TYPE OF ARTICLE: Clinical Case review

TITLE: Novel, Integrated Rapid Exchange Pre-mounted, Single-Stent, Self-Detaching Delivery System for Biliary Stent Placement: Case of First use review experience.

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Introduction

Current commercially available biliary stent delivery systems often encounter issues with maintaining guidewire positioning after plastic stent deployment. This challenge is particularly pronounced in cases requiring complex ductal access, leading to the need for additional interventions after the initial plastic stent placement. To address these challenges, a novel biliary stent delivery system has been developed. The S-PATH system, designed by EndoGI Medical, incorporates an integrated rapid exchange (RX) and self-detaching mechanism. This innovative design aims to minimize guidewire positioning loss and improve procedural efficiency.

The primary evaluation criteria for the S-PATH system focused on:

- Successful stent delivery.
- Accurate localization of the stent within the bile ducts.
- Secure post-delivery guidewire fixation.

Secondary objectives included assessing the system's capability to:

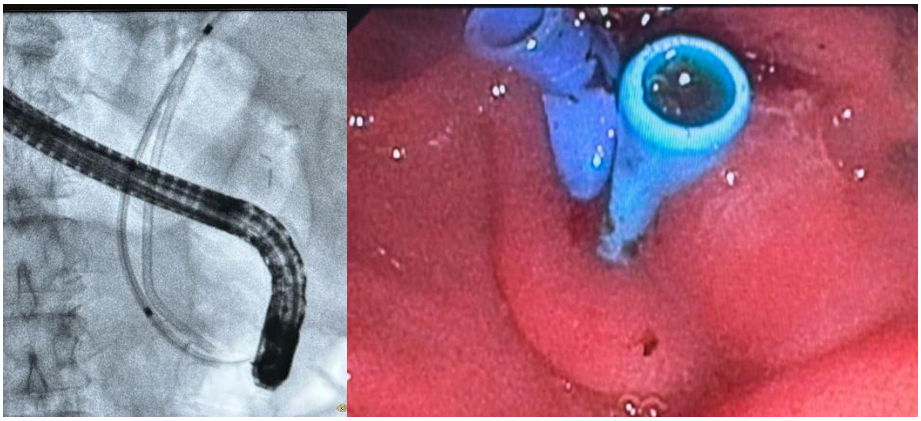
- Reach its intended location within the bile duct.
- Ensure the precise placement of the stent.

Overall, the S-PATH system represents a significant advancement in biliary plastic stent delivery technology, addressing key limitations of existing systems and enhancing procedural outcomes

Case Series

In this case series, one patient with biliary obstruction resulting from a challenging long cystic duct post-cholecystectomy was treated using the S-PATH system. The initial deployment of the S-PATH system was performed with relative ease, successfully positioning the stent without any displacement of the guidewire, which remained securely in place throughout the procedure. Following the initial stent placement, an on-the-wire system was employed to place an additional standard stent. The S-PATH delivery system was rated as easy to use and demonstrated exceptional stability in situ, with no migration observed after the initial stent deployment.

This case highlights the effectiveness of the S-PATH system in managing complex biliary obstructions, ensuring accurate stent localization, and maintaining guidewire positioning, thereby reducing the need for additional interventions



CONCLUSION

The single-stent delivery system was successfully utilized to deploy a 10FR by 90cm plastic stent using the S-PATH system, while maintaining wire accessibility. An identical-sized Cook One-Action system was also employed for a patient requiring stenting in the common bile duct region.

Both stents were placed in situ without any procedural complications. The use of the S-PATH system significantly enhanced procedural simplicity by eliminating four procedural steps, reducing overall time, and ensuring secure and accurate ductal access. Additionally, the design minimized re-cannulation risks, demonstrating the system's effectiveness in complex biliary interventions.

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