Occupational Medicine 2007;**57**:569–574
Published online 4 August 2007 doi:10.1093/occmed/kqm080

Observed and predicted silicosis risks in heavy clay workers

Brian G. Miller and Colin A. Soutar

Background There is increasing pressure to tighten the regulation of workers' exposures to airborne silica, which can lead to severe and in some cases rapid development of disease. However, estimated risks from respirable silica vary greatly across industries.

Aim To clarify differences in risks between workers in the heavy clay and coal industries with documented exposures to respirable silica, in order to assist decisions on whether further investigation of possible differences might be justified.

Methods We applied a published equation for radiological risks from exposure to respirable silica, from a study of Scottish coalworkers (with unusually high exposures) to exposure estimates from an epidemiological study of heavy clay workers, by the same research team and using similar methods.

Results The equation based on coalworkers' risks predicted in the heavy clay workers 31 cases of abnormalities at grade 2/1+ on the International Labour Organization scale, greatly in excess of the eight cases observed. Statistical variation is an implausible explanation ($P < 0.0001$).

Conclusions While there were some methodological differences between the studies, the disparity in risks provides some support for the case for further investigation of possible differences.

Key words Coal; heavy clay; risk; silica; silicosis.

Introduction

Health hazards of exposure to respirable crystalline silica (quartz) in certain industries have been well documented for centuries. However, there has been much debate about the transferability of epidemiological results between industries, concerning the risks of silicosis [1,2] and of lung cancer [3–5]. The risks presented by respirable silica vary greatly, probably with the age and condition of the quartz particles and their contact with other minerals such as clays.

The current debate over occupational exposure limits for respirable quartz in the UK and elsewhere is driven by worst-case scenarios such as that experienced in a Scottish colliery. In a recent series of studies, Buchanan *et al.* [6,7] demonstrated a strong exposure–response relationship between cumulative exposure to respirable quartz and subsequent development of radiographic abnormalities. The regression equations summarizing these relationships became prominent in the regulatory debate.

Workers in the heavy clay industry are also exposed to respirable dust containing quartz. In a study at 18 sites [8,9], radiographic abnormalities were present but relatively infrequent compared to other quartz-exposed workers. These studies showed evidence of a relationship with estimates of individual exposure to respirable dust and quartz.

The results seemed to suggest that the risks in the heavy clay industry were lower than those in the Scottish colliery. However, a more studied comparison was needed, to take into account any differences between the exposures experienced. The present limited study was therefore undertaken to examine whether the published risk equations from the Scottish colliery study correctly predicted the frequencies of pneumoconiosis observed in the study by Love *et al.* [8,9]. The results from this approach may be easier to interpret than comparing coefficients from logistic regression analyses from the two studies.

The aim of this study was to compare observed frequencies of radiographic abnormalities in heavy clay workers [8] with those predicted from an exposure–response relationship in Scottish coalworkers [7].

Institute of Occupational Medicine, Research Avenue North, Riccarton, Edinburgh, EH14 4AP, UK.

Correspondence to: Brian G. Miller, Institute of Occupational Medicine, Research Avenue North, Riccarton, Edinburgh, EH14 4AP, UK.
Tel: +44 131 449 8044; fax: +44 870 850 5132;
e-mail: brian.miller@iom-world.org

© The Author 2007. Published by Oxford University Press on behalf of the Society of Occupational Medicine.
All rights reserved. For Permissions, please email: journals.permissions@oxfordjournals.org

Methods

Love *et al.* [8] employed a job-based approach to estimating individual exposures to respirable dust and to respirable silica in the heavy clay industry. Estimates of mean respirable quartz concentrations were based on a cross-sectional programme of intensive personal sampling and characterization of respirable dust. There was variation in the concentrations between the 18 sites visited and within the 12 occupational groups at each site. Mean concentrations were calculated for combinations of site and occupational group, and were considered appropriate for jobs at these sites over at least the previous 20 years, except on the eight sites where tunnel kilns had replaced Hoffmann kilns. At these sites, adjustment factors were applied from the date of change. For heavy clay jobs at sites other than that where the employees were surveyed, job-specific average concentrations were applied [8]. No estimates were made of exposures in jobs outside the heavy clay industry. To calculate an individual's cumulative exposure to respirable quartz, the duration in years of each job in the heavy clay industry was multiplied by the appropriate mean respirable quartz concentration in milligram per cubic metre. Exposures were then summed over all an individual's jobs, to give a total cumulative quartz exposure.

