SAFETY OF REPROCESSING OF SINGLE-USE ENDOSCOPIC BIOPSY FORCEPS: A SINGLE-CENTER CROSS-SECTIONAL STUDY

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ABSTRACT

Significance: The increasing cost of endoscopic accessories has prompted the utilization of reprocessing of these single-use devices (SUD) to allow reuse. Although some endoscopy centers have adapted reprocessing to minimize cost, studies on its safety and efficacy are lacking and results are conflicting. The objective of this study is to demonstrate the safety of reprocessing of single-use endoscopic biopsy forceps measured in terms of bioburden after reprocessing.

Methods: This is a cross-sectional study. Endoscopy forceps were chosen by simple random sampling to undergo a standard reprocessing protocol. Forceps used in patients who are receiving antibiotics and with bacterial, viral or fungal infection were excluded. Included forceps were swabbed and cultured for any organism. Bioburden was measured in which the growth of a high-concern organism with ≥ 1 colony-forming unit or any other bacteria with ≥10 CFU was considered significant.

Results: Twenty-four endoscopy forceps were included (12 from upper GI and 12 from lower GI endoscopy). No growth of any organism was recorded in all reprocessed forceps with a mean time of incubation of 3 days. There was zero bioburden.

Conclusion: Reprocessed endoscopy forceps are safe to use with the reprocessing protocol used in this study. If adapted and standardized, reprocessing of SUDs will have positive implications in healthcare in terms of minimizing the cost and increasing accessibility of such devices.

Keywords: Cross-sectional study, reprocessing, single-use devices, single-use endoscopy forceps, bioburden

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I. INTRODUCTION

More than 5 million upper GI endoscopies and more than 12 million colonoscopies are performed annually in the United States. It is presumed that most, if not all these procedures will require diagnostic devices such as biopsy forceps to complete the procedure. However, most available endoscopic devices are marketed for single-use only. This places great economic burden on the patient and may limit their options for endoscopy.

Some endoscopy centers all over the world have developed their own protocols for the reprocessing of single-use devices (SUD). However, there is no universal guideline for reprocessing and the safety and efficacy of re-use has not been firmly established. This study aims to demonstrate the safety of reprocessing of single-use endoscopic biopsy forceps.

The increasing healthcare cost and cost of instruments has prompted the application of reprocessing of medical devices, such as endoscopic devices, which are marketed for single-use. If found that such reprocessing is safe, then patients and healthcare companies will have a lighter burden in terms of costs.

II. BACKGROUND

The reuse of medical devices has been in place since the 1970s. Devices made of steel or glass or metal were usually sterilized or cleaned with a cleaning solution before use for the next patient. After the 1970s, however, with the advent of more complex designs of medical devices, manufacturers started to produce single-use devices in order to prevent the harm induced with reuse, such as that of malfunction due to wear-and-tear.[1]

Reusable devices, as defined by the US Food and Drug Administration, are those devices that are reprocessed and reused on multiple patients. On the other hand, single-use devices or disposable devices are intended for use on one patient during a single procedure.[2] Devices are classified by their risk of transmission of infection based

on Spaulding's Classification. Critical devices are those that come in contact with blood or tissue, such as surgical forceps and scissors. Semi-critical devices are those that come in contact with intact mucus membranes, such as endoscopes. Non-critical devices are those that come in contact with unbroken skin, such as stethoscopes and blood pressure apparatuses. The minimum required activation level for each classification is as follows: Critical devices would require sterilization, semi-critical devices would require high-level disinfection, and non-critical devices would require low-level to intermediate disinfection.[3] Biopsy forceps, which come into contact with gastric and colonic mucosa, are classified as critical devices.

Reprocessing includes disinfection, sterilization, cleaning and repackaging and relabeling a medical device in order to be used again. The process can be done within the hospital or by outside reprocessing facilities (also called *third-party reprocessors*). In 2002, a Medical Device User Fee and Modernization Act was passed in US Congress which required that reprocessing must follow the same disinfection procedure and use the same disinfection equipment as the original manufacturers.[4] There is no such law in the rest of the world.

