Access this article online
Quick Response Code:
Website:
www.jacmjournal.org
DOI:
10.4103/jacm.jacm_1_18

Comparing sterilization efficacy and cost implications of various gas-based sterilization methods used in a Central Sterile Supply Department: A short review

Debabrata Basu, Subhas Chandra Bag, Arijit Das, John Debdutta Rozario, Gaurav Goel

Abstract:

Low-temperature sterilisation basically depends on four types of sterilisation systems, i.e. gamma irradiation, Ethylene oxide sterilisation, Hydrogen peroxide (H_2O_2) and steam Formaldehyde sterilisation. The article has been described on the basis of these low-temperature sterilisation systems with their infrastructural ease, regulatory requirements, cycle time, sterilisation efficacy, safety features and cost. In our experience, the H_2O_2-based sterilisation system is superior over the other methods due to its easy installation and cycle time that helps to perform more procedure in a day and reduces infection by providing terminal sterilisation (ready-to-use) processes. Besides due to the short cycle time of the H_2O_2 steriliser, it requires fewer inventories and saves cost to the management in the long run.

Keywords:

Cost involvement, Ethylene oxide, Formaldehyde, Hydrogen peroxide, low-temperature gas-based sterilisation

Introduction

Sterilisation at low-temperature without the application of significant pressure, heat and moisture is necessary for those items which are labile to these environmental conditions. Currently, there are two approaches to achieve this objective: a) gas-based sterilisation and b) Gamma-ray sterilisation. Gamma-ray sterilisation, although very effective as a cold sterilisation approach, is difficult to implement because of infrastructure issues, regulatory requirement and radiation hazards. This leaves gas-based sterilisation as the only practically implementable approach in most Central Sterile Supply Departments (CSSDs) in healthcare services.

There are specially three varieties of gas-based sterilisation methods used in a central sterile supply department of a hospital. These include Ethylene oxide (EO), Hydrogen peroxide (H_2O_2) and steam Formaldehyde (SF).[1] The objective of this review is to inform CSSD and infection control practitioners about the relative merits and demerits of various gas-based sterilisation methods so that an informed decision could be taken about procurement of these systems for low-temperature sterilisation purposes. The procurement of the individual systems would depend on the assessment of various factors. These include materials compatibility, sterilisation efficacy, safety features, infrastructure issues, chamber capacity, cycle time and cost [Table 1].

Department of Microbiology, Tata Medical Center, Kolkata, West Bengal, India

Address for correspondence:
Mr. Debabrata Basu, Tata Medical Center, 14, Major Arterial Road (EW), New Town, Kolkata - 700 156, West Bengal, India.
E-mail: debabrata.basu@tmckolkata.com

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

How to cite this article: Basu D, Bag SC, Das A, Rozario JD, Goel G. Comparing sterilisation efficacy and cost implications of various gas-based sterilisation methods used in a Central Sterile Supply Department: A short review. J Acad Clin Microbiol 2018;20:108-10.

© 2019 Journal of The Academy of Clinical Microbiologists | Published by Wolters Kluwer - Medknow

Table 1: Cost comparison (each set) of various gas based sterilisation methods

Cost parameters	Ethylene oxide 8 XL (3M) (4 STU sterilizer)	Hydrogen peroxide 100 NX (Sterrard) (2 STU sterilizer)	Steam Formaldehyde (Getinge) (6 STU sterilizer)
Biological indicator cost per piece	Rs. 115.8 ($1.72)	Rs. 310 ($4.62)	Rs. 125.00 ($1.86)
Chemical indicator cost per piece	Rs. 20.68 ($0.30)	Rs. 10.14 ($0.15)	Rs. 48.00 ($0.71)
Sterilising agent cost per cycle	Rs. 940.00 ($14.02)	Rs. 801.68 ($11.96)	Rs. 50.00 ($0.74)
Packaging materials cost per cycle	Rs. 200.00 ($2.98)	Rs. 100.00 ($1.49)	Rs. 400.00 ($5.96)
Electricity consumption cost per cycle	Rs. 360.00 ($5.37)	Rs. 50.00 ($0.74)	Rs. 1600.00 ($23.88)
Water consumption cost per cycle	NA	NA	Rs. 75.00 ($1.11)
Cost of each cycle	Rs. 1636.48 ($24.42)	Rs. 1271.82 ($18.98)	Rs. 2298.00 ($34.29)
Cost per each set (1 STU)	Rs. 409.12 ($6.10)	Rs. 635.91 ($9.49)	Rs. 383.00 ($5.71)

