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ORIGINAL ARTICLE

내시경기기 소독에 있어 과초산계 소독제(엔도파®)의 효과

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Efficacy of Peracetic Acid (EndoPA®) for Disinfection of Endoscopes

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Background/Aims: We aimed to investigate the efficacy of peracetic acid (EndoPA®; Firson Co., Ltd., Cheonan, Korea) in disinfecting endoscopes.
Methods: We prospectively investigated the gastroscopes (Part I) utilized in 100 gastroscopic examinations and colonoscopes (Part II) utilized in 30 colonoscopic examinations after disinfecting them with 0.2% peracetic acid (EndoPA®; Firson Co., Ltd.). These instruments had been collected consecutively throughout the study period. We reprocessed and disinfected the endoscopes according to the guidelines for cleaning and disinfecting gastrointestinal endoscopes laid down by the Korean Society of Gastrointestinal Endoscopy in 2017. Three culture samples were obtained from each examination, based on different sampling methods. The primary outcome was a positive culture rate.
Results: In Part I of our study, two of 300 samples were positive. The culture positive rate after disinfection was 0.7% (2/300). The culture positive rate was not significantly different based on the exposure time to EndoPA® or the age of the scopes (p=0.7 or 0.2, respectively). In Part II of our study, all samples (n=90) were negative.
Conclusions: We conclude that 0.2% peracetic acid (EndoPA®) appears to be a good disinfectant for both gastroscopes and colonoscopes. **(Korean J Gastroenterol 2018;71:319-323)**

Key Words: Peracetic acid; Endoscope; Disinfection; Efficacy

INTRODUCTION

Secondary infections caused by gastrointestinal endoscopes are known to occur infrequently.[1-3] However, a few bacterial and viral infections could be caused by the following: examiner-related practices, endoscope disinfection machine itself, and/or washing/cleaning solution.[4] Therefore, guidelines pertaining to the disinfection of equipment have been established in Korea, as well as in the United States and Europe to recommend and ensure a high level of disinfection.[5-7] The most widely used disinfectant in clinical practice has been 2% glutaraldehyde (GA). It is recommended that this agent remain in contact with the used endoscopes for 20 minutes after complete cleaning.[5,8] The steady rise in the number of endoscopic examinations performed has led to an increase in the need for disinfectants that can be used rapidly and efficiently.

Peracetic acid used as a disinfectant is an oxidizing agent

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that destroys cell walls of microorganisms and oxidizes sulfur bonds in proteins and enzymes to produce a rapid antibacterial effect against a wide range of microorganisms.[9] This solution requires 5 minutes of contact time to demonstrate its bactericidal effect and 10 minutes of contact time to demonstrate its sporicidal effect.[10] A Korean study performed in 2004 using peracetic acid disinfectant (Scotelin®; Huons Medicare, Busan, Korea) demonstrated that the culture positive rate after 10 minutes of exposure to Scotelin® was not significantly different from that noted with the use of GA.[11] A recent Chinese study has shown that peracetic acid was more powerful than other disinfectants, such as 2% GA and 0.55% ortho-phthalaldehyde (OPA).[12]

EndoPA® is a new peracetic acid disinfectant that increases the concentration of peracetic acid from 0.15 to 0.2%, thereby increasing its disinfection power and stability. Furthermore, it offers an added advantage of improving the typical odor of peracetic acid.

Here, we evaluated the efficacy of EndoPA® for the disinfection of endoscopes in clinical practice.

SUBJECTS AND METHODS

This was a prospective study performed between September and October 2017 at St. Vincent's Hospital, the Catholic University of Korea. We divided the study into 2 parts. Part I involved the study of gastroscopes, and Part II involved the study of colonoscopes. We reprocessed and disinfected the endoscopes based on the guidelines laid down by the Korean Society of Gastrointestinal Endoscopy in 2017 for the cleaning and disinfection of gastrointestinal (GI) endoscopes.[7] This study was approved by the Institutional Research Ethics Board of the Catholic University of Korea (VC17ZESI0170).

1. Endoscope reprocessing and disinfection

1) Part I

We randomly selected 4 gastroscopes (GIF-H260; Olympus Optical Co., Ltd., Tokyo, Japan). Among these, 2 had been purchased in 2012 and the remaining ones in 2016. Each endoscope had been used to perform 25 examinations, for a total of 100 upper endoscopic examinations.

Pre-cleaning was performed after each examination by rubbing the surfaces and flushing the channels using a detergent (Endozime® AW Triple Plus with APA; RUHOF Co., Ltd., NY, USA). The components of the gastroscope were then disconnected and disassembled and transported to the cleaning room. These instruments were contacted in the Endozime®. Endoscope, including all its channels and valves, was cleaned and immersed in the Endozime® solution. This solution was cleaned with water, and the scope and its accessories were put into one of two automated endoscope reprocessors, in a random manner. Fifty endoscopes were processed by each automated endoscope reprocessor-the 2 automated endoscope reprocessors used in the study were purchased in 2015.

