TYPE OF ARTICLE: Case Study white paper

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

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INTRODUCTION

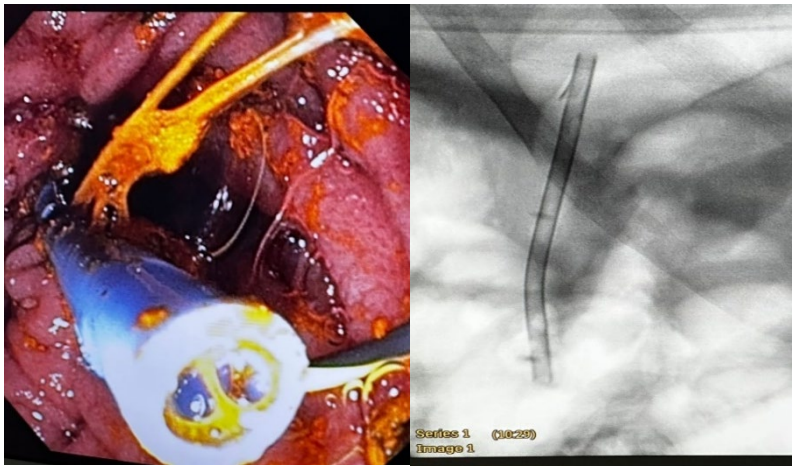
Current commercially available biliary stent delivery systems are limited by the loss of guidewire positioning after stent delivery, particularly in cases with difficult ductal access that require additional intervention following the initial stent placement. A novel biliary stent delivery system, the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

PRIMARY OBJECTIVES

Were to test 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, as well as the placement and location of the stent.



CASE STUDY

Conversion from Percutaneous Transhepatic Biliary Drainage (PTBD) to Endoscopic Retrograde Cholangiopancreatography (ERCP) Using the S-Path Stent Delivery System

BACKGROUND

A patient with biliary obstruction underwent a conversion procedure from PTBD (external drainage system) to ERCP (internal drainage system) using a novel stent delivery system.

PROCEDURE

1. Guidewire Placement: Using a Papillotome, the external stent served as a conduit for the insertion of a guidewire. The guidewire was advanced through the bile duct until it successfully reached the hilar ducts.
2. External Stent Extraction: Once the guidewire was in place, the plastic stent external drainage system was extracted, leaving the guidewire in place.
3. Stent Placement Using the S-Path System: A 10FR by 60mm plastic stent was deployed using the S-Path system. This system's unique design allows it to detach from the guidewire, thereby mitigating the risk of guidewire displacement. The stent was placed in the desired position without losing the guidewire.

OUTCOME

The S-Path stent delivery system was rated as easy to use. The stent was successfully positioned without any wire dislocation. Post-deployment, the stents remained in situ without migration. The S-Path system proved to be effective in securing the guidewire during the conversion procedure from PTBD to ERCP, reducing the risk of complications and eliminating the need for repeated external drainage procedures. The S-Path system was effective in securing the guidewire during the conversion procedure from PTBD to ERCP while deploying a 10FR by 60mm stent. In this case of a patient requiring stenting in the region of the common bile duct, the stent was successfully placed in situ with no procedural complications. The use of the S-Path system enhanced procedural simplicity, reduced procedural steps and time, and minimized the risk of complications, eliminating the need for repeated external drainage procedures.

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