Balloon Occlusion Cholangiography and Dilation Catheter

A Novel Device for Simplifying Laparoscopic Common Bile Duct Exploration

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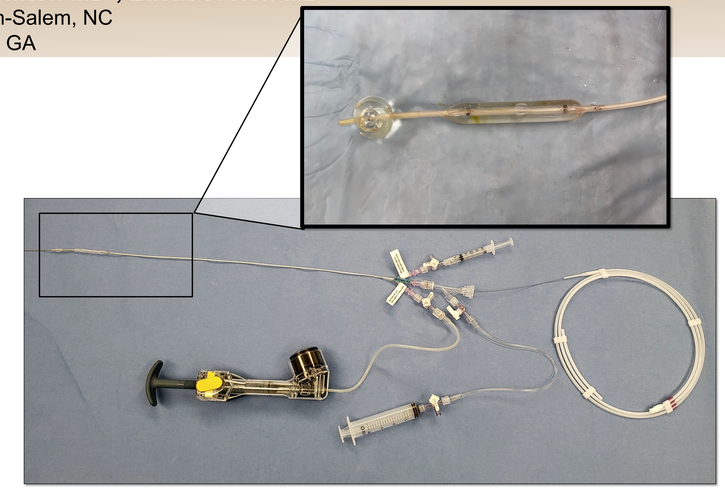
BACKGROUND

Choledocholithiasis can be managed safely by either laparoscopic cholecystectomy (LC) with pre-/post-operative endoscopic retrograde cholangiopancreatography (ERCP) or LC with intraoperative laparoscopic common bile duct exploration (LCBDE).

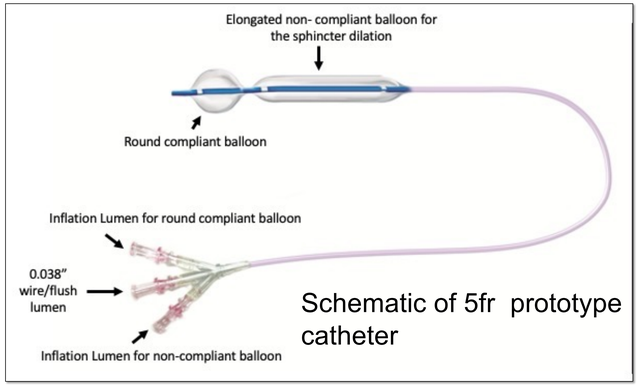
- LC + LCBDE = one-step, one-anesthetic process
- ↓ Utilization of LCBDE in the US over last decade
- We piloted a stepwise technique to perform transcystic balloon sphincteroplasty as a LCBDE adjunct
- Adoption of the technique prompted improvement and innovation
- A novel device was designed by the surgical team to streamline LCBDE and provide flexibility for cholangiography, cystic duct dilation for endoscopy, stone retrieval and balloon sphincteroplasty with a single device.

METHODS

- Initial prototypes were constructed by a catheter design firm with appropriate medical device design controls
- A proof-of-concept trial was performed in a swine model. Peanuts were inserted into the common bile duct to act as common bile duct stones. Clearance of the duct was attempted with the novel catheter.



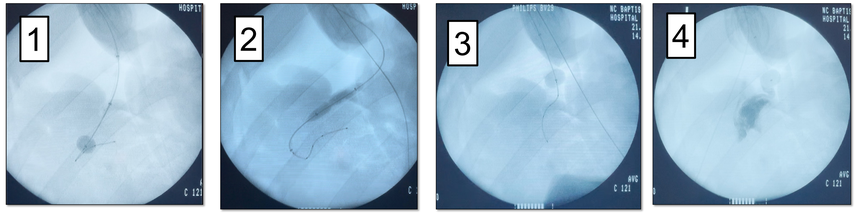
5 Fr prototype catheter with cholangiogram set up and rotational inflation device



Schematic of 5fr prototype catheter

RESULTS

Initial fluoroscopy demonstrated the "stones" (peanuts) in the common bile duct of the animal. The CBD was sealed with the distal balloon and a subsequent cholangiogram was performed. The catheter's compliant balloon was inflated and pulled back to access location and angle of the sphincter (1). The sphincter was dilated by the more proximal elongated balloon. A waist is seen at the sphincter (2). After dilation, the proximal balloon was deflated, and the catheter was withdrawn. The distal balloon re-created a seal for final cholangiogram/power flushing (3). The "stones" were noted to flush forward with contrast seen in the duodenum (4).



CONCLUSIONS

The balloon occlusion cholangiography and sphincteroplasty catheter is a novel device that allows for 1) cholangiography 2) pressurized flushing of the CBD 3) dilation of the cystic duct for choledochoscope insertion 4) delivery of stone retrieval baskets 5) sphincter of Oddi dilation. This simple catheter was successful in clearance of common bile duct stones in an animal model and may prove to be helpful in an operative setting.