Worldwide, most of the exposure–response relationships for coal workers have been based on estimated cumulative exposures, usually up to the time of measurement of the response. Because the response to respired silica may depend not only on the total exposure but also on its residence time and possibly on the intensity of peak exposures, the analyses of Buchanan *et al.* [6,7] used a more detailed approach. The exposure data for the coal workers were in two parts, individual airborne concentration measurements (representing a range of coalmine occupations) and the percentage of crystalline silica in the dust determined from pooled samples. Data on the time spent in these different occupations were available accumulated by quarter year and was matched to mean concentrations of respirable dust and silica for those quarters. This facilitated analyses using exposure metrics more complicated than simple cumulative exposure, investigating the influence of timing and intensity of exposure.

Detailed analyses of the responses in the Scottish colliery [10] showed no effect of smoking on the risk of opacities 2/1+, as expected showing that small opacities of this severity are not caused by smoking. The risks were concentrated in men who had worked in coalface jobs in one seam where unusually high quartz concentrations had been recorded between about 1970 and 1976, and among those men there was no evidence that risks varied with age. The subsequent analyses of Buchanan *et al.* [7] therefore resulted in models to predict risk that depended solely on the exposures to respirable silica. One well-fitting model split exposures into two components, depending on whether the assigned mean quartz concentration was above or below 2 mg/m^3. The results of this analysis have featured strongly in the UK Health and Safety Executive's risk assessment for possible limits, and it was decided for the present study to follow this model.

The exposure–response relationship of Buchanan *et al.* [7] was based on risks assessed by a radiographic follow-up study ~15 years after the exposures ceased. We therefore returned to the source data on times spent in occupational groups and mean concentrations, and calculated risks for heavy clay workers based on re-calculated exposures that omitted all contributions from the 15 years immediately prior to the date on which the subject was surveyed.

Exposures are calculated by multiplying time spent in a job by average concentration, so the units of an exposure are mass × time/volume. In research for the coal industry, exposures were traditionally expressed as gram hours per cubic metre (gh/m^3). However, Love *et al.* [8,9] expressed their concentrations in milligram years per cubic metre (mgy/m^3). The coal research, including Buchanan *et al.* [7], assumed 1740 working hours in a year. On this assumption, exposures in mgy/m^3 can be converted to gh/m^3 simply by multiplying by 1.74. We have converted the heavy clay exposures in that way, since the risk equations of Buchanan *et al.* [7] were expressed in gh/m^3.

Results

The principal results of Love *et al.* [8] were based on 1831 men from the heavy clay industry who all had job histories, data on smoking habits and radiographs of sufficient quality. All the results presented here refer to that set of men.

Figure 1 compares the distributions of cumulative quartz exposures in the heavy clay workers, omitting the 15 years prior to survey, and for comparison, the respirable quartz exposures of 371 coalworkers aged 55–74, on which the exposure–response relationships [6,7] were based. In the box-plots, the interquartile range between the 25th and 75th percentile values is drawn as a box with a line indicating the median, whiskers outside the box extend to the 10th and 90th percentiles and the 10% smallest and 10% largest values are shown as individual points (here triangles).

The restricted exposures in clayworkers omitting the last 15 years before the surveys were considerably lower, on average, than those of the coalworkers. In particular, the median of the restricted exposures was indistinguishable from zero, because 1025 of the heavy clay workers had no exposure before the 15-year cut-off. Nevertheless, the exposures from both industries covered broadly the same range.

