

OCCUPATIONAL EXPOSURE TO ETHYLENE OXIDE OF HOSPITAL STAFF

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Abstract. Occupational exposure to ethylene oxide was assessed among the workers remaining in direct contact with ethylene oxide or with ethylene oxide-sterilized instruments in 13 hospitals located in the city of Łódź and its suburbs.

Individual dosimetry and stationary sampling methods were employed. The samples collected from the occupational environment were analysed by gas chromatography with mass detection. The analytical method enabled determination of low ethylene oxide concentrations in the presence of the accompanying chemicals, such as ethyl alcohol, isopropyl alcohol, ethyl ether and isoflurene. In total, 227 determinations were made, and ethylene oxide at concentrations above 0.01 mg/m³ (which was the detection limit of the method) was found to be present in 164 samples.

The ethylene oxide levels were found to vary widely, from lower than 0.01 TLV to several hundred times the TLV value.

INTRODUCTION

Ethylene oxide (EtO) sterilization is one of various methods used to sterilize medical instruments and apparatus. An increasing number of items which cannot be sterilized with steam leads to widespread use of ethylene oxide for sterilization, rubber, plastics, implants and various surgical equipment (2). Although quantities of ethylene oxide used for sterilization are relatively small, many health-care workers are exposed. Exposure levels largely depend on the extent of sterilization and employed techniques. The results of experimental study indicate that EtO is teratogen in mice when administered intravenously on 6-8 day of gestation in a dose of 150 mg/kg not toxic to mother (6). Decreased implantation numbers, smaller ratio of fetuses born to the number of implants, and decreased number of newborns per

litter were observed when rats were exposed by inhalation to EtO at 180 mg/m³, 12 weeks before gestation and during pregnancy (9).

During the past two decades, a number of studies have analysed the relationship between occupational exposure to sterilizing chemicals and the rate of spontaneous abortions. Some authors report a positive relationship between occupational exposure to these agents and increased risk of spontaneous abortions among sterilizing staff (1). The study conducted among hospital sterilizing staff in Finland indicated that the frequency of spontaneous abortions was 11.3% for this group of women and 10.6% for the nursing auxiliaries used as the control. When the staff were involved in sterilizing procedures during their pregnancy, the frequency was 16.7% vs. 5.6% for the non-exposed pregnant women (3). Another publication of these authors presents a new analysis of the data. Only pregnancies that started during hospital working were analysed in all groups. Among women exposed to EtO, the spontaneous abortion rate was still highest (20.4%) and was significantly different compared with the control group (11.3%) (4). Among EtO-exposed female dental assistants, the age-adjusted relative risk of spontaneous abortion was 2.5 (95% CI = 1.0–6.3), for preterm birth 2.7 (CI = 0.8–8.8) and 2.1 (CI = 0.7–5.9) for postterm birth. Results of the study suggest that ethylene oxide is a possible reproductive toxicant in humans (8).

The aim of this study was to assess occupational exposure to EtO of Polish hospital personnel. This is the first part of the study, reporting on the frequency of spontaneous abortions in hospital staff using ethylene oxide for sterilization.

MATERIALS AND METHODS

The population studied

Studies on the assessment of occupational exposure to ethylene oxide were conducted in 1997–98 in thirteen hospitals of Łódź and its satellite towns. EtO concentrations were determined by gas chromatography, and air was sampled by individual or stationary pumps. The people to be monitored and the sampling sites were selected so as to be representative for the specific occupational environment. During the selection, the authors were aided by suggestions from the head nurses, who were well aware of the conditions prevailing in their occupational environment. Working conditions of the women selected to participate in the tests varied depending on the state of the sterilizer, available room, and widely varying systems of work organisation. All those factors evidently affect the value of the occupational exposure.

Considering the above, the subjects were classified into 5 groups plus one additional (stationary sampling) group.

Group I – Operators of sterilizers located in separate sterilizing rooms, directly exposed to ethylene oxide.

Group II – People exposed to ethylene oxide in operating room housing the sterilizer.

Group III – Operators of sterilizers and people staying in the vicinity of sterilizers located in other than sterilising rooms (such as intensive care units).



Group IV — People indirectly exposed to ethylene oxide in treatment or dialysis rooms and intensive care units because of using ethylene oxide-sterilised instruments.

Group V — People exposed to ethylene oxide in operating room not provided with a gas sterilizer who use ethylene oxide-sterilized instruments and materials.

Group VI — Stationary momentary and mean (nominal working time) samples collected at time and place of maximum concentrations.

Air sampling strategy

Individual dosimetry method was used for air sampling in all hospitals. The subjects were provided with personal pumps which they carried during all daily routine operations. The duration of the sampling period was always close to the nominal working time, not shorter than 75% of an eight-hour working shift, in accordance with the adopted uniform criteria for the work environment monitoring (7).

Apparatus

A gas chromatograph HP-5890 (series II), with an electronic pressure programmer and split/splitless injector equipped with HP-7673 autosampler was used. Ethylene oxide was separated on a HP-PONA capillary column (length 50 m, ID 0.2 mm, film thickness 0.5 mm). The detection was carried out in a HP-MSD mass spectrometer detector (HP-5972 MSD-EI from Hewlett-Packard, Waldbronn, Germany).

