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Results of Gastroscope Bacterial Decontamination by Enzymatic Detergent Compared to Chlorhexidine

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ABSTRACT

Background: Currently, the standard practice for endoscope reprocessing requires high level of disinfection. Chlorhexidine is one of the solutions that have been accepted for endoscope cleaning. However, persistent bacterial contamination due to the bacterial biofilm may occur. Enzymatic detergent (3E-ZYME, Hartfordshire, UK) has been proposed to use in order to reduce this problem but the efficacy of this detergent has never been compared to chlorhexidine.

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

Materials and Methods: A prospective randomized controlled study was undertaken to evaluate the disinfection capacity of gastroscope by these 2 agents. There were 260 samples collected from 5 different gastroscopes. Manual cleaning was done for 10 minutes by these 2 agents separately (n = 130 each). Then all scopes underwent 2% glutaraldehyde soaking for 20 minutes. After 70% alcohol rinsed, sterile normal saline was flushed into each scope channel and 40 mL of sample was collected. The sample was sent for aerobic bacterial culture after membrane filtered method. Significant bacterial growth was defined as a colony count more than 180 cfu/mL. (MMWR Recomm 2003)

Results: The significant positive culture rates from enzymatic detergent and chlorhexidine group were 4.6% (n = 6) and 3.1% (n = 4) respectively. Pseudomonas species was the main organism detected from both groups (60%). Multiple organisms were found from 4 specimens (enzymatic detergent group = 1, chorhexidine group = 3)

Conclusion: The rate of significant bacterial contamination of gastroscopes after enzymatic bacterial decontamination was low but not significantly lower than conventional chlorhexidine cleaning technique. Enzymatic detergent was not better than 4% chlorhexidine for gastroscope bacterial decontamination.

Key words : gastroscope, bacterial decontamination, enzymatic detergent, chlorhexidine

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BACKGROUND

The endoscope is a complex, reusable device that requires reprocessing before being used on subsequent patients. The most commonly used methods for reprocessing endoscopes result in high-level disinfection. To date, all published episodes of pathogen transmission related to GI endoscopy have been associated with failure to follow established cleaning and disinfection/ sterilization guidelines or with the use of defective equipment.[1-3]

Guidelines for reprocessing flexible gastrointestinal endoscopes have been recommended by several professional organizations.[6-11] However, different professional organizations do not have similar recommended practices. Cleaning solutions are one of the different factors. Generally, Chlorhexidine is one of the popular solutions that have been accepted for endoscope cleaning. Unfortunately, there were some reports on bacterial transmission from this standard endoscope reprocessing practice.[7] One of the factor that interferes the cleaning efficacy of chlorhexidine is bacterial biofilm.

Biofilms consist of colonies of organisms forming structures which can be maximized 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 will have an important role in endoscope disinfection because biofilms have been found to adhere to the internal channels of endoscopes.[4,7]

Recently, many professional organization already recommended enzymatic detergent for endoscope cleaning.[1,7,9,11] However, there is no randomized controlled study to demonstrate the efficacy of this agent over chlorhexidine yet. Hence, the aim of the study was to compare the efficacy of enzymatic detergent with chlorhexidine for gastroscope reprocessing.

MATERIALS AND METHODS

A prospective randomized controlled study was undertaken to evaluate the disinfection capacity of gastroscope cleansing by these 2 agents. All specimens were collected at Gastroenterology Unit, King Chulalongkorn Memorial Hospital between July 2004 and October 2004. There were 260 samples collected from 5 different gastroscopes. These samples were randomized 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 (Medisafe UK Limited, Hartfordshire, UK) label indicates "3E-ZYME" is a non foaming, triple enzymatic detergent, is designed for use in endoscope processing. 3E-ZYME is a neutral pH formulation that 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˚C - 60˚C) water and the devices should be immersed for 1 minutes. In the present, the detergent was diluted 25 mL to 5 L of tap water, and the endoscopes were exposed for 10 minutes. In the other

Box 1 Steps for gastroscope reprocessing in the present study.