In the context of silicosis, category 2/1 or greater small opacities represents well-established disease. The analyses of Buchanan *et al.* [7] fitted logistic regression equations for the risk of showing radiographic small opacities at a profusion category 2/1 or greater (2/1+). The equation can be used to calculate a predicted risk in two steps as follows:

$$l = -4.826 + 0.4434 \times \mathrm{CE}_{<2} + 1.323 \times \mathrm{CE}_{>2},$$

$$\mathrm{risk}(2/1+) = \mathrm{e}^{l}/(1 + \mathrm{e}^{l}) \times 100\%,$$

where $\mathrm{CE}_{<2}$ and $\mathrm{CE}_{>2}$ represent the cumulative exposures to respirable quartz contributed by concentrations above and below 2 mg/m^3. In the heavy clay workers, there was no contribution from concentrations >2 mg/m^3, so the first part of the formula simplified to

$$l = -4.826 + 0.4434 \times \mathrm{CE}_{<2}.$$

These equations were based on 371 coalworkers aged 50–74 years when surveyed between 1990 and 1991 and on exposures accrued from 1964, with some men exposed to particularly high peak concentrations of quartz in the early 1970s. The gap between the last significant quartz exposure and the surveys varied by individual, but for many men it was around 15 years [11].

If we substitute zero for the exposures in these formulae, we predict the risk of showing abnormalities in the absence of any quartz exposure (although such predictions may be less secure, implying an extrapolation outside the range of the data). Here, this leads to a prediction of 0.8% risk of 2/1+ in unexposed individuals, which is ignorable. A lifetime cumulative quartz exposure of 20 gh/m^3 predicts a 98% risk of 2/1+ opacities.

Risk predictions for each of the 1831 heavy clay workers were calculated and are summarized in Table 1, which shows, for each of five exposure groups, the smallest and largest exposure, and the median and mean cumulative exposures calculated with 15 years omitted for latency. There were 1025 men with zero contributing time in heavy clay occupations, and therefore zero quartz concentrations. The other four groups contain equal numbers of men; in these, the mean and median exposures were very similar except in the group with the highest exposures, which was heavily skewed to the right. Within each group are tabulated the observed frequency (%) of opacities 2/1+, and for comparison the mean of the predicted risks. Approximate 95% confidence intervals on the observed and predicted risks are based on assumptions of binomial variation. The predictions are clearly much greater than the corresponding observed frequencies in all the groups.

Figure 2 summarizes the comparison in numbers of observed and predicted cases, cumulated over the ordered distribution of cumulative exposure estimates. Each heavy clay worker is represented by a small triangle,

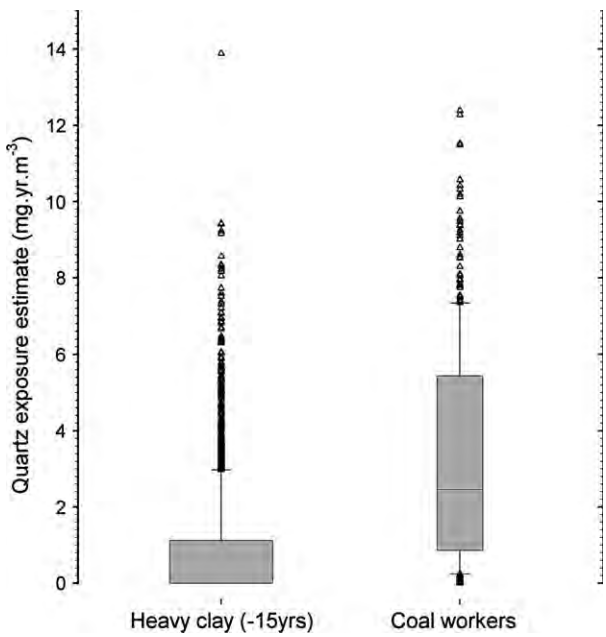

Figure 1. Box-plots summarizing distributions of estimated cumulative exposures to respirable quartz in heavy clay industry (with the most recent 15 years' exposure omitted for latency) and for Scottish coalworkers.

