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Major Article

Prospective microbiologic evaluation of the forceps elevator in closed-channel duodenoscopes after reprocessing

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Background: Endoscopes are well-known sources of bacterial transmission in health care facilities offering endoscopy services. The association between multidrug-resistant bacterial infections in patients who had undergone an endoscopic retrograde cholangiopancreatography procedure with reprocessed duodenoscopes has been much discussed. Bacterial contamination of duodenoscopes has been attributed to difficulties with reprocessing these devices, specifically the distal end of the scope, which features a movable forceps elevator. In light of a recent Food and Drug Administration warning letter to Olympus regarding their closed-channel duodenoscope model TJF-Q180V, the aim of our study was to prospectively evaluate the efficacy and safety of our current reprocessing procedures with regard to the TJF-Q180V duodenoscope models used in our hospital.

Methods: From August 2015-March 2016, we prospectively collected microbiologic surveillance samples from 6 TJF-Q180V model duodenoscopes in routine use at the Division of Gastroenterology and Hepatology using the ESwab collection system (COPAN Diagnostics Inc, Murrieta, CA).

Results: A total of 237 microbiologic samples from the forceps elevator were obtained during the survey period. None of the samples yielded microorganism growth.

Conclusion: These findings suggest that when following a diligent and validated reprocessing standard in accordance with manufacturer's recommendations, closed-channel endoscope models can still be used. Nevertheless, validated adaptions of current closed-channel duodenoscope models are needed to allow for simple and safe reprocessing. Furthermore, comprehensive postmarket surveillance needs to be established.

INTRODUCTION

In recent years, outbreaks of patient infections with multidrug-resistant pathogens such as carbapenem-resistant Enterobacteriaceae (CRE) have been reported following endoscopic retrograde cholangiopancreatography (ERCP) procedures.[1-6] In response to the increasing number of published outbreak reports, the Food and Drug Administration (FDA) issued a statement in February 2015 to raise awareness among health care professionals of the problems with effective reprocessing of flexible endoscopes with regard to their complex design.[7] In the past, postprocedure infection transmissions were overwhelmingly attributed to identifiable breaches of the essential reprocessing steps.[1] In light of the recent clusters of CRE-related infections and the FDA's response, the overall safety of standard reprocessing practices for flexible endoscopes as well as their complicated design have become the focus of the issue.

Duodenoscopes feature a movable forceps elevator mechanism at the distal end of the instrument's wire channel, called the Albarran lever, which is used during procedures to adjust the movement of accessories passed through the scope's channels. In newer duodenoscope models, the elevator wire channel is closed off from the Albarran lever by a seal intended to keep debris and liquid out of the channel (thus the name closed-channel duodenoscope). The intricacy of the forceps lever's manufacture pattern is a likely source for bacterial contamination, because it is challenging to access during high-level disinfection (HLD). Although the areas of potential difficulty during reprocessing are brought to the user's awareness, the critical appraisal of ERCP-related infections suggest that a higher reprocessing standard, heightened frequency of surveillance cultures,

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and optimized endoscope design could enhance the margins of patient safety.[8,9]

During August 2015, the FDA sent warning letters to 3 major manufacturers of duodenoscopes (Olympus, Pentax, and Fujifilm), because the companies failed to report problems with the scopes as required by law and in some cases failed to ensure that the devices could be adequately cleaned.[10] In their warning letter to Olympus dated August 12, 2015, the FDA admonishes the company for failure to report reprocessing faults in their duodenovideoscope TJF-Q180V (Olympus, Tokyo, Japan).[11] This model has been linked to an outbreak of VIM-2 *Pseudomonas aeruginosa* in the Netherlands, with explicit reference to the scope's hard-to-clean design as a risk factor for bacterial infection.[12] The vast majority of duodenoscopes used for ERCP procedures at our Division of Gastroenterology and Hepatology correspond to this specific model. Olympus Austria had announced it would start modification and replacement of these duodenoscopes during June 2016 at the earliest. Due to this widespread use at our institution it was not possible to withdraw this particular type of duodenoscope without drastic consequences for routine clinical service at our endoscopy unit. In light of the FDA warning letter to Olympus, the aim of our study was to prospectively evaluate the efficacy and safety of our current reprocessing procedures with regard to the closed-channel duodenoscope models used in our hospital. Each duodenoscope in use at the Division of Gastroenterology and Hepatology was sampled before ERCP procedures to verify the success of our actual bundle of reprocessing procedures and to monitor possible contamination of the TJF-Q180V, given its relevant safety profile.