Infectious disease complications of endoscopic procedures are rare. There is a zero to 8% chance of bacteremia from esophagogastroduodenoscopy (EGD) with biopsy. The highest rate of bacteremia is seen in EGD with esophageal dilation at 22.8%. Infection from endoscopic procedures is thought to occur due to entry of microbial flora into possible mucosal trauma or instrumentation during the procedure[5].

Data on the safety and efficacy of reprocessed SUDs is scarce and conflicting. A study in a medical center in Alabama tested the safety of single-use endoscopic biopsy forceps and snares after submitting them for reprocessing by a licensed third-party reprocessor. The results were unfavorable; demonstrating that 79% of reprocessed devices collected were positive for significant microbial growth by Day 10 of incubation[6].

A pilot study conducted in 2017 by the Mayo Clinic in Massachusetts tested single-use endoscopic variceal band ligators for bioburden after reprocessing. It showed better results compared to the Alabama study in that 95% of the devices collected showed no microbial growth. This study concluded that reprocessing of single-use devices is safe and effective[7].

The performance of a reprocessed device is more difficult to measure. There are no guidelines to ensure how a device is assured of its quality and performance after reprocessing. Several studies have depended on the surgeon or endoscopist's opinion

on the performance of the device. In a study in 2010, laparoscopic surgical trocars were found to have decreased performance after repeated reprocessing. Trocars were found to be faulty and less flexible in terms of adjustment and had to be replaced intra-operatively[8]. A Korean study in 2012 compared the efficacy of disposable and reprocessed endoscopic biopsy forceps. Forceps performance were graded based on size of bite, ease of opening and closing. They concluded that disposable forceps performed better than reused forceps[9]. However, the study had possible significant bias, since only one endoscopist and three nurses graded all forceps used in an arbitrary manner (on a scale of 1 to 5, with 5 being excellent) and none of them were blinded.

Another study using reusable versus disposable forceps in obtaining endoscopic samples from canine patients was done in a veterinary hospital in Edinburgh, United Kingdom. Quality of biopsy samples in this study was measured in terms of adequacy of sample, depth of the sample, number of crush artifacts and villi number seen. The study was promising in that there was no difference in quality of biopsy samples using either forceps even after 10 to 15 uses[10].

If proven to be safe and effective, reprocessing of single-use devices will have significant impact on the healthcare system. It might mean significantly less financial burden to patients and endoscopy units. It might pave the way for the better regulation of reprocessing practices across health institutions. The objective of this study is to demonstrate the safety of reprocessing of single-use endoscopic devices, specifically, biopsy forceps used during endoscopy, measured in terms of the bioburden in reprocessed devices.

III. METHODOLOGY

Inclusion and Exclusion Criteria

Biopsy forceps used and reprocessed in our institution's endoscopy unit were swabbed and cultured. Bioburden was measured and based on the description of surveillance for bacterial contamination of duodenoscopes after reprocessing as described by the Center for Diseases Control and Prevention. Growth of Gram-negative bacilli such as *Escherichia coli, Klebsiella pneumoniae* and other Enterobacteriacea, and *Pseudomonas aeruginosa, Staphyloccoccus* and *Enterococcus* (which are considered "high-concern" organisms) of more than or equal to 1 colony-forming unit (CFU) was considered to be a positive result. Growth of other types of bacteria not mentioned

(considered as “low-concern” organisms) were also considered a positive result if more than or equal to 10 CFUs will be found on culture[11].

The study included reprocessed biopsy forceps used during endoscopy and which have undergone the standard reprocessing protocol in our institution. Forceps used in patients who are receiving antibiotics during the endoscopic procedure and those who have known ongoing bacterial, viral or fungal infection were excluded.

