Original Article

Comparison of efficacy and cost-effectiveness of 0.55% ortho-phthalaldehyde and 2% glutaraldehyde for disinfection of laryngoscopes: A prospective pilot study

Address for correspondence:
Dr. Priyanka Pradeep Karnik, B-404, Om Deep Sai Pooja CHS, Dr. Lazarus Road, Charai Naka, Thane (West) - 400 602, Mumbai, Maharashtra, India.
E-mail: drpriyankakarnik@gmail.com

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Priyanka Pradeep Karnik, Nandini Malay Dave, Gita Nataraj[1], Rajarshi Gupta[1], Madhu Garasia

Departments of Anesthesiology and [1]Microbiology, Seth G. S. Medical College, K.E.M. Hospital, Mumbai, Maharashtra, India

ABSTRACT

Background and Aims: The laryngoscope is a potential source of cross-infection as it involves contact with the mucous membrane, saliva and occasionally blood. This study compared efficacy and cost-effectiveness of two Centre for Disease Control approved agents for disinfection of laryngoscope blades. **Methods:** One hundred and sixty patients requiring laryngoscopy and intubation for general anaesthesia were randomly allocated into two groups. After tracheal intubation, used laryngoscope blades were cleaned with tap water. The blades were then immersed in either 2% w/v glutaraldehyde for a contact time of 20 min or 0.55% w/v ortho-phthalaldehyde (OPA) for 10 min. The handles were wiped with 0.5% w/v chlorhexidine wipes. Samples were collected using sterile cotton swabs from the tip, flange and light bulb area of the laryngoscope blade and one from the handle. They were cultured aerobically on blood and McConkey agar. **Results:** In 2% glutaraldehyde group, of 240 samples sent from the blades, 2 (0.8%) showed the growth of methicillin-resistant coagulase-negative staphylococci (MRCONS) and *Enterobacter*. In OPA group, of 240 samples, 2 (0.8%) showed growth of MRCONS. Thus, 2% glutaraldehyde and 0.55% OPA were comparable in terms of efficacy of disinfection. Growth was seen on 4 out of 160 handles. **Conclusions:** We suggest OPA for high-level disinfection of laryngoscope blades as it is equally efficacious as compared to glutaraldehyde, with a shorter contact time and available as a ready to use formulation.

Key words: Disinfection, glutaraldehyde, laryngoscope, ortho-phthalaldehyde

INTRODUCTION

The laryngoscope has been identified as a potential source of cross-infection as it involves contact with the mucous membrane, saliva and at times blood. In a pilot study conducted by us, we found the growth of methicillin-resistant coagulase-negative staphylococci (MRCONS), *Acinetobacter baumannii*, *Enterobacter*, etc., on nine out of ten samples taken from the blade of the laryngoscope. According to Centre for Disease Control (CDC) recommendations, semi-critical items like laryngoscope blades should undergo cleaning followed by high-level disinfection (HLD) or sterilisation.[1] Steam sterilisation is the ideal method for processing of laryngoscope blades. However, repeated steam sterilisation leads to decrease in the light intensity of laryngoscopes.[2] There is a need for a HLD agent which is both cost effective and easily available. In a questionnaire-based survey conducted by us at a regional conference in 2015 regarding

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awareness of disinfection practices of laryngoscopes, it was found that out of 150 respondents, 12% used only tap water for cleaning while 88% used a chemical agent after rinsing with water.[3] Of those, 51% used detergent/soap solution, 19% would wash and then soak in disinfectant or germicidal agents and 12% would wipe the blade with an alcohol swab. In a survey conducted among 100 anaesthesiologists from 45 different institutions, it was seen that 54% did not use any method for disinfection. Only 22% used a chemical disinfectant.[4] Thus, there are no fixed protocols for disinfection and neither is the adequacy of disinfection confirmed. Although glutaraldehyde has been recommended for HLD in previous studies, it requires a contact time of 20 min.[3] It is desirable to have an HLD with a rapid action due to time constraints in our operation theatres. In India, there are no specific guidelines for disinfection of laryngoscopes.[1,4] Ortho-phthalaldehyde (OPA) is a new CDC approved HLD agent with a shorter contact time. Hence, we decided to conduct a prospective study comparing efficacy and cost-effectiveness of two CDC approved HLD agents 2% glutaraldehyde and 0.55% OPA for disinfection of laryngoscope blades.

