Applied Occupational and Environmental Hygiene

ISSN: 1047-322X (Print) 1521-0898 (Online) Journal homepage: https://www.tandfonline.com/loi/uaoh20

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Epidemiologic studies of embalmers and funeral directors have found excess risks of mortality due to leukemia and brain cancer. To investigate specific occupational exposures that might account for these associations, a case-control study of these diseases among embalmers is under way. To quantify exposure levels for this study, a series of embalmings was performed using an experimental design to determine the effect of certain work parameters on the concentration of airborne contaminants. Personal exposures and area concentrations of formaldehyde, methanol, phenol, and particulates were measured during 25 embalmings while controlling the level of ventilation, the concentration of the embalming solution, and the type of case (autopsy or intact body). In addition, bischloromethyl ether (BCME) and selected microorganisms (total, fungi, and bacteria) were measured during a few embalmings. Personal formaldehyde exposures ranged from 0.31 to 8.72 parts per million (ppm) for full-period exposures (51–121 min) with an arithmetic mean (AM) of 2.58 ppm, a geometric mean (GM) of 1.90 ppm, and a geometric standard deviation (GSD) of 1.88. Peak exposures for 15 min were as high as 21 ppm. Methanol levels ranged from 0.54 to 21.83 ppm (GM = 3.77, GSD = 4.03). Particulate mass concentrations were low (AM = 0.26 mg/m^3, GM = 0.21 mg/m^3), and measurable phenol levels were observed in only 40 percent of procedures. Airborne microorganisms were also found to be at low levels and no BCME was detected. By analysis of the means it was found that ventilation played the most important role out of three variables that were controlled. Analyses will be performed to determine if regression models can be used to predict exposure levels in the epidemiologic study.
Stewart, P.A.; Herrick, R.F.; Feigley, C.E.; Utterback, D.F.; Hornung, R.; Mahar, H.; Hayes, R.; Douthit, D.E.; Blair, A.: Study Design for Assessing Exposures of Embalmers for a Case–Control Study. Part I. Monitoring Results. Appl. Occup. Environ. Hyg. 7(8):532–540; 1992.

Introduction

Epidemiologic studies have consistently noted excess mortality risks for leukemia and brain cancer among embalmers, anatomists, and pathologists.(1–6) Although these findings suggest possible associations with formaldehyde exposure, none included a detailed assessment for formaldehyde or any of the other exposures that may be experienced in embalming or in tissue preservation.(7) The evidence for excesses of leukemia and brain cancer among industrial workers exposed to formaldehyde is less convincing.(8) This inconsistency suggests perhaps that the pattern of formaldehyde exposure (such as peaks) or other chemical exposures in the embalming environment might account for the excesses among embalmers. Detailed exposure evaluations are needed to evaluate this issue.

To accomplish this, we have initiated a project to evaluate cancer risks among embalmers and funeral directors in relation to specific exposures arising from the practice of embalming. This project consists of three parts: a proportionate mortality study of embalmers, a nested case–control study of leukemia and brain cancer with a detailed exposure assessment, and a biologic monitoring project designed to identify early damage to critical tissues from recent exposures to formaldehyde.

The first part of this study, a proportionate mortality study of over 4000 deceased embalmers, found excesses of non-Hodgkin's lymphoma and cancer of the nasopharynx, in addition to leukemia and brain cancer.(9) The second part of the investigation, a nested case–control study of these subjects dying of these latter cancers, is designed to associate cancer risks with quantitative estimates of specific exposures on the basis of the work and exposure histories of the subjects. To develop quantitative exposure estimates, information on the chemicals used, work practices followed, and the exposure conditions experienced by the subjects are being obtained by interview of the next of kin or work colleagues of the subjects and linked to the monitoring data.

Various approaches have been taken to develop quantitative estimates of exposures in epidemiologic studies. Modeling of monitoring data provides an objective and therefore attractive approach. If sufficient monitoring data were available on how the various working conditions and work practices experienced by these workers affect levels of exposure, predictions from the model could be linked with the work practice information collected from the interviews to estimate exposure levels. There is, however, little monitoring information in the literature[10–14] to perform this type of analysis. To generate this information, we conducted an experimental air-monitoring study at a college of mortuary science. The purpose of the study was to evaluate the relative importance of various workplace conditions on the air levels of several chemicals during the embalming procedure. Environmental conditions were set up that simulated historical conditions of less effective ventilation controls and solutions of higher formaldehyde concentrations for both intact and autopsied bodies. Results of the air monitoring under the various experimental conditions are presented here.

These data will be used to develop predictive models using the variables found to be important in the study. The models will be tested by conducting air monitoring in several funeral homes. If validated, the models will be used to predict the exposure levels received from the work practices and environment of the subjects in the case–control study.

Methods

Study Design

Prior to the start of the experiment, information on work practices and chemicals used was collected from a review of the literature and from visits to funeral homes in the Washington, DC area. Fourteen funeral homes were selected to get a representative picture of the variability of embalming practices. Selection criteria for these visits included location (urban and rural), size of the establishment, and type of clientele (white non-Jewish, black non-Jewish, Jewish). The variables that appeared to be most likely to affect exposure levels were the level of ventilation; the strength, or concentration, of the embalming solution; and the type of case, that is, intact or autopsied.

