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Environmental Monitoring and Assessment of Short-Term Exposures to Hazardous Chemicals of a Sterilization Process in Hospital Working Environments

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In order to assess short-term exposures to ethylene oxide, formaldehyde and glutaraldehyde in a sterilization process, the authors conducted continuous environmental monitoring of these chemicals in the breathing zone of workers in 2 hospitals. The arithmetic mean of ethylene oxide was 1.2 ppm near unventilated cabinets housing sterilizing materials, and environmental concentrations of ethylene oxide could not be reduced under threshold limit values time weighted average by only managing general ventilation. Environmental concentration of formaldehyde was lower in a properly ventilated pathology division in which no large specimens were stored (0.3 ppm) than in the pathology division where large specimens were stored (2.3 ppm). Although environmental concentrations of glutaraldehyde in an endoscopy unit with proper general ventilation were not detectable, environmental concentration levels in an endoscopy unit without general ventilation system were 0.2 and 0.5 ppm. According to the results of environmental monitoring in the breathing zone of workers, extremely high concentrations were observed in some work practices (ethylene oxide, 300 ppm; formaldehyde, 8.6 ppm; glutaraldehyde, 2.6 ppm). In order to avoid occupational exposures to these chemicals and prevent potential chronic and acute health hazards, good communications with these chemicals, good work practices, appropriate personal protective equipment, and engineering controls should be required.

Key words: ethylene oxide, formaldehyde, glutaraldehyde, short-term exposure, health care workers

Health care workers are exposed to a variety of hazardous chemicals in the workplace. In order to lessen the risks to such workers, occupational safety and health professionals should pay close attention to these chemicals and their handling in the workplace (1-3). Although about 100 chemicals have been listed and regulated by Japanese Occupational Safety and Health Acts (OSHActs), there are a few chemical substances in hospitals listed and regulated by Japanese OSHActs. Anesthetic gases, sterilizing chemical substances and antineoplastic drugs are some chemicals which have been ruled out by Japanese OSHActs, and the potential chronic and acute health hazards of these chemicals have been reported (1-3). In order to prevent these health hazards, the American Conference of Governmental Industrial Hygienists (ACGIH) and the U.S. National Institute for Occupational Safety and Health (NIOSH) have proposed occupational exposure limits for nitrous oxide, ethylene oxide, formaldehyde and glutaraldehyde (4, 5).

Ethylene oxide has been focused on as an occupational carcinogen, mutagen and teratogen (6-8). Hogstedt *et al.* (9, 10) have reported that the observed/estimated ratios of total cancer, stomach cancer and leukemia among workers exposed to ethylene oxide were significantly elevated, and the International Agency for Research on Cancer (IARC) (11) proposed that ethylene oxide is a carcinogenic agent in humans (group 1). Moreover, high concentrations of ethylene oxide are known to cause irritation of the mucous membranes, erythema, dyspnea, cyanosis, pulmonary edema, headache, nausea, vomiting and drowsiness. The U.S. NIOSH proposed the IDLH (immediately dangerous to

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life or health) concentration of ethylene oxide and recommended appropriate personal protection (5). Formaldehyde and glutaraldehyde are known to be irritant chemicals. Formaldehyde has been reported to produce neurobehavioral changes and to be a carcinogen (12-15). Although the epidemiologic evidence on formaldehyde as a human carcinogen remains in question (16, 17), the IARC proposed that formaldehyde should be controlled as a suspected human carcinogen (group 2A) (18). In general, exposure to formaldehyde vapors irritates the eyes, whereas inhaled formaldehyde primarily affects the airway, resulting in acute and chronic respiratory diseases (1-3, 19). In last decade, there have been an increasing number of reports (20-24) of skin, respiratory and other health problems related to glutaraldehyde exposures. The ACGIH and U.S. NIOSH have proposed ceiling values for formaldehyde and glutaraldehyde to prevent acute health hazards (4, 5).

