Review/Critique of the asbestos study paper "Study on health hazards/Environmental hazards resulting from the use of Chrysotile variety of Asbestos in the country

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Executive summary

We present here our review of the studies titled, "Study on health hazards/Environmental hazards resulting from the use of Chrysotile variety of Asbestos in the country", and "Study on health hazards/Environmental hazards resulting from the use of Chrysotile variety of Asbestos in the country (report of the Kolkata study)". We analyzed the study and found that both the study plan, the execution of the study at Kolkata and its reporting had serious methodological shortcomings, nonconventional data presentation, and interpretations. Before this study can be used as a sufficient documentary evidence for policy framing, it need to be revised for methods and contents, and possibly re-done. It's recommended to revise the study plans and re-analyze the original data to start with.

Comments

The study protocol/plan document was inadequate to address the problem presented. The source population, the eligible population and the sample population selected for this study was not defined. The authors selected the following industries:

- Chrysotile asbestos manufacturing industries
    - Cement
    - Brake linings
    - Jointing
    - Pipes

There are other industrial settings that were omitted. These included:

- Automotive workers (workers working with brake linings and shoes)
- Those in the ship breaking industries
- Workers working in housing and constructions, since they are exposed to asbestos in cement for prolonged periods
- Asbestos miners

Selection crtieria for the industries covered were not mentioned, neither there was any mention why these other industrial groups were omitted.

In the epidemiological study section, the authors mentioned that every individual will be interviewed with a pre-designed questionnaireto collect information about personal, occupational and morbidity details. However, the study type was not clearly mentioned. We assumed that since this study was based on questionnaires, it could possibly be a cross-sectional survey. Cross sectional surveys for studying occupational health hazards are inadequate and are open to interviewer, and respondent bias, as well as errors resulting from “healthy worker effect”. Healthy worker effect is defined as the situation where selectively healthy workers are present on the day of the interview to respond to quesitons and workers who are too ill to attend the factory/industry on the particular day of the quesioning are omitted altogether from the studies, thus introducing selection bias and potentially invalidating the study. It was not clear from the plan how this was dealt with, if at all. Further, the investigators did not mention any comparison with any baseline data. Typically, occupational epidemiological studies are based on retrospective or prospective cohort studies, where disease failures are either prospectively (ie, from present through to future), or retrospectively (ie, setting up an initial time (zero time) and a final cut off time) with survival/hazard analyses. Hence, the study plan as proposed here was unconventional and there was no justification why this study plan was taken up from the investigators in the report. The results from this study are likely to have serious observer and respondent misclassification bias that can potentially invalidate the study altogether. The investigators reported that they would employ a pre-tested questionnaire. However, they did not mention if they would be using a validated pre-tested questionnaire, neither a proper validation plan.

Comments on the report of the Kolkata study

This study was carried out in an asbestos sheet manufacturing industry. The study period was for two weeks in the month of August through September (rainy season and the risk of having asbestos fibers or suspended particulate matters in air likely to be low). This was a cross sectional survey and the time period was clearly too narrow to capture the health status of workers in the industry or those who were too sick to attend the quesionnaires.

The study aimed to captur all workers of this industry but out of 200 workers, 188 (94%) attended the quesitonnaires. What happened to the rest 12 (6%) workers. Were they too ill to attend the

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questionnaires, or did they refuse to participate or were they eliminated because they were not eligible to participate in the study? These questions need to be answered. Also, were the demographic, social, and exposure criteria of these workers considerably different from the rest of the workers who attended the study?

It was also not clear if the pre-designed questionnaire was validated as well to be used for an epidemiological survey. Validation would indicate, inter alia, using the questionnaire in another but comparable population to obtain values of key variables that could then be mapped to assess that the instruments used (questions used) in this questionnaire were appropriate (this is content validity of the questionnaire). Additionally, as part of the validation exercise, it also needed to be ensured that an appropriate translation of the questionnaire would be available and used (with proper back and forward translations) for workers who would not speak english or not prefer to respond in english language. If a validated questionnaire was not used for this study, the results of this study could not be interpreted correctly.

The investigators reported that 82% of the workers were non-smokers, and that these workers largely belonged to the age group between 25 through 50 years (about 89% workers belonged to age groups between 25 through 50 years), and about 76% workers had secondary level education or lower. With these statistics, the figure of 82% non-smokers appear to be over reported. Were there other methods to validate this number? If there weren't, this is a lead that there were considerable observer and respondent biases in this study.

The investigators reported that 82% of the workers they studied had worked for at least 10 years in that industry. This indicated that these people were exposed to asbestos fibers for prolonged period and assuming that the technology has changed to be safer for the last ten years, they were also at higher exposure level earlier compared to their current exposure status. Since no exposure assessment data were reported for the earlier period, current exposure levels were likely to be lower than their lifetime exposure levels. In this study, no lifetime exposure levels were calculated based on their job-exposure matrix, or at least not reported in this study. This omission need to be explained.

In Table 1, the investigators reported that they found only 19% workers had only restrictive abnormality based on pulmonary function tests, and an additonal 6% workers had mixed abnormality – thus about 25% workers studied had restrictive pulmonary diseases based on PFT. However, given the fact that over 80% workers were exposed to asbestos dusts in this industry for at least 10 years, the 25% prevalence is open to question and possibly indicates:

- Observation bias (PFTs are not objective tests, neither are chest Xray interpretation)

- Healthy worker effect (described above. This is a selection bias where relatively healthier population was sampled and hence non-representative)
- Other types of calculation error that need to be rechecked.

In Table 2, the purpose of the table appears to be studying the association between years of exposure and risk of mixed, obstructive and restrictive lung diseases and (normal/abnormal status). First, the layout of the table is unconventional in that exposure variables (years of exposure) are in columns and outcome variables are in rows. Traditionally, outcome variables (types of lung diseases) are in columns and the exposure variables are in rows. Second, the investigators have reported column percentages for years of exposure as opposed to percentages of diseases within years of exposures (row percentages). In other words, the investigators chose to show how within same years of exposure, the risks of normal/abnormal, mixed/obstructive/restrictive lung diseases vary. Even with this, one can see that with increasing years of exposure, the risk of abnormal lung diseases are high (21.9% for less than 9 years of exposure) through to 40% for exposure of 20 years or more. When the table is conventionally oriented and the percentages are studied columnwise, we get the following table:

Table 1. Conventionally oriented table studying association between years of exposure and lung disease status

Duration	Normal (%)	Abnormal(%)	Restrictive (%)	Obstructive (%)	Mixed (%)
< 5	1 (0.78)	1 (1.67)	1 (2.78)	0 ())	0 (0)
5—9	25 (19.5)	7 (11.7)	4 (11.1)	3 (23.1)	0 (0)
10—14	45 (35.2)	12 (20.0)	7 (19.4)	3 (23.1)	2 (18.2)
15—19	18 (14.1)	14 (23.3)	8 (22.2)	3 (23.1)	3 (27.3)
>=20	39 (30.5)	26 (43.3)	16 (44.4)	4 (30.8)	6 (54.6)

It should be clear from the same table as presented in Table 2 in the report but now reformatted that prolonged exposure to asbestos fibers are associated with increasing risks of restrictive lung diseases

and less likely to be associated with increased risk of obstructive lung diseases according to the findings of this limited study itself.

Conclusion

This study had several methodological shortcomings and biases that need to be addressed before this study can be used as a valid evidence base for making policy decisions. If necessary and possible, we can reanalyze the original data, or re-do the investigations. A more serious approach to study any association between exposure to asbestos dust and health effects with more rigorous epidemiological methods is necessary.