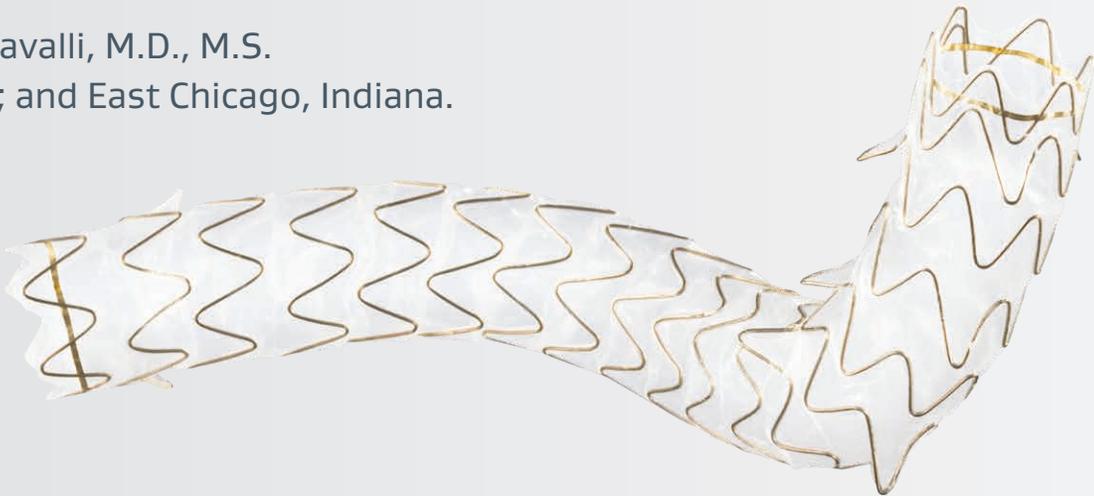


CASE REVIEW

Successful resolution of malignant biliary obstruction of the common bile duct with normalization of serum bilirubin and decreased pain.

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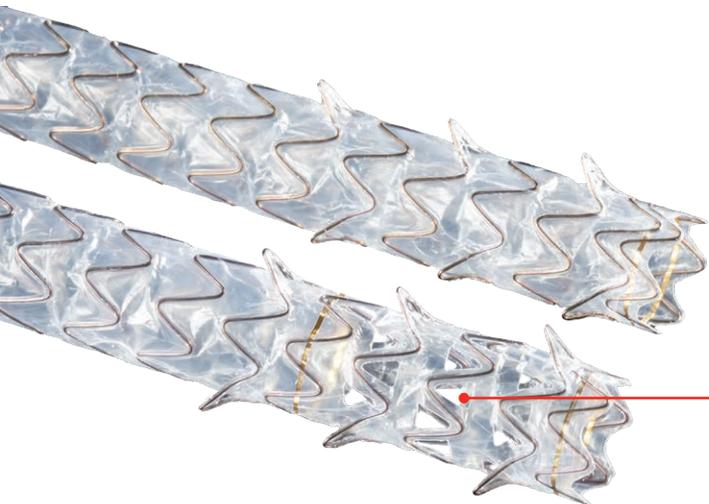
GORE® VIABIL®
Biliary Endoprosthesis

CASE TAKEAWAYS



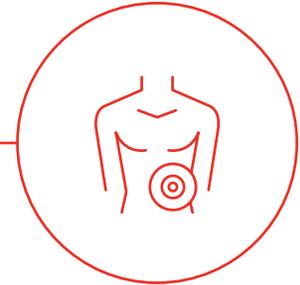
This case illustrates the benefits of important design features of the GORE® VIABIL® Biliary Endoprosthesis in a clinical setting:

- The 10 mm diameter device allowed for decreased resistance to bile flow.
- The fenestrations (or holes) of the device allowed placement across the cystic duct, decreasing likelihood of cystic duct obstruction and resultant cholecystitis.
- The anti-migration anchoring fins of the device are designed to reduce the chance of migration due to peristalsis of the small bowel or due to other reasons, such as slippage.



Transmural drainage holes

PATIENT CHARACTERISTICS



- **Patient gender:** Female
- **Patient age:** 38
- **Patient condition(s)/diagnosis:** Adenocarcinoma of the head of the pancreas with stricture of the common bile duct.
- **Patient revisions/history:** Endoscopic retrograde cholangiopancreatography (ERCP) attempted but unsuccessful ampulla cannulation. Placement of an internal-external biliary drainage was done at a different facility.