To achieve a high-level of disinfection, 50 endoscopes were immersed in EndoPA® for 5 minutes at room temperature (Group 5), and the remaining 50 were immersed in the same solution for 10 minutes at room temperature (Group 10). After this procedure, the gastroscope was cleaned and its channels were washed with sterile water. The scope was then made dry with forced air.

2) Part II

We randomly selected 3 colonoscopes (CF-H260AI; Olympus Optical Co., Ltd., Tokyo, Japan). Each colonoscope had been used for 10 examinations, for a total of 30 colonoscopic examinations. The detailed reprocessing methods used were the same as those described in Part I. All endoscopes were placed in contact with EndoPA® for 5 minutes at room temperature.

2. Sampling and culture

Following disinfection, 3 culture samples were obtained from each scope. We flushed 30 mL of aseptic saline through the operating channel, and this fluid was gathered in an aseptic bottle at the end of the scope (sample 1). Then, we smeared this fluid on a blood agar plate promptly. The openings of the suction (sample 2) and biopsy channel (sample 3) were wiped with cotton swabs moistened with sterile saline, which were then coated on the surface of the blood agar plates. All study specimens were tested in the same manner by the operators, who were blinded to the random assignment. The blood agar plates were incubated at 35℃ in 5% carbon dioxide for 48 hours. The number of colonies on each plate was counted, and Gram staining was performed to identify microorganisms.[11,13] This method was useful to culture bac-

teria and fungi.

3. Statistics

Chi-square test was used to compare the culture rates in Part I. P-value of less than 0.05 was considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics 20 (IBM, Armonk, NY, USA).

RESULTS

1. Part I

Among the total 300 culture samples, 2 were positive-1 showed a Gram-positive and a nonfermenting Gram-negative bacillus, and coagulase-negative *Staphylococcus* on sample 2 in Group 5 and the other showed a nonfermenting Gram-negative bacillus on sample 1 in Group 10. The culture positive rate after disinfection was 0.7% (2/300) (Table 1). The culture positive rate was not significantly different, based on the duration of exposure to EndoPA® and the age of the scopes (p=0.7 or 0.2, respectively) (Table 2, 3).

Table 1. Culture Positive Rate after Disinfection

	Part I[a] (n=300)	Part II[b] (n=90)
Sample 1[c]	1.0% (1/100)	0% (0/30)
Sample 2[d]	1.0% (1/100)	0% (0/30)
Sample 3[e]	0% (0/100)	0% (0/30)
Total	0.7% (2/300)	0% (0/90)

[a]Part I, using 100 gastroscopes, total 300 of culture samples; [b]Part II, using 30 colonoscopes, total 90 of culture samples; [c]Sample 1, washing specimen from suction channel; [d]Sample 2, swabbed specimen from tip of insertion tube; [e]Sample 3, swabbed specimen from angulation knob.

Table 2. Culture Positive Rate Based on Exposure Time of EndoPA® in Part I of Our Study

	Group-5[a] (n=150)	Group-10[b] (n=150)
Sample 1[c]	0% (0/50)	2% (1/50)
Sample 2[d]	2% (1/50)	0% (0/50)
Sample 3[e]	0% (0/50)	0% (0/50)
Total	0.7% (1/150)	0.7% (1/150)

[a]Group-5, 50 gastroscopes contacted with EndoPA® for 5 minutes, total 150 of culture samples; [b]Group-10, 50 gastroscopes contacted with EndoPA® for 10 minutes, total 150 of culture samples; [c]Sample 1, washing specimen from suction channel; [d]Sample 2, swabbed specimen from tip of insertion tube; [e]Sample 3, swabbed specimen from angulation knob.

2. Part II

All 90 culture samples obtained from the 30 colonoscopes were negative (Table 1).

DISCUSSION

This present study, to the best of our knowledge, is the first Korean study to investigate the efficacy of EndoPA® as a disinfectant for endoscopes in a clinical setting. The culture positive rate after disinfection was 0.5% (2/390). This figure was significantly lower than that observed in recent studies using other disinfectants,[11,13] indicating good efficacy of EndoPA®.

In Part I of our study, which included 100 cases of upper GI endoscopic examinations, we observed that the culture positive rate was 0.7% (2/300) with 1 endoscope being culture positive from Group 5 and 1 from Group 10. The time of exposure to the disinfectant did not appear to affect the efficacy of disinfectant. Additionally, all endoscopes that were culture positive were observed to be those that had been used over a period of 1 year. Thus, the age of scopes was not associated with the culture positive rates in this study.

