



# Getting the Bugs Out: Disposable Duodenoscopes Have a Shallower Learning Curve but Face a Steep Climb in Usability

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Infection following endoscopic retrograde cholangiopancreatography (ERCP), one of the most important procedure-related adverse events include endogenous infection from the gastrointestinal tract or biliary system, or exogenous transmission from a contaminated duodenoscope, in particular due to carbapenem-resistant *Escherichia coli* infection [1]. With many outbreaks [2, 3], there was an impetus to redesign the duodenoscope to reduce residual contamination from the elevator backside and other notoriously difficult-to-clean areas. Though the detachable distal cap was reported to reduce contamination [4, 5] primarily from the elevator area, the accessory channel remained contaminated [6] due to wear after prolonged use. Therefore, the single-use duodenoscope has been advocated due to its very low probability of exogenous transmission of infection. Now in its third generation, a recent global prospective case series of ERCPs from 11 countries [7] demonstrated its practical use for most ERCP indications. As expected, the risk of bacterial transmission from a contaminated scope was zero, though endogenous transmission occurred. Interestingly, the ERCP completion rate in this study were remarkably high (> 94%) whether by senior experts (> 2000 ERCPs/lifetime) and less-expert endoscopists (< 2000 ERCPs/lifetime) working in high-volume academic centers. Many investigators have participated in the development of this duodenoscope prototype [7]. Of note, 44% of the patients in this global series already undergone biliary or pancreatic sphincterotomy, facilitating cannulation to the desired duct, although they still reported that 29% of the cases were considered difficult. Thus, doubt

was raised regarding the ease-of-use of the single-use unit for complex cases performed by community endoscopists.

In this issue of *Digestive Diseases and Sciences*, Saleem et al. [8] of the Indiana University ERCP team, one of the largest referral centers in the United States, prospectively analyzed the learning curve for the single-use duodenoscope, on the basis of data collected from 31 patients who underwent ERCP for a wide variety of indications, of which 80% were classified as ASGE complexity levels I-III [8]. All 31 procedures were performed by one highly experienced (2500 ERCPs over 5 years with the standard reusable duodenoscope) endoscopist. The proficiency in learning curve was assessed by the cumulative sum (CUSUM) curve for two objectives: the number of attempts to cannulate, and the time to cannulate the desired duct. Proficiency was defined as the number of procedures needed to achieve an inflection point of the graph.

The authors reported an overall success rate without crossover to the reusable duodenoscope of 87% (27/31). For both objectives, the inflection point was reached at 10 cases. The main limitation was the small number of cases, and that the procedure was performed by only one endoscopist. Furthermore, only one fifth of the subjects had a native papilla (6/31), 2/6 had a failed cannulation attempt, and crossover to a reusable

duodenoscope was required in four patients. These results challenge the perception that proficiency is difficult to achieve for this duodenoscope, although, generalizability is limited since such a small fraction of subjects had a native papilla.

That failed ERCP attempts required crossover to the standard duodenoscope were evenly distributed across operator performance significantly reflects either the difference in the complexity of the cases or the suboptimal performance of this duodenoscope. As with any new technology, there is always a learning curve prior to achieving proficiency; furthermore, it is not intuitively obvious how a costly precision electro-optico-mechanical device could

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be made cheaply enough to be disposable. The requisite technical performance of the duodenoscope relies on four functions: maneuverability, mechanics, imaging clarity, and the ability to perform desired functions [9]. Ideal maneuverability facilitates intubation by smoothly passing through the esophagus and stomach and settling in the duodenum with adequate orientation of the papilla. Mechanics embodies many components of the duodenoscope, including the angle of elevator and the stiffness of distal shaft that must be optimized to ensure a successful ERCP. These factors were highlighted by the authors who stated that suboptimal shaft stiffness and impaired visibility may have contributed to procedural failure and the need for crossover. With the advancements of manufacturing that include customizable 3-D printing [10], it may become possible for manufacturers to quickly modify the instrument to address its deficiencies.

Another concern is the application of this duodenoscope to real-world practice. In the study, only patients considered to be at high risk for exogenous infection such as those with post-liver transplant biliary strictures were studied, amounting to only 31 patients, implying that even in a large referral center, only a few experienced endoscopists should perform ERCP with this special duodenoscope to ensure a high success rate.

In conclusion, the authors have demonstrated that in the hands of an experienced ERCP endoscopist, the use of the third generation single-use duodenoscope in non-complex cases required only a small number of cases to reach maximum proficiency although the overall performance of this duodenoscope is still far from perfect. For complex ERCP cases, the single-use duodenoscope may not be the appropriate choice since the risk of failure in completing the procedure may outweigh the risk of exogenous infection. In the future, a single-use duodenoscope whose ergonomics and performance rivals that of its reusable brethren would overcome these obstacles while ensuring freedom from exogenous infections.

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