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Current Status and Future Course of Disposable-Component and Single-Use Duodenoscopes

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G&H What prompted the recent interest in the development of novel duodenoscope designs?

NF Over the past several years, there have been many reports of outbreaks related to infectious transmission within gastrointestinal endoscopy, with duodenoscopes being the most commonly implicated type of endoscope, in part because the elevator mechanism is difficult to access and clean. In response to the rising rate of these reports over the last decade, the US Food and Drug Administration (FDA) has become increasingly concerned about this issue. What has been particularly concerning about these reports, and what remains an ongoing issue, is that several of these infections are from multidrug-resistant organisms (MDROs). Many MDRO infections are very difficult to treat, and they are associated with high levels of morbidity and mortality for patients. Although the rate of clinically significant infectious events is low, the outcomes can be catastrophic if they do occur. Given these circumstances, the FDA has identified duodenoscope-related infection as a priority, which has in turn prompted medical device companies and researchers to develop and study novel solutions to this problem.

G&H What are some other potential solutions to reducing the risk of duodenoscope-transmitted infections?

NF Duodenoscope-transmitted infections are a multilayered problem with many considerations. Accordingly, the FDA takes a very holistic approach when it comes to recommending steps to mitigate or reduce these risks as best as possible. It recommends that health care providers, staff, and unit managers should always adhere to manufacturer instructions and reprocessing protocols at their given institution. Ideally, endoscopy units should monitor and/or formally audit their own reprocessing procedures and measure their rates of persistent microbial contamination following high-level disinfection. Beyond these general measures, as of today, the novel technologies that aim to offer solutions to this issue fall into three broad categories: the entirely disposable or single-use duodenoscope; the removable and/or disposable cap device, in which the elevator mechanism remains part of the duodenoscope; and the disposable elevator cap (DEC) device, which has a distal endcap that contains the elevator mechanism itself and is completely disposable.

G&H What are potential downsides to using disposable duodenoscopes?

NF There are three main barriers currently preventing their universal adoption. One potential issue is cost. If all endoscopic retrograde cholangiopancreatography (ERCP) procedures used single-use duodenoscopes, the infection transmission risk would be zero, which is obviously ideal, but in their present form, the costs associated with the single-use versions would be substantially higher than with standard duodenoscopes.

A second potential barrier to use is the technical performance associated with single-use duodenoscopes. An initial randomized trial with 98 patients comparing

single-use duodenoscopes to standard duodenoscopes reported some important differences in technical performance characteristics of the single-use duodenoscopes. However, several subsequent observational studies have shown that the rate of technical failure with single-use duodenoscopes requiring crossover to a standard duodenoscope is probably 10% or less. As more practitioners become comfortable with using these devices, it seems like there is a reasonable chance of achieving levels of technical performance comparable to that of standard duodenoscopes. Furthermore, newer generations of single-use duodenoscopes are becoming available, which should lead to improvements in technical performance parameters.

The third current barrier to widespread utilization of single-use duodenoscopes is their unknown ecological impact. It is not yet known how green these devices are—how they are disposed of, recycled, or reprocessed after their use. If there is a significant ecological footprint associated with the use of these devices, then that is obviously problematic. Device manufacturers are looking into these ecological aspects because they know sustainability is a global priority. Many in our field might assume that the disposable devices are associated with a bigger ecological footprint, but it is important to remember that when an endoscope is not reprocessed, currently used elements such as detergents, heat, and energy in the reprocessing department (as examples) are not needed. Therefore, the competing impacts of duodenoscope reprocessing vs disposal are still not entirely clear. Researchers are developing modeling studies using various types of methodologies to try and better understand what the actual ecological footprint might be with use of these devices compared with the status quo.

G&H What have comparative studies between novel and standard duodenoscopes revealed about their technical performance?

NF The comparative randomized trial I mentioned comparing single-use duodenoscopes to standard duodenoscopes was small, with only about 50 patients in each arm, and so it is difficult to draw meaningful generalizable conclusions based on that one study alone. However, some technical differences were noted with the single-use duodenoscopes in terms of worse maneuverability, air-water functionality, image stability, and image quality. Encouragingly, the ability to cannulate the duct(s) of interest was no worse with the single-use duodenoscopes. That is the only study I am aware of that directly compared technical performance and outcomes between single-use and standard duodenoscopes, with others being single-arm observational studies.

In terms of the DEC duodenoscopes, our group's ICECAP study, published earlier this year, was a randomized controlled trial assessing both persistent microbial colonization and technical performance in DEC duodenoscopes compared with standard duodenoscopes. A panel of blinded outcome adjudicators judged technical success of ERCP procedures based on a set of a priori criteria without knowing which duodenoscope was used for each procedure. In the 518 patients who underwent ERCP (259 with DEC duodenoscopes, 259 with standard duodenoscopes), the DEC group had 94.6% technical success vs 90.7% in the standard group, which led us to conclude that the DEC duodenoscope was noninferior in technical performance.