Twenty-four biopsy forceps were used in the study; twelve each for upper GI endoscopy and for lower GI endoscopy forceps. The sample size was calculated based on the proportion of reprocessed biopsy forceps with bacterial growth after a single use assumed to be 79% (in the study by Hambrick, 2001). With a maximum allowable error of 20% and a probability of 90%, the sample size for each group was 12 for determination of bacterial growth in the upper and lower GI tract. The forceps were chosen at random. For every other endoscopy procedure done in a day at our center, the biopsy forceps, if used during the procedure, was evaluated for inclusion in the study. This type of sampling was done until adequate sample size was reached. Twenty upper GI endoscopy forceps were evaluated for inclusion into the study. Seven were excluded due to the following: 3 had positive rapid urease test, 2 had ongoing antibiotic treatment, and 2 had ongoing systemic infection (sepsis). For lower GI endoscopy, fifteen colonoscopy forceps were evaluated for inclusion. Three were excluded due to the following: 1 due to suspicion of infectious colitis, 1 had ongoing antibiotic treatment, and 1 had suspicion of schistosomiasis. Twelve forceps for each group were then reprocessed and results were evaluated. This process is summarized in Figure 1.

Selected biopsy forceps were reprocessed using the standard reprocessing protocol of our institution. Forceps were soaked in Cidezyme ® , an enzymatic detergent solution for 20 minutes. The forceps were hung to dry in a positive pressure room for 30 minutes and then sent for central sterilization to undergo Sterrad ®, a sterilization procedure that uses low temperature gas plasma and peroxide.

After reprocessing, each biopsy forceps was swabbed from its handle to the tip using sterile technique. The swabbed specimens were sent for culture for any organism. Based on the reference on endoscope bioburden of the Center of Disease Control and Prevention, a significant result is the detection of a high-concern organism - Gram

negative bacilli with ≥ 1 colony-forming unit or any other bacteria with ≥10 CFUs. Bioburden was based on percentage of positive growth over the whole population.

Ethical Considerations

Informed consent for this protocol was waived. The research presented no more than minimal risk to the subjects and a waiver did not adversely affect the rights and welfare of the subjects. The clinical protocol and all relevant documents were reviewed and approved by the St. Luke's Medical Center Research and Biotechnology Division and the Institutional Ethics Review Committee. Patient confidentiality was respected by ensuring anonymity of patient records. All study data was recorded and investigators were held accountable for the integrity of the data such as accuracy, completeness and legibility. The manner of disseminating and communicating the study results guaranteed the protection of the confidentiality of the patient's data. The data for this study will be kept for a maximum of three years by the investigators. Once the study is concluded, all physical and electronic data such as data collection forms and digitized data collection forms shall be destroyed by paper shredding and electronically deleted, respectively