A factorial design was developed to evaluate the effects of three levels of ventilation, two levels of the solution strength, and two levels of type of case (intact or autopsy). To have a power of more than 95 percent to detect a difference of 35 percent between levels of any of the design factors at a significance level of 0.05, 48 embalmings were originally scheduled to be monitored, with four replicates for each set of conditions. Because of difficulties in obtaining cases that were considered to be representative of normal embalming practices and because of unanticipated costs, the number was modified to 24, resulting in a power of 82 percent for detecting 35 percent differences between levels of design factors. The decision to reduce the number of embalmings in the study was made after the experiment was under way. At the time of this change, one set of conditions had already been monitored three times, so that a total of 25 embalmings were monitored.

Each particular set of the three conditions was ordered randomly. When the first embalming was scheduled, the first set of conditions was arranged; thereafter, the conditions of the subsequent embalmings were those dictated by the ordered list. Because the type of case being embalmed and the strength of solution was dependent on the condition of the case being embalmed, the conditions assigned by the ordering could not always be followed. In such situations, the next set of conditions appropriate to the case was selected, and the skipped set remained at the top of the list, to be selected for the next appropriate incoming case. This random ordering was intended to reduce any bias in exposure levels that might have resulted from changes in seasons, work practices, and so on, over the 3 months of the study.

The embalmings took place in a mortuary college's isolation room, which was designed for the containment of infectious cases. The room was 3.0 × 3.7 m with a 2.4-m wall (10 × 12.1 × 8 ft) and was under negative pressure, with air exhausted through a duct opening 20 × 20 cm (8 × 8 in.) located 28 cm (11 in.) from the floor (Figure 1). To reduce the variability that could result from different work practices, one embalmer (DED) performed all 25 embalmings. He worked to the right of the table in the figure. On occasion, a

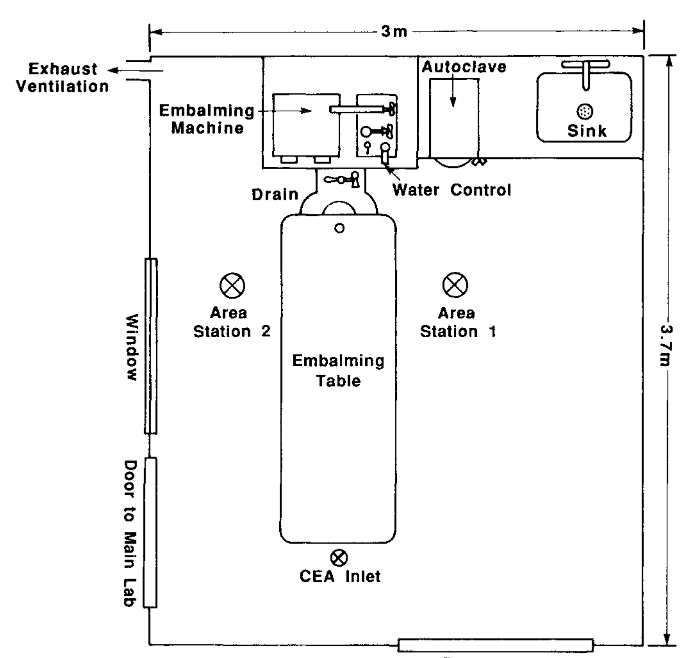

FIGURE 1. Room layout. See text for definition of area stations 1 and 2.

student assisted by preparing the equipment and making incisions, but did not actually inject the embalming solution or apply the other chemicals. Mixing of the solution was done at the embalming machine.

Because manipulation of the workplace conditions could result in exposures to chemicals above the permissible limit, the embalmer, any student present in the room, and the industrial hygienist performing the monitoring wore air-supplied hoods, a long laboratory coat or scrub suit, disposable shoe covers, and latex gloves. Cases known to be infected with hepatitis, AIDS, meningitis, and other infectious diseases were not included in the study.

Experimental Variables

The ventilation rate was measured by using a Shortridge Instruments Flow Hood, calibrated according to manufacturer's specifications. The room was exhausted at a mean rate of 215.1 ft^3/min (standard deviation (SD) = 0.6) or 13.7 air changes per hour. The air intake was located in the ceiling centered over the embalming table. Ventilation rates were modified by blocking the overhead intake entirely and partially blocking the exhaust opening to achieve a moderate ventilation rate (mean of 85.7 ft^3/min (SD = 2.75) or 5.5 air changes per hour). The intake and exhaust were completely blocked to mimic a situation with no ventilation, although make-up air entered the room by infiltration around ceiling tiles and other small openings and the air-supplied hoods (6–18 ft^3/hr or 0.4–1.1 air changes per hour). Under all conditions of ventilation the doors were taped shut. The three levels of ventilation were measured on the first, the 37th, and the 76th day of the study.