MATERIALS AND METHODS

Study setting

The Vienna General Hospital (VGH) is a tertiary-care medical university teaching hospital with 1,990 beds. In our Division of Gastroenterology and Hepatology, currently about 5,200 diagnostic endoscopic procedures are performed yearly, 450 of them therapeutically as well as diagnostically with duodenoscopes harboring an Albarran mechanism. In this study, sampling of all clinically used duodenoscopes was performed exclusively at the Albarran lever of each scope.

A sample size calculation was performed before the commencement of the study to ensure that our findings are representative in regard to the overall population of 450 duodenoscopies performed at the hospital per year. The requisite number of microbiologic samples needed to represent the respective population was determined at 208, with a 95% confidence interval and 5% margin of error.

Reprocessing of endoscopes

At the VGH, reprocessing of endoscopes as well as their accessories follows quality controlled, standard operating procedures in accordance with international professional guidelines.[13] These consist of pretreatment of the endoscope after patient examination (including dry-wiping the outer mantle and flushing the channels); manual cleaning of the endoscopes (including brushing of the distal end); high-level disinfection in an automated endoscope washer disinfector (AEWD) using a glutaraldehyde solution; drying (as part of the AEWD program); and proper storage in a closed, dust-free cabinet. Additional requirements for endoscopes with an Albarran lever include the manual cleaning of the Albarran lever with a designated single-use soft brush issued by the manufacturer (MAJ-1888) for additional manual precleaning of the forceps elevator in light of the model TJF-Q180V's safety risks. Furthermore, the Albarran lever has to be brought into midposition before loading the AEWD. For older models, the Albarran tube adapter has to be fitted to the allocated cleaning channel. Training of endoscopy unit personnel involved in reprocessing is ensured at regular intervals, but at least once a year. Training units are organized and conducted in the scope of intradepartmental quality control by the head of the endoscopy reprocessing staff. Supplemental training by a manufacturer's representative is performed with the arrival of new equipment or when manufacturer reprocessing guidelines are updated. Written reprocessing guidelines are available to all reprocessing staff and are in conjunction with strict adherence to the manufacturer's recommendations.

As described earlier,[14] flexible endoscopes at our institution are reprocessed in AEWDs (Olympus GmbH, Hamburg, Germany) according to manufacturer's instructions. All reprocessing steps are documented, traceable, and stored for 10 years. Performance criteria of our AEWDs are validated according to the European standard EN ISO 15883-4[15] before initial use and revalidated once a year and additionally after any repair work or modification in programming or chemistry.

Storage of duodenoscopes

Reprocessed and fully dried duodenoscopes are stored in closed, dust-free, nonventilated cabinets in a hanging position, with the distal end down. The insertion tube of the scope (including the distal end) is protected by a sterile sheath, which is dressed directly after complete reprocessing and drying, and before transfer to the storage cabinet. The sheath is removed directly before the scope is used on a prepped patient.

Device characteristics

There are a total of 6 duodenoscopes in routine clinical use at the Division of Gastroenterology and Hepatology, all of them Olympus model TJF-Q180V; only these scopes were eligible for study inclusion due to their possession of an Albarran lever, the sampling focus of this investigation. All of the duodenoscopes sampled during the study are in frequent rotational clinical use and therefore subjected to regular reprocessing after each use. Up to 9 ERCPs are performed each week at the department during regular business hours.

Microbiologic sampling

Sampling protocol

From August 2015-March 2016, samples from patient-ready duodenoscopes with an Albarran lever were collected prospectively using the ESwab collection system (COPAN Diagnostics Inc, Murrieta, CA). The samples were gathered immediately after removal of the sterile sheath and before commencing the endoscopic procedure on the patient. Sample collection was performed exclusively by onsite endoscopy nursing staff. The applied sampling technique was predefined, demonstrated, and trained to endoscopy staff by study coordinators from the Department of Hospital Hygiene and Infection Control. This technique (swabbing the Albarran lever at midposition) is identical to that employed during routine microbiologic surveillance sampling. The order of duodenoscope selection for the ERCP procedure was chosen by the nursing staff on the basis of clinical imperative. Thus, there was no specific sequence in which duodenoscopes were assigned for patient use. However, no duodenoscope was in an idle state for longer than approximately 4 days.

Documentation system

All endoscopy nursing staff members were aware of the ongoing study to ensure that no sampling opportunity was missed. Each