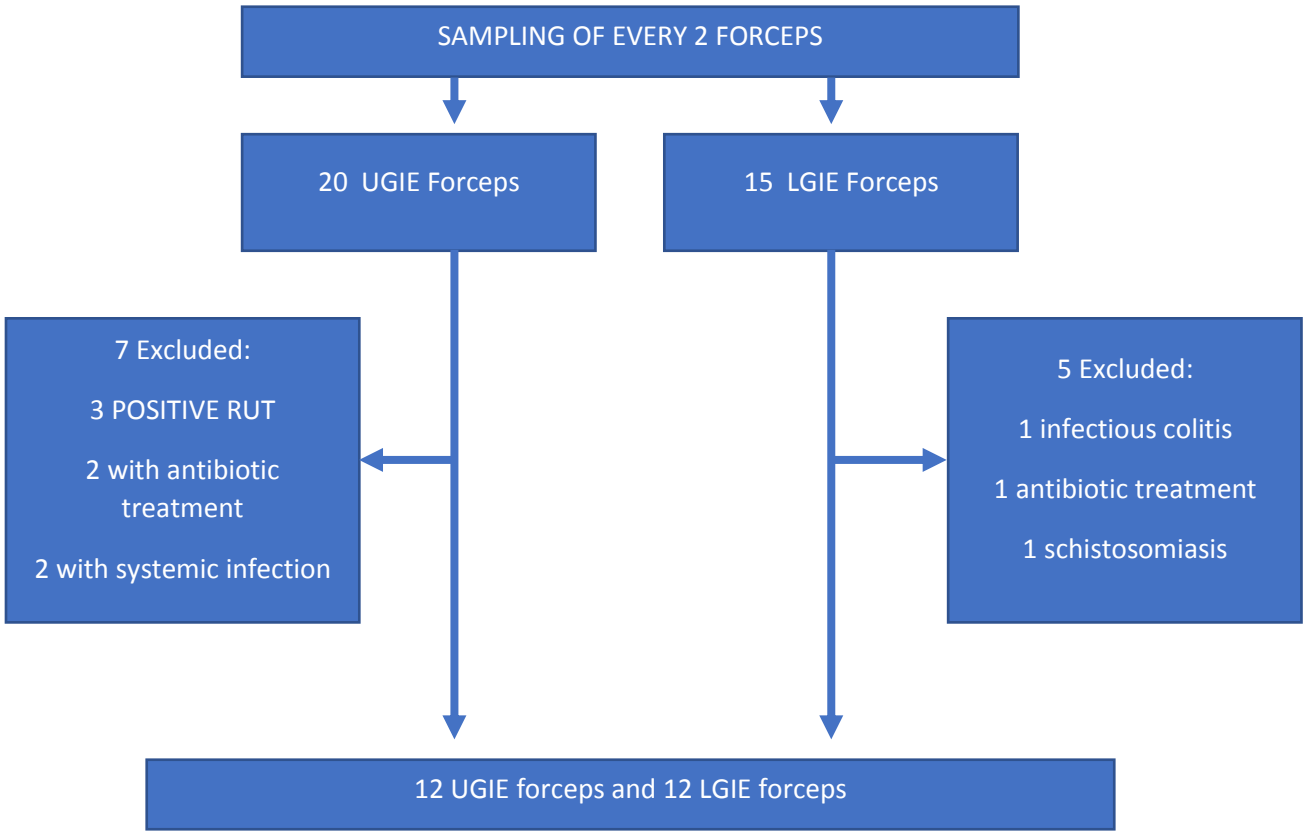

Figure 1. ***Methodology: Sampling and Inclusion of Endoscopy Forceps***

IV. RESULTS

Characteristics of the biopsy forceps included in the study are summarized in Table 1. The most common indication for esophagogastroduodenoscopy was uninvestigated dyspepsia while biopsy in the upper GI tract was mainly for rapid urease testing. The most common indication for colonoscopy was for screening while biopsy in the lower GI tract was mainly for biopsy of polyps.

All 12 upper GI endoscopy forceps and all 12 lower GI endoscopy forceps did not show any growth of any organism at a mean time of three days of incubation. Culture results were re-examined at a maximum of 5 days and no growth was recorded at this time. No bioburden was noted with these results.

Table 1. Characteristics of Biopsy Forceps Included in the Study

	UGI Endoscopy Forceps (n = 12)	LGI Endoscopy Forceps (n = 12)
Indication for Endoscopy		
Uninvestigated Dyspepsia	9	N/A
Recurrent Reflux	3	N/A
Constipation	N/A	1
Lower GI Bleeding	N/A	10
Screening	N/A	1
Indication for Biopsy		
Polyp	2	12
For Rapid Urease Test	10	N/A

V. DISCUSSION

Rationale For Reprocessing

There are several reasons why health care providers have started to reprocess single-use devices. The most obvious and strongest argument for reprocessing is cost. This is especially true in developing countries where the high cost of healthcare can limit proper medical management to patients. This is also true in resource-limited settings wherein new devices for each procedure cannot be regularly acquired. Cost of reprocessed biopsy forceps

may be negotiated to a much lower price, which is a great concern to many Filipinos, of whom many still pay for health care out-of-pocket. For example, an economic analysis in Canada computed about 49% savings when reprocessing of SUDs was utilized[12]. In a French study in 2003, the cost per use of reprocessed endoscopic biopsy forceps was cut in half per use. In this study, the mean number of uses was an average of 90 reuses per forceps[13].

