Advanced Balloon Trocar for Therapeutic Endoscopy

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Aim: We describe the design and features of a new balloon trocar and provide initial test results.

Introduction

- Therapeutic interventions on organs surrounding the GI lumen require a stable and secure pathway that is maintained throughout the procedure.
- Currently, access is gained with a 19G FNA needle and 035in guidewire, then intervention is performed over the wire.
- This method is acceptable for pseudocyst drainage as the pseudocyst is often adhered to the stomach wall, thereby preventing leakage into the peritoneal cavity.
- However when target lumens are not adhered to the stomach wall, such as the bile duct or gall bladder, a device that ensures lumenal apposition, alignment and leakage prevention immediately following the initial penetration is imperative.

Herein we describe a "balloon trocar" that first creates access, then immediately secures the target organ to the GI lumen wall via a combination of balloon inflation and proximal traction.

Deployed trocar tip & blade

Methods

- The device was tested ex-vivo: bench-top measurements of the pressure required to dislodge the trocar balloon were made using a test fixture and porcine stomach tissue.

Fully-inflated balloon trocar

- The device was also tested in-vivo in 1 animal using EUS guidance: access from the stomach to the gallbladder was obtained with the trocar.
- The gallbladder was then secured to the stomach wall using slight proximal traction on the inflated balloon.
- A 3.4mm tapered catheter was advanced directly over the trocar into the gall bladder.

Results

The bench test results showed that the force required to dislodge the trocar balloon from the stomach tissue was 2.0psi.

In the animal experiment, gallbladder access was obtained upon first penetration, alignment of the two lumens was readily achieved, apposition of the gallbladder to the stomach wall was held for over 1hr, and the catheter was advanced into the gallbladder, all confirmed by EUS.

Conclusion

Initial laboratory experiments indicate that a novel EUS-directed balloon trocar can provide an improved method to safely access and secure lumenal structures adjacent to the GI lumen, while facilitating device advancement directly over the trocar.

Disclosures: *Drs. Lightdale and Binmoeller serve as Advisors to Xlumena.*