As for chronic health hazards, we can assess time-weighted average concentrations for long-time exposures by comparison of occupational exposure limits, but it is very difficult to assess the short-term exposure for preventing acute health hazards and there have been a few reports (20, 25-28) which have pointed out the magnitude of short-term exposures to these chemicals in hospitals. Ethylene oxide, formaldehyde and glutaraldehyde are the typical chemicals which have been pointed out the magnitude of short-term exposures and acute health hazards. These chemicals have been mainly used for sterilization or disinfection in central supply divisions, pathology divisions, operating rooms and endoscopy units of hospitals. We conducted continuous environmental monitoring in order to assess short-term exposure levels to ethylene oxide, formaldehyde and glutaraldehyde in central supply divisions, pathology divisions, operating rooms and endoscopy units of hospitals, and we also examined the degree of engineering controls and type of work practices in these workplaces.

Materials and Methods

This study included work practice interviews, work-site inspections and environmental monitoring. In order to determine the exposure levels to ethylene oxide, formaldehyde and glutaraldehyde among health care workers, 2 public general hospitals were chosen, both of which have adopted different ventilation systems in their central supply divisions, pathology divisions and endoscopy units. Two hospitals were studied: Hospital A, which contains 200 beds, and hospital B, which contains 310 beds. In hospital A, 3 female workers (40, 46, 53 yrs) in the central supply division, 2 male workers (31, 42 yrs) in the pathology division and 2 female workers (38, 43 yrs) in the endoscopy unit were interviewed regarding work practices concerning chemicals and their health effects. In hospital B, 2 male (44, 48 yrs) and 3 female (38, 51, 53 yrs) workers in the central supply division, 2 male (29, 35 yrs) and 1 female (26 yrs) workers in the pathology division, 4 female workers (44, 46, 53, 55 yrs) in the operating room and 2 female workers (44, 47 yrs) in the endoscopy unit were inter-viewed. These workers had been at these positions from 5 to 27 years. The target chemicals were ethylene oxide (C_2H_4O), formaldehyde (HCHO) and glutaraldehyde ($OCH(CH_2)_3CHO$), which are used in sterilization or disinfection processes.

Environmental monitoring was performed with a quantitative gas analyzer which works according to the photoacoustic infra-red detection method (Brüel & Kjær Multi-gas Monitor Type 1302 and Multipoint Sampler and Doser Type 1303) and employs specific optical filters (ethylene oxide: Type UA-0978; formaldehyde and glutaraldehyde: Type UA-0986). The 1302 monitor was calibrated with nitrogen gas (99.9990 %), and by a single-point span calibration method using ethylene oxide (26.0 ppm) and formaldehyde (11.9 ppm). The detection range of this monitor at 20 °C and 1 atmosphere of pressure are: 0.1-1,000 ppm for ethylene oxide; 0.04-400 ppm for formaldehyde; and 0.2-2,000 ppm for glutaraldehyde. The reproducibility expressed as coefficient of variation was 0.02-0.03 for ethylene oxide, formaldehyde and glutaraldehyde in laboratory tests (n = 100, respectively). The measured concentrations of these chemicals are calibrated automatically adjusting for room temperature, pressure in atmospheres and humidity. As there are many chemicals present in hospitals, we performed cross-interference calibration (nitrous oxide and ethanol). Air-samplings were performed with the 1,303 monitor (volume flow rate: 15 ml/s) using Teflon tubes (10 m), and the target chemicals were monitored every 2 or 3 min. The sampling points were set near the workers' breathing zone in order to assess short-term exposure, and in another part of the work area to assess the general work environmental concentration levels. The exposure limits of ethylene oxide, formaldehyde and glutaraldehyde proposed by the ACGIH and the U.S. NIOSH are shown in Table 1.