Gastroscope reprocessing

Cleaning

1. After completion of procedure, the insertion 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.
2. 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 minutes
3. The scope was removed from the detergent solution and then submerged in 5 L of tap water. An all-channel irrigator was used to flush water through it.
4. Leak testing of the scope was performed.

Disinfection

5. After manual cleansing, the gastroscope underwent high-level disinfection in a container using 2 % glutaraldehyde with a 20-min soak time.
6. The scope was removed from the 2 % glutaraldehyde and then submerged in 5 L of tap water. An all-channel irrigator was used to flush water through it.

Rinsing and Drying

7. The suction / biopsy channel was rinsed with 70 % alcohol 20 ml. and this channel was dried for 5 minutes.
8. The suction / biopsy channel was sampled with the use of the flush method (Figure 1).

group, Hexene was used as conventional cleaning detergent. Hexene is an aqueous solution of 4 % (weight/volume) chlorhexidine gluconate.

Gastroscope reprocessing was performed in accordance with recognized standards for infection control and endoscope reprocessing. All personnels were well trained to comply with the protocol. The protocol for gastroscope reprocessing in this study is shown in Box 1. Two different types of detergents were randomized for each group during cleaning step. After gastroscope, reprocessing was completely performed, sample was collected by the flush method. (Figure 1) All samples were sent for aerobic bacterial cultures after membrane filtering.

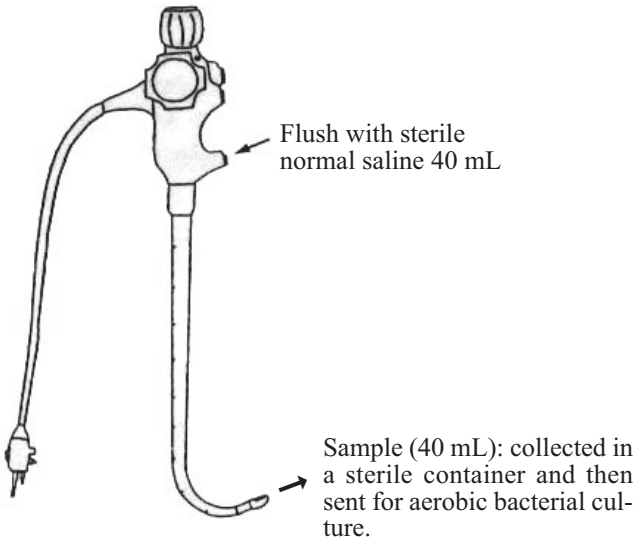

Figure 1 Lumen sample collection with the flush method.

Table 1 Characteristics of endoscopes in both groups

	Group 1	Group 2
Number of specimen	130	130
Endoscope		
Olympus GIF-V	30	30
Olympus GIUF-IT140	30	30
Pentax 2970 K	35	35
Pentax 2930 K	22	22
Pentax 3830 TK	13	13

Quatitative culture, membrane filter method was performed in this study (limit of detection, 1 cfu/specimen). All inoculated plates were incubated aerobically at 37˚C for 24 to 48 hours before the number of colonies were counted. Culture results were variably reported as colony counts per milliliter. Significant bacterial growth was defined as a colony count more than 180 cfu/mL.

Whenever the significant bacterial overgrowth was detected, the endoscopy list for that day was reviewed to identify the patient who subsequently underwent endoscopy with that contaminated scope. Thereafter, telephone interview and medical record search were performed to evaluate the infectious consequence that may occur after the procedure.

Descriptive statistics are expressed as number(%). Statistical analysis was performed by Chi-square or Fisher exact test. P-valvue <0.05 was consider to be statistically significant. Data were analyzed with the Statistic of Package for Social Sciences (SPSS 11.5) program (chicago, IL, USA).

