutes after the administration of 400 micrograms of salbutamol.
* Subjects with forced expiratory volume in 1 second and forced vital capacity ratio (FEV1/FVC) value of less than 0.7 were regarded as COPD patients.
* The stages of COPD were also determined according to GOLD criteria.
* All relevant data will be recorded in data collection sheet designed for this study.

**Procedure of data analysis and interpretation**

* Data will be processed manually and analyzed with the help of SPSS (Statistical package for social sciences) Version 25.0
* Result will be tabulated and presented by appropriate method i.e. frequency table, bar chart and pie diagram etc.

**Quality assurance strategy**

All the data will be kept confidential. Only the researcher and ethical committee members will get full access to the data. Every records will be cross-checked by the supervisor.

**Ethical implications**

* The study protocol will be submitted for the approval of the ethical review committee of Sylhet MAG Osmani Medical College, Sylhet.
* Informed written consent will be taken from each of the respondents before taking any interview. A co-worker will be the witness of taking informed consent.
* The purpose and method of the study, confidentiality of the interviews, risks and benefits of participating in the study, respondent’s right to participate voluntarily and right to withdraw at any point will be explained in the local language from a printed handout.
* All information will be collected with complete respect to the worker’s wish and without any force or pressure.

**Result:** Result will be presented by appropriate tables graphs and charts.

**Discussion:** Discussion will be made comparing the result of the study with other study finding on relevant topics.

**Conclusion:** Conclusion will be drawn from result and discussion.

**Recommendation:** Recommendation will be made on the basis of findings.

**Flow Chart**

**Time table**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Activities** | **Month Year** | **Month Year** | **Month Year** | **Month Year** | **Month Year** | **Month Year** | **Month Year** | **Month Year** | **Month Year** | **Month Year** |
| **Designing the Study** | Sep, 2018 |  |  |  |  |  |  |  |  |  |
| **Review of Literature** | Sep, 2018 | Oct, 2018 | Nov, 2018 |  |  |  |  |  |  |  |
| **Development and Approval of Proposal** |  |  | Nov, 2018 |  |  |  |  |  |  |  |
| **Development of Data Collection Tools** |  |  |  | Dec, 2018 |  |  |  |  |  |  |
| **Pretesting Questionnaire** |  |  |  |  | Jan, 2019 |  |  |  |  |  |
| **Data Collection, Entry and Analysis** |  |  |  |  |  | Jan, 2019 to Dec, 2019 |  |  |  |  |
| **Report Writing** |  |  |  |  |  |  | Jan, 2020 |  |  |  |
| **Submission and Approval** |  |  |  |  |  |  |  | Feb, 2020 | March, 2020 |  |
| **Printing, Binding and Final Submission** |  |  |  |  |  |  |  |  |  | Apr, 2020 |

**Operational definitions**

* FEV**1**: the volume of air that the patient is able to exhale in the first second of forced expiration after a maximal inspiration
* FVC: the total volume of air that the patient can forcibly exhale in one breath after a maximal inspiration
* FEV**1**/FVC: the ratio of FEV**1** to FVC expressed as a percentage.
* COPD: Subjects with compatible history and forced expiratory volume in 1 second and forced vital capacity ratio (FEV1/FVC) value of less than 0.7 were regarded as COPD patients.

**Total budget**

* Spirometry: Tk. 1,50,000
* Travel to the site of data collection: Tk. 25,000
* Bronchodilator: TK.5,000
* Books and literature: Tk. 5,000
* Data analysis and compose: Tk. 10,000
* Printing and binding: Tk. 10,000

