REVISTA ESPAÑOLA DE
ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

Title:
Disposable duodenoscopes. Is healthcare system affordability the main hindrance?

Authors:
Enrique Vázquez-Sequeiros, Juan Ángel González Martín, Agustín Albillos Martínez

DOI: 10.17235/reed.2022.8570/2021
Link: PubMed (Epub ahead of print)

Please cite this article as:
Vázquez-Sequeiros Enrique, González Martín Juan Ángel, Albillos Martínez Agustín. Disposable duodenoscopes. Is healthcare system affordability the main hindrance?. Rev Esp Enferm Dig 2022. doi: 10.17235/reed.2022.8570/2021.

REVISTA ESPAÑOLA DE
ENFERMEDADES DIGESTIVAS
The Spanish Journal of Gastroenterology

ED 8570

Disposable duodenoscopes. Is healthcare system affordability the main hindrance?

Enrique Vázquez-Sequeiros, Juan Ángel González Martín, and Agustín Albillos Martínez

Endoscopy Unit. Department of Gastroenterology and Hepatology, Hospital Universitario Ramón y Cajal, and Fundación para la Investigación Biomédica, Hospital Universitario Ramón y Cajal (IRYCIS). Madrid, Spain

Conflicts of interest: EVS has received money for lectures and/or consultancy from Ella-Biomed, Boston Scientific, Olympus.

The performance of an endoscopic procedure involves introducing an endoscope through the mouth or the anus, which may potentially lead to lethal infection. The risk increases when complex and difficult-to-clean scopes are used, as in the case of duodenoscopes (1). Side-viewing duodenoscopes are complex in design, with the camera and working channel exit located on one side of the endoscope's distal end, and with an elevator nail also located at this point for catheter redirection. This complex design may facilitate the presence of blind areas not easy to access for cleaning, resulting in suboptimal disinfection of the duodenoscope and therefore a higher risk of bacterial infection. This is of particular importance in particularly vulnerable patients like those who are immunosuppressed (e.g., transplanted patients) or have a malignant disease and are receiving chemotherapy. Moreover, in the era of ¨superbugs¨, like carbapenem-resistant *Enterobacteriaceae*, infection outbreaks related to endoscopic retrograde cholangiopancreatography (ERCP) have been reported with a significant mortality rate (2,3).

The medical community has raised concern regarding the effectiveness of conventional disinfection methods, designed for forward-viewing endoscopes, in side-viewing duodenoscopes. A number of solutions have been suggested to solve this problem.

Some have suggested duodenoscope sterilization as a safer method, but it does not appear to be a good option since sterilization is time-consuming, and also these complex and delicate scopes may be damaged by the high temperatures needed for sterilization, which may certainly reduce the lifecycle of these expensive endoscopes (4). At present, this is not an accepted option except for carefully selected cases (4). Some manufacturers have modified the protocols and materials used for manual cleaning of the distal end of modern duodenoscopes to improve effectiveness. In the very last years, all manufacturing companies (Fujifilm Corporation, Olympus Medical Systems, and Pentax Medical) have introduced disposable parts in their latest version of their duodenoscopes (e.g., disposable end cap or disposable elevator nail), to minimize the risk for infection transmission (5-7). The aim is to replace rather than clean or disinfect these critical parts of the duodenoscope by rendering them disposable. However, although these initiatives may reduce the risk of infection, chances still remain. For this reason, some companies have developed fully disposable duodenoscopes (Ambu Innovation GmbH and Boston Scientific Corporation) that completely avoid transmission of bacteria from one patient to another (7,8). Fully disposable duodenoscopes have similar characteristics when compared to non-disposable ones in terms of working channel length (1240 mm), insertion tube outer diameter (11.3 mm), angulation range (up: 120°; down: 90°; right: 110°; left: 90°), working channel inner diameter (4.2 mm), and field of view (108-130°). Initial reports have demonstrated that these new endoscopes are technically adequate to perform ERCP with reasonable clinical results (7,8). This was elegantly shown in a recent multicenter study conducted at 6 academic medical centers including 60 patients (8). The study demonstrated that 96.7 % of patients were successfully treated with a disposable duodenoscope, and only 2 of them required the use of a conventional duodenoscope. Cases requiring crossover of scopes had an ERCP with a Grade-2 or -3 complexity score according to the American Society for Gastrointestinal Endoscopy (ASGE) (highest complexity score: Grade 4) (8,9). A similar technical performance and safety profile have also been reported in a randomized controlled trial comparing fully disposable and standard duodenoscopes in low-complexity ERCP (10). Whether or not these fully disposable duodenoscopes have an adequate performance in complex

cases (Grade 4) remains untested, and future studies should provide information in this regard.

