Advanced Translumenal Access Device for Pseudocyst Drainage

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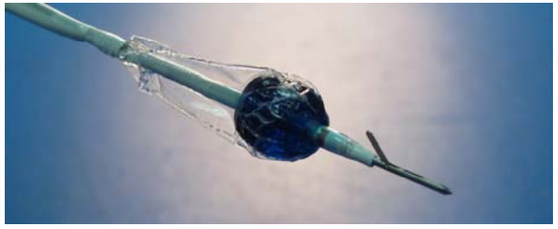
The aim of this study is to evaluate the deployment of a new Translumenal Access Device (TAD) in a benchtop model.

Introduction

EUS-guided pseudocyst drainage provides internal drainage without the need for surgical intervention. **Current methods require multi-step access through the GI lumen wall into the pseudocyst**, creation of a cystgastrotomy tract, and placement of multiple 7-10F plastic stents.

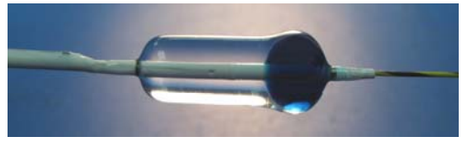


Inflated distal anchoring balloon

Access and dilation steps are often tedious and difficult to perform due to the lack of a suitable stent delivery devices. **Herein we describe a fully integrated translumenal access device that creates and dilates an access tract, then facilitates placement of two guidewires.**

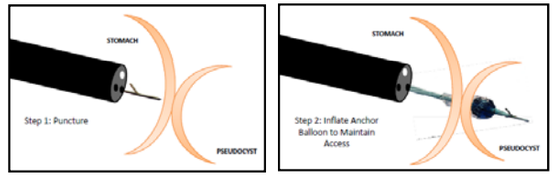
Description

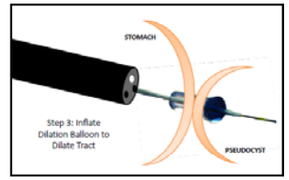
- The TAD is a 140cm long, 2.5mm diameter device that coaxially incorporates a 19g trocar, a 3cm long balloon and two separate 0.035in guidewire lumens.
- The TAD handle provides precise and independent control of both the balloon and trocar.
- The 19g trocar tip incorporates an “extending blade” that creates an incision significantly larger than its constrained profile, thereby allowing easy passage of the balloon catheter directly over it.
- The 3cm balloon is activated in two stages: 4-6atm of pressure inflates a 20mm diameter distal anchoring balloon flange to maintain pseudocyst access, while 10-12atm of pressure inflates a 10mm diameter dilation balloon section.



Inflated dilation & anchor balloons

- When the balloon catheter is retracted proximally, the distal anchoring balloon flange ensures apposition of the cyst and GI walls while placing the dilation portion of the balloon in an ideal tract dilation position.





Methods

The following bench-top force measurements were made using a test fixture housing ex-vivo porcine stomach tissue: (a) the force required for the TAD trocar to puncture tissue, (b) the force required for the TAD balloon catheter to advance through punctured tissue, and (c) the force required to pull the distal anchoring balloon flange through the punctured tissue.

Results

The force required for the TAD trocar to puncture tissue averaged 0.64psi, similar to the 19g control needle. The force required to advance the TAD balloon catheter through the tissue punctured by the TAD trocar ranged from 5.7-10.9 times *less* than the force required to advance the same catheter through tissue punctured by the 19g control needle. The distal anchoring balloon required more than 2lbs of force to dislodge the catheter, indicating it’s effectiveness in securing a stable operating platform.

Conclusion

This advanced translumenal access device provides significant conceptual improvements over current access and dilation methods.

Disclosures: *Drs. Brugge, Binmoeller & Shah serve as Advisors to Xlumena.*