Chromatographic conditions

Injector temperature was 120°C, temperature of the GC-MS interface (transfer-line) was 120°C. Initial column temperature was 50°C for 2 min, then the temperature was raised at a rate of 5°C/min to 100°C and held at that level for 1 min. Initial pressure was 90 kPa for 3 min, then the pressure was raised at a rate of 10 kPa/min to 160 kPa and held for 4 min. The linear velocity of the helium carrier gas was 17.3 cm/sec (0.378 ml/min) for 3 min. Injection was performed in split mode, the split ratio was 1:20. 1 ml of the sample was injected into GC-MSD. The total run time was 17 min.

Mass spectrometry

The mass spectrometer was operated in electron impact ionisation mode (EI) and selected ion monitoring mode (SIM) for two groups of ions. The first group of ions (Analyte 1): 15, 26, 27, 29, 31, 44, 45, 46, 51, 58, 59, 74, 115, 117 amu were monitored for ethylene oxide and other substances, such as ethanol, acetone, diethylether, isopropanol and forane (1-chloro-2,2,2-trifluoroethyl difluoromethyl ether). Dwell time was 25 ms. The second group of ions (n-Octane): 57, 71, 85, 114 amu were monitored for n-octane (internal standard). Dwell time was 100 ms. The mass spectrometer detector was tuned using the Maximum Sensitivity Autotune procedure. Electron multiplier voltage (EM Voltage) was 2600 V.

Sample collection

Air was sampled by passing a known volume of air through sorbent tubes containing three sections of petroleum carbon-ORBO33 (50 mg rear, 400 mg middle, and 50 mg front section) using SKC personal pumps model 222-4.

Sample preparation

Ethylene oxide trapped in petroleum carbon tubes (ORBO33) during sampling was desorbed with 950 ml carbon disulphide and 50 ml standard solution (2000 $\mu\text{g}/\text{ml}$ CS_2 n-Octane) into 2 ml screw-capped vials. The eluate was analysed by gas chromatography. Fig 1. shows a typical chromatogram obtained by this method. Fig 2. shows a part of the chromatogram from Fig. 1.

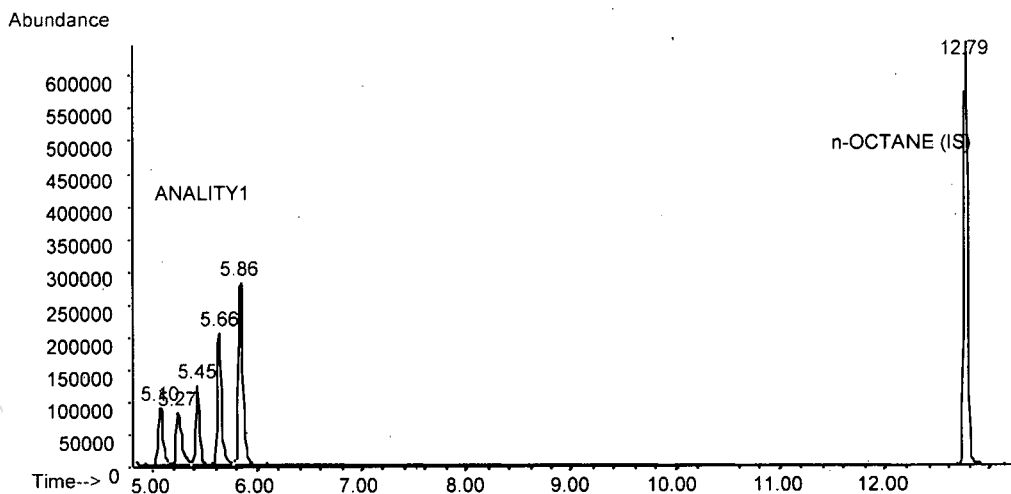


Fig 1. Typical chromatogram of calibration mixture 20 $\mu\text{g}/\text{ml}$ CS_2 :

1 — ethylene oxide, 2 — ethanol, 3 — forane, 4 — isopropanol, 5 — diethylether.

