TYPE OF ARTICLE: Case Series white paper

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

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INTRODUCTION

Current commercially available biliary stent delivery systems are limited by the loss of guidewire positioning after stent delivery, particularly in cases with difficult ductal access that require additional intervention following the initial stent placement. A novel biliary stent delivery system, the S-PATH system by EndoGI Medical, has been developed to address these limitations with its integrated rapid exchange and self-detaching mechanism.

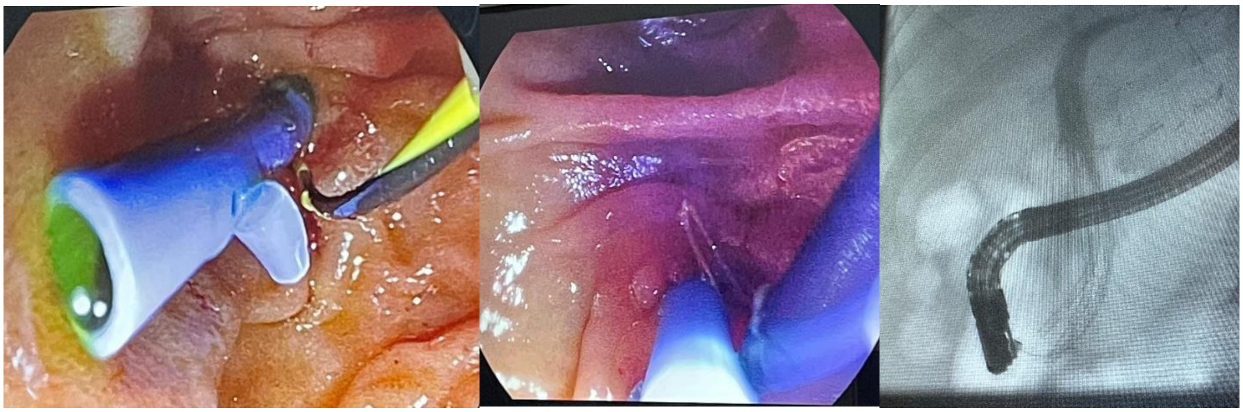
The primary objectives were to evaluate this delivery system in human subjects to assess the success of stent delivery, the localization of the stent within the bile ducts, and post-delivery wire in-situ fixation. Secondary objectives included evaluating the device's ability to reach its location within the bile duct and the placement and location of the stent.

CASE SERIES

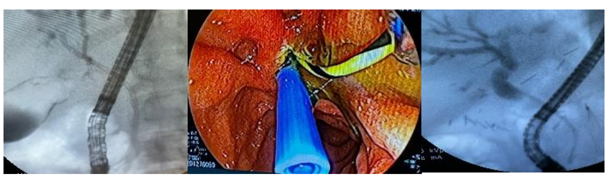
This case series describes five patients undergoing biliary stent procedures for biliary obstruction due to post-liver transplant anastomotic stricture (n=2), benign biliary stricture (n=2), and complicated stone disease (n=1).

The system was deployed with relative ease, and all stents were successfully placed in the required position without any wire dislocation. The delivery system was rated as easy to use and appears to remain in situ without migration following the initial stent delivery.

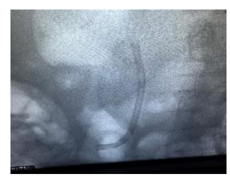
Post liver transplant anastomotic stricture



Benign biliary stricture



Complicated stone disease



CONCLUSION

The novel single stent delivery system was successfully deployed using a 10FR by various lengths (60 90 120 mm) plastic stent in the case of a patient requiring stenting in the region of the common bile duct. The stents were successfully placed in situ, with no procedural complications. This system enhanced procedural simplicity by reducing the number of procedural steps and time required, while ensuring secure and accurate ductal access and minimizing the risks associated with re-cannulation.

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