RESULTS

All five gastroscopes were equally distributed into 2 groups. (Table 1)

The rates of bacterial contamination (>180 cfu/mL) in both groups are shown. (Table 2) Six positive

Table 2 Results of bacterial contamination after gastroscope reprocessing in both groups

	Group 1 (n = 130)	Group 2 (n = 130)	p
Type of endoscope (Olympus : Pentax)	60:70	60:70	
Positive culture (>180 cfu/mL)	6 (4.6%)	4 (3.1%)	0.747a
Single organism	5 (3.8%)	1 (0.8%)	0.213b
Mixed organisms	1 (0.8%)	3 (2.3%)	0.622b
Pseudomonas spp.	4 (3.1%)	5 (3.8%)	1.000b
Non *Pseudomonas* spp.	3 (2.3%)	3 (2.3%)	1.000b

a = Chi square
b = Fisher's Exact

samples (4.6%) were found from group 1 and four positive samples (3.1%) were found from group 2. The rates of positive culture from both groups did not reach statistical difference. (p = 0.747)

Pseudomonas specie was the predominant organism that was founded in both groups. [group 1 (n = 4, 3.1%) and group 2 (n = 5, 3.8%)] (Table 2)

Overall, the rate of bacterial contamination (>180 cfu/mL) was 3.9% (10/260 samples). (Figure 2) The incidence and types of organisms during the study period were shown. (Table 3) The most common organism was *Pseudomonas* spp (60%). Other organisms included *Klebsella* spp (13.3%), *Enterobacter* spp (6.7%), *Acinetobacter baumannii* (6.7%), *Staphylococcus coagulase negative* (6.7%) and *Staphylococcus aureus* (6.7%) also found.

There was no report on any infectious consequence such as fever in any of 10 patients who underwent endoscopy subsequently used by contaminated gastroscopes.

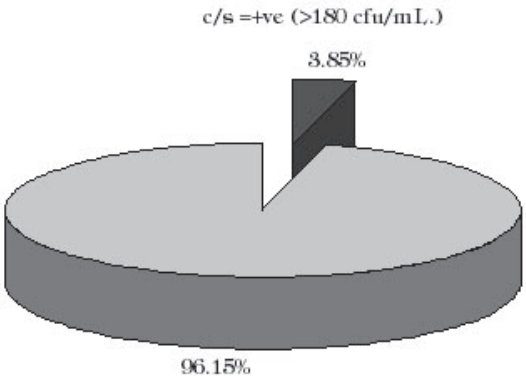

Figure 2 The rate of bacterial contamination > 180 cfu/mL in overall.

DISCUSSION

To ensure the safety of patients undergoing GI 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 its use need to contact mucosa only but no tissue penetration.[12] Generally, the reprocessing of endoscopes is susceptible to multiple errors, as it is a multisteps process relying on both human and material for reprocessing. The reprocessing involves with meticulous manual cleaning and rinsing. These are usually followed by high-level disinfection with liquid chemical germicide. In the ideal setting, most endoscopy practice detailed protocol with reliable cleaning agent such as chlorhexidine. In general, chlorhexideine is good enough to decontaminate bacteria from endoscope before undergoing high-level disinfection process. However, recent reports from the Center of Disease Control and Prevention suggested that there was significant number of infection transmitted during endoscopic procedures after reprocessing the scope under the strict guideline.[7] Reported organisms are mostly bacteria. Critical analysis of those cases revealed either a breakdown in the reprocessing process, or as a result of damage equipment.[6,13] Apart from those mistakes, there is a possibility of inadequate bacterial decontamination from chlorhexidine by failure of this agent to clear bacterial biofilm. Generally, biofilm consisting of bacteria enclosed in a matrix of exopolysaccharide (EPS) which can form on many medical devices such as catheters and endoscopes. Chemical cleaning methods by agent liked chlorhexidine are often ineffective because biofilm has a strong resistance to these biocides. According to a recent study, bacte-

