Comparison of the efficacy of disinfectants in automated endoscope reprocessors for colonoscopes: tertiary amine compound (Sencron2®) versus ortho-phthalaldehyde (Cidex® OPA)

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Background/Aims: To prevent the transmission of pathogens by endoscopes, following established reprocessing guidelines is critical. An ideal reprocessing step is simple, fast, and inexpensive. Here, we evaluated and compared the efficacy and safety of two disinfectants, a tertiary amine compound (TAC) and ortho-phthalaldehyde (OPA). Methods: A total of 100 colonoscopes were randomly reprocessed using two same automated endoscope reprocessors, according to disinfectant. The exposure time was 10 minutes for 0.55% OPA (Cidex® OPA, Johnson & Johnson) and 5 minutes for 4% TAC (Sencron2®, Bab Gencel Pharma & Chemical Ind. Co.). Three culture samples were obtained from each colonoscope after reprocessing. Results: A total of nine samples were positive among the 300 culture samples. The positive culture rate was not statistically different between the two groups (4% for OPA and 2% for TAC, P=0.501). There were no incidents related to safety during the study period. Conclusions: TAC was non-inferior in terms of reprocessing efficacy to OPA and was safe to use. Therefore, TAC seems to be a good alternative disinfectant with a relatively short exposure time and is also less expensive than OPA. (Intest Res 2016;14:178-182)

Key Words: Colonoscopes; Cost; Disinfectants; Endoscopes

INTRODUCTION

Gastrointestinal (GI) endoscopes are used worldwide for the screening, diagnosis, and treatment of GI diseases. Although the incidence of pathogen transmission is very low,1 Salmonella spp., Pseudomonas, Mycobacteria, Helicobacter pylori, HBV, HCV, and other pathogens can be transmitted through GI endoscopy.2,3 These microorganisms can be transmitted by the endoscope and its accessories, contaminated reprocessing equipment, and/or contaminated disinfectant solution.4 Most endoscope-related microbial transmissions can be prevented by adequate endoscope reprocessing. Many organizations have introduced guidelines for the reprocessing of GI endoscopes.5-7 For these guidelines to be followed diligently in practice, the reprocessing procedure must be simple, fast, and inexpensive. Currently, many endoscopic units use automated endoscope reprocessors (AERs). Glutaraldehyde solution (2%) is the most commonly used disinfectant in GI endoscope reprocessing,8 and according to multi-society guidelines, at least 20 minutes of contact time at 20°C is required for it to be effective.9 In contrast, a contact time of only 5–12 minutes at 20°C is required for another disinfectant, ortho-phthalaldehyde (OPA), with the recommended contact time varying according to coun-
Although use of OPA is more time-efficient than use of glutaraldehyde solution, OPA is more expensive than glutaraldehyde solution.

Given this tradeoff, we evaluated the efficacy and safety of a relatively inexpensive tertiary amine compound (TAC) solution for reprocessing endoscopes. This solution requires only 5 minutes of contact time at 20°C and is already used in European countries (Certificate Number: 1984-MDD-14-262) (Table 1).

**METHODS**

This was a prospective, randomized study conducted at a tertiary referral center in Seoul, Korea, between February 2014 and May 2014. The study protocol was approved by the institutional review board of Kangbuk Samsung Hospital, Seoul, Korea.

1. **Endoscopes and AERs**

   We used colonoscopes (CF-H260AI and CF-Q260AI, Olympus Optical Co., Ltd., Tokyo, Japan) and two AERs (CYW-201, Choyang Medical Industry Ltd., Seongnam, Korea), which have the same duration of use. We used only one type of disinfectant for each AER during the study period. Colonoscopes were randomly assigned to each AER at a 1:1 ratio using a computer-generated random code list, without categorization according to the endoscopist. Fifty cases were processed by each AER.

2. **Endoscope Reprocessing and Disinfection**

   Based on the guidelines for cleaning and disinfecting GI endoscopes as reported by the Korean Society of Gastrointestinal Endoscopy in 2012, we reprocessed the endoscopes as follows.

   After each use of the colonoscope, pre-cleaning was performed at the point of use. The pre-cleaning procedure included wiping the surfaces and flushing the channels with a detergent solution (Cidezyme®, Johnson & Johnson, New Brunswick, NJ, USA). The endoscope components were then disconnected and disassembled. Pressure/leak testing was carried out after pre-cleaning in each endoscopy room. Using the containers, we transported the endoscopes and their components to the reprocessing room.