CASE DETAILS



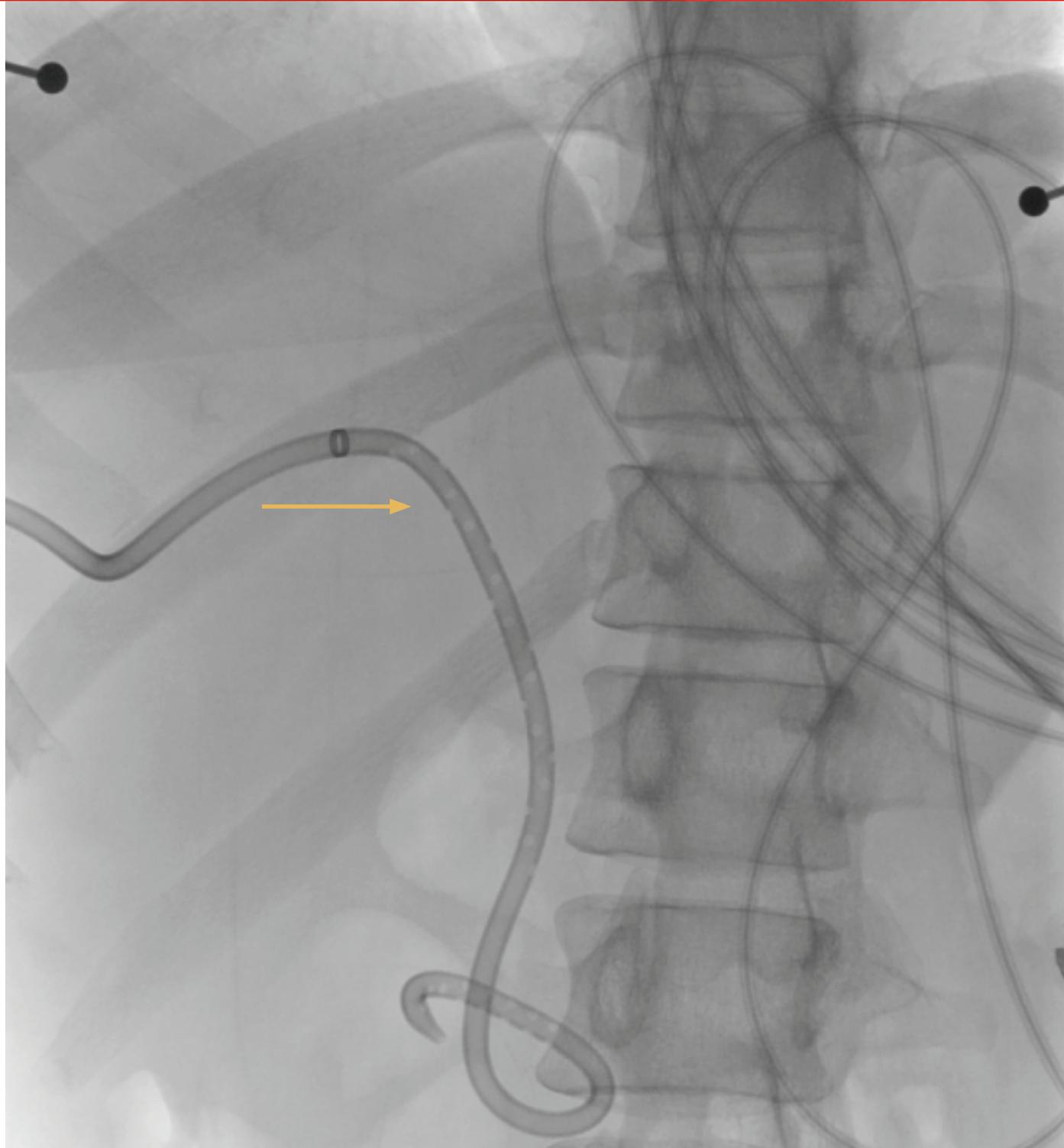
- **Presenting issue:**
 - Metastatic pancreatic adenocarcinoma with malignant biliary obstruction due to a mass within the head of the pancreas. Internal-external biliary drainage catheter was causing the patient extreme discomfort and significantly impacting quality of life.
 - Patient was also having persistent hyperbilirubinemia, with jaundice, and diffuse pruritis even with the internal-external biliary drainage catheter in place.
- **Description of treatment approach:** Percutaneous transhepatic cholangiography (PTC) with the goal of exchanging the internal-external biliary drainage catheter for a fully covered self-expanding metal stent (FCSEMS).

