TYPE OF ARTICLE: Case Series White Paper

TITLE: Novel, Integrated Rapid Exchange Pre-mounted, Single-Plastic Stent, Self-Detaching Delivery System for Biliary Stent Placement: Case Series-Initial Experience.

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INTRODUCTION

Current commercially available biliary stent delivery systems face limitations, such as the loss of guidewire positioning after stent delivery. This issue is particularly prevalent in cases with challenging ductal access, often necessitating additional interventions after the initial stent placement. To address these limitations, a novel biliary stent delivery system has been developed, featuring an integrated rapid exchange and self-detaching mechanism.

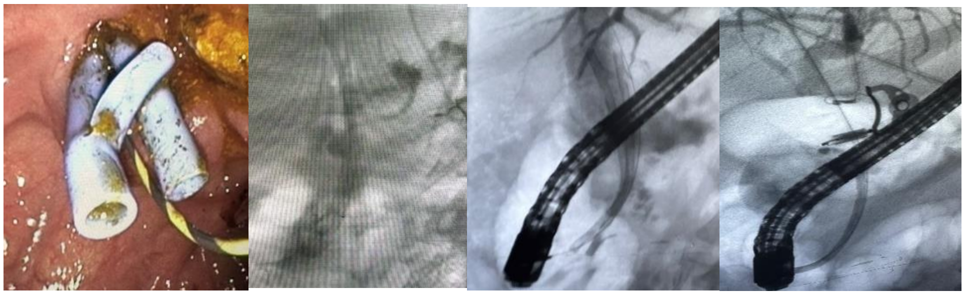
OBJECTIVE

The primary objective was to evaluate the success rate of the novel delivery system in real-world scenarios human subjects Requiring maintaining guidewire access after stent release, in single or multiple stent placements.

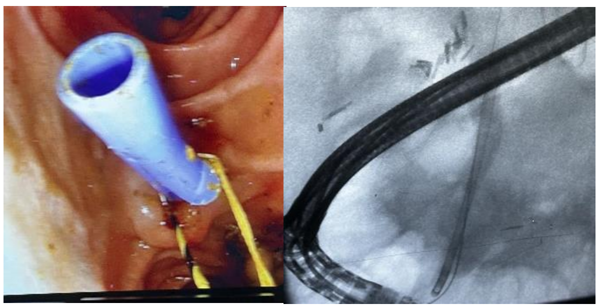
CASE SERIES

This case series reports on a total of ten patients with varying conditions: benign stricture (n=5), complicated biliary stone disease (n=2), malignant tumor (n=2), and post-sleeve gastrectomy leak (off-label) (n=1). These patients underwent an ERCP procedure, which involved the placement of single or multiple 10FR stents. Different biliary straight stents, ranging in length from 9-12 cm, and pigtail stents, 10FR up to 7 cm in length, were deployed with relative ease using the novel integrated rapid exchange and self-detaching delivery mechanism. All stents were successfully placed without any wire dislocation. The delivery system was rated as easy to use and maintained its position without migration following the initial stent delivery.

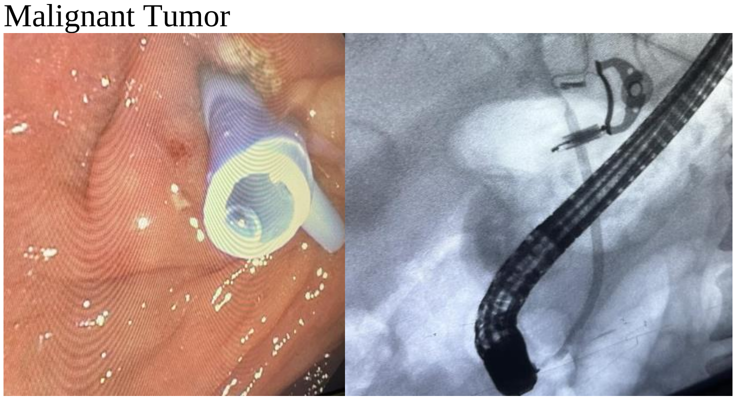
Benign stricture



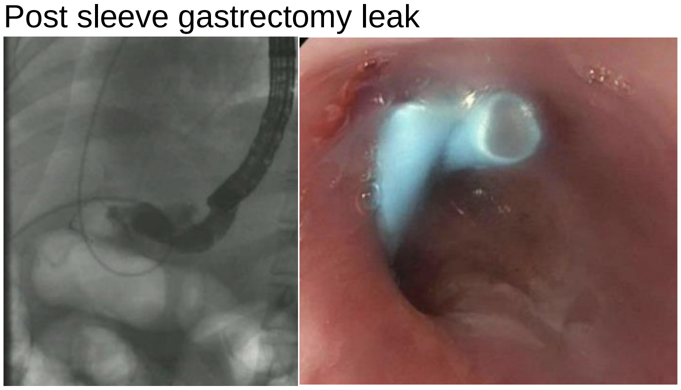
Complicated biliary stone disease



Malignant Tumor



Post sleeve gastrectomy leak



CONCLUSION

In this experience with the novel integrated rapid exchange and self-detaching delivery system, we can confidently assert that it is safe and easy to use. The results indicate a trend towards a reduction in procedure length, particularly in patients requiring multiple stent placements.

Keywords: Biliary Stent, Pre-mounted, Novel Delivery System, In-situ Wire