Table 1 The exposure limits of ethylene oxide, formaldehyde and glutaraldehyde

	ACGIH	U.S.NIOSH	JSOH
Ethylene oxide	1 ppm (TLV-TWA)	< 0.1 ppm (REL) 5 ppm (C, 10-min) 800 ppm (IDLH)	1 ppm (OEL)
Formaldehyde	0.3 ppm (TLV-C)	0.016 ppm (REL) 0.1 ppm (C, 15-min) 20 ppm (IDLH)	0.5 ppm (OEL)
Glutaraldehyde	0.05 ppm (TLV-C)	0.2 ppm (C)	Not proposed

ACGIH: American Conference of Governmental Industrial Hygienists; NIOSH: National Institute for Occupational Safety and Health; JSOH: Japan Society for Occupational Health; OEL: Occupational Exposure Limits; C: Ceiling value; IDLH: Immediately dangerous to life or health.

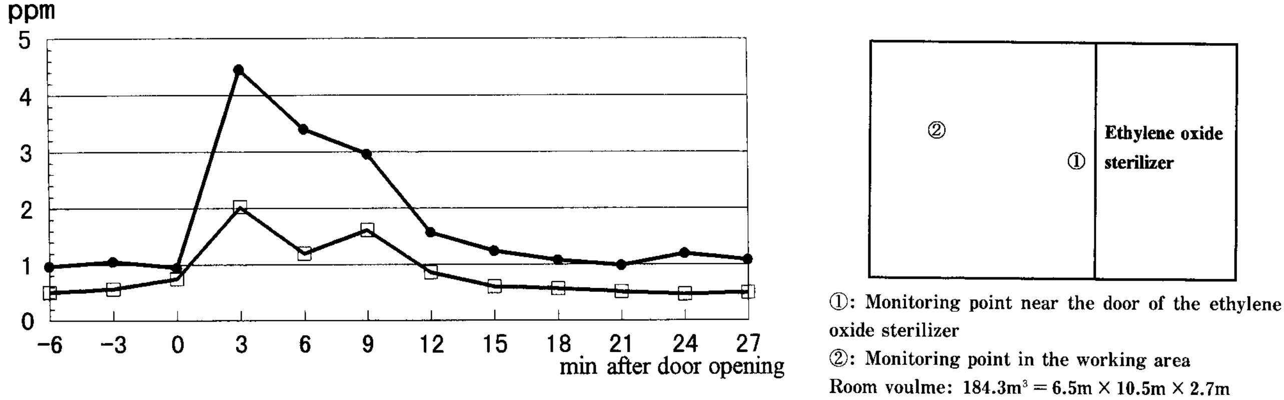

Fig. 1 The ethylene oxide concentration during work practice after the aeration process completed and environmental monitoring points in central supply division of hospital B. ◆: Ethylene oxide concentration near the door of the sterilizer; ▭ : Ethylene oxide concentration at working area.

Results

Ethylene oxide. The arithmetic means of the environmental concentration levels of ethylene oxide were 0.4 ppm (n = 322, 0.1–0.6 ppm) in the working area and 0.3 ppm (n = 322, 0.1–0.6 ppm) near the ethylene oxide sterilizer in the central supply division of hospital A which has a general ventilation system and local exhaust system located near the sterilizer. On the other hand, the arithmetic means of the environmental levels of ethylene oxide were 0.5 ppm (n = 298, 0.3–0.8 ppm) in the working area and 1.2 ppm (n = 35, 1.1–1.3 ppm) near unventilated cabinets housing sterilizing materials in the central supply division of hospital B which has only a general ventilation system.

As the workers might be exposed to high concentration of ethylene oxide in opening the door of an ethylene oxide sterilizer, we conducted environmental monitoring at this work practice. In ordinary work practice (1–2 times a day), the workers open the door of the sterilizer after the aeration process practice is complete, but the workers must also open the door of the sterilizer before aeration process is complete in case of emergency operations (several times a month). Representative cases of after and before aeration process completed were shown in Figs. 1 and 2. The environmental concentration of ethylene oxide near the door of the sterilizer increased to 4.5 ppm during ordinary work (Fig. 1), but the concentration of ethylene oxide near the door increased to 300 ppm before the aeration process was complete (several times a month). We estimated that it takes about 30 min after opening the door until the environmental concentration of ethylene oxide returns to its former level (Fig. 2). These results suggest that opening the door before the aeration process is complete would expose the workers to high concentration of ethylene oxide and would thus be extremely dangerous.

