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RAPID COMMUNICATION

Results of gastroscope bacterial decontamination by enzymatic detergent compared to chlorhexidine

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Abstract

AIM: To compare the efficacy of enzymatic detergent with chlorhexidine for gastroscope bacterial decontamination.

METHODS: A prospective randomized controlled study was undertaken to evaluate the ability of these 2 agents to achieve high level disinfection in a gastroscope. A total of 260 samples were collected from 5 different gastroscopes. Manual cleaning was done for 10 min with these 2 agents separately (n = 130 each). Then all specimens underwent 2% glutaraldehyde soaking for 20 min. After 70% alcohol was rinsed, sterile normal saline was flushed into each gastroscope channel and 40 mL of sample was collected. The sample was sent for aerobic bacterial culture after membrane was filtered. A colony count greater than 200 cfu/mL was considered significant.

RESULTS: The positive culture rate was 4.6% in the enzymatic detergent arm and 3.1% in the chlorhexidine arm. Pseudomonas species were the main organism detected from both groups (60%). Multiple organisms were found from 4 specimens (enzymatic detergent arm = 1, chlorhexidine arm = 3).

CONCLUSION: The contamination rate of both types of cleaning solution is equivalent.

Key words: Enzymatic detergent; Gastroscope; Bacterial decontamination

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INTRODUCTION

The endoscope is a complex, reusable device that requires reprocessing before being used in subsequent patients. Generally, a high-level of disinfection is required for reprocessing endoscopes[1-2]. To date, all published incidents of pathogen transmission related to gastrointestinal (GI) endoscopy are associated with failure to follow established cleaning and disinfection/sterilization guidelines or with the use of defective equipments[3-5].

Guidelines for reprocessing flexible gastrointestinal endoscopes have been recommended by several professional organizations[6-10]. However, different professional organizations do not have similar recommended practices[6-9]. Cleaning solutions are one of the different factors. In USA, multi-society guidelines for reprocessing flexible gastrointestinal endoscopes recommend to use enzymatic detergent as an initial endoscopic cleaning agent[1]. However, different countries select different agents for this purpose. Chlorhexidine is one of the popular solutions that have been accepted for endoscope cleaning in Thailand. Unfortunately, there are some reports on bacterial transmission from this standard endoscope reprocessing practice[7]. Bacterial biofilm is known to interfere with the cleaning efficacy of chlorhexidine. Biofilms consist of colonies of organisms forming structures to maximize growth potential. The ability of bacteria to form biofilms is an important factor in the pathogenesis of endoscopy-related infections, particularly as biofilms interfere with disinfection. Strategies aimed at decreasing biofilm formation and viability play an important role in endoscope disinfection because biofilms adhere to the internal channels of endoscopes[4,7].

Recently, many professional organizations have accepted enzymatic detergent for endoscope cleaning[1,7,9,11]. However, there is no randomized controlled study to demonstrate the efficacy of this agent for scope cleaning over chlorhexidine. Hence, the aim of this study was to evaluate the cleaning ability of these 2 agents combined with a standard disinfectant like glutaraldehyde to achieve high level disinfection for gastroscope cleaning.

MATERIALS AND METHODS

A prospective randomized controlled study was undertaken to evaluate the cleaning capacity of gastroscope reprocessing by 3E-ZYME (Medisafe UK Limited, Hartfordshire, UK) and hexene (Osoth Inter Laboratoreis, Chonburi, Thailand). All specimens were collected at the Gastroenterology Unit, King Chulalongkorn Memorial Hospital between July 2004 and October 2004. A total of 260 samples were collected from 5 different gastroscopes. These samples were divided into two groups by stratified randomization and block of 4. Group 1 (n = 130) received enzymatic detergent during endoscope cleaning, and group 2 (n = 130) received chlorhexidine detergent during endoscope cleaning.

The 3E-ZYME is a non-foaming, triple enzymatic detergent and designed for use in endoscope processing. It has a neutral pH formulation and is safe for instruments when used as directed. The directions indicate that 3E-ZYME should be diluted 3-7 milliliters (mL) to every liter (L) of warm (40℃-60℃) water and that the devices should be immersed for 1 min. In the other group, hexene was used as the conventional cleaning detergent. Hexene is an aqueous solution of 4% (weight/volume) chlorhexidine gluconate. In the present study, hexene was diluted from 25 mL to 5 L with filtered water, and the endoscopes were also immersed for 10 min.

