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FIRST IN HUMAN CASE SERIES ON NOVEL MULTIPLE BILIARY STENT DELIVERY SYSTEM

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PURPOSE

- Biliary stenting facilitates drainage for reasons such as benign or malignant strictures, incomplete ductal clearance, infection, or bile leak.
- Some scenarios, such as benign or anastomotic strictures, may benefit from placement of multiple stents side-by-side in order to increase the dilation effect.
- All stents available in the US require the biliary guidewire to be withdrawn during stent deployment, necessitating repeat cannulation if further stenting is required
- Repeat cannulation increases procedure time and thereby risks of the procedure, including pancreatitis, perforation, hemorrhage, and infection (1,2)
- A novel multiple biliary stent delivery system has been developed, which allows for maintenance of the biliary guidewire after stent deployment, allowing for rapid placement of additional stents.
- This multicenter case series aimed to document first in-human uses and evaluate the novel system.

METHODS

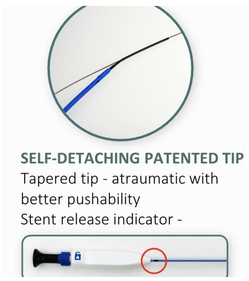
- Invited endoscopist worldwide and with varied experience from 250 to >5,000 ERCPs
- Trained by company representative and a 2-minute video clip
- Primary objective: to evaluate and document in humans the success of this delivery system, localization of stent placement and guidewire retention post-stent delivery
- Other data collected included endoscopist review of system, stent indication, demographics, and number of stents placed

RESULTS

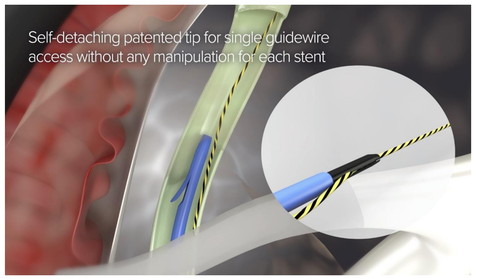
- 25 cases across 7 global sites
- Indications for stent placement included stricture (14), residual choledocholithiasis or prophylaxis (9), tumor (1), and cholangitis (1).
- 1 to 4 stents in parallel
- 24/25 cases (96%); unsuccessful in one case attributed to difficult angulation at the ampulla
- Endoscopist review: ease of use, enhanced procedural simplicity, reduced steps and time while ensuring ductal access, and decreased risk of re-cannulation failure and adverse events
- No immediate medical adverse events reported

NOVEL MULTIPLE STENT DELIVERY SYSTEM

- Novel biliary system with a patented self-detaching tip
- Initial pre-loaded 10Fr x 9cm plastic stent (can be exchanged if needed)
- Compatible with 0.025” or 0.035” guidewire and any 10Fr stents



SELF-DETACHING PATENTED TIP
Tapered tip - atraumatic with better pushability
Stent release indicator -



25 cases across 7 global sites
First in-human use
Novel multiple biliary stent delivery system demonstrates successful stent placement with guidewire retention post-stent delivery, decreased procedural time, and facilitation of parallel stenting

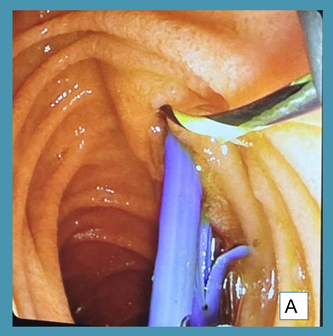


Figure A: Two stents in parallel across anastomotic, long and high CBD stricture

Figure B: Two stents emanating from papilla with adjacent guidewire fixed in place

Age	Sex	Stent Indication	Stent size	Stents
71	F	Anastomotic stricture	10Fr x 9cm	Multiple
65	F	Biliary duct stricture	10Fr x 9cm	4
70	M	Biliary duct stricture	10Fr x 9cm	4
55	F	Malignant tumor	10Fr x 9cm	4
68	M	Anastomotic stricture	10Fr x 9cm	4
51	F	Anastomotic stricture	10Fr x 9cm	3
43	M	Biliary duct stricture	10Fr x 9cm	3
68	M	Anastomotic stricture	10Fr x 9cm	3
61	M	Anastomotic stricture	10Fr x 9cm	3
40	F	Biliary obstruction due to gallstone	10Fr x 9cm	2
61	F	Biliary obstruction due to gallstone	10Fr x 9cm, 7Fr x 7cm	2
29	F	Anastomotic stricture	10Fr x 12cm	2
55	F	Biliary obstruction due to gallstone	10Fr x 9cm, 7.5Fr x 8cm	2
50	F	Post-cholecystectomy stricture	10Fr x 9cm	2
75	F	Anastomotic stricture	10Fr x 9cm, 10Fr x 12cm	2
54	M	Biliary obstrcution due to gallstone	10Fr x 9cm	2
56	M	Biliary duct stricture	10Fr x 9cm	1
56	M	Biliary obstruction due to gallstone	10Fr x 9cm	1
69	M	Biliary obstruction due to gallstone	10Fr x 7cm	1
69	M	Cholangitis	10Fr x 9cm	1
80	F	Biliary obstruction due to gallstone	10Fr x 9cm	1
25	F	Biliary obstruction due to gallstone	10Fr x 9cm	1
67	M	Anastomotic stricture	10Fr x 9cm	1
37	F	Biliary obstruction due to gallstone	10Fr x 9cm	1
65	M	Anastomotic stricture	10Fr x 9cm	1

CONCLUSION

- Novel biliary stent system allows for rapid sequential stent placement without removal of the index guidewire after initial stent delivery
- Rated favorably across all users at multiple centers
- In cases where multiple stents were required, there was a perceived reduction in procedural time and reduction in the potential risks of re-cannulation failure and associated adverse events
- Novel multiple stent delivery system could alleviate some of the challenges of placing multiple stents and could serve as a useful tool in specific scenarios

REFERENCES

1. Fatima J, Baron TH, Topazian MD, et al. Pancreaticobiliary and duodenal perforations after periampullary endoscopic procedures: diagnosis and management. Arch Surg. 2007;142(5):448–455. doi: 10.1001/archsurg.142.5.448.
2. Freeman ML, DiSario JA, Nelson DB, et al. Risk factors for post-ERCP pancreatitis: a prospective, multicenter study. Gastrointest Endosc. 2001;54(4):425–434. 10.1067/mge.2001.117550.