PROCEDURE

- In the Interventional Radiology suite, the scout image obtained showed appropriate positioning of the internal-external biliary drainage catheter.
- An initial cholangiogram showed the pigtail of the catheter to be in the duodenum, as expected.
- There was no significant extrahepatic or intrahepatic biliary ductal dilatation.

Figure 1: X-ray scout image showing internal-external biliary drain (gold arrow).

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- The catheter was transected, and a guidewire was advanced through the catheter into the duodenum. The drainage catheter was removed over the wire.
- A 10 Fr sheath was placed at the access site. Repeat cholangiogram was performed by injection through the sheath.

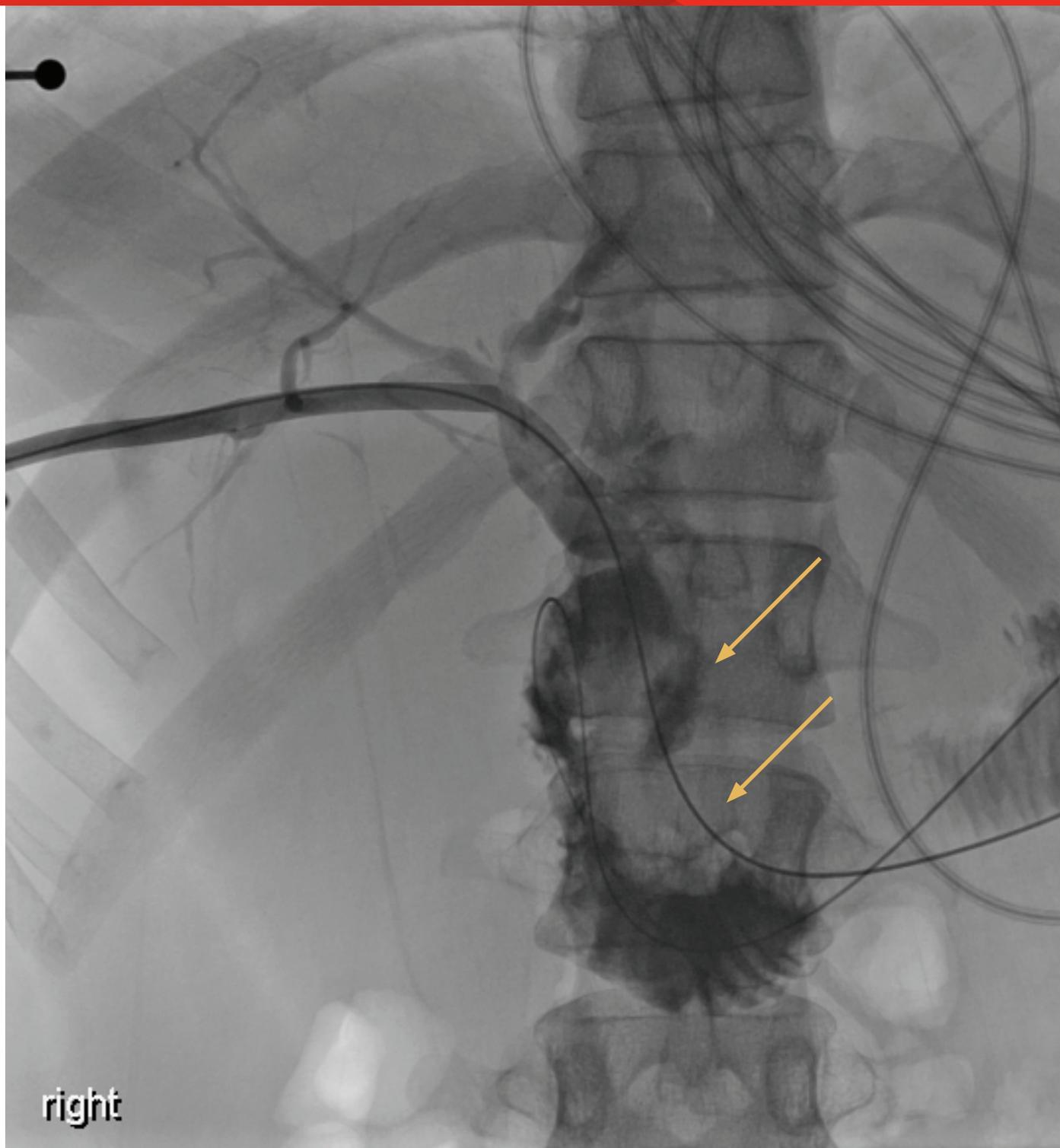


Figure 2: Initial cholangiogram after drain removal demonstrates occlusive common bile duct stricture (gold arrows).