Formaldehyde. We monitored environmental concentrations of formaldehyde in the breathing zone of workers in pathology divisions of hospitals A and B, each of which has different ventilation systems. Representative cases of good and poor general ventilation are shown in Fig. 3. As there was large specimen storage in the pathology division of hospital B, the arithmetic mean of environmental formaldehyde levels was 2.3 ppm (n = 62, 0.8-5.0 ppm). When the pathologist was dissecting organic tissues (2-3 times a week), the ceiling value of formaldehyde reached 8.6 ppm within a short-time. Because the pathology division technician felt irritant eyes and opened a window, the concentration levels decreased to 0.6-1.0 ppm (n = 13). When the technician shut the window, the ceiling value of formaldehyde reached 6.3 ppm again. On the other hand, the environmental concentration levels of formaldehyde in the pathology division of hospital A, in which there is no large specimen storage, were about 0.2-0.4 ppm (n = 185, the arithmetic mean = 0.3 ppm) even when the pathologist was dissecting organic tissues. Although there were no local exhaust system in either of these pathology divisions, the general ventilation system in hospital A provided 18.0 changes of air per hour and that of hospital B provided 12.5 changes of air per hour.

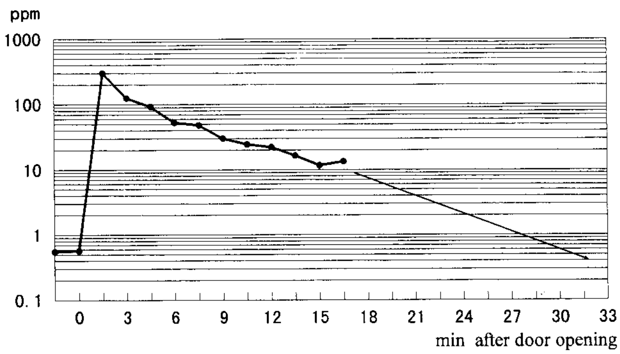

Fig. 2 The ethylene oxide concentration during work practice before the aeration process completed.

Glutaraldehyde. Glutaraldehyde is a popular sterilant chemical substance in endoscope units. The arithmetic means of environmental concentration levels of glutaraldehyde were 0.2 ppm (n = 41, 0.1-0.3 ppm) and 0.5 ppm (n = 41, 0.4-0.8 ppm) at 2 measurement points in endoscope unit of hospital B without general ventilation system. On the other hand, there was a specific room with general ventilation system (90 air changes per hour) for sterilizing endoscopes in hospital A, and environmental concentration levels of glutaraldehyde were not detectable at 2 measurement points.

The staff in the operating rooms sterilize the floor and operating table in the operating room (several times a week) after operations on patients suffering from blood borne infectious diseases (hepatitis B or C, human immunodeficiency virus) or emergency operations (traffic accidents). The representative environmental concentration levels of glutaraldehyde in the operating room are