Total: Tk. 20,5000

References

* ATS. 1995a. Standards for the diagnosis and care of patients with chronic obstructive pulmonary disease.AmJ Respir Crit Care Med 152: S77–121.
* Benfield T, Lange P, Vestbo J. COPD stage and risk of hospitalization for infectious disease. Secondary COPD stage and risk of hospitalization for infectious disease 2008.
* Blanc PD, Menezes AMB, Plana E, et al. Occupational exposures and COPD: an ecological analysis of international data. Secondary Occupational exposures and COPD: an ecological analysis of international data 2009.
* Blum A, Simsolo C, Sirchan R, Haiek S. "Obesity paradox" in chronic obstructive pulmonary disease. Secondary "Obesity paradox" in chronic obstructive pulmonary disease 2011.
* Boots AW, Haenen GRMM, Bast A. Oxidant metabolism in chronic obstructive pulmonary disease. Secondary Oxidant metabolism in chronic obstructive pulmonary disease 2003. http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med4&NEWS=N&AN=14621103.
* Barr RG, Herbstman J, Speizer FE, Camargo CA, Jr. 2002. Validation of self-reported chronic obstructive pulmonary disease in a cohort study of nurses. Am J Epidemiol 155:965–971.
* Bushra Iftikhar, Muhammad H., Hamid H.,Mahzar I.& Gulam sarwar.2009.`Relationship between silica dust exposure and COPD in workers of dust generating industries of distric peshware’ Gomal journal of medical science January-june 2009,vol.7 No.1,pp.46.
* Carey RN, Driscoll TR, Peters S, et al. Occup Environ Med 2014;71:55–62.
* Coggon D, Newman Taylor A. 1998. Coal mining and chronic obstructive pulmonary disease: A review of the evidence. Thorax 53:398–407.
* C. J. Reynolds, S. J. MacNeill, J. Williams, N. G. Hodges, M. J. Campbell, A. J. Newman Taylor and P. Cullinan, 2016, oxford university press on behalf of the society of occupational medicine.
* Dement JM, Welch L, Ringen K, Bingham E, Quinn P. 2010. Airways obstruction among older construction and trade workers at Department of Energy nuclear sites. Am J Ind Med 53:224–240.
* Dhadke VN, Dhadke SV, Raut N. Clinical Profile on Chronic Obstructive Pulmonary Disease Patients and Their Evaluation with Spirometry and 2D Echo. International Journal of Current Research 2015; 7(2): 12480-8
* Eisner MD, Anthonisen N, Coultas D, Kuenzli N, Perez-Padilla R, Postma D, Romieu I, Silverman EK, Balmes JR. 2010. An official American Thoracic Society public policy statement: Novel risk factors and the global burden of chronic obstructive pulmonary disease. Am J Respir Crit Care Med 182:693–718.
* Fell AK, Sikkeland LI, Svendsen MV, Kongerud J. 2010. Airway inflammation in cement production workers. Occup Environ Med 67:395–400.
* Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management and prevention of COPD. Updated:on 2018. Global Initiative for Chronic Obstructive Lung Disease, Inc.
* Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (Updated December 2010): Medical Communication Recourses, Ink. 2010. [displayed 22 November 2011]. Available at [http://www.goldcopd.com](http://www.goldcopd.com/)
* Hart JE, Laden F, Eisen EA, Smith TJ, Garshick E. 2009. Chronic obstructive pulmonary disease mortality in railroad workers. Occup Environ Med 66:221–226.
* Helvaci MR, Aydin LY, Aydin Y. Chronic obstructive pulmonary disease may be one of the terminal end points of metabolic syndrome. Pak J Med Sci 2012; 28: 376-9.
* John J. Reilly Jr, Edwin K Silverman, Stepen D Shapiro. 2011. Chronic Obstructive Pulmonary Disease. In: Longo D L., editor. Harrison’s principles of Internal Medicine. 18th edition. New York: Mc Graw Hill, p. 2142-6.
* Lesley Rushton. 2007`Chronic obstructive pulmonary diseases and occupational exposure to silica’,Reviews of envirnomental health,vol 22,No.4,pp.255-56,retrieved jan 2007.
* Mannino DM, Homa DM, Akinbami LJ, Ford ES, Redd SC. 2002. Chronic obstructive pulmonary disease surveillance-United States, 1971–2000. Respir Care 47:1184–1199.
* Ralston, S., Penman, I., Strachan, M. and Hobson, R. (2018). *Davidson's principles and practice of medicine*. 23rd ed. Churchill Livingstone Elsevier.
* Salvi SS, Barnes PJ. Chronic obstructive pulmonary disease in non-smokers. Lancet 2009;374:733-43.
* Seaton, A., Seaton, D., Leitch, A. and Crofton, J. (2000). *Crofton and Douglas's respiratory diseases*. 5th ed. Malden, Mass.: Wiley-Blackwell.
* Selim, M. and Ali, A. (2017). ’পাথর ব্যবসায় হরিলুট’, Jugantor, 26 February. [online] Available at: https://www.jugantor.com/news-archive/economics/2017/02/26/104354/%E0%A6%AA%E0%A6%BE%E0%A6%A5%E0%A6%B0-%E0%A6%AC%E0%A7%8D%E0%A6%AF%E0%A6%AC%E0%A6%B8%E0%A6%BE%E0%A7%9F-%E0%A6%B9%E0%A6%B0%E0%A6%BF%E0%A6%B2%E0%A7%81%E0%A6%9F [Accessed 29 Aug. 2018].
* Stuart, H., Penman, I., Strachan, M. and Hobson, R. (2018). *Davidson's principles and practice of medicine*. 23rd ed. Churchill Livingstone Elsevier.
* Toren K, Jarvholm B. 2014. Effect of occupational exposure to vapors, gases, dusts, and fumes on COPD mortality risk among Swedish construction workers: A longitudinal cohort study. Chest 145:992–997.

**Appendix-1**

**Data collection sheet**

SL.No : Date:

Name :

Age :

Sex : 1. Male 2. Female

Education :

Soscioeconomic cobdition:

Address : 1. Illiterate 2.Primary 3. Above

Mobile No :