Embalming fluids generally consist of formaldehyde, methanol, and additives (the latter varies by manufacturer and intended use). Embalmers usually maintain a number of fluids in the funeral home because the type of fluid needed depends upon characteristics of the case, including age, weight, and condition of the body. After selecting the appropriate fluid, the embalmer dilutes it in the embalming machine with the amount of water appropriate for the case. This diluted fluid, called a solution, is pumped throughout the arterial system to infuse the head and limbs with formaldehyde. For this study one arterial fluid, used for all embalmings, was diluted to achieve a concentration of 1.25 percent (low strength) or 2.5 percent (high strength). A second product, cavity fluid, is used to embalm the organs. Cavity fluid contains a higher concentration of formaldehyde than arterial fluid and is not diluted. One cavity fluid (concentration of 35 percent) was used for all embalmings. Cases that required other fluids or concentrations were excluded from the study.

The type of case was either autopsied or intact. For this study, autopsied cases were defined as having the internal organs removed. The organs were provided with the body.

When evaluating the exposures received by embalmers, several agents were identified as being possible etiologic agents to the diseases of interest. Historically, formaldehyde has been the active ingredient in embalming fluids, and methanol, a stabilizer to the formaldehyde, is another major constituent in most embalming fluids. Formaldehyde-ladened particulates were measured because of the possible association with nasal cancer.[8] Phenol is another often-encountered chemical in embalming chemicals. It has been reported that bischloromethyl ether (BCME), a recognized carcinogen, has been generated by a reaction of formaldehyde with an acidic solution.[15] BCME is a well-established carcinogen, although an association with the sites of interest in this study has not been reported.[7] Biologic agents were measured as a surrogate for viruses, which have been associated with brain cancer and leukemia.[16] Although the use of biologic agents as a marker of viruses is not known, an estimation of the level of agents was thought to be appropriate.

Formaldehyde Measurements

Personal and area air levels of formaldehyde were measured using the Occupational Safety and Health Administration (OSHA) method 52, which calls for sampling air through a tube filled with XAD-2 absorbent coated with (2-hydroxymethyl)piperidine (Supelco ORBO-24) and analyzing the sample by gas chromatography using a nitrogen-selective detector.[17] The standard error at 3 ppm is 7.3 percent, and the method is not reported to be affected by humidity.[17]

Personal samples were taken to cover each of the major tasks of the embalming process.[12] Three partial-period personal samples were generally collected during the embalming of intact bodies and four samples were usually collected for autopsied bodies. The first partial-period sample, which lasted about 20 min (SD = 8.1 min), covered the preparation of the body, washing and shaving of the body, making the incisions, and mixing the embalming solution. The second sample, lasting an average 30 min (SD = 9.3 min), started with injection of the arteries with embalming solution and ended after any waste liquid that had collected in the abdominal cavity from the arterial injection had been removed.

For intact bodies, the third sample started with injection of cavity fluid into the internal organs of the intact bodies and ended after the instruments and room had been cleaned. These samples averaged 32 min (SD = 15.3 min) in duration. On certain intact cases, osmotic gel was used. This thick gel, containing concentrated (22 percent) formaldehyde, is liberally applied to the skin to allow formaldehyde to diffuse into parts of the body that cannot be reached by the arterial injection because of vascular obstruction. For cases on which osmotic gel was used, and for most autopsied bodies, the third sample also started with injection of cavity fluid, but ended at the closing of the incisions. A fourth sample covered the application of osmotic gel (which occurred after the incision closing) through final cleanup. These samples lasted an average of 9 min (SD = 6.7 min). The results of the partial-period samples are not reported individually, but combined to form a time-weighted average (TWA) for the embalming period. The sampling was done outside the air-supplied hood on the embalmer's shoulder. In addition to the personal samples, two full-period area samples were taken, one located about 0.7 m above the head of the embalmer at his normal working position (A1) and the other 1 m across the embalming table at the same height (A2) (see Figure 1).

Because embalming chemicals were stored in the room, an odor of embalming chemicals could generally be smelled in the empty embalming area. The air of the sealed room was monitored under the high ventilation rate for about 2 hours prior to the embalming to ensure that the exposure levels measured during the embalming procedure were due to the procedure and not to residual concentrations from a previous embalming.

The TGM-555 Toxic Gas Monitor manufactured by CEA (referred to here as the CEA instrument) and equipped with a digital data logger and strip chart recorder (RustRak Ranger, Gulton, Inc.) was used to measure real-time formaldehyde concentrations during the embalming procedure. The limit of detection (LOD) is 0.167 ppm. The intake for this instrument was located at approximately the breathing zone level at the head of the embalming table about 1 m from area samples A1 and A2 (see Figure 1). The instrument was zeroed and calibrated prior to and after each embalming.

Measurement of Other Chemicals

Methanol was monitored following the National Institute for Occupational Safety and Health (NIOSH) method 2000, using Supelco ORBO 52 solid sorbent tubes, and analyzed using a gas chromatograph.[18] Three full-period samples were collected during each embalming. One was a personal sample, and two were area samples that were placed together with the formaldehyde area samples.

