Reevaluation of Residual Ethylene Oxide in Sterilized Plastic Materials for Medical Use.

Naomi Betsumiya, Takumi Kajiura, Hiroyoshi Kobayashi
1) Tokyo Healthcare University Postgraduate School, Division of Infection Prevention and Control, 2) Seirei Sakura Citizen Hospital

**Background**

Ethylene oxide (EO) has negative effects on persons' health, and remains in sterilized medical devices. It is necessary to remove residual EO in the sterilized medical devices. It is questionable that the management of the current devices are safe considering the residual EO value of the legal regulation in Japan. This study examines the aeration time at hospitals that is less than Food and Drug Administration (FDA) regulatory value of the sterilization.

**Residual EO value**

FDA advocated the regulation value of 250ppm (=250㎍/g) in the 1970s. According to report of previous studies, inhalation toxicity is 33ppm and hemolysis is 80ppm.

**Optimal aeration time**

Association for the Advancement of Medical Instrumentation (AAMI) advocated the optimal aeration time of 8 hours at 60°C or 12 hours at 50°C in the 1970s.

**Materials & Method**

The residual EO in three types of plastics; polyvinyl chloride (PVC), polyoxymethylene (POM), and thermoplastic polyurethane (TPU) were examined with a gas chromatography after 12-, 24-, 48-, and 72-hour aeration (n=5). A comparison between the analytical value and the specified value of FDA was compared to verify the more appropriate aeration.

**Results & Discussion**

The plastics after 12–24 hour sterilization were high in residual EO concentration. The results suggest longer aeration time is necessary. There was differences in degree the residual EO for the same plastic, the difficulty of management in the medical devices has been speculated. There was a correlation between EO residual values and removal time.

There was a correlation between EO residual values and removal time, which shows the correlation of the contribution rate from 0.84 to 0.95. And it enables to calculate the definite aeration time. It was suggested, possibility of medical devices that are insufficient EO removal in clinical settings, which reduce the safety. The device management should be practiced considering the residual EO, because the aeration time heavily depends on the type of plastic.

**Conclusions**

The EO residual value and removal time showed correlation, which offers an index for the optimal aeration time in clinical settings at hospitals.

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