Gastroscope reprocessing was performed in accordance with recognized standards for infection control and endoscope reprocessing. All personnel were well trained to comply with the protocol. The protocol for gastroscope reprocessing in the present study is shown in Table 1. Endoscope was randomly selected to be cleaned by one of the two cleaning agents. After gastroscope reprocessing was completely performed, a sample was collected by the flush method (injecting sterile water from the top of accessory channel of the endoscope and subsequently, the sample was collected from the distal tip of the endoscope). All samples were sent for aerobic bacterial cultures using a membrane filtering. Anaerobic bacterial, fungal and viral cultures were not performed due to insufficient information regarding the effect of bacterial biofilm over these organisms.

For quantitative culture, membrane filter method was performed in this study (limit of detection, 1 cfu/specimen). All inoculated plates were incubated aerobically at 37℃ for 24-48 h before the number of colonies was counted. Culture results were variably reported as colony counts per milliliter. A colony count greater than 200 cfu/mL was considered significant.

Chulalongkorn University Institutional Board Review approved and supported all ethical issues related to this study. Descriptive statistics were expressed as n (%). Statistical analysis was performed by chi-square or Fisher's exact test. $P < 0.05$ was considered statistically significant. Data were analyzed with the Statistic of Package for Social Sciences (SPSS 11.5) program (Chicago, IL, USA).

RESULTS

All the five gastroscopes were equally distributed in the 2 groups (Table 2). The rates of bacterial contamination (> 200 cfu/mL) in both groups are shown in Table 3. The positive culture rate was 4.6% from the enzymatic detergent group and 3.1% from the chlorhexidine group. This was not statistically significant (P = 0.747).

Overall, the rate of bacterial contamination was 3.85% (10/260 samples). The incidences and types of organisms during study period are shown in Table 4. The most common organism was Pseudomonas (60%) in group 1 (n = 4, 3.1%) and group 2 (n = 5, 3.8%) (Table 3). Other organisms included Klebseilla species (13.33%), Enterobacter species (6.66%), Acinetobacter baumannii

Table 1 Steps for gastroscope reprocessing in the present study

Gastroscope reprocessing
Cleaning After completion of the cleaning procedure, the inserted tube was wiped with a wet cloth and soaked in detergent solution (chlorhexidine or 3E-ZYME). Detergent solution was suctioned through the biopsy channel until the solution was visibly clean.
While the scope was submerged, mechanical cleaning was performed by washing all debris from the exterior. All removable parts were separately cleaned. A soft cleaning brush was used to clean all accessible channels. Manual cleansing was done for 10 min.
The scope was removed from the detergent solution and then submerged in 5 L of filtered water. An all-channel irrigator was used to flush water through it.
Leak testing of the scope was performed.
Disinfection After manual cleaning, the gastroscope underwent high-level disinfection in a container using 2% glutaraldehyde with a 20-min soak time.
The scope was removed from 2% glutaraldehyde and then submerged in 5 L of filtered water. An all-channel irrigator was used to flush water through it.
Rinsing and Drying The suction/biopsy channel was rinsed with 70% alcohol 20 mL and dried for 5 min.
The suction/biopsy channel was sampled using the flush method.

Table 2 Characteristics of endoscopes in both groups

	Enzymatic detergent	Chlorhexidine
Specimen (n)	130	130
Endoscopes		
Olympus GIF-V	30	30
Olympus GIF-IT 140	30	30
Pentax 2970 K	35	35
Pentax 2930 K	22	22
Pentax 3830 TK	13	13

Table 3 Results of bacterial contamination after gastroscope reprocessing in both groups

	Enzymatic detergent (n = 130)	Chlorhexidine (n = 130)	P
Type of endoscope (Olympus:Pentax)	60:70	60:70	
Positive culture (> 200 cfu/mL)	6 (4.6%)	4 (3.1%)	0.747[a]
Single organism	5 (3.8%)	1 (0.8%)	0.213[b]
Mixed organism	1 (0.8%)	3 (2.3%)	0.622[b]
Pseudomonas aeruginosa	4 (3.1%)	5 (3.8%)	1.000[b]
Non Pseudomonas spp.	3 (2.3%)	3 (2.3%)	1.000[b]

a: chi square test; b: Fisher's exact test.