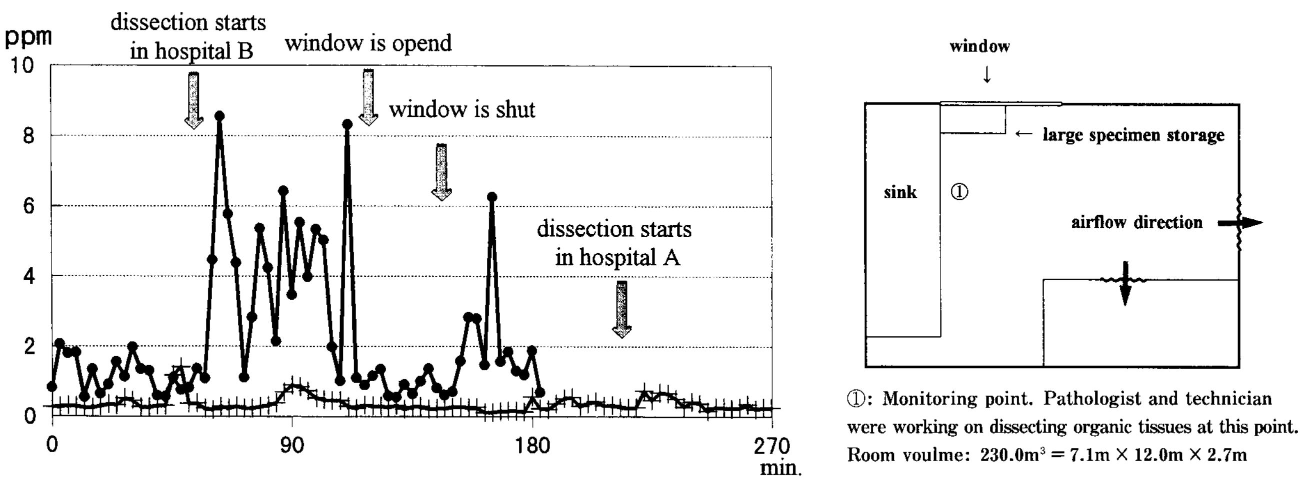

Fig. 3 The concentration of formaldehyde in the air of pathology divisions and environmental monitoring point in pathology division of hospital B. -●-: The concentration in hospital B; -+-: The concentration of hospital A.

shown in Fig. 4. In one case, the staff switched off the general ventilation system during first hour and the concentration of glutaraldehyde increased to 2.6 ppm. After switching on the general ventilation system, the concentration decreased. This work practice exposes the staff to high concentrations of glutaraldehyde during the sterilizing the floor and operating table in the operating room, and there is a risk of exposure when the staff enters the operating room.

Health effects related to ethylene oxide, formaldehyde and glutaraldehyde exposure. No chronic or acute symptoms related to ethylene oxide exposure were found among the central supply workers of either hospital. However, acute symptoms related to formaldehyde and glutaraldehyde exposure were found among workers in the pathology and endoscopy divisions of hospital B, where poor working environmental controls were provided. All workers in the pathology division of hospital B complained of irritated eyes, nose and throat, and cough symptoms related to formaldehyde exposure during dissection of organic tissues. Furthermore, all workers in the endoscopy unit of hospital B complained of irritated eyes, nose and throat, as well as headaches. One workers also complained of skin symptoms (dry, cracked skin and skin rash) related to glutaraldehyde exposure. To clarify the relationship between these symptoms and chemical exposure, an epidemiological study is necessary.

Discussion

Elliott *et al.* (29) reported that the time-weighted average exposure to ethylene oxide ranged from non-

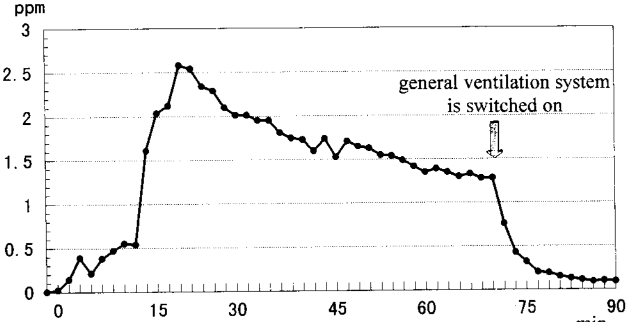

Fig. 4 The concentration of glutaraldehyde in the air of sterilizing operating room.

detectable to 6.3 ppm for sterilizer operators and from nondetectable to 6.7 ppm for folders and packers. They also reported that the short-term (2 to 30 min) exposure levels for sterilizer operators ranged from nondetectable to 103 ppm. These researchers discussed the TWA and short-term exposure to ethylene oxide in relation to engineering controls and work practices, and pointed out that engineering controls and/or good work practices can effectively reduce exposure to ethylene oxide. The results of this study indicate that general ventilation systems are not sufficient to keep concentrations of ethylene oxide under the ACGIH's TLV-TWA exposure limits in work areas around cabinets and shelving which house sterilizing materials. Moreover, our results show the hazards of opening the door of an ethylene oxide sterilizer before the aeration process is completed. When the workers have to open the door of the sterilizer before the aeration process is completed, the workers should be aware the risk of this work practice and wear personal protective equipment. And a safety procedure manual should be required for operators of the ethylene oxide sterilizer.