Particulates are generated from the use of "paraform" and a phenol-containing cauterant. "Paraform," as used in embalming practices and also known as hardening compound, is actually an inert dust, often wood dust, that has been mixed with a small amount of paraformaldehyde (~3 percent). The hardening compound is used to directly treat the surface of organs of an autopsied body by breaking down and releasing formaldehyde. Particulates were collected at a flow rate of 2.0 L/min on polyvinyl chloride filters, and analyzed gravimetrically. Two personal samples were taken during each embalming—one a full-period sample, and one that started immediately prior to the opening of the paraform container and ran until the end of the embalming procedure. Two full-period area samples were also placed with the formaldehyde area samples.

Because paraform slowly releases formaldehyde, it was not known how the CEA instrument would respond to the dust, particularly if some of the dust remained in the sampling lines. To investigate this concern, paraform was mechanically dispersed in a chamber and the CEA instrument allowed to run. It was determined that the instrument responded positively to suspended paraform dust, but continued to respond to any dust deposited in the sampling lines for only a short period (<1 min). This response was considered acceptable.

Phenol, which is contained in the cauterant used to close incisions, was measured following OSHA method 32, using an XAD-7 solid sampling tube (Supelco Custom ORBO sorbent tubes), and analyzed by high pressure liquid chromatography.[19] One phenol sample was collected over the full period as a personal sample and two other full-period samples were collected as area samples located with the formaldehyde area samples.

Although disinfectants that were used to clean the working surfaces of the embalming room were alkaline in nature, two samples for BCME were taken with a Chromosorb 101 tube as a chlorine-containing disinfectant was being applied to the working surfaces. The samples were analyzed using gas chromatography and mass spectroscopy for BCME, benzene, and other organic chemicals.[20]

Measurement of Biologic Agents

Infectious cases had been excluded from the study, but to determine exposures to biologic fluids, tissues, and/or organisms from noninfectious cases, microorganisms were measured in two ways. Wipe samples of blood residue were taken on the working surfaces and gloves, and analyzed using the technique described by Beaumont[21], which employs Hemastix® to indicate the presence of blood. The results are determined colorimetrically and categorized as negative, nonhemolytic trace, hemolyzed trace, small, moderate, and large. Measurements were made for three embalmings, with five samples taken before the embalming and five taken after the embalming.

Airborne microorganisms were measured using a Mattson–Garvin Air Sampler, model 200, single-stage, slit impactor at a flow rate of 1.0 ft^3/min for 30 min. Duplicate samples were collected on two media: trypticase soy agar (TSA), which grows a wide range of microorganisms including fungi, and MacConkey's agar, which primarily grows gram-negative organisms and is therefore considered a better indicator of aerosolized body fluids.[22–24] These samples started with the removal of waste fluids by aspiration of the abdominal cavity and ended with closing of the cavity for the autopsied cases or with the end of the procedure for the intact cases. Four embalmings were sampled—two autopsied cases under low ventilation, one intact case under low ventilation, and one intact case under high ventilation.

Other Considerations

Temperature, wet-bulb temperature, and barometric pressure were also measured. All pumps were SKC model 224 constant flow sampling pumps and were calibrated before and after each embalming.

To assure accuracy and precision of the sample results, a quality control protocol was followed that included calibration of laboratory analytical instruments on a daily basis with known standards at five concentrations over the range of the expected concentrations. Other aspects of the quality control protocol were submission of at least one field blank per day, submission of spiked samples (coded as field samples) at three concentrations, and use of a sample custody form for each real, blank, or spiked sample. One formaldehyde, two phenol, and two methanol spiked samples per day were submitted the first week of sampling and once a week throughout the rest of the study.

Statistical Methods

Arithmetic means, their standard deviations, and F and t tests were calculated for all personal samples using standard SAS programs.[25] The t statistic tests whether the means of the samples are statistically different. Twenty of the first-period samples and five of the second-period samples were below the limit of detection. Nondetectable formaldehyde and methanol results were recalculated using the analytic limit of detection corrected for the air volume and divided by the square root of two.[26]

Results

The measured (observed) to spiked (expected) ratios of the 24 internal quality control samples for formaldehyde, taken over the study, are shown in Figure 2. When samples 14–16 exceeded the upper confidence limit, investigation of the analytical methods used by the American Industrial Hygiene Association-accredited laboratory found trace amounts of formaldehyde in the water used for dilution of the standards. Subsequently, the remainder of the samples were diluted with methanol. The effect of this change resulted in an increase in the LOD from 0.4 μg to 1.2 μg. Results for quality assurance samples 14–16 and the corresponding field samples were then calculated with the more accurate calibration data from the methanol dilutions. However, because formaldehyde contamination could not be confirmed or estimated in the earlier samples, no adjustment was made to those results.