Currently, disinfectants that are commonly used for a high-level of disinfection of GI endoscopic equipment include GA, OPA, and peracetic acid (Table 4). Peracetic acid is less toxic than GA and OPA, and is known to be a powerful disinfectant showing a broad-spectrum of antimicrobial activity that can effectively disinfect viral, fungal, and bacterial spores.[14-16] Although GA and OPA are widely used to disinfect endoscopic equipment, there is limited data available regarding the use of peracetic acid as a disinfectant for endoscopic equipment.[14,17,18] A recent study designed as an experimental model for a GI endoscope that had been contaminated with 9 strains of microorganisms, including a few antibiotic-resistant bacteria (methicillin-resistant

Table 3. Culture Positive Rate Based on the Age of the Gastroscopes in Part I of Our Study

	5 years (n=150)	1 year (n=150)
Sample 1[a]	0% (0/50)	2% (1/50)
Sample 2[b]	0% (0/50)	2% (1/50)
Sample 3[c]	0% (0/50)	0% (0/50)
Total	0% (0/150)	1.3% (2/150)

[a]Sample 1, washing specimen from suction channel; [b]Sample 2, swabbed specimen from tip of insertion tube; [c]Sample 3, swabbed specimen from angulation knob.

Table 4. Summary of Currently Used Disinfectants for Endoscopic Reprocessing

Disinfectants	Advantages[10]	Disadvantages[10]	Sporicidal Activity[12]		
			Inocula applied to the endoscope (CFU)	Number of survivors (CFU)	Reprocessing time[a] (min)
GA	In-use solution stable for 14 days Does not damage equipment	Action against bacterial spores and mycobacteria is slow. Irritation to skin, eyes, and respiratory tract. Solution stains skin. Insufficient rinsing of devices may influence next subject for endoscopy. Tendency of residue film creation. Ventilation of reprocessing room is recommended.	2.77×10^8 (2% GA)	1,885 (1,000-5,500)[b] (2% GA)	24 (2% GA, disinfection time: 10 minutes)
OPA	In-use solution stable for 7-14 days Does not damage equipment	Action against bacterial spores is slow. Irritation to eyes and respiratory tract. Solution stains skin. Little data on hazards of long-term exposure and on safe exposure levels. Ventilation of reprocessing room is recommended.	2.31×10^8 (0.55% OPA)	2,360 (700-10,375)[b] (0.55% OPA)	19 (0.55% OPA, disinfection time: 5 minutes)
PAA/HPO	Prompt disinfection and sporicidal activity In-use solutions are stable for 1-14 days depending on products Does not harm the environment No chemical cross-linking of protein residues	Irritation to skin, eyes, and respiratory tract. Acidic odor. Ventilation of reprocessing room is recommended. Material compatibility depends on pH and temperature. Acid-related coagulation of proteins is possible, depending on pH.	3.01×10^8 (850 ppm PAA)	2 (0-90)[b] (850 ppm PAA)	19 (850 ppm PAA: disinfection time: 5 minutes)

GA, glutaraldehyde; OPA, orthophthalaldehyde; PAA/HPO, peracetic acid/hydrogen peroxide; CFU, colony-forming unit.
[a]The time of one endoscope was reprocessing by the manual method; [b]The values given are residual bacteria counting numbers (minimum and maximum numbers).

Staphylococcus aureus, vancomycin-resistant *Enterococcus,* and *Clostridium difficile*), showed that the number of residual bacterial colonies in the endoscopes that were disinfected using peracetic acid was significantly lower than that observed using GA and OPA.[12]

The methods utilized for endoscope reprocessing and disinfection should be simple and rapid. This is an important issue in Korea due to a high turnover rate of endoscopic examinations. Peracetic acid requires a short time to disinfect the equipment (5 minutes for most bacteria and 10 minutes for *Mycobacterium tuberculosis*).[10] Based on the aforementioned recent study, peracetic acid shows both, excellent disinfection ability, as well as a short-exposure/contact time to achieve adequate disinfection. The peracetic acid and OPA groups both required 19 minutes each for adequate cleaning and disinfection of endoscopes, whereas the GA group required 24 minutes.[12] Therefore, it can be concluded that the power and efficiency of peracetic acid as an agent used for endoscopic equipment disinfection could be superior to that of GA or OPA.

Previous studies have reported skin and eye irritation as a few of the limitations associated with the use of peracetic acid.[14,19,20] In this study, no discomfort was reported by any of the researchers/personnel, who performed the disinfection. However, further studies will be needed to evaluate the safety of this agent in such users.

There are several limitations to consider when interpreting our results. First, this study was not performed using endoscopes that had been contaminated with the same strains of microorganisms. However, it could be expected that our results are more practical and relevant because endoscopes used in a real-world clinical setting are usually randomly selected. Moreover, the sample size of our study group was not small. Second, we sampled/studied the inner surface of the endoscope channel using a simple cleaning technique. This could be a less efficient method for detecting microorganisms within the lumen of these channels. However, no optimal method has been established thus far to evaluate the outcome of endoscopic reprocessing, and such methods have already been used in various previous studies.[11,13]

Third, the lack of a control group was a limitation. We could not obtain accurate results regarding the efficacy of EndoPA® as a disinfectant. However, this agent showed a much lower culture positive rate than that observed in a previous study using similar methods.[11]

In conclusion, this study showed that EndoPA® could be a useful disinfectant for endoscopic equipment in real-world clinical practice. Our results might provide a reference to help select appropriate disinfectants for cleaning and disinfecting endoscopes.

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