

Duodenoscope-related infections and potential role of single-use duodenoscopes



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ERCP has been used for management of pancreaticobiliary diseases since the 1960s. The use of ERCP has continued to increase over the past decade in the United States.¹ Over this timeframe, several duodenoscope-related infections have been reported.² Many of these cases have occurred in the setting of standard high-level disinfection protocols.³ As a result, more novel methods to prevent duodenoscope-related infections have been pursued.

Devices and tools have been developed to eliminate the risk of duodenoscope-related infections. These include disposable endcaps and elevators, with limited studies done evaluating risk of duodenoscope-related infections.⁴ In December 2019, the Food and Drug Administration (FDA) approved the EXALT Model D (Boston Scientific, Marlborough Mass, USA) (Fig. 1), the first fully disposable duodenoscope.⁵ Only a limited number of cases have been done to date; however, they have been successful in a wide array of cases.⁶ At our institution, we have used this single-use duodenoscope as part of a clinical trial and for ERCP in patients with COVID-19 or those under investigation for COVID-19. Another single-use duodenoscope was recently approved by the Food and Drug Administration. This endoscope is called the aScope Duodeno (Ambu, Copenhagen, Denmark) (Fig. 2).⁷

The cost of single-use duodenoscopes can vary based on manufacturer and hospital contracts with manufacturers and can range from \$1900 to \$4000. In this video (Video 1, available online at www.giejournal.org), we provide an overview of duodenoscope-related infections, practical considerations, and challenges in incorporating single-use duodenoscopes in the endoscopy suite.

SETTING UP THE SINGLE-USE DUODENOSCOPE

At our institution, the single-use duodenoscope is stored in the endoscopy suite alongside other endoscopic accessories. Once you are ready to plan for ERCP, remove the single-use duodenoscope from the sterile packaging. The device can then be carefully pulled from the mounting card. Next, test the rotation of the big knob and small knob

and actuation of the elevator mechanism. The Orca (Boston Scientific) air/water valve can then be inserted into the blue air/water port on the control head, and the Orca suction valve can be inserted into the red suction port on the control head. Attach the biopsy cap to the accessory port on the control head.

The controller can then be powered on. Insert the umbilicus connector into the controller. Once the live image is verified, connect the air/water tubing of the Hydra (Boston Scientific) water bottle cap to the air/water connector on the umbilicus just like any other endoscope. Of note, the controller does not have its own air insufflator built into



Figure 1. Exalt Model D single-use duodenoscope.



Figure 2. aScope duodenoscope.

it, and an external insufflation method is needed. Refer to [Video 1](#) for a demonstration of these steps.

INTRAPROCEDURE AND POSTPROCEDURE CONSIDERATIONS

The functionality of the single-use duodenoscope is designed to be similar to the traditional duodenoscope. To date, 15 cases have been done at our institution, with the majority as part of a previously published clinical study, including the case examples ([Video 1](#)), with this device.⁶ In [Video 1](#), 3 case examples of successful use of the single-use duodenoscope in common bile duct stone removal, biliary plastic stent placement, and single-operator cholangioscopy have been demonstrated.

Upon completion of the procedure, the duodenoscope can be disconnected from the processor. After the procedure is completed, the single-use duodenoscope is placed into a bag, which is placed into a manufacturer-provided dedicated recycling bin placed inside the hospital.

LIMITATIONS

Unanswered questions remain for single-use duodenoscopes. The cost of these novel endoscopes compared with reusable duodenoscopes needs to be further assessed. Although there has been success with different complexities of ERCP cases, the operators performing these cases were expert endoscopists.⁶ The success of ERCP with single-use duodenoscopes will need to be evaluated among early-career advanced endoscopists to establish whether there is a learning curve and whether that will affect the adverse events associated with ERCP. Furthermore, the environmental impact of single-use duodenoscopes will need to be evaluated.

CONCLUSION

In early studies, single-use duodenoscopes have shown promise of clinical efficacy and safety similar to that of standard duodenoscopes. However, considerations regarding cost, environmental impact, and efficacy in the hands of early-career advanced endoscopists need to be further evaluated.

DISCLOSURE

Dr Cohen is a consultant for Boston Scientific. Dr Berzin is a consultant for Boston Scientific, Medtronic, and Fuji. Dr Pleskow is a consultant for Boston Scientific, Medtronic, Olympus, and Fuji. All other authors disclosed no financial relationships.

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