There was good agreement between the observed and expected quality control samples. The regression equations for the methanol and phenol analyses were

$$\text{Methanol expected} = 1.05\ (\text{spike conc. in mg}) + 0.085 \quad (R^2 = 0.998)$$

$$\text{Phenol expected} = 0.986\ (\text{spike conc. in mg}) - 0.13\ \text{mg} \quad (R^2 = 0.985)$$

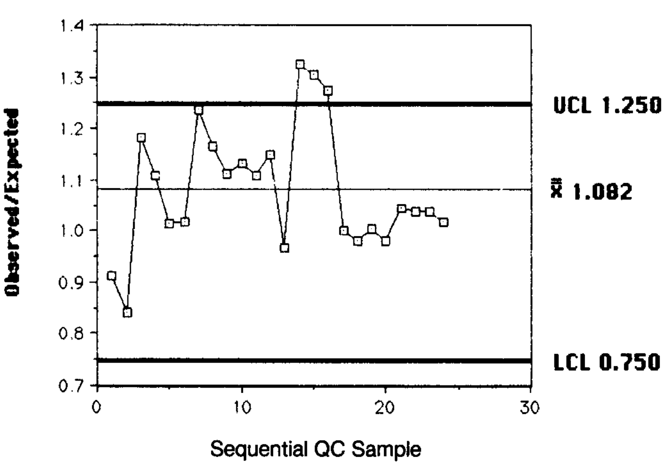

FIGURE 2. Results of quality control samples. UCL = upper confidence limit.

TABLE I. Air Monitoring Results*

	Formaldehyde (ppm)			Methanol (ppm)	Particulate (mg/m^3)
	Personal	Area 1	Area 2	Personal	Personal
Range	0.31–8.72	0.23–7.52	0.28–8.15	0.54–21.83	0.07–0.78
AM	2.58	2.03	2.16	7.90	0.26
SD	1.43	0.97	1.10	7.07	0.21
GM	1.90	1.43	1.60	3.77	0.21
GSD	1.88	1.61	1.66	4.03	1.81

*n = 25 for all substances, AM = arithmetic mean, SD = standard deviation, GM = geometric mean, GSD = geometric standard deviation.

The arithmetic mean (AM) of the personal samples was 2.58 ppm (SD = 1.43) and the results ranged from 0.31 to 8.72 ppm (Table I). The geometric mean (GM) TWA concentration for formaldehyde over the 25 procedures was 1.90 ppm and the variability of these air samples was relatively low (geometric standard deviation (GSD) = 1.88). The means and the variability of the two sets of area sample results for formaldehyde were somewhat lower than the personal samples (GM = 1.43 and 1.60 and GSD = 1.61 and 1.66).

Levels of methanol ranged from 0.54 to 21.83 ppm with an AM of 7.90 ppm, a GM of 3.77, and a GSD of 4.03 (Table I). Levels of particulates were low (AM = 0.26; GM = 0.21 mg/m^3) and variability was low (GSD = 1.81). Concentrations of phenol were generally below the LOD (n = 15) and never exceeded 0.55 ppm (not shown). In only two procedures did the concentration exceed 0.16 ppm; those occurred when large amounts of phenol-containing cauterant were used. No BCME or benzene was detected on either of the two samples. The mass spectrometer did, however, find toluene present, as well as small amounts of xylene, phenol, and other organic chemicals.

Results of sampling various working surfaces for blood residue ranged from negative to a moderate presence of blood residue, and there was little change (either increase or decrease) in the residue levels after an embalming had occurred. Table II presents the results of the microbial sampling in colony forming units per cubic meter of air (cfu/m^3). Low levels of organisms were found on both the TSA and MacConkey's agars. When the cases were autopsied (designs 22 and 24), few fungi were seen, and only total microbials are reported. For designs 6 and 23, however, fungi made up a large number of the total microorganisms found, and both types of organisms are reported. The presence of fungi on the agar may indicate high levels of airborne fungal spores. *Aspergillus fumigatus* was found on the agar from design 24, although at low levels. The concentration of gram-negative microorganisms, as measured by MacConkey's agar, was very low.[22] There appeared to be no increase in the airborne microorganism level from embalm-

TABLE II. Results of Microbal Samples (cfu/m³)

	TSA Agar				MacConkey's Agar			
Design:	22[A]	24[B,C]	6[D]	23[E]	22	24	6	23[F]
Sample	T[G]	T	T,F	T,F				
Air								
Before embalming	76	21	71, 63	32, 13	1	1	<1.2	6
During embalming	33	75	45, 36	124, 38	0	4	<1.2	6
After embalming	74	50	14,7	57,39	1	<1	<1.2	11
Wipe								
Outside glove	200	140	0	3[H]	2	0	0	0
Finger (glove removed)	45	1	1	45[H]	0	0	0	0

[A]Low ventilation, low solution strength, autopsied case.
[B]Low ventilation, low solution strength, autopsied case.
[C]*Aspergillus fumigatus* was found at low levels.
[D]Low ventilation, low solution strength, intact case.
[E]High ventilation, high solution strength, intact case.
[F]All colonies were fungi.
[G]T = total microorganisms, F = fungi.
[H]Bacteria count.