Environmental issues have also emerged in that the disposal of single-use devices contribute to the already growing medical waste. Reprocessing medical devices can help in reducing this environmental burden. It would take about 1 US dollar to properly discard each pound of medical waste. In a 2013 article, a hospital in Boston estimated that 10,000 pounds of medical waste was avoided with reprocessing[14]. In actuality, many healthcare institutions around the world have already taken to reprocessing single-use devices for the reasons stated above.

Issues in Reprocessing

The latest medical devices have been engineered in such complex ways in order to serve their medical purpose. The materials and parts of a device may be fragile and intricate so that it may only be used once for it to perform adequately. Manufacturers label a device as "single-use" when they can only claim its safety and efficacy for only one use on one patient. After reprocessing, manufactures are not liable for any adverse effect in terms of performance of the device.

The World Health Organization has also passed a memorandum citing additional concerns with use of reprocessed SUDs. Reprocessing may alter the device design and material which may affect function. Reprocessed SUDs may harbor infectious agents retained by cross-contamination which may not be adequately removed during reprocessing[2,4].

Once a health center has decided to proceed with reprocessing of SUDs, certain procedures need to be in place in order to alleviate risks. The reprocessed device should be properly labeled, with a forward and backward tracing in order to determine the reprocessing events and the performance of the device after reprocessing.

Issues on patient consent have also emerged with the use of reprocessed SUDs. It is argued that if proper reprocessing protocols are in place, then a patient's consent to use a reprocessed SUD may not be needed. On the other hand, it has also been argued that hospitals

may be violating the patient's right to decide on the matter[15]. To date, there is no specific law that prohibits the reprocessing of SUDs, except in France, where it is illegal.

In the USA, the Medical Fee Act of 2002 regulates the reprocessing of SUDs and requires regular submission of data on reprocessed devices. In fact up to 30% of US hospitals report that they use reprocessed SUDs. Most other countries do not have such validation and regulation practices. In Canada, for example, each healthcare institution is given the independence to have their own guidelines and policies on reprocessing as long as they follow the original disinfection procedure done by the original manufacturer. In the United Kingdom, reprocessing is discouraged due to possible legal consequences. On the other hand, in European countries such as Germany and Spain, up to 40-80% of hospitals reprocess single-use devices. In the Middle East and in Asia, which includes the Philippines, there are no government regulations in place and most reprocessing is done within the same healthcare institution and conforms to each institution's standard protocol on reprocessing[2,4,18]

Some of these issues may be easily overcome in our country if a standardized reprocessing protocol is used and if a governing independent body will continuously monitor the quality of reprocessing in each endoscopy unit. Ethical considerations such as patient consent in the use of reprocessed forceps may be discussed as per each hospital's ethical committee.

VI. CONCLUSION AND RECOMMENDATIONS

With the institutional reprocessing protocol used in this study, no bioburden was seen which makes reprocessed endoscopic biopsy forceps safe to use after one reprocessing cycle. However, certain limitations to this study are still present. Bacterial bioburden was only measured and not viral or fungal bioburden. Although other international studies have measured the safety of more than one use for reprocessed forceps, this study is limited in that safety was determined after only one reprocessing cycle. Additional data is needed to determine if the bioburden remains to be zero after more than one cycle. Effectivity of the forceps is a different issue but it is worth mentioning here and that further studies are needed in order to prove that reprocessing does not affect the performance of the forceps.

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