Breathing zone formaldehyde levels in gross anatomy laboratories have been reported to range from 0.70 ppm to 1.61 ppm (the geometric means of TWA) (27, 30–33). The differences in formaldehyde exposure levels might be explained by the differences in ventilation systems and the variations in workplace design and practices. Akbar-Khanzadeh *et al.* (27) pointed out that more than 94 % of measured samples were exposed to formaldehyde in excess of the ceiling limit of 0.3 ppm proposed by the ACGIH, and recommended that exposure monitoring be conducted in order to assess short-term exposure to formaldehyde. Environmental monitoring near the breathing zone in hospital B showed that the ceiling value (8.6 ppm) was quite a bit higher than the arithmetic mean of concentration levels (2.3 ppm), which provides us with important information for assessing the magnitude of short-term exposure. The results of this study suggest that high concentrations of formaldehyde are related to the work practice of dissecting organic tissues and poor general ventilation. They also suggest that local exhaust ventilation should be installed over work stations where formalin is used, and large specimens preserved in formalin should be isolated from the working area.

Norback (20) reported that the geometric mean of short-term (15 min) exposure to glutaraldehyde during cold sterilization work was 0.012 ppm, and that the geometric mean under poor ventilation (0.035 ppm) was higher than that under proper ventilation (0.004 ppm). Pisaniello *et al.* (24) reported that personal inhalation exposures in operating theaters and endoscopy areas were significantly lower (GM = 0.014 and 0.022 ppm, respectively) where local exhaust ventilation was provided than where it was not provided (GM = 0.034 and 0.093 ppm, respectively). The results of this study also suggest that proper local or general ventilation is important for avoiding exposure of glutaraldehyde over TLV-C. And being familiar with material safety data sheet (MSDS) of glutaraldehyde, appropriate personal protective equipment and safety procedure manual should be required in work practice in the sterilizing room involving glutaraldehyde.

As the purpose of this study was to assess short-term exposure to ethylene oxide, formaldehyde and glutaraldehyde and not to evaluate acute health effects among health care workers epidemiologically, the limited information on health hazards among them could be obtained. But several episodes, like irritation of eyes and upper respiratory system related with exposure to ethylene oxide, buring and tearing of eyes related with exposure to formaldehyde and irritation of eyes and dermatitis in arm and legs related with exposure to glutaraldehyde, could be obtained by a interview study. The analyses of acute health hazards among health care workers related with short-term exposure to these chemicals remain to be solved in the future.

As for ethylene oxide, formaldehyde and glutaraldehyde, not only TLV-TWA for long time exposure but also TLV-STEL and TLV-C for short-term exposure are proposed. It is hard to assess short-term exposure or ceiling exposure values by measuring only personal exposure, and the results of this study can provide health care workers with important information for assessing short-term exposure or near ceiling values of these chemicals. In order to assess the levels of acute exposure to chemical substances which might cause acute health hazards, quantitative and continuous environmental monitoring is a useful method, and data acquired by this method should be made available to those in charge of safety and environmental procedures in the workplace.

There are many hazardous chemical substances in hospitals and many work practices which expose health care workers to high concentrations of these chemicals. In order to prevent potential chronic and acute health problems, the following steps should be taken: workers and managers should be familiar with the MSDSs of the chemicals they work with; work environments should be properly ventilated and other environmental safety equipment should be installed where necessary; safety manuals and the appropriate personal protective equipment should be issued to all workers.

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