

Original Research Article

Prospective study on sterilization of rigid endoscopes in various otolaryngology clinics

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ABSTRACT

Background: Rigid endoscopes have revolutionized the diagnosis and management of upper aerodigestive pathologies. Inadequate disinfection and sterilization techniques carry increased risk for cross infection. Hence, they require high level disinfection to effectively reduce the bacterial and fungal contamination of rigid endoscopes. The present study analyses the various techniques of sterilization practised in Mangaluru, Karnataka, at different Otorhinolaryngology clinics.

Methods: This prospective descriptive study was done on 30 rigid endoscopes. Swabs were taken from the endoscopes and container, and sent for detailed microbiological examination. The different methods practised at various centres were documented.

Results: The various sterilization technique practised was predominantly cetrimide and chlorhexidine solution (savlon) wash, ETO and Formaldehyde. However, among all techniques the microbiological studies revealed no growth.

Conclusions: Rigid endoscopes have emerged as the best diagnostic equipment for otorhinolaryngologists. With regard to high level disinfection and sterilization, the endoscope must undergo recommended techniques. In our study the most commonly used techniques was cetrimide and chlorhexidine solution wash and less commonly ETO and Formaldehyde. The use of standard sterilization technique and maintaining the rigid endoscopes in sterile storage container is the key to maintain an organism free environment. The standard technique of prewash with water and soap water, then washing with cetrimide and chlorhexidine solution, then store the endoscope in sterile container is our recommendation.

Keywords: Endoscope sterilization, Rigid endoscopes, High level disinfection, Sterilization technique

INTRODUCTION

With invent of rigid endoscopes, it has revolutionized the way of diagnosis and management of upper aerodigestive pathologies. Otolaryngologists deal with rigid endoscopes for detailed examination and meticulous management of various conditions. Rigid endoscopes are being used multiple times a day which has preponderance for introduction of pathogenic microbes.

Failure to disinfect and sterilize reusable medical equipments carries risk of cross infection. Reports do suggest outbreak of infections due to use of contaminated endoscopes that could have been reduced by improved disinfection techniques. When properly done, disinfection and sterilization can ensure the safe use of reusable medical devices.

The method of disinfection and sterilization depends on the intended use of the medical device. Critical items

(those that contact sterile tissue) must be sterilized prior to use. Semi critical items (those that contact mucous membranes or non-intact skin) must undergo high-level disinfection and noncritical items (those that contact intact skin) should undergo low-level disinfection.¹ This spaulding classification scheme has been accepted by Centre for Disease Control and Prevention and the USA Food and Drug Administration (FDA), has considered endoscopes as semi-critical as they come in contact with mucous membrane.^{2,3}

High-level disinfection provides a reasonably effective method of reducing bacterial and fungal contamination of rigid endoscopes.⁴ More outbreaks of nosocomial infection and pseudo-infection (i.e. where patients do not develop clinical symptoms) have been linked to contaminated endoscopes than to any other single medical device. Hence, appropriate sterilization technique should be used in each clinical setting with rigid endoscopes to ensure effective disinfection.

METHODS

This was a prospective descriptive study done on 30 endoscopes, done over a period of 2 weeks (June - July 2016) in various Otorhinolaryngology clinics and hospitals in Mangaluru, Karnataka. Our primary objective was to determine the various pathological organisms those reside on the endoscopes and to determine the adequacy of sterilization.

After Institutional ethical clearance and consent form the concerned doctors swabs were taken from the endoscopes. A total of 30 endoscopes were included in this study, swabs were taken from the endoscopes and the containers.

Under strict aseptic precautions sterile swab was wiped over the endoscope including the optic tip and around the light source connector. Swabs were taken from the endoscope container, a total of 30 swabs. Most of the endoscopes were kept in foam container, some in stainless steel perforated container and 2 in formaldehyde chamber. Transport medium Thyoglycolate was used if a delay of more than 2 hours was anticipated. Collected swabs were sent for detailed microbiological examination.

The methods of disinfection practised at various clinics and hospitals were accounted. All the concerned doctors were informed in advance about the study and clinics were visited by surprise. The various sterilization techniques practised were accounted, the time spent on each sterilization and the average number of time to endoscopes were used in each day was also noted.

RESULTS

A total of 30 endoscopes and 28 endoscopic containers were included in the present study. Of the 30 endoscopes,

22 (73.33%) endoscopes were disinfected by savlon wash, 6 (20%) endoscopes were disinfected by ETO (Ethylene Oxide Sterilization) and remaining 2 (6.67%) endoscopes were disinfected by placing them in formaldehyde chamber. On an average in most centres endoscopes was used for 6 patients every day.

Table 1: Methods practised for disinfection / sterilization.

Method of disinfection / sterilization	N	Percentage
Chlorhexidine with cetrимide	22	73.33%
Ethylene oxide sterilization	6	20%
Formaldehyde chamber	2	6.67

Method of pre-sterilization of the rigid endoscopes was also accounted. Out of the 30 endoscopes studied, 18 (60%) rigid endoscopes were washed with water alone and 12 (40%) rigid endoscopes were washed with water and soap after each use, prior to the preferred sterilization technique.

Swabs that were sent for detailed microbiological screening aerobes, anaerobes, gram positive and gram negative, examination revealed no growth

DISCUSSION

Rigid endoscopes have already emerged to become the best diagnostic equipment for the otorhinolaryngologists. It is an emerging market with manufacturers selling around 10,000 units of rigid endoscopes yearly, quality of the product with regard to maintaining an organism free environment being questionable.