Table 1. Predicted risks and observed frequencies of radiographic abnormalities (with 95% confidence intervals), grouped by cumulative quartz exposure (with last 15 years omitted for latency)

No. of men	Quartz exposure (gh/m^3)				Risk of opacities profusion 2/1+ (%)	
	Minimum	Median	Mean	Maximum	Observed (95% CI)	Predicted (95% CI)
1025	0.00	0.00	0.00	0.00	0.20 (0.00, 0.47)	0.80 (0.25, 1.35)
201	0.003	0.25	0.26	0.56	0.00 (0.00, 1.03)	0.90 (0.00, 2.20)
202	0.56	0.93	0.94	1.39	0.99 (0.00, 2.36)	1.21 (0.00, 2.68)
201	1.40	2.00	2.02	2.74	0.50 (0.00, 1.47)	1.95 (0.03, 3.85)
202	2.74	4.05	4.55	13.88	1.49 (0.00, 3.15)	7.28 (3.69, 10.86)
1831	Total				0.44 (0.13, 0.74)	1.64 (1.10, 2.28)

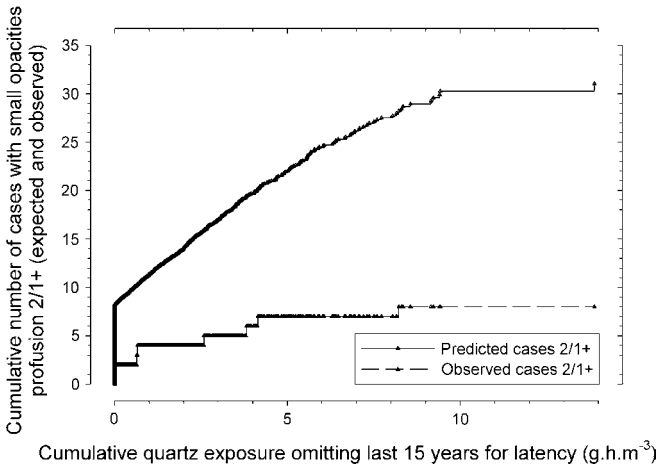

Figure 2. Predicted risks and observed abnormalities, against cumulative quartz exposure.

and the line rises at each exposure point at which a subject had a radiograph scored 2/1+.

Since predicted risks are independent, they can be summed over the workers, and we may therefore calculate in the same way a cumulative distribution for the predicted risks, shown by the upper line. Here the triangles have the same exposure distribution horizontally, but the increments correspond to the individual predicted risks.

The upper line shows that the coalworkers' equation would predict 31 cases of opacities 2/1+ for this distribution of silica exposures. The lower line terminates at eight, being the number of 2/1+ cases among the heavy clay workers. The predicted risks are hugely in excess of the cases actually recorded, across the whole exposure distribution.

Discussion

We have found that the prediction equations based on observed silicosis risks in coalworkers predict much higher risks than were observed in the heavy clay workers studied, after we ignored the last 15 years of exposure for latency. Predictions of the risk of showing abnormalities of profusion grade 2/1 or higher (2/1+), usually considered a prerequisite for compensation, suggested an expected number of 31 cases, whereas only eight were observed [8].

This discrepancy cannot be explained by mere statistical variation: assuming a Poisson distribution, $P(X \leq 8 \mid \mu = 31) < 0.0001$. It is clear that the observed frequency of abnormalities in the heavy clay workers was much lower than the equation of Buchanan *et al.* [7] predicts, suggesting that such a prediction is based on formulations of risk that may not be relevant for the heavy clay industry.

The present prediction relies on an equation from the analysis of silica-related risks in a Scottish colliery, which was part of the Pneumoconiosis Field Research (PFR) programme in selected British collieries between the 1950s and the 1980s. The characterization of individual exposures to respirable quartz and dust in the PFR was based on a detailed and sustained programme of sampling in the vicinity of a wide range of different underground jobs, and the resulting exposures were considered to be of a detail, range and quality unmatched in any occupational study except those involving the use of individual radiation badges. The analysis leading to the prediction equations was unusually detailed [6].