Based on these promising reports, and on the need to find a solution to the infection problem, should we just abandon the use of non-disposable duodenoscopes, reserve the disposable ones only for high risk patients, or just use the newly-designed partially disposable duodenoscopes? Certainly, at present there is no definitive answer to this difficult question. We will try to individually answer the question as follows:

1. **Replacement of all non-disposable duodenoscopes by single-use ones.** Cost analyses of disposable duodenoscopes, considering aspects like endoscope lifecycle (longevity) at 3 years, cost of duodenoscope, scope washer, cleaning supplies, and labor costs, as well as the cost associated with the treatment of related infection, have been conducted (11). The average cost per ERCP procedure in low-volume centers (< 50 procedures per year) was estimated to range from $ 1,318 to $ 2,068, whereas in higher-volume institutions (> 125-150 procedures per year) the cost was smaller and ranged from $ 797 to $ 1,547. Based on these numbers, the authors estimated that if each reusable duodenoscope is used on average 200 times a year, replacing reusable duodenoscopes with single-use scopes would result in an extra cost of $ 612 per procedure in high-volume institutions (a little more in low-volume centers) (11). Based on these numbers, although one might be tempted to use fully disposable devices in all cases for the benefit of patients, the current high cost of these devices is difficult to assume in a healthcare system like ours.
2. **Selective use of disposable duodenoscopes.** This is another approach that deserves consideration. As the extra cost per procedure has been estimated to be around $ 612 per procedure (in high-volume institutions) (11), it seems more reasonable to keep the available ¨bullets¨, in terms of economic resources, for those patients at an increased risk of being infected (e.g., patients receiving immunosuppressants or a transplant) and for those with a major probability of being carriers of multidrug-resistant bacteria (e.g., patients with a long hospitalization or who have stayed in an Intensive Care Unit). In the latter group of patients, chances of having a ¨superbug¨ that may colonize

duodenoscopes even after disinfection is high, and the likelihood of an infection outbreak may increase. Other potential uses for this type of endoscope may include an ERCP indicated outside the Endoscopy Unit (easy-to-transport processor) or a patient with a condition such as bile duct stricture associated with prior relapsing cholangitis. This selective approach to using disposable duodenoscopes may restrict work volume to < 5-10 % of patients referred for ERCP in most institutions, and may certainly represent a more economically affordable approach. A marginal increase in cost (only a small percentage of patients) by specifically targeting those with a higher risk of infection seems an appropriate choice. We foresee this strategy may be a reasonable one and would certainly advocate for it.

3. **Use of duodenoscopes with a disposable cup.** Any initiative allowing an easier, potentially more efficient cleaning of a reusable duodenoscope should certainly be promoted. The latest modifications of the distal cup by duodenoscope manufacturers may certainly help reduce adverse events, and should probably be used in conjunction with other tools like single-use duodenoscopes. We agree with the recommendations issued by regulatory agencies like the United States (US) Food and Drug Administration (FDA), which support a gradual replacement of older duodenoscopes by these newly-designed, potentially safer, and partially disposable scopes (12,13). Unfortunately, this alternative, aimed at facilitating cleaning of the most critical part of a duodenoscope, does not completely exclude the risk of infection since other duodenoscope parts remain that have to be reused from patient to patient. A recent prospective, randomized study conducted in 108 patients demonstrated that reusable duodenoscopes with detachable end caps had organic residue contamination after reprocessing in up to 37 % of cases (76 % in duodenoscopes with no disposable end cap) (14). A combination of these newer, partially disposable duodenoscopes and fully disposable ones for selected cases may be a good alternative to balance safety, efficacy, and economy.

In addition to economic issues, another aspect that should not be forgotten before making a decision is that the use of these disposable endoscopes consumes an

important amount of material resources (plastic, wires, chips, etc) every year, and will generate residues that may have an important environmental impact. Recent publications have raised concerns on the environmental impact of endoscopy, especially with single-use endoscopes (15). The authors estimated that each endoscopy procedure generates 2.1 kg of disposable waste (46 liters in volume), of which only 9 % is finally recycled. In a country like the USA these estimates represent annually 38,000 metric tons (like 25,000 passenger cars) and an extension of 117 soccer fields with a depth of 1 meter. Furthermore, the authors estimated that by replacing reusable endoscopes with disposable ones, and accounting for the reduced waste in the reprocessing of the latter, net waste (total weight mass) would increase by 40 %. Reaching a reasonable balance between potential patient benefits, cost, and environmental impact seems mandatory.