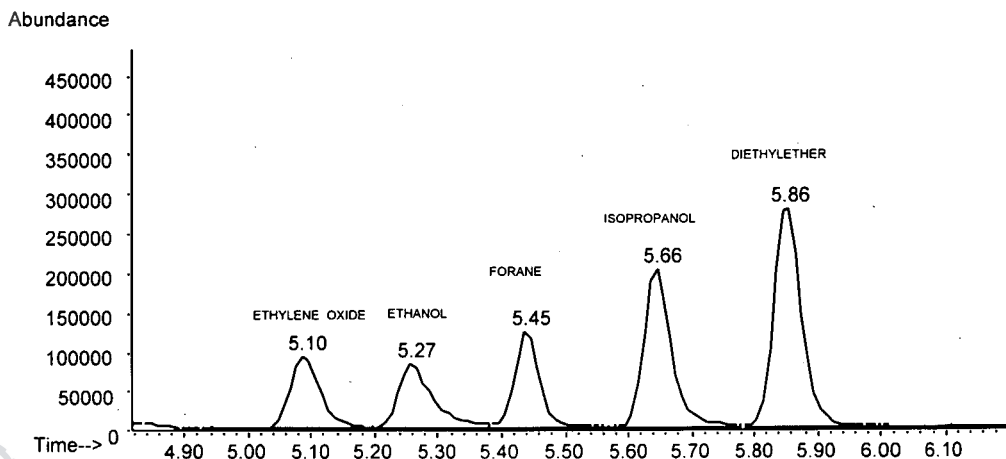


Fig. 2. Part of chromatogram of 20 $\mu\text{g}/\text{ml}$ CS_2 calibration mixture (IS omitted).



RESULTS AND DISCUSSION

Exposure to ethylene oxide was assessed in 196 people. Female workers exposed directly or indirectly to EtO were monitored. Stationary samples (a total of 31 samples) were collected in order to determine momentary (5 samples) and mean concentrations in rooms where the sterilizers were operated or EtO-sterilized instruments used (26 samples).

In total, 227 determinations of occupational exposure, ambient concentration, and momentary measurements were performed. Ethylene oxide at concentrations exceeding the 0.01 mg/m^3 detection limit of the method was found in 164 samples. Maximum and minimum values, and arithmetic and geometric mean values were calculated for each group.

Table 1 gives the data on occupational exposure determined for each of 5 groups of the female staff. The numerical values for groups I–V represent time-weighted average (TWA) concentrations for up to an 8-hour work-day.

Table 1 shows a very wide scatter of the detected concentrations, both in the whole population and within some individual groups.

Table 1. Ethylene oxide concentrations (mg/m^3) in the ambient air of the work environment

	Groups						All samples
	I	II	III	IV	V	VI	
Total number of determinations	18	40	16	42	80	31	227
Number of determinations above the detection limit	18 (9)	28 (4)	16 (0)	22 (4)	50 (0)	30 (14) ^a	164 (31)
Maximum value	316.6	230.6	0.7	6.2	0.98	1057.6	1057.6
Minimum value	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Arithmetic mean	23.2	8.7	0.19	0.67	0.13	68.4	16.7
Geometric mean	0.69	0.32	0.10	0.11	0.07	1.80	0.23

No of samples above TLV-value in parentheses

a — conc. EtO in 5 samples above 3 mg/m^3 (STEL-value); conc. EtO in 9 samples above 1 mg/m^3 (TLV-value).

Our results reveal that TLV values for ethylene oxide were exceeded in about 13% of individual samples, and 35% of stationary samples from sterilizing rooms as well as from other locations where sterilized instruments were used, such as operating rooms or intensive care units. In all five momentary samples collected by the stationary method, EtO concentrations were significantly higher than the 3 mg/m^3 STEL value (5) and ranged from 21.9 mg/m^3 to even as high as 1057.6 mg/m^3 . The sampling was done by an expert industrial hygienist from an accredited laboratory, who was skilled in relevant sampling procedures and, therefore, it would not be reasonable to postulate that those high EtO concentrations were caused, e.g. by sampling faults and should be rejected because of being encumbered with a 'gross error'.

This is an exceptionally high but acceptable value occurring for short time only, during which personal protection means can be used. The high maximum

concentration values in groups I and II seem to be more distressing. These represent the values of the individual exposure determinations. In extreme cases, the currently permissible time-weighted average value of 1 mg/m^3 is exceeded by several hundreds. Fortunately, these are few cases only, but there are no grounds for rejecting them as unreliable. When the geometric mean is used as a measure which is most useful in comparing particular groups of individual samples (from I to V), the highest values are found in groups I and II. In both groups, the exposed people are in direct contact with ethylene oxide. In group I this is inevitable, while in group II this may be attributable either to inadequate room or failure to observe fundamental principles of chemical safety. The third place in this discreditable statistics is occupied by people (group IV) exposed to ethylene oxide by contact with EtO-sterilized instruments which had not been sufficiently (if at all) ventilated before they were supplied to the operating room. The next place is occupied by the intensive care staff (group III).

The exposures within particular groups do not depend on how modern a hospital is or how high is the rank of the institution in charge of the hospital. The awareness of the risks associated with ethylene oxide exposure among hospital personnel and its safety service seems to be essential for keeping the exposure as low as possible.

CONCLUSIONS

1. Our assessment of exposure to ethylene oxide among the medical personnel indicated fairly frequent situations where the TLV or STEL limits were significantly exceeded.

2. The analysis of over 220 air samples collected by individual dosimetry or stationary sampling, using gas chromatography with mass detection, revealed exceeded TLV values in about 12% of individual samples and 35% of stationary samples, and exceeded STEL values in all five momentary samples.

3. The highest individual-sample EtO concentrations were found in the group of operators of sterilizing apparatus located in separate sterilizing rooms and in the personnel working in operating rooms housing sterilizing apparatus.

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