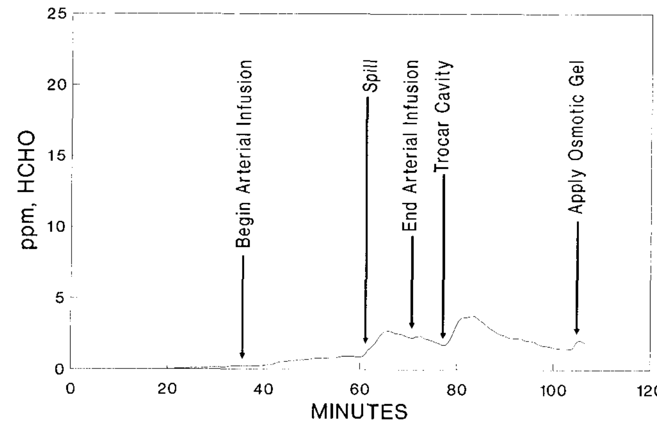

FIGURE 3. Real-time concentrations during an embalming under conditions of high ventilation, a high strength solution, and an intact case.

ing autopsied bodies; however, the wipe samples from the gloves showed much higher microorganisms from autopsied cases compared with intact cases.

The effect of the different variables on formaldehyde exposure levels can be seen in Table III. Higher air concentrations of formaldehyde were found under conditions of low ventilation, high concentration of solutions, and autopsied cases. Only the mean for the high ventilation rate, when compared with the means of either the medium or the low ventilation rate, was statistically significant. The occurrence of spills also affected levels (2.06 ppm with spills and 1.56 ppm without) and this difference was statistically significant. It is also interesting to note the decrease in the variability of the exposures with increasing levels of ventilation, although again, only the mean of the high ventilation rate, compared with the mean of either of the other two rates, was statistically significant.

Running 15-min averages from the CEA direct-reading instrument were calculated. The highest average seen was 21 ppm under conditions of low ventilation, high solution concentration, an autopsied case, and a spill (see Table III). Peak levels appeared to be affected primarily by ventilation and the presence of spills.

Figures 3–5 present the formaldehyde air concentration profiles over three embalming procedures as measured by the CEA instrument. Figure 3 shows results for a high ventilation rate, a high strength solution, and an intact case. The data indicated that mixing of solutions (which started at 11 min) contributed very little to the overall concentration. Once the procedure started, however, there was a gradual increase in formaldehyde concentrations with jumps in the concentration when paraform (at 80 min) or osmotic gel (at 103 min) was applied. A small spill of solution occurred at 62 min.

In Figure 4 the profile shows the effect of moderate ventilation, high strength solution, and an autopsied case.

TABLE III. Unadjusted Effect of the Variables on Formaldehyde Concentrations (ppm)

Variable	n	AM[A]	SD	Range	t[B]	F[C]	Peak
Ventilation rate							
Low	8	4.06	2.37	0.99–8.72	1.30	1.99	21
					(vs. medium)		
Medium	8	2.73	1.68	0.63–5.51	−2.52*	7.10*	16
					(vs. high)		
High	9	1.14	0.63	0.31–2.33	−3.38**	14.14**	7
					(vs. low)		
Solution concentration							
Low	13	2.41	1.67	0.49–5.51			16
High	12	2.78	2.42	0.31–8.72	0.45	2.10	21
Type of case							
Intact	12	2.27	1.65	0.31–5.51			20
Autopsied	13	2.87	2.36	0.63–8.72	−0.73	2.06	21
Spill							
No	13	1.66	1.56	0.31–5.85			13
Yes	12	3.58	2.06	1.37–8.72	−2.64*	1.73	21

[A]AM = Arithmetic mean, SD = standard deviation.
[B]Test of whether the two means are equal.
* = $p < 0.05$
** = $p < 0.01$
[C]Test of whether the variances are equal.

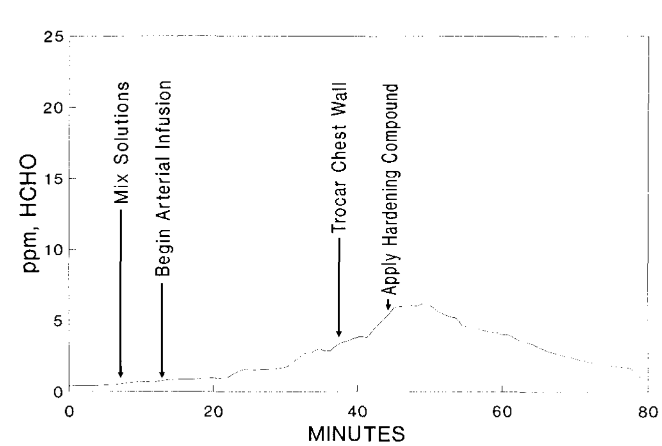

FIGURE 4. Real-time concentrations during an embalming under conditions of moderate ventilation, a high strength solution, and an autopsied case.