In summary, we have at our disposal an excellent tool to treat patients with pancreatic and biliary diseases in a safe and effective manner. Due to its high cost and environmental impact, a wise and selective use of disposable duodenoscopes is probably the way to go at present. We suggest the use of the newer, partially disposable duodenoscopes while reserving the fully disposable units for selected cases. Validated scores to address the risk of infection should help identify patients more likely to benefit from disposable duodenoscopes.

REFERENCES

1. Ha J, Son BK. Current issues in duodenoscope-associated infections: now is the time to take action. Clin Endosc 2015;48:361-3. DOI: 10.5946/ce.2015.48.5.361
2. Aumeran C, Poincloux L, Souweine B, et al. Multidrug-resistant Klebsiella pneumoniae outbreak after endoscopic retrograde cholangiopancreatography. Endoscopy 2010;42:895-9. DOI: 10.1055/s-0030-1255647
3. Epstein L, Hunter JC, Arwady MA, et al. New Delhi metallo-β-lactamase-producing carbapenem-resistant escherichia coli associated with exposure to duodenoscopes. JAMA 2014;312:1447-55. DOI: 10.1001/jama.2014.12720
4. Naryzhny I, Silas D, Chi K. Impact of ethylene oxide gas sterilization of duodenoscopes after a carbapenem-resistant Enterobacteriaceae outbreak. Gastrointest Endosc 2016;84:259-62. DOI: 10.1016/j.gie.2016.01.055
5. Vickery K, Ngo Q-D, Zou J, Cossart YE. The effect of multiple cycles of contamination, detergent washing, and disinfection on the development of biofilm in endoscope tubing. Am J Infect Control 2009;37:470-5. DOI: 10.1016/j.ajic.2008.09.016
6. Verfaillie CJ, Bruno MJ, Voor in 't Holt AF, et al. Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing Pseudomonas aeruginosa. Endoscopy 2015;47:493-502. DOI: 10.1055/s-0034-1392080
7. Trindale AJ, Copland A, Bhatt A, et al. Single-use duodenoscopes and duodenoscopes with disposable end caps. Gastrointest Endosc 2021;93:997-1005. DOI: 10.1016/j.gie.2020.12.033
8. Muthusamy VR, Bruno MJ, Kozarek RA, et al. Clinical evaluation of a single-use duodenoscope for endoscopic retrograde cholangiopancreatography. Clin Gastroenterol Hepatol 2020;18:2108-17.e3. DOI: 10.1016/j.cgh.2019.10.052
9. Cotton PB, Eisen G, Romagnuolo J, et al. Grading the complexity of endoscopic procedures: results of an ASGE working party. Gastrointest Endosc 2011;73:868-74. DOI: 10.1016/j.gie.2010.12.036
10. Bang JY, Hawes R, Varadarajulu S. Equivalent performance of single-use and reusable duodenoscopes in a randomised trial. Gut 2021;70:838-44. DOI:

10.1136/gutjnl-2020-321836

11. Bang JY, Sutton B, Hawes R, et al. Concept of disposable duodenoscope: at what cost? Gut 2019;68:1915-7. DOI: 10.1136/gutjnl-2019-318227
12. United States Food and Drug Administration. Infections associated with reprocessed duodenoscopes. [Accessed May 15, 2021]. Available at: https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infectionsassociated-reprocessed-duodenoscopes.
13. Larsen S, Russell RV, Ockert LK, et al. Rate and impact of duodenoscope contamination: A systematic review and meta-analysis. EClin Med 2020;25:100451. DOI: 10.1016/j.eclinm.2020.100451
14. Ridtitid W, Pakvisal P, Chatsuwan T, et al. A newly designed duodenoscope with detachable distal cap significantly reduces organic residue contamination after reprocessing. Endoscopy 2020;52:754-60. DOI: 10.1055/a-1145-3562
15. Namburar S, von Renteln D, Damianos J, et al. Estimating the environmental impact of disposable endoscopic equipment and endoscopes. Gut 2021;0:1-6. DOI: 10.1136/gutjnl-2021-324729