NA: Not available

A review of the advantages and disadvantages of different low-temperature sterilisation processes

Ethylene oxide

Almost all materials can be sterilised by EO except those containing linen and liquid. This technology is Food and Drug Administration (FDA) approved.[3] EO is the best among the gas-based sterilising agents in terms of penetration capacity through luminal devices (penetration capacity as per the Helix process challenge device [PCD] is more than 2.5 mm diameter with 4000 mm length as per the European Norms [EN 1422]).[3] EO gas is flammable with carcinogenic properties.[4] It requires proper installation of safety pipelines, ventilation system and catalytic converter to change EO gas to carbon dioxide and water. An external EO detector needs to be installed to detect residual EO for occupational safety. Permissible exposure limit is 1 ppm measured as an 8-hour time-weighted average (TWA) according to the Occupational Safety and Health Administration (OSHA).[5] The design of the EO room should include: negative air pressure room (–2.5––7.5 Pa),[6] equipment installation near the maintenance shaft for gas exhaust, moisture-free compressed air system and uninterrupted power supply. In the health-care industry, most EO sterilisers have a chamber capacity of 200–250 l. The total cycle time including aeration varies between 14 and 16 h depending on sterilisation temperature.[7]

Hydrogen peroxide

This method is useful for surface sterilisation of most materials except liquid and cellulose-containing items. The technology is FDA approved.[8] There is some limitation for sterilising long lumen devices, but if the concentration of H_2O_2 is increased (using vaporiser condenser), then this barrier can be overcome.[8] As per FDA guideline for polyethylene- and Teflon-flexible endoscope, the maximum penetration capacity of H_2O_2 steriliser is for an internal diameter of 1 mm or larger and a length of 875 mm or shorter.[8] H_2O_2 is corrosive in nature and is harmful on ingestion; it is irritating to the skin, nose, throat and eye. H_2O_2 sterilisers have minimal infrastructural requirements for installation and no special ventilation or monitoring systems are required. Employee exposure is limited to 1 ppm measured as an 8-hour TWA according to OSHA.[9] The by-product of this gas is considered eco-friendly because of the sterilisers' inbuilt catalytic converter that breaks H_2O_2 gas into water and oxygen. An additional safety feature is the use of radiofrequency energy to convert the residual H_2O_2 vapour into plasma which is then eliminated by converting into water and oxygen. In health-care industry, the usual chamber capacity for H_2O_2 sterilisers vary between 100 and 200 l. As per Sterrad 100 NX steriliser (Johnson and Johnson, USA), the total cycle time varies between 24 min (express cycle) and 52 min (Duos cycle).[8]

Steam Formaldehyde

This technology is suitable for all items except liquid or cellulose-containing materials. SF sterilisation is suitable for long lumen devices. The technology is Conformité Européene approved.[7] Penetration of Formaldehyde is better than H_2O_2 but less than EO, especially for hollow devices based on Helix PCD test (e.g. 1.5 mm diameter and 2000 mm length, according to EN 867-5).[3,10] Formaldehyde is degraded by photochemical reaction in air to carbon dioxide and water. However, Formaldehyde is a mutagen and a potential human carcinogen that the OSHA regulates.[10] The employee exposure limit for Formaldehyde in work areas is 0.75 ppm as per the OSHA.[7] The gas is also removed from the chamber by repeated alternate evacuations and flushing with steam and air. Infrastructure requirements for Formaldehyde based sterilisation are the significant and special design of the premises is required. These include negative air pressure room, drainage system for liquid discharge, mineral-free chilled water (15°C), three-phase electrical connection and dry compressed air system. The chamber capacity is usually between 400 and 600 l.[10] The total cycle time is four hours at 55°C, three hours at 65°C and two hours at 80°C.[10]