(6.66%), Staphylococcus coagulase negative (6.66%) and Staphylococcus aureus (6.66%).

DISCUSSION

Ensuring safety in patients undergoing endoscopy, proper endoscope reprocessing is required. According to Spaulding classification of disinfection of medical and surgical instruments, flexible GI endoscope reprocessing is categorized as semicritical level since endoscopy has no involvement with tissue penetration[12].The reprocessing of endoscopes is susceptible to multiple errors, as it is a multi-step process relying on both human and material for reprocessing. The reprocessing involves meticulous manual cleaning and rinsing. This step is followed by high-level disinfection with liquid chemical germicide. Chlorhexidine is commonly used to decontaminate an endoscope prior to high level disinfection. However, recent reports from the Center of Disease Control and Prevention suggested that a significant number of infections are transmitted during endoscopic procedures after reprocessing these scopes under both manual and automated cleanings[7]. Detailed analysis of these cases has identified either a breakdown in the cleaning process or a damage by equipment as the causative factor[6,13]. It is possible that bacterial biofilm contributes to the failure of adequate endoscope reprocessing in certain instances. Vickery *et al*[14] showed that bacterial biofilm is an important factor in endoscope contamination, and that routine cleaning procedures do not remove biofilm reliably from endoscope channels. Generally, biofilm consisting of bacteria enclosed in a matrix of exopolysaccharide (EPS) can form on many medical devices such as catheters and endoscopes. Chemical cleaning methods by agents like chlorhexidine are often ineffective because biofilm has a strong resistance to these biocides. Biofilm removal by physical methods such as ultrasound and mechanical cleaning is reasonably effective but it is difficult to supervise in practice.

To solve this problem, agents that can be used to remove the bacterial biofilm during the process of endoscope cleaning are desirable. The efficacy of enzymatic cleaning agents to reduce the bacterial load and biofilm in laboratory setting has been studied recently[15]. In addition, the ASGE and the SHEA have recently endorsed enzymatic detergents in reprocessing endoscopes and reusable accessories[1].

Enzymatic detergents generally containing various combinations of protease, lipase and amylase, require a minimum contact time to enable them to adequately remove the bacterial biofilm[16]. To date, there has been no report on the bacterial decontamination rate of these enzymatic detergents for endoscope reprocessing.

The bacterial concentration cultured from an endoscope after decontamination is an important factor in determining the risk of transmission from an endoscope to a patient. At present there is no standard bacterial concentration above which the endoscope is considered contaminated. We used the AAMI[17,18] guidelines established for hemodialysis water, < 200 cfu/mL.

In our series, the overall rate of bacterial contamination above the cut off level from enzymatic detergent and chlorhexidine was very low (3.85%). This is significantly different from previous studies that mainly used non-enzymatic cleaning agents which demonstrated a contamination rate as high as 24%[1,5]. The majority of bacteria identified in this study were Gram-negative bacilli. Pseudomonas aeruginosa was the most common species. This is similar to other published series[19,20]. Though we did not observe any adverse clinical outcomes in the patients exposed to the contaminated endoscopes, the primary goals of this study were not to address this question.

Table 4 Incidence and types of organisms during study period

Type of organism	Enzymatic detergent (samples, *n*)	Chlorhexidine (samples, *n*)	Total, *n* (%)
Pseudomonas aeruginosa	4	5	9 (60)
Klebsiella species	1	1	2 (13.3)
Enterobacter species	1	0	1 (6.7)
Acinetobacter baumanii	0	1	1 (6.7)
Staphylococcus coagulase negative	1	0	1 (6.7)
Staphylococcus aureus	0	1	1 (6.7)
Total	7	8	15 (100)

A group from Walter Reed Army Medical Center reported that their surveillance of bacterial culture result from GI endoscopes is as high as 14.5% and that more than half of positive cultures are obtained from therapeutic scopes that were used during emergency procedure, which might be attributed to faulty mechanical cleaning by non-nursing personnel after emergent procedures[5]. Furthermore, adherence to the standard guideline for endoscope reprocessing can result in a low rate of disease transmission[1].

In conclusion, 4% chlorhexidine is not worse than enzymatic detergent for endoscope decontamination. Both of them have a very low rate of significant positive bacterial cultures. Further investigations on the effectiveness of the enzymatic agent on decontamination of other organisms apart from aerobic bacteria are required.

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