Endoscopic Translumenal Cholecystoscopy & Gallbladder Drainage Using a Novel Lumenal Apposition Device in the Porcine Model

Kenneth Binmoeller MD,[1] John Lunsford,[2] Hoang Phan,[2] Fiona Sander[2]

[1]California Pacific Medical Center, [2]Xlumena, Inc.

Aim: Evaluate the feasibility of translumenal cholecystoscopy and gallbladder drainage in the porcine model using the lumenal apposition device.

Introduction

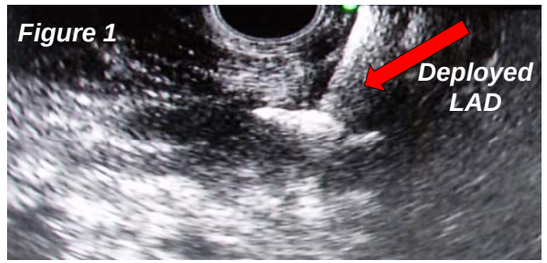
The gallbladder is the "final frontier" of biliary endoscopy. Per oral transpapillary cholecystoscopy followed by lithotripsy was recently reported (Chen et al, GIE 2008; 67:132). Endoscopic ultrasound (EUS) guided gallbladder drainage has been reported in several case series for acute cholecystitis. This is the first report of translumenal cholecystoscopy and gallbladder drainage using a novel Lumenal Apposition Device (LAD).

Materials

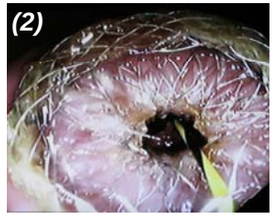
The prototype LAD consists of nitinol wire braided heat-set into a dual flange configuration (Fig. 6). Fully expanded, the flange & body diameters measure 20mm and 10mm, respectively. The body is covered with a coating to prevent leakage and in-growth. The LAD is constrained onto a 10.5Fr delivery catheter.

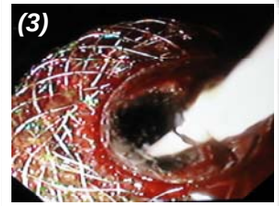
Methods

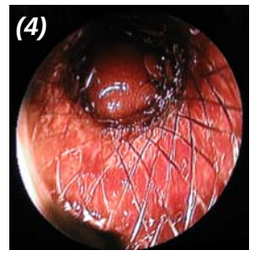
Four survival pigs were studied under general anesthesia. The gallbladder was located transgastrically using a 3.7mm channel curved array echoendoscope (Olympus) and punctured with a 19G FNA needle under EUS guidance at a site of abutment against the gastric wall. At least two T-tags (Cook) were deployed to retain apposition of the gallbladder against the gastric wall.

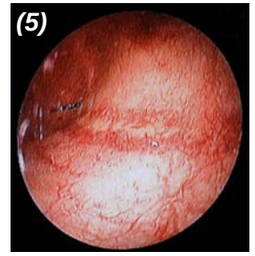


The gallbladder was re-punctured at a site adjacent to the T-tags, and a guidewire was inserted through the 19G needle and looped in the gallbladder (Fig. 2). Keeping the T-tag sutures under constant traction, the cholecystgastrostomy tract was dilated with a 4mm non-compliant balloon (Boston Scientific). The LAD (Xlumena) was deployed across the cholecystgastrostomy tract under combined EUS (Fig. 1) and endoscopic guidance.









The deployed LAD lumen was easily intubated with a constrained balloon catheter and dilated to 10mm (fig. 3). Vigorous bile drainage into the stomach was observed after dilation. The echoendoscope was exchanged for a 5.8mm diagnostic endoscope (Fujinon). The LAD lumen was traversed and the gallbladder lumen entered to perform cholecystoscopy (fig. 4 & 5). The cystic duct orifice and deployed T-tags were visualized. The T-tag sutures were cut using endoscopic scissors before withdrawing the endoscope.

Results

No acute complications, including bleeding or perforation, occurred. The LAD did not migrate, dislodge or otherwise change position after deployment. There was no evidence of acute tissue injury. Survival data in 4animals will be presented.

Conclusion

EUS guided deployment of the LAD is feasible and enables cholecystoscopy and gallbladder drainage. Further studies are warranted. The LAD can extend the boundaries of interventional biliary endoscopy into the gallbladder.

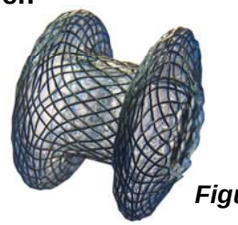


Figure 6

Disclosures: *Dr. Binmoeller serves as an Advisor to Xlumena.*