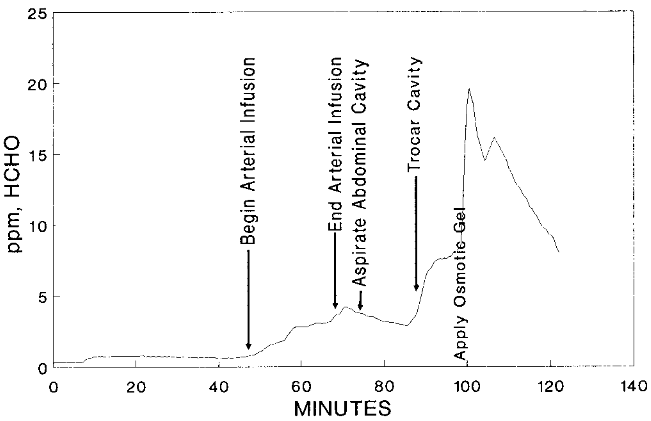

FIGURE 5. Real-time concentrations during an embalming under conditions of low ventilation, a high strength solution, and an intact case.

Again, mixing had a small, although slightly greater effect (reflecting the lower ventilation rates) than the procedure in Figure 3. The formaldehyde concentration also increased much faster and reached a higher level than in the first procedure shown, and it jumped with the application of the hardening compound. No osmotic gel was used in this procedure.

Figure 5 shows a very different profile from Figures 3 and 4. The sampling was performed under the same conditions as Figure 3 except that the ventilation rate was low. In this design, air concentrations increased much more rapidly and to much greater levels than under the other two procedures. The effect of osmotic gel was also much more dramatic under the low ventilation conditions than when the ventilation rate was higher.

Table IV shows the effect of the variables on the methanol concentrations. A concentration gradient was seen for the three ventilation rates, the concentration of solution, the type of case, and the occurrence of spills. None of the differences in the means was statistically significant. The effect of the same variables on particulate concentration is shown in Table V. The only statistically significant differences detected occurred when comparing high ventilation to either medium or low ventilation rates.

Discussion

This study reported here was designed to mimic workplace conditions that occurred more than 10 years ago, to provide quantitative estimates of exposures in a case-control study, and therefore may not represent current embalming practices. For example, concentrations of solutions used in this experimental design were higher than those typically used today. Nevertheless, we found concentrations similar to those reported by others.[10–14] The effects of the strength of solution, spills, and osmotic gel on exposure levels has not, to our knowledge, been examined by others. If these formaldehyde levels approximate exposures currently received, the results indicate a profession needing attention by the industrial hygienist. Although the levels do not generally suggest that the recent OSHA 8-hr TWA of 1 ppm[27] is likely to be exceeded if only one embalming is performed daily, many embalmers regularly perform more than one a day. If this occurs, the current standard could very well be exceeded. These data also indicate that the short-term exposure limit (STEL) of 2 ppm for 15 min could also be exceeded. The American Conference of Governmental Industrial Hygienists (ACGIH) has reduced the

TABLE IV. Unadjusted Effect of the Variables on Methanol Concentrations (ppm)

Variable	n	AM^A	SD	Range	t^B	F^C
Ventilation rate						
Low	8	11.72	6.96	2.16–21.83	1.63	2.25
					(vs. medium)	
Medium	8	6.91	4.64	1.92–13.73	−0.31	2.72
					(vs. high)	
High	9	5.95	7.65	0.54–20.65	−1.62	1.21
					(vs. low)	
Solution concentration						
Low	13	7.78	5.41	0.89–16.16		
High	12	8.46	8.32	0.54–21.83	0.24	2.37
Type of case						
Intact	12	6.91	7.26	0.89–20.65		
Autopsied	13	9.21	6.48	0.54–21.83	−0.84	1.26
Spill						
No	13	5.96	5.89	0.89–16.16		
Yes	12	10.43	7.22	0.54–21.83	−1.70	1.50

^A AM = Arithmetic mean, SD = standard deviation.
^B Test of whether the two means are equal.
* = $p < 0.05$
** = $p < 0.01$
^C Test of whether the variances are equal.

TABLE V. Unadjusted Effect of the Variables on Particulate Concentrations (mg/m^3)

Variable	n	AM^A	SD	Range	t^B	F^C
Ventilation rate						
Low	8	0.52	0.19	0.30–0.76	0.29	1.46
					(vs. medium)	
Medium	8	0.49	0.22	0.20–0.78	−2.50*	2.19
					(vs. high)	
High	9	0.26	0.15	0.07–0.55	−3.17**	1.50
					(vs. low)	
Solution concentration						
Low	13	0.43	0.21	0.20–0.76		
High	12	0.40	0.23	0.07–0.78	−0.39	1.28
Type of case						
Intact	12	0.41	0.24	0.07–0.78		
Autopsied	13	0.42	0.21	0.12–0.76	−0.12	1.32
Spill						
No	13	0.43	0.21	0.07–0.78		
Yes	12	0.41	0.23	0.12–0.74	0.27	1.12

^A AM = Arithmetic mean, SD = standard deviation.
^B Test of whether the two means are equal.
* = $p < 0.05$
** = $p < 0.01$
^C Test of whether the variances are equal.

threshold limit value (TLV) to 0.3 ppm as a ceiling value.[28] The NIOSH recommended exposure level (REL) is 0.16 ppm as an 8-hr TWA and 0.1 ppm as a 15-min ceiling.[29]

Formaldehyde 15-min running averages ranged up to 21 ppm, which are higher than others have reported. One study monitored over a half-hour period and found 0.4 and 2.1 ppm for intact and autopsied bodies, respectively.[10] Another took consecutive 15-min short-term measurements and reported that the highest values ranged from less than 0.2 to 2.9 ppm.[11] The differences from our study may be because we were able to measure real-time exposure levels and did not have to decide *a priori* when to take the 15-min samples.