Cost involvement

The processing costs of a sterilisation system are dependent on various factors such as cost of a biological indicator (in every cycle), cost of chemical indicator (in every set), cost of sterilising agent (per cycle), cost of packaging materials (twice in every set) and the cost of electricity and water. Table 1 shows a comparison of the costs of the main manufacturers of these systems.

Gas-based sterilisation of temperature, moisture and pressure-sensitive medical devices are an integral part of the CSSD processes.[1] The sterilisation technology should be chosen carefully by their specific requirements, safety features, turnaround time, efficiency and cost. Based on various aspects discussed, we think that H_2O_2 sterilisation method is the best among all gas-based sterilisation technologies, for their minimal infrastructure and regulatory requirements and safety features. However, the penetration capacity of H_2O_2 is less than the other two methods. It has been observed that as per criticality categorisation (Spaulding classification) length of most medical devices are shorter than three feet (875 mm) (except a few cardiac catheters) and they can be sterilised by H_2O_2 method. When cost of sterilisation was compared, it was found that the H_2O_2-based method was approximately 1.5 times costlier than that of EO and 1.7 times that of low-temperature SF -based sterilisation method [Table 1]. However, from a staff and environmental safety point of view and also from the perspective of infrastructural requirements needed for EO and SF, it may be justified to opt for H_2O_2-based sterilisation in CSSD.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

References

1. Kanemitsu K, Imasaka T, Ishikawa S, Kunishima H, Harigae H, Ueno K, *et al.* A comparative study of ethylene oxide gas, hydrogen peroxide gas plasma, and low-temperature steam formaldehyde sterilization. Infect Control Hosp Epidemiol 2005;26:486-9.
2. List of FDA-Cleared Ethylene Oxide Sterilizers. Available from: https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194573.htm. [Last accessed on 2017 Apr 08].
3. gke Steri-Record® Testsets and PCDs for Validation, Process and Batch Monitoring of Sterilization Processes. Available from: http://www.gke.de/en/helix-pcd-testset-steam-ci.html. [Last accessed on 2017 Apr 08].
4. Boiano JM, Steege AL. Ethylene oxide and hydrogen peroxide gas plasma sterilization: Precautionary practices in U.S. Hospitals. Zentralsterilisation (Wiesb) 2015;23:262-8.
5. Occupational Safety and Health Administration Fact Sheet. What is Ethylene Oxide. Available from: https://www.osha.gov/OshDoc/data_General_Facts/ethylene-oxide-factsheet.pdf. [Last accessed on 2017 Apr 08].
6. Ciofi-Silva CL, Hansen LL, Almeida AG, Kawagoe JY, Padoveze MC, Graziano KU, *et al.* Negative pressure of the environmental air in the cleaning area of the materials and sterilization center: A systematic review. Rev Lat Am Enfermagem 2016;24:e2781.
7. Rutala WA, Weber DJ; The Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for Disinfection and Sterilization in Healthcare Facilities; 2008. Available from: https://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. [Last accessed on 2017 Apr 08].
8. Department of Health and Human Services. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160818.pdf. [Last accessed on 2017 Apr 08].
9. Occupational Safety and Health Administration Hydrogen Peroxide. Available from: https://www.osha.gov/dts/chemicalsampling/data/CH_246600.html. [Last accessed on 2017 Apr 08].
10. Low-Temperature Sterilization Using Low-Temperature Steam and Formaldehyde. Available from: http://www.deconidi.ie/html/educ/articles/educcommercial_0003.pdf. [Last accessed on 2017 Apr 08].