

Single-use Albarran module: A removable elevator system to enhance safety in biliary endoscopy?



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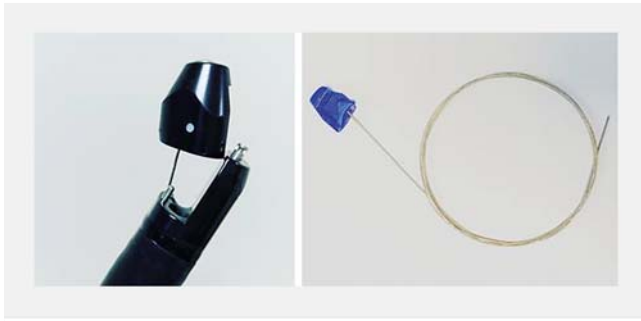
Bacterial infections are a major burden in biliary endoscopy. Besides incomplete manual cleaning of endoscopes, hard-to-clean components of duodenoscopes are responsible for a substantial rate of bacterial contamination. A large meta-analysis showed that 15% of duodenoscopes harbored microorganisms of gastrointestinal or oral origin, independent from the colony forming unit (CFU) count. This indicates that the current reprocessing and process control procedures, even with ethylene oxide (ETO), could be insufficient [1]. Therefore, US Food and Drug Administration (FDA) warnings led companies to redesign duodenoscopes with the aim of enhancing safety. Disposable caps or caps + elevator are available options on the market [2–3]. Moreover, two disposable duodenoscopes models have recently been approved by the FDA: the Boston Scientific EXALT Model D and the Ambu A/S Ambu aScope Duodeno. Studies on disposable duodenoscope feasibility and possible economic impact on the market yielded interesting results, although the data are still preliminary [4–8].

In this paper, we present an innovative solution of a duodenoscope with a removable cap, wire, and distal lever mechanism. This elevator system is called the single-use Albarran module (Karl Storz) (► **Fig. 1**). With it, a large, open surface can be created that is easy to brush and clean, as is the case with any other instrument without a bifurcated channel. Basically, the module is assembled and removed before and after every procedure, to be reprocessed separately from the rest of the duodenoscope (even with ETO). Interestingly, the distal end of the duodenoscope belongs to the removable module

(► **Fig. 2**). This detail makes the cleaning both the channel and the tip easier. Karl Storz conducted some tests on duodenoscopes contaminated with organic fluids, such as blood. After removal of the single-use Albarran module and duodenoscope reprocessing, the instruments achieved the officially required level of cleaning (i. e. <6.4 µg/cm² for protein, <2.4 µg/cm² for hemoglobin and <4 Log₁₀/cm² for bacteria) [9].

Ten endoscopic retrograde cholangiopancreatographies (ERCPs) were performed in nine consecutive patients using the single-use Albarran module. Data are summarized in ► **Table 1**. The setting was urgent in one case and elective in nine. A native papilla was present in seven patients (70%); the bile duct cannulation and successful procedure rates were both 100%. Mean procedure time was 30 minutes. Indications for ERCP were biliary lithiasis in seven cases and cancer palliation in two cases. Sphincterotomy and balloon dilation were performed in five and four cases, respectively. Mechanical lithotripsy was performed only once, whereas stone clearing required balloon dilation in six cases. Brushing for cytology was done in one case and stenting for palliation in two.

The aim of this small study was to gain insights into this novel device, with special attention directed towards identifying any technical problems related to use of the disposable systems. Notably, we did not find any issues with devices insertion, grip, friction, strength, or width of the elevator movements, in contrast to the study by Bang et al. [10] Because of the type of study (case series) and small sample size, it was not possible to compare the single-use Albarran maneuverability and mechan-



► **Fig. 1** The image on the left shows the lever mechanism to remove the cap; the image on the right shows the wire that is inserted in the cap.



► **Fig. 2** The image shows the distal portion of the endoscope, without wire and cap.

► **Table 1** Elevator performance evaluation¹.

Patient (sex; age)	Indication	Bile duct cannulation	Operative procedure	Operative device	Stent characteristics	Procedure setting/duration (min)	Elevator performance
M,83	Biliary AP	Yes	Precut, plastic stent placement		Plastic, 10 Fr, 5 cm	Elective/31	Good
M,76	CBD stones	Yes (previous sphincterotomy)	Stent removal, balloon dilation, mechanic lithotripsy, stent placement	CRE Boston Scientific, balloon dilator 12–15 mm, Fogarty catheters	NA	Elective/34	Good
F,82	Biliary hilar stricture	Yes	Balloon dilation of main hepatic ducts	CONMED balloon dilator 6.00 mm	NA	Elective/43	Good
M,53	Cancer palliation	Yes	Stent placement		Partially covered SEMS 10 mm Ø, 6 cm	Elective/19	Good
M,59	CBD stones	Yes	Balloon dilation CBD clearance	Dormia basket, CRE Boston Scientific, balloon dilator 12–15 mm	NA	Elective/20	Good
M,76	Biliary AP	Yes	Stent placement		Plastic 10 Fr, 5 cm	Urgent/43	Good
M;71	CBD stones	Yes	CBD clearance		NA	Elective/22	Good
F;42	Cancer palliation	Yes	Balloon dilation Stent placement	CRE Boston Scientific, balloon dilator 10–12 mm	Partially covered SEMS	Elective/30	Good
F;82	2 nd look	Yes (previous sphincterotomy)	Stent removal Brushing Stent placement		2 plastic stents, 10 Fr, 12 cm	Elective/43	Good
M;41	2 nd look	Yes (previous sphincterotomy)	CBD clearance		NA	Elective/15	Good

NA, not applicable; AP, acute pancreatitis; CBD, common bile duct; PC, pancreatic cancer; SEMS, self-expandable metallic stent.

¹ Special attention was given to ease of accessory insertion, grip, friction, strength, and width of the movement, rated as good=no problems nor difficulties; fair=any problem occurred with no interference with the outcome of the procedure; poor=any problem occurred significant enough to interrupt the procedure or change the elevator.

ical features with the standard module. The only difference from the standard Albarran module was a shorter width during the elevator stroke, which did not hinder the planned interventions. In our experience, the disposable device allows the use of all devices commonly employed in biliary endoscopy. Importantly, no cases of sepsis or infectious events were reported. Unfortunately, a direct comparison of infectious event rate between the standard and single-use Albarran module is not possible at this time, due to the small sample size in the present case series. However, to our knowledge, this is the first description of single-use Albarran module use during routine endoscopy in real-life settings. Further studies and randomized controlled trials are needed to address comparisons with the standard duodenoscopes and to better evaluate its use in clinical practice.

Competing interests

The authors declare that they have no conflict of interest.

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