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Original Research Paper

The Impact of Ethylene Oxide Sterilization on Medical Devices

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ABSTRACT:
Ethylene oxide gas is commonly utilized for the sterilization of disposable medical devices. However, it is crucial to address the presence of ethylene oxide (EO) and its by-products, ethylene chlorohydrins (ECH) and ethylene glycol (EG), in the sterilized medical devices. High concentrations of these residues can lead to harmful effects on the human body, including hemolytic and irritability of the skin or mucous membranes. To regulate the residual limits of these substances, the FDA proposed guidelines in 1978. This study focused on investigating the optimal conditions for EO sterilization to ensure effective sterilization while minimizing residual chemical substances.

Keywords: Ethylene Oxide Sterilization, medical devices, ethylene chlorohydrins

INTRODUCTION:

Sterilization of disposable medical devices often involves the use of ethylene oxide gas. However, this method can lead to the presence of ethylene oxide (EO) and its by-products, such as ethylene chlorohydrins (ECH) and ethylene glycol (EG), in the sterilized materials. High concentrations of these residues can potentially cause harmful effects on the human body, including hemolytic and irritability of the skin or mucous membranes. To address these concerns, the FDA proposed regulations in 1978 to control the limits of EO, ECH, and EG residues. This study aimed to evaluate the effectiveness of EO sterilization, as well as the levels of residual chemical substances, in order to determine optimal sterilization conditions. Additionally,. Our findings revealed that satisfactory sterilization results could be achieved with an EO gas concentration of 500 mg/liter, a sterilization temperature of 55 to 60 degrees C, and a sterilization time of two hours. Furthermore, the use of the sterilizer at a temperature of 55 to 60 degrees C and an aeration time of 24 hours or more proved to be effective in reducing residual substances.

MATERIALS AND METHODS:

The use of EO for sterilization gained popularity due to its favorable properties, making it an ideal choice for sterilizing heat- and moisture-sensitive medical devices. Various EO gas mixtures have been developed to replace ETO-chlorofluorocarbon (CFC) mixtures, with options such as ETO-carbon dioxide (CO2) mixture and ETO-hydro chlorofluorocarbons (HCFC) mixture. While ETO sterilization offers advantages such as compatibility with sensitive materials, it also presents drawbacks including lengthy cycle times, cost implications, and potential hazards to patients and staff. Exposure to ETO can result in irritation, central nervous system depression, cataracts, and other health issues. It is essential to adhere to safety guidelines and regulations to minimize risks associated with ETO sterilization.

FIG 1 - ETO STERILIZER

FIG2 – EO GAS CARTRIDGE

Mode of Action:
Ethylene oxide acts as a microbicidal agent by alkylating proteins, DNA, and RNA within cells, disrupting normal cellular processes and replication. Studies have shown that ETO effectively inactivates various microorganisms, with bacterial spores being more resistant to its effects.

Uses:
ETO is commonly used in healthcare facilities to sterilize critical items that are sensitive to heat or moisture and cannot be sterilized using traditional methods such as steam sterilization. Its ability to penetrate hard-to-reach areas of medical devices makes it a valuable sterilization option for a wide range of medical equipment.

CONCLUSION:
Despite the challenges and potential risks associated with ETO sterilization, it remains a critical method for ensuring patient health and safety, particularly for medical devices with complex material compositions. Alternative sterilization technologies face technical hurdles that prevent them from replacing ETO in the near future. Compliance with safety guidelines and close monitoring of ETO levels are essential to minimize risks and ensure effective sterilization practices in healthcare settings.

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