The survey of the Scottish coalworkers that underpinned the risk estimates took place around 10 years after the colliery closed, and it proved much harder to contact the men and to recruit them for study as leavers from the industry than had been the case while they were still employed. It is therefore not known to what extent non-response may have affected the results, but >50% of the survivors were surveyed, and we have no reason to believe that they were seriously atypical. Even a radiographic profusion grade of 2/1 is usually without noticeable symptoms, so we do not expect that the responders will have been seriously biased with respect to radiographic abnormalities. In any case, if we had believed that response was biased away from the most seriously affected, this could not plausibly have led to an overestimation of risk in those responding. The focus on 2/1+ as a response precludes confounding of the outcome with the low-grade opacities (usually at profusions 0/1, 1/0 or even 1/1, and of predominantly irregular shape) that can be observed in long-term heavy smokers.

The study of heavy clay workers [8,9] was based on workers employed in the industry at the time of the surveys. Pilot work had suggested that response rates in leavers would be so low as to be unsatisfactory, and leavers were not studied. In another study of coal miners [12], leavers showed slightly higher prevalences of radiographic abnormalities than current employees (7% in current men, 9% in a slightly older group of leavers under the age of 65), but the exposure–response relationships were the same. If a similar pattern existed in the clay workers, the true prevalence of radiographic abnormalities might have been slightly underestimated by this study, but this seems unlikely to have been sufficient to account for the very low observed prevalence.

Individual radiographs were taken by the same mobile units that had been used for the studies of coal workers, and the radiographs were read to the International Labour Organization standards, by three readers with extensive experience of reading coal and other workers' chest radiographs. It is well recognized that reader differences in interpretation occur, but the reading panels in the two studies had two of their three readers in common. Therefore while, in theory, between- and within-reader

differences could have had some influence, it is quite improbable that reader variation could account for the large difference between predicted and observed incidence.

While exposure characterization in the coalworkers was based largely on a detailed and prospective programme of measurements and job records, characterization in the clay workers was based on an extensive cross-sectional programme of personal sampling and occupational histories. An important difference was identified between kiln types, with conditions in jobs in Hoffman kilns 50% dustier than the same jobs in tunnel kilns. Reconstruction of past exposures by experienced exposure assessors took this into account. The intentional selection of plants where conditions had not changed significantly for several decades should have minimized any bias in the exposure estimates, but the extent and direction of any residual bias is uncertain.

The personal sampling employed in the heavy clay study contrasts with the procedures used in the PFR studies of coalworkers, where the samples were taken by static samplers, carried by nominated workers portal to portal and placed in positions that represented their personal exposures. However, for respirable dust particles within the coalmining environment, the static samplers were expected to return appropriate concentrations, and direct comparisons in coalface occupations showed that personal sampling returned average concentrations only 8% higher than static samplers [13]. Again, this small difference cannot explain the differences in prevalence of opacities.

In the coalworkers' study, most of the men seen had had little or no exposure to dust, and negligible exposure to quartz, in an approximately 15-year period from the mid-1970s to the follow-up surveys in 1990–01, but many of them showed at follow-up considerable progression of abnormalities over that period: this is typical of silica exposures, but not of coal mine dust. Some workers were exposed to particularly high quartz concentrations in one seam in the early 1970s [10], and opacities were observed in a few men as early as 1978, in a colliery with very little history of dust-related pneumoconiosis [14]. In some other industries, exposure to airborne quartz particles with freshly fractured surfaces can lead to abnormalities appearing rapidly, and developing for considerable periods after exposure ceases.

The exposures for the heavy clay workers had originally been calculated from job histories right up to their surveys [9], but this made no allowance for latency, however defined. We have attempted to allow for potential latency of effects by calculating an alternative exposure that omitted the 15-year period up to survey. The quartz exposures driving the coalworkers' responses had all been experienced within around 20 years of the analysed responses, while some of those in the heavy clay workers predated this; had a suitable model been available to allow for this, it is likely that the risks predicted for the heavy clay would have been increased, and this would have accentuated the gap between prediction and observation. We believe that the discrepancy between the results of the heavy clay and coalworkers' studies cannot be explained by potential latency.