METHODS

Approval was obtained from the Institutional Ethics Committee for this randomised prospective study. Waiver of consent was granted as there was no direct contact of the study agent with the patient. The inclusion criterion was all patients undergoing laryngoscopy and intubation in paediatric surgery operation theatre as a part of anaesthesia. There were no exclusion criteria. This was a prospective pilot study. Out of 160 patients who needed laryngoscopy during anaesthesia in paediatric surgery operation theatre, the patients were randomly allocated into two groups. Randomisation was done using the website www.randomization.com which generated a plan to divide 160 patients randomly into two groups. The person collecting the samples from the laryngoscopes and those analysing the samples were blinded to the allocation. After tracheal intubation, used laryngoscope blades were cleaned with tap water. The blades were then immersed in either 2% w/v glutaraldehyde (Sanidex C®, Siramaxo Chemicals, Mumbai, Maharashtra, India) for a contact time of 20 min or 0.55% w/v OPA (SanidexOPA®, Siramaxo Chemicals, Mumbai, Maharashtra, India) for a contact time of 10 min. In both groups, the handles were wiped with 0.5% w/v chlorhexidine (Saniscrub C®, Siramaxo Chemicals, Mumbai, Maharashtra, India) wipes. After disinfection, samples were collected from the tip, flange and light bulb area of laryngoscope blade and one from the handle with all aseptic precautions. They were cultured aerobically on blood and McConkey agar after neutralising of any residual disinfectant picked up on the swab. The neutralising solution contained polysorbate 80 (Tween™ 80 HP), sodium thiosulphate, lecithin and sodium bisulphite. The neutralising solution inactivates the bactericidal and bacteriostatic effects of the disinfectant solutions. This permits the transfer of swabbed organisms to the laboratory without loss in viability. Any growth was identified up to the species level. Based on the species isolated, the microbial growth was classified as commensal oropharyngeal flora, pathogenic microorganisms or contaminants. The personnel collecting the samples and performing microbiological analysis were blinded to the agent used for disinfection. After disinfection, the laryngoscope blades were rinsed with sterile water and then air-dried. During the study, the rinse water used for terminal rinsing was cultured; every time a sample was collected to rule out intrinsic contamination. The potency of the solutions was checked daily using test strips.

Descriptive statistics were presented in terms of numbers and percentages for categorical variables. The data were analysed using Chi-square test.

RESULTS

Out of 160 laryngoscopes, 80 were disinfected using 2% glutaraldehyde and 80 were disinfected with 0.55% OPA. For each laryngoscope, three samples were sent from the blade and one from the handle. In the 2% glutaraldehyde group, out of 240 samples sent from the blades, 2 (0.8%) showed growth of MRCONS and *Enterobacter*. In the OPA group, out of 240 samples from the blade, 2 (0.8%) showed growth of MRCONS [Figure 1]. Thus, 2% glutaraldehyde and 0.55% OPA were comparable in terms of efficacy of disinfection ($P = 1.0$). Among the handles, growth was seen on four handles which included *Acinetobacter* and MRCONS. There was no growth seen in the terminal rinse water.

DISCUSSION

According to the Spaulding classification, laryngoscope blades are classified as semicritical items, that is, items which come in contact with mucous membranes

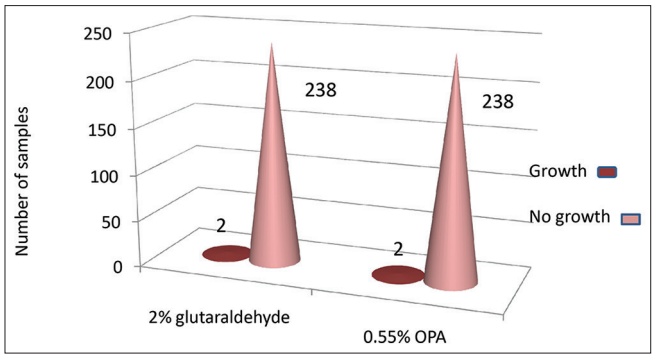

Figure 1: Relative proportions of samples showing growth and no growth in glutaraldehyde and ortho-phthalaldehyde group

or non-intact skin. Intact mucous membranes, such as those of the lungs and the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria and viruses.[1] In a study conducted at a public hospital in South Africa, the contamination rate of laryngoscopes was found to be a staggering 53% with high-level contamination with bacteria such as *Enterobacter*, *A. baumannii*, etc., found in 22.6%.[5] In India, oral hygiene varies and may be suboptimal depending on economic, social and cultural factors. After cleaning with tap water alone, considerable growth of pathogenic microbes was found on laryngoscope blades in a study conducted at a tertiary hospital. Overall, bacterial growth was 58% (29 out of 50 blades) after tap-water cleaning (of which 60% were pathogenic organisms).[6] As per CDC guidelines, semi-critical items require sterilisation or HLD using chemical disinfectants such as glutaraldehyde, peracetic acid, OPD and hydrogen peroxide.[1]