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right

- Repeat cholangiogram was performed using a COOK® Kumpe Access Catheter (KMP). The distance from the level of the stricture to the ampulla was then measured using the angiography unit.

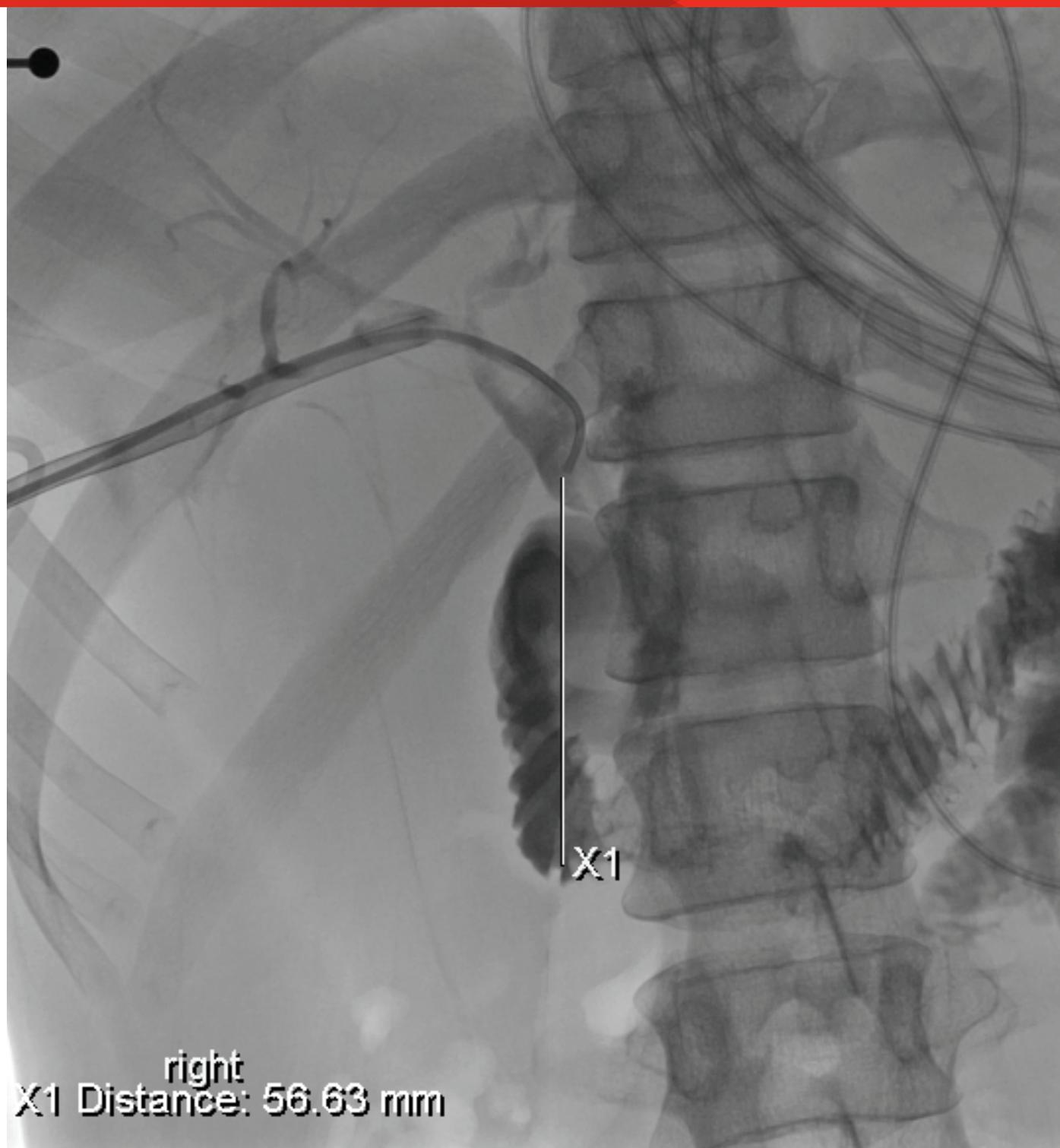


Figure 3: X-ray image showing measurement of the initial length to select the appropriate stent graft.

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- A 10 mm diameter x 8 cm length GORE® VIABIL® Biliary Endoprosthesis with holes was selected and advanced through the sheath over the wire and positioned across the stricture. The fenestrated option (holes) was utilized as the patient still had her gallbladder which necessitated maintaining flow through the cystic duct.
- Care was taken to visualize the location of the cystic duct insertion on the common bile duct.

