ADVANCES IN ENDOSCOPY

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Challenges in Defining and Preventing Suspected Duodenoscope Infections

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G&H How common are duodenoscope infections in patients undergoing endoscopic retrograde cholangiopancreatography?

SH At this time, estimates have been made based on so-called napkin math—that is, how many infections and procedures are known but have not been systematically collected for calculation. These data, of course, are not ideal. Data are also available regarding known outbreaks and contaminated duodenoscopes. For example, Larsen and colleagues recently reviewed data on 925 contaminated duodenoscopes from 13,112 samples and found a 15% contamination rate for reprocessed patient-ready duodenoscopes. However, these data do not clearly show incidence in patients; they only reveal information about duodenoscopes. Studies in the Netherlands have shown that 22% of duodenoscopes have bacterial contamination after reprocessing sufficient to quarantine the scope. In manufacturer examinations of contamination after reprocessing mandated by the US Food and Drug Administration (FDA), 5% of culture samples from reprocessed duodenoscopes had organisms of high concern, including *Escherichia coli* and *Pseudomonas aeruginosa*. In fact, an early study by Spach and colleagues that attempted to examine the incidence of infection concluded that assessment was rife with limitations and that the true incidence would be impossible to determine retrospectively.

G&H What challenges underlie establishing the incidence and causality of duodenoscope infections?

SH Incidence and causality are very difficult to establish for duodenoscope infections in comparison with other procedures. When looking at colonoscopy and other procedures in which patients are discharged home the same day, it is relatively easy to isolate the cause when an infection emerges. For example, when a patient undergoes a colonoscopy and is discharged home, it is likely that not much else occurs to the patient medically over the next several hours. In the setting of endoscopic retrograde cholangiopancreatography (ERCP), however, a fair number of patients stay overnight in the hospital. Exposure to all types of infectious risks can occur, making it more difficult to isolate the duodenoscope as the potential cause of infection.

Another confounding issue is that endoscopic procedures in gastroenterology are not meant to be a sterile environment. Duodenoscopes are exposed to normal flora and potential pathogens during passage through the oral cavity, esophagus, and duodenum. In addition, ERCP is not performed in a surgical suite. That being said, the duodenoscope should be as sterile as possible, although, as I noted, statistics on colonization of duodenoscopes reveal information about duodenoscopes, not

patients. In the same vein, some information is available on outbreaks that emerge in the aftermath of patient hospitalization. An infection is reported to a county health department, and then an investigation ensues to determine who else has been exposed to the same duodenoscope. The aforementioned study by Larsen and colleagues found that double high-level disinfection and ethylene oxide gas sterilization were superior to single high-level disinfection but were still short of truly effective duodenoscope cleaning. The researchers also found that outbreaks were not associated with higher duodenoscope contamination rates compared with data from studies conducted outside the context of outbreaks.

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When investigating cause, questions arise as to whether it is the patient, duodenoscope, or environment. ERCP-related infections develop as a result of a complex interplay between infectious organisms, procedural factors, underlying pancreaticobiliary issues, and environmental factors, such as the infection control procedures for the endoscopy unit. It is necessary to investigate the underlying characteristics of the affected patient that could lead to an infection, examine the design and reprocessing of the duodenoscope (including whether it is disposable or single use), and examine the environment. Underlying conditions that put the patient at risk for infection, such as age and immune status, clearly must be assessed. Questions regarding environmental risk may include what occurs in the recovery room of the endoscopy unit, in the hospital if the patient stays overnight, and in the home environment.

G&H Specifically, which patients are most at risk for duodenoscope infections?

SH Patients who are elderly, have cancer, and are hospitalized, as well as those with autoimmune diseases, are at high risk for infections in relation to ERCP. However, indications for ERCP generally apply to patients who are at high risk for infections in the first place. As previously mentioned, this circumstance makes it more difficult to isolate the role that the duodenoscope itself played if an infection develops after the procedure. Clinicians should remember when discussing risks of ERCP with their patients that the benefits do outweigh the risks.

G&H How can clinicians help with surveillance of duodenoscope infections?

SH Clinicians should consider reporting infections associated with ERCP to the Manufacturer and User Facility Device Experience (MAUDE) database, which is available online at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

G&H What are the implications of delayed recognition of infection following ERCP?

SH The roles of the patient, duodenoscope, or environment might be over- or underrecognized. Clinicians need to talk clearly to patients and their caregivers regarding the symptoms of early infection so that patients can be treated for suspected infection as soon as possible. Most practices already do this, and I think practices are likely doing a good job now because patients are routinely seen postprocedure, and high-risk patients are kept in the care setting for observation.

G&H What preventive measures have been established?

SH The FDA has required manufacturers to reexamine duodenoscope design as well as the steps for reprocessing. The FDA collects patient-, provider-, and manufacturer-reported adverse events through the MAUDE database, and it also performs mandated studies to examine contamination rates of duodenoscopes after reprocessing.

In many ways, protocols that are meant to be followed in endoscopy units are similar to those mandated for providing care in the setting of the coronavirus disease 2019 (COVID-19) pandemic. For example, the use of N95 masks when interacting with patients at high

risk for infection is not a practice specific to COVID-19. This protocol was in play in the ERCP setting before COVID-19. Now, N95 mask use is mandatory when dealing with any patient, not only those patients at high risk. Everyone has become more aware of infection control practices because of COVID-19.

Manufacturer guidelines and duodenoscope design also have been areas of focus. Wider training on how to reprocess duodenoscopes in an endoscopy unit is important. If the training is limited to a small group of clinicians, it may send the message that duodenoscope reprocessing is not everyone's responsibility. In my opinion, everyone in the endoscopy unit should know how to reprocess a duodenoscope, including the treating gastroenterologist. The more discussions that occur about the importance of reprocessing and about best practices for infection control, the more they become part of the culture.

G&H Do safer alternatives to the standard duodenoscope exist?

SH Single-use disposable duodenoscopes are entering the market. A clinician might consider prioritizing single-use duodenoscopes in the patients most likely to be at risk for infection. As discussed, those would include patients with cancer and those who are elderly. The clinician also may want to prioritize any patients who have been in the hospital in the 30 days prior to ERCP. A specific example for which a single-use duodenoscope might be opted may be a patient who previously underwent ERCP and was hospitalized for an infection afterward.

When considering single-use duodenoscopes, cost constraints enter the picture. A specific Current Procedural Terminology (CPT) code for a single-use duodenoscope procedure that allows for an extra payment was approved last June, but, as of this past December, no instances of that CPT code have been recorded in Medicare claims. Therefore, it is not possible to track infections that may be associated with disposable duodenoscopes using Medicare claims. This has left a large question mark regarding utilization and data on potential associated infection risk.

Very large practices have multiple brands of duodenoscopes and have the option of deciding which brand is the best for a particular patient and procedure. Single-use duodenoscopes become another option. If a clinician suspects that a duodenoscope played a role in an infection, he or she should contact the MAUDE database and his or her hospital's infection control.

G&H What is the most important point for clinicians to consider regarding the potential risk of duodenoscope infections?

SH Clinicians are always thinking about benefits vs risks. In the case of ERCP, it is important to remind concerned patients about the benefits of the procedure vs the potential risk of infection.

Disclosures

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Suggested Reading

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