There are different levels of sterilization and disinfection of instruments, cleaning is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The FDA definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6-log₁₀ kill of an appropriate *Mycobacterium* species. Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities.⁵

Pre-cleaning process of the endoscope in the patient care area should start immediately after the patient's procedure. Use sterile or tap water or, ideally, enzymatic detergent solution and complete the following steps:

firstly, flush the channels with solution using a syringe or suction the solution through the channels. Then, wipe the surfaces with a sponge dampened with water or enzymatic detergent or use an enzymatic detergent sponge. Rinse the surface and suction the channels with tap or sterile water. Secure the endoscope in a transport container with a lid or a transport bag to keep it moist during transport. Place the secured endoscope within an enclosed transport cart and ensure there are no instruments or equipment lying on top of the endoscope. Transport the secured endoscope to the central sterile and supply department (CSSD) or designated reprocessing area as soon as possible for terminal reprocessing.⁶

The techniques practised in the present study include Ethylene oxide (EO) sterilization, Formaldehyde chamber and savlon (Chlorhexidine + cetrimide) wash.

EO sterilization has emerged as the sterilization method of choice for medical devices because of its undeniable advantages compared with other technologies. The high reactivity, by its exergonic combustion reaction, in combination with its high diffusivity, lead to powerful alkylation reaction with cellular constituents of organisms such as nucleic acid and functional proteins, including enzymes, which eventually leads to consequent denaturation and eventually inactivation of microorganism.⁷

Formaldehyde is also a potent high level disinfectant and sterilant which is a bactericide, tuberculocide, fungicide, virucide and sporicide, in both liquid and gaseous form. It inactivates the microorganisms by alkylating the amino and sulfhydryl groups of proteins and ring nitrogen atoms of purine bases.⁵ Formaldehyde in its gaseous form is

usually is kept along with the medical devices in the chamber, and chamber needs to be kept moist. However since it is a corrosive agent its use has been limited.⁸

Chlorhexidine is an important Biguanides, probably the most widely used biocide in antiseptic products. In particular, hand washing and oral products but also as a disinfectant and preservative. It is a sprorostatic and mycobacteriostatic; hence its use has been widely used in OPD clinics.⁹ It is commonly used in the brand name of Savlon (Chlorhexidine 1.5 g and Cetrimide 15 g) in 100 ml solution. Aqueous solution of 1:100 (10ml made up in 100 mL with water) can be used for disinfection when instruments kept in for 30 mins.

Glutaraldehyde is an important dialdehyde that has found usage as a low temperature disinfectant and sterilization of endoscopes. Glutaraldehyde has a broad spectrum of activity against bacteria and their spores, fungi, and viruses.⁹ A 2.0% (w/v) glutaraldehyde buffered to alkaline pH by addition of 0.3% (w/v) sodium bicarbonate was advocated to provide the minimum concentration and conditions necessary for rapid sporicidal activity, when kept for 4-6 hours. This solution has a greater sporicidal activity than 8% formaldehyde. The main advantages claimed for its use as a chemosterilizer are, its broad spectrum of activity, especially good sporicidal properties, its activity in the presence of organic matter, its rapid antimicrobial action, its non-corrosive action towards metals, rubber, lenses and most materials, its lack of deleterious effects on cement or lenses of bronchoscopes, cystoscopes or telescopes, and its mild odour, inability to irritate and ease of use.¹⁰

Table 2: Summary of mechanisms of antibacterial action of antiseptics and disinfectants.

Target	Sterilant / Disinfectant	Mechanism of action
Cell envelope (Cell wall, Outer membrane)	Glutaraldehyde	- Cross linking proteins
Cytoplasmic (inner) membrane	Chlorhexidine	- Low concentrations affect membrane integrity, high concentration causes congealing of cytoplasm
	Formaldehyde	- Cross linking of proteins, RNA and DNA
Cross linking of macromolecules	Glutaraldehyde	- Cross linking of proteins in cell envelope and elsewhere in the cell
	Ethylene oxide sterilization	- Exergonic combustion reaction leads to powerful alkylation reaction of cellular constituents
Nucleic acid, functional proteins, including enzymes		

Most commonly practised disinfection/ sterilization technique in present study include wash with Savlon, probably due to its low cost and easy availability. After each use all the endoscopes were washed with either water alone or with water and soap water then washed with Savlon and kept in the container. ETO oxide sterilization was the second preferred method in our study, but was done once weekly. 2 of the endoscopes were kept in Formaldehyde container after prewash to achieve sterilization.

Use of standard sterilization technique and maintaining the rigid endoscopes in a sterile storage container is the key to maintain an organism free environment. In this study, factors associated to provide such environment probably would be technique, quality of the endoscopes and storage container.

CONCLUSIONS

This study cannot ascertain the adequacy of disinfection/sterilization being achieved by the routinely

performed technique on endoscopes. However the practised technique was able to provide an organism free environment. Study need to be done in larger proportion and standardization must be brought in this. Recommended sterilization protocol is not practical in India probably due to the high cost, availability of raw materials and refraining from ETO because of the chances to damaging the optics of endoscopes.

The practised standard techniques which include pre-washing with soap water and water followed by Savlon and storing rigid endoscopes in a sterile container are our recommendation.

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