Table 3 The incidence and types of organisms during this study period

Type of organisms	Group 1 (samples)	Group 2 (samples)	Total
Pseudomonas spp.	4	5	9 (60%)
Klebsiella spp.	1	1	2 (13.33%)
Enterobacter spp.	1	0	1 (6.66%)
Acinetobacter baumannii	0	1	1 (6.66%)
Staphylococcus coagulase negative	1	0	1 (6.66%)
Staphylococcus aureus	0	1	1 (6.66%)
Total	**7**	**8**	**15 (100%)**

rial biofilm has been confirmed as one of the important factors for the failure of decontamination.[14] Moreover, the same group from Australia demonstrated that routine cleaning procedures did not remove biofilm reliably from endoscope channels, and this may explain the unexpected failure of decontamination encountered in practice despite good adherence to infection control guidelines.[15] Even though, 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, agent that can be used to remove bacterial biofim during the process of endoscope cleaning is required. Recently, there were many reports on efficacy of enzymatic cleaning agents to reduce bacterial load and biofilm in laboratory setting.[16] In addition, last year enzymatic deter gent has been advocated by ASGE (the American Society of Gastrointestinal Endoscopy) and SHEA (the Society for Healthcare Epidemiology of America) to use during mechanical cleaning process for endoscopes and reusable accessories.[1]

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

The number of bacteria culture from endoscope after reprocessing is one of the important factors that can determine the risk of bacterial transmission from endoscope to subsequent patient. So far, there is no standard for acceptable level of positive bacterial culture for the endoscope. Therefore, we applied the allowed number of bacterial culture from the guideline for hemodialysis water on bacterial decontamination to be used in our study as a cut off level. Generally, agent to be used for hemodialysis is classified as critical level for disinfection but endoscope reprocessing requires only semicritical level. According to Association for the advancement of Medical Instrumentation (AAMI), the acceptable level of number of organism in product water for hemodialysis should below 200 cfu/mL.[18] Our significant bacterial growth was defined as a colony count more than 180 cfu/mL after quantitative membrane filtered of the specimen[17]. This standard method was very sensitive and able to detect small amount of organism from 0 to180 cfu/mL.

The rate of bacterial contamination above the cut off level from enzymatic detergent in our series was very low (3.85%). This is significantly different from previous studies that mainly use non-enzymatic cleaning agents which demonstrated a higher rate of contamination to be as high as 24%[1,5]. In addition, there was no report on any significant transmission of any infectious diseases in our series. None of our 10 patients who subsequently underwent endoscopy by using contaminated gastroscopes reported fever or significant illness that required medical care. However, asymptomatic bacteremia could not be determined because routine blood culture after endoscopy was not done in our protocol.

Our series demonstrated that the rate of bacterial decontamination by chlorhexidine was already low. Therefore, enzymatic detergent was not able to demonstrate better efficacy over cholrhexidine. This may be due to our adherence to protocol for endoscope reprocessing. In addition, the incidence of bacterial biofilm formation in our study might be very low. A group from Walter Reed army medical center reported their surveillance culture result form GI endoscopes to be as high as 14.5%. They also found that more than half of positive cultures were obtained from therapeutic scopes that were used during emergency procedure. This was 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. This was also advocated by multisociety guideline.[1]

Our series revealed that majority of bacteria grew significantly above the cut off level were gram negative bacilli and the most common species was *Pseudomonas*. This result is similar to other reports on endoscope bacterial decontamination.[19,20] However, we did not demonstrate benefit of these two agents over highly resistant organism such as Mycobacterium and spores. To eradicate these organisms, the cleaning process may need better detergents and sterilization products to ensure the safety after the endoscope has been used on patient with mycobacterium infection. Commercially available agents emerging in the field is varies. Unfortunately, there are insufficient published data on this purpose.[21,22] The disposable sterile-sheath flexible endoscope has been designed to be clinically equivalent to standard models, with significant decrease in reprocessing work and turnaround time.[23] Its use

for this purpose is also required further investigation.

In conclusion, our study has proved that enzymatic detergent is not better than 4% chlorhexidine for endoscope decontamination. They both had a very low rate of significant positive bacterial cultures. This may be due to our strict adherence of guideline after bacterial decontamination with proper disinfection process. Further investigation on the effectiveness of the enzymatic agent on decontamination of other organisms apart from bacteria is required.

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