Recent review articles also suggest ineffectiveness of current methods of disinfection of reusable laryngoscopes and poor compliance with the established protocols.[7,8] In a review, 2% glutaraldehyde and other products that achieve HLD is recommended for reprocessing semi-critical items like laryngoscopes to prevent nosocomial infections.[9] The study showed that 2% glutaraldehyde and 0.55% OPD are equally effective for disinfection of laryngoscopes. However, the recommended contact period for 2% glutaraldehyde is 20 min while that of OPA is 10 min making the latter more expeditious. Furthermore, glutaraldehyde solution has to be activated before use by adding an activator supplied along with it while OPA is ready to use. A review article also states that OPA can achieve faster disinfection, has fewer side effects and can be discarded through the drain without a neutraliser.[8] Thus, OPA is preferable to glutaraldehyde in high turnover operation theatres or in settings where the number of laryngoscopes is limited. The cost of 1 L of 2% glutaraldehyde is INR 233 while the cost of 1 L OPA is INR 600. Two litres of the solution was used for disinfection in each group for 15 days. The cost of disinfection per day was INR 31 for 2% glutaraldehyde and INR 80 for 0.55% OPA. Thus, 2% glutaraldehyde is less expensive than OPA.

Acute or chronic exposure to glutaraldehyde >0.05 ppm can result in skin irritation or dermatitis, mucous membrane irritation (eye, nose and mouth) or pulmonary symptoms. Epistaxis, allergic contact dermatitis, asthma and rhinitis also have been reported in health-care workers exposed to glutaraldehyde. OPA only causes staining of the tissues, especially mucous membrane and skin on exposure if not adequately rinsed. Disinfectant solutions should be neutralised before disposal into the sewer system.[1] The laryngoscope handles can also act as a source of infection even if they do not come in direct contact with the mucosa. They can get contaminated by blood or secretions from the gloves or tip of the laryngoscope blade when it is folded.[10,11] A study showed that 86% of the handles grew some or the other aerobes.[11] Another study found drug-resistant organisms on 45% of the laryngoscope handles that were cultured.[12] As per recommendations, there should be thorough low-level disinfection of laryngoscope handles.[11] Although we used chlorhexidine wipes for wiping of the laryngoscope handles, bacterial growth was found on 2.5% of samples. This highlights the need for a better alternative for disinfection of laryngoscope handles.

One of the limitations of our study is that we did not attempt to culture anaerobic organisms or detect viruses and fungal growth. Laryngoscope blades may become contaminated with prion proteins, especially if used at the end of adenoidectomy and tonsillectomy.[13] Our study does not include detecting prions since they are extremely resistant to inactivation by sterilisation processes and disinfecting agents. There are an increasing number of single use laryngoscopes available.[13] However, due to economic constraints, they are not popular in India. Sterile laryngoscope sheaths can be used to reduce the extent of cleaning required. However, CDC still recommends HLD as the integrity of these sheaths may get compromised.[1] As

much as it is important to ensure adequate disinfection of laryngoscopes, it is also imperative that we store aseptically for subsequent use after disinfection. There are several choices for packaging of instruments after sterilisation, including rigid containers, peel-open pouches (e.g., self-sealed or heat-sealed plastic and paper pouches), roll stock or reels and sterilisation wraps (woven and non-woven). An ideal sterilisation wrap would successfully address barrier effectiveness, aeration, ease of use, drapeability, flexibility, puncture resistance, tear strength, toxicity, odour, waste disposal, cost and transparency.[1]

CONCLUSIONS

We suggest the use of 0.55% OPD for HLD of laryngoscope blades as it is equally efficacious as compared to 2% glutaraldehyde, with a shorter contact time and available as a ready to use formulation. Since growth was found in 2.5% of laryngoscope handles after cleaning with 0.5% chlorhexidine wipes, it is necessary to use a better agent for decontamination of laryngoscope handles.

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Conflicts of interest

There are no conflicts of interest.

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