   The endoscope and its components were immersed in the detergent solution. The entire endoscope was cleaned with a sponge and brush in detergent solution, including all channels and valves. The detergent was then washed off with tap water and the endoscope and its components were placed randomly into one of the AERs. High-level disinfection was carried out as follows. (1) Control group: 0.55% OPA (Cidex® OPA, Johnson & Johnson), exposure time: 10 minutes at room temperature. (2) Experimental group: 4% TAC (Sencron®2, Bab Gencel Pharma & Chemical Ind. Co., Ankara, Turkey), exposure time: 5 minutes at room temperature.

   Following this, the endoscope was rinsed and the channels were flushed with sterile water to remove the disinfectant solution. The endoscope was dried using forced air.

3. **Sampling and Culture**

   After reprocessing, three culture samples were obtained from each endoscope.

   Sample 1: 30 mL of sterile saline was flushed through the operating channel and the flow-through was collected into...
a sterile container (15 mL BD Falcon tube, BD Biosciences, Bedford, MA, USA) at the end of the scope (sample 1). These solutions were filtered through a 0.22 μm cellulose nitrate membrane filter (Falcon Easy Flow 7105, Becton, Dickinson and Company, Franklin Lakes, NJ, USA) under negative pressure, and then, the membrane was immediately spread on a blood agar plate in a sterile manner. Samples 2 and 3: The openings of the suction (sample 2) and biopsy (sample 3) channel were swabbed with sterile saline-soaked cotton swabs (Copan Italia S.p.A., Brescia, Italy), which were then smeared on the surface of blood agar plates. All study samples were tested in the same manner and by the same personnel, who were blinded to the randomization assignment as routine procedure, as was also done with patients’ specimens. Blood agar plates were incubated at 35°C in 5% CO₂ for 48 hours. The number of colonies on each plate was counted, and Gram staining for microorganisms was carried out.

4. Statistics

This study was designed to assess the non-inferiority of 4% TAC to 0.55% OPA in terms of successful reprocessing. The sample size for non-inferiority analysis was based on data from the reference "Comparison on the efficacy of disinfectants used in automated endoscope reprocessors: PHMB-DBAC versus Orthophthalaldehyde,"11 which was calculated with 90% power at a significance level of 5%. And in which 86 endoscope reprocessings (43 endoscopes for each group) were eventually enrolled. Fisher’s exact test was used to compare culture rates. P-values <0.05 were considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics 21.0 (IBM, Armonk, NY, USA).

RESULTS

1. Microbiologic Efficacy

This study included 50 colonoscopes with 150 samples for each arm, which were collected consecutively during the study period. Among a total of 300 culture samples, nine samples were positive: eight had Gram-positive rods and one had Gram-negative Raoultella planticola. These positive results occurred sporadically at intervals during the study period and did not represent skin flora. Therefore, all isolated bacteria were considered to have resulted from insufficient disinfection, not from contamination. Seven of nine positive cultures were obtained from the biopsy channel opening.

The positive culture rate was not significantly different between the two groups (Table 2). Among the nine positive cultures, two were obtained from one endoscope (from both the suction and biopsy channels). We also compared positive culture rates according to endoscope, but there was no difference between the two groups (6% [3/50 endoscopes] for TAC and 10% [5/50 endoscopes] for OPA, P=0.715).

2. Safety

No adverse events attributable to OPA or TAC were observed by the staff in the endoscopy unit, including the reprocessing room, such as mucosal irritation, anaphylaxis-like reactions, respiratory symptoms, or eye irritation. In our reprocessing room, all personnel wear appropriate gloves, gowns, and eyewear, and an adequate ventilation system is always operational during working hours. There were no patient-related complications such as infection, anaphylaxis, or mucosal irritation. Furthermore, no instrument-related complications were observed during the study period.

DISCUSSION

Our results show that the efficacy of TAC was not inferior to that of OPA with regard to high-level disinfection. In addition, there were no complications related to either of these two disinfectants. Based on these results, we conclude that the two disinfectants did not differ in microbiologic or safety aspects. As determined in this study, TAC needs only 5 minutes of contact time at room temperature and is less expensive than OPA (Table 1). TAC is therefore a good alternative disinfectant to OPA for GI endoscope reprocessing using an AER.

In this study, we used colonoscopes rather than gastrosopes because the former are in greater contact with potential pathogens during the endoscopic examination or

| Variable               | TAC (Sencron2®) | OPA (Cidex® OPA) | P-value |
|------------------------|-----------------|-----------------|---------|
| Suction                 | 0/50            | 1/50            | 1.000   |
| Biopsy                 | 2/50            | 5/50            | 0.436   |
| Operating channel      | 1/50            | 0/50            | 1.000   |

*Suction and biopsy refer to the openings of the suction and biopsy channels, respectively.
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