Exposures to other chemicals were generally below legal and recommended exposure limits. The OSHA standard for methanol is 200 ppm and for phenol it is 5 ppm,[27] whereas we found levels less than 22 ppm and 0.50 ppm, respectively. The ACGIH TLVs for methanol and phenol are the same as the OSHA permissible exposure limits (PELs).[28] The NIOSH REL for methanol is 200 ppm for a TWA and 250 ppm for a 15-min STEL.[30] For phenol, the REL is 5 ppm for a TWA and 15.6 ppm for a 15-min STEL.

The presence of blood residue on the working surfaces prior to embalming suggests that normal cleaning practices may not remove all contamination. This could indicate a potential risk for blood-borne infectious diseases. In fact, a recent report suggests that members of this profession may have an increased risk of hepatitis.[31] The level of airborne microorganisms was measured as a surrogate for viruses. The level, <200 cfu for total microorganisms (including fungi) and <50 cfu for bacteria, is considered low.[22] Outdoor fungus spore levels can be 1000–100,000 cfu/m^3, while indoor levels may be less than a third of that.[32] Levels greater than 500 cfu/m^3 of bacteria suggest that remedial action be taken.[22] The number of airborne microorganisms appeared to be related to the number of people in the room, rather than the type of case. *Aspergillus fumigatus,* which poses a health risk only to an immunocompromised person, was found at low levels. Higher levels of microorganisms from wipe sampling the gloves were found when embalming autopsied cases than intact cases, but gloves appeared to reduce the actual exposure received by the hand. In design 23 (see Table II), the bacterial levels were much lower on the outside of the glove than on the hand. It could be that the bacteria were on the hand prior to the embalming.

These data will be used to quantitatively evaluate exposures in a case-control study. The findings presented in this paper suggest that ventilation and spills and, to a lesser degree, embalming of autopsied bodies and the concentration of solutions, affect exposure levels. The data will be used in models developed by multiple regression analyses to predict exposure levels to formaldehyde and other chemicals. This statistical approach will identify the independent contribution of the several variables identified here on the dependent variable (the exposure level). After the best predictor models have been developed they will be evaluated by monitoring in several funeral homes to allow comparison of the predicted levels to the monitoring results. If the models are validated, they will be used in the case-control study with information on the working conditions of the subjects obtained from administering a questionnaire to their next of kin and co-workers. Interviews with work colleagues of the subjects are included because it was expected that many next of kin would not be able to answer detailed questions on the workplace.

Modeling of exposure data has been performed in other studies to estimate quantitative levels of historical exposures.[33–35] These studies, however, have used historical data generated at the time of the exposure. We did not have such data available to us. This study is, therefore, unique in that the exposure data were generated especially for the purposes of this study. As such, it suggests a novel approach to evaluating exposure levels when data are nonexistent. It may be useful in other epidemiologic studies where historical monitoring data are not available but are needed to assess exposure levels.

Summary

This report describes an unusual approach for estimating exposure levels for an epidemiologic study. It was necessary because sufficient monitoring data were not available on this study population. To our knowledge, this type of experimental design for developing data for a statistical model has not been used previously for estimating exposure levels for case–control studies. Although this approach may not be feasible in a study where multiple jobs are held in multiple facilities, it may be useful in other case-control studies of particular professions or in a cohort study of a particular industry.

This report describes the methods used and results of the first phase of the exposure assessment process: the monitoring of air levels under controlled conditions for contaminants generated during the embalming procedure. Ventilation and the occurrence of spills were the major influences on exposure levels. In the next step, a statistical model will be developed that best explains the variables described here. Exposures will then be monitored in several funeral homes under normal conditions. If exposure levels can be predicted by the models, the variables and coefficients will be used with the information collected in the questionnaire to estimate exposure levels of the subjects in the case–control study.

Recommendations

Under conditions of low to moderate ventilation rates, embalming can result in formaldehyde concentrations that exceed the recent OSHA 8-hr TWA of 1 ppm and the STEL of 2 ppm for 15 min. Other exposures monitored appeared to be below recommended limits. Contamination of working surfaces with blood was found and could be a route for infectious diseases. Use of this type of design to estimate exposure levels in a case-control study should be considered when the members of the study population are in a single or limited number of professions and/or when monitoring data are not available.

Acknowledgments

The authors thank Dr. Michael McCawley, Dr. Eugene Kennedy, Virginia Ringenburg, and Michael G. Gressel at the National Institute for Occupational Safety and Health and Michael Shulsky at the Occupational Safety and Health Administration for their valuable assistance in this project.

Disclaimer

Mention of any product or manufacturer does not constitute endorsement by the National Cancer Institute or the National Institute for Occupational Safety and Health.

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Received 2/15/91; accepted 2/28/92