The Scottish coalworkers were part of a longitudinal study of respiratory health in the industry, and the follow-up survey from which the prediction equations were derived took place when they were no longer employed in coal mining. The study of heavy clay workers, on the other hand, was a single cross-sectional survey of current workers. Many of the heavy clay sites surveyed are still in production. This provides a number of options for further study of the industry, tailored to the specific scientific questions of interest. Possibilities include:

- a second longitudinal study of current workers, and
- a follow-up study of the workers seen in the first study.

A study of current workers would have the advantage of relatively high response rates, but would enable the study of progression in only that proportion of the workers still employed, which may be small. Experience has shown that response rates can be very poor when attempting to recruit leavers.

Key points

- Risks of silicosis in heavy clay workers were much lower than predicted from an influential study of coalworkers.
- Silica risks may not be well characterized by mass exposures alone.
- Regulators may need to consider context when setting exposure limits for respirable silica.

Funding

British Ceramic Confederation.

Conflicts of interest

None declared.

References

1. Pilkington A, Maclaren W, Searl A, Davis JMG, Hurley JF, Soutar CA. *Scientific Opinion on the Health Effects of Airborne Silica*. IOM Report TM/95/08. Edinburgh, UK: Institute of Occupational Medicine, 1995.

2. Steenland K. One agent, many diseases: exposure-response data and comparative risks of different outcomes following silica exposure. *Am J Ind Med* 2005;**48**:16–23.
3. International Agency for Research on Cancer Working Group. *Silica, Some Silicates, Coal Dust and Para-Aramid Fibrils. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans*, vol. 68. Lyon: IARC, 1997.
4. Soutar CA, Robertson A, Miller BG, Searl A, Bignon J. Epidemiological evidence on the carcinogenicity of silica: factors in scientific judgement. *Ann Occup Hyg* 2000;**44**: 3–14.
5. Steenland K, Mannetje A, Boffetta P *et al.* Pooled exposure-response analyses and risk assessment for lung cancer in 10 cohorts of silica-exposed workers: an IARC multicentre study. *Cancer Causes Control* 2001;**12**:773–784.
6. Buchanan D, Miller BG, Soutar CA. *Quantitative Relationships Between Exposure to Respirable Quartz and Risk of Silicosis at one Scottish Colliery.* IOM Report TM/01/03. Edinburgh, UK: Institute of Occupational Medicine, 2001.
7. Buchanan D, Miller BG, Soutar CA. Quantitative relations between exposure to respirable quartz and risk of silicosis. *Occup Environ Med* 2003;**60**:159–164.
8. Love RG, Waclawski ER, Maclaren WM *et al. Cross-sectional Study of Risks of Respiratory Disease in Relation to Exposures of Airborne Quartz in the Heavy Clay Industry.* IOM Report TM/94/07. Edinburgh, UK: Institute of Occupational Medicine, 2004.
9. Love RG, Waclawski ER, Maclaren WM *et al.* Risks of respiratory disease in the heavy clay industry. *Occup Environ Med* 1999;**56**:124–133.
10. Miller BG, Hagen S, Love RG *et al. A Follow-up Study of Coalminers Exposed to Unusual Concentrations of Quartz.* IOM Report TM/95/03. Edinburgh, UK: Institute of Occupational Medicine, 1995.
11. Miller BG, Hagen S, Love RG *et al.* Risks of silicosis in coalworkers exposed to unusual concentrations of respirable quartz. *Occup Environ Med* 1998;**55**:52–58.
12. Soutar CA, Maclaren W, Annis R, Melville A. Quantitative relations between exposure to respirable coalmine dust and coalworkers' simple pneumoconiosis in men who have worked as miners but who have left the industry. *Br J Ind Med* 1986;**43**:29–36.
13. Hadden GG, Jones CO, Thorpe HL. *A Comparative Assessment of Dust Surveillance Procedures Including the Use of Personal and Fixed Position Sampling Instruments. Final Report on CEC Contract 6253-21/8/015.* IOM Report TM/77/15. Edinburgh, UK: Institute of Occupational Medicine, 1977.
14. Seaton A, Dick JA, Dodgson J, Jacobsen M. Quartz and pneumoconiosis in coalminers. *Lancet* 1981;**2**:1272–1275.