G&H How do fully disposable and partially disposable duodenoscopes compare?

NF I am not aware of any studies directly comparing partially disposable and single-use duodenoscopes. Currently, the results of several observational (noncomparative) studies assessing single-use duodenoscopes are available; these indicate that they are certainly approaching comparability to our standard devices in terms of technical performance but are perhaps not quite there yet. With next-generation devices, there should be improvements in performance. One could design a head-to-head study comparing the technical performance of DEC duodenoscopes with single-use duodenoscopes; however, to power such a study to be able to detect a significant difference in clinically meaningful infections would be virtually impossible because it would require hundreds of thousands of patients. Obviously, this was a limitation we faced in designing the ICECAP trial as well. Practically, therefore, although comparison of technical performance is achievable in head-to-head studies, assessment of infection risk will likely continue to rely on surrogate markers such as post-disinfection microbial colonization.

G&H How feasible is it to incorporate disposable duodenoscopes into practice?

NF I believe that is a fairly complex question. Some economic modeling studies have been performed with a few different considerations, such as how many procedures are performed per year in a given unit. For a small endoscopy unit that performs, for example, 100 ERCP procedures a year, a cost savings might actually be achievable with use of single-use duodenoscopes if the cost of reprocessing is higher than the cost of the disposable devices. Once the number of procedures increases to a large volume of, for example, over 1500 ERCPs a year, the exclusive use of single-use duodenoscopes would come at

significant additional costs. One must also consider the costs of maintenance and repairs over the life span of a nondisposable duodenoscope in addition to the eventual costs of replacement.

One potential approach is to consider the middle ground between full use of one duodenoscope design and another. Cost utility analysis models have been developed to compare the economic impacts of various strategies currently employed to reduce the risk of infection via duodenoscopes. From a cost utility perspective, results have suggested a potential role for use of disposable duodenoscopes in patients who are at high risk for either harboring an existing infection (eg, patients with cholangitis or patients known to be colonized or infected with an MDRO at the time of the procedure) or developing poor outcomes from an infection (eg, patients who are immunocompromised). For high-risk patients, it might make sense to perform ERCP with single-use duodenoscopes. For all patients, incorporating the best practices mentioned above and switching to a partially disposable duodenoscope (such as a DEC device) might add marginal cost to the procedure but may also provide a substantial reduction in infection risk. None of these approaches are evidence-based at this point, nor are there society-based recommendations on the criteria that might inform such decisions at either the patient or unit level.

G&H What enhancements to duodenoscopes might further reduce the risk of infection?

NF We are already at a place where 100% eradication of infection is feasible. For single-use duodenoscopes, the infection risk is zero if the procedure and disposal of the device are being performed properly. It could simply be a matter of reducing the associated costs, learning more about the ecological considerations, and making the technical adaptations that ideally improve disposable devices to the point where their adoption is feasible.

As for other disposable device classes, including DEC duodenoscopes, there is still an incomplete understanding of the precise mechanism(s) regarding how these microorganisms can survive high-level disinfection and how they are eventually transmitted from duodenoscope to patient. What is known is that this process involves the formation of bacterial biofilms. These extremely adherent layers of bioburden are difficult to eradicate even with high-level disinfection. It is also known that the elevator mechanism seen in duodenoscopes and linear echoendoscopes is implicated in some way; otherwise, infection transmission would be observed much more frequently with luminal endoscopes, but it is not.

In the ICECAP trial, we found that the rate of persistent microbial contamination after high-level disinfection was 3.8% for DEC duodenoscopes and 11.2% for standard duodenoscopes. This was a significant difference, with a number needed to treat of 13.6 to avoid one case of persistent contamination. Importantly, the comparator arm in our study involved use of a duodenoscope with a removable cap but whose elevator was still attached. However, speaking to our incomplete understanding, persistent contamination still occurred at a nonzero rate in the DEC duodenoscopes, and was mostly observed in the channel, rather than in the elevator region. More research is needed to provide a better understanding of these biofilms, how and where they form, and to what extent microinjuries in the duodenoscope channel increase the risk of infection, in DEC devices or otherwise. In summary, I believe single-use duodenoscopes are an extremely promising modality. If the three major current barriers to their use are addressed thoughtfully, they could represent a real paradigm shift in how pancreaticobiliary endoscopy is performed. In the meantime, practitioners and units should be aware of the available devices and strategies proven to reduce, but not eliminate, infection risk.

Disclosures

Dr Forbes is a speaker for Boston Scientific and PENTAX Medical and is a consultant for Boston Scientific, PENTAX Medical, and AstraZeneca. He has received research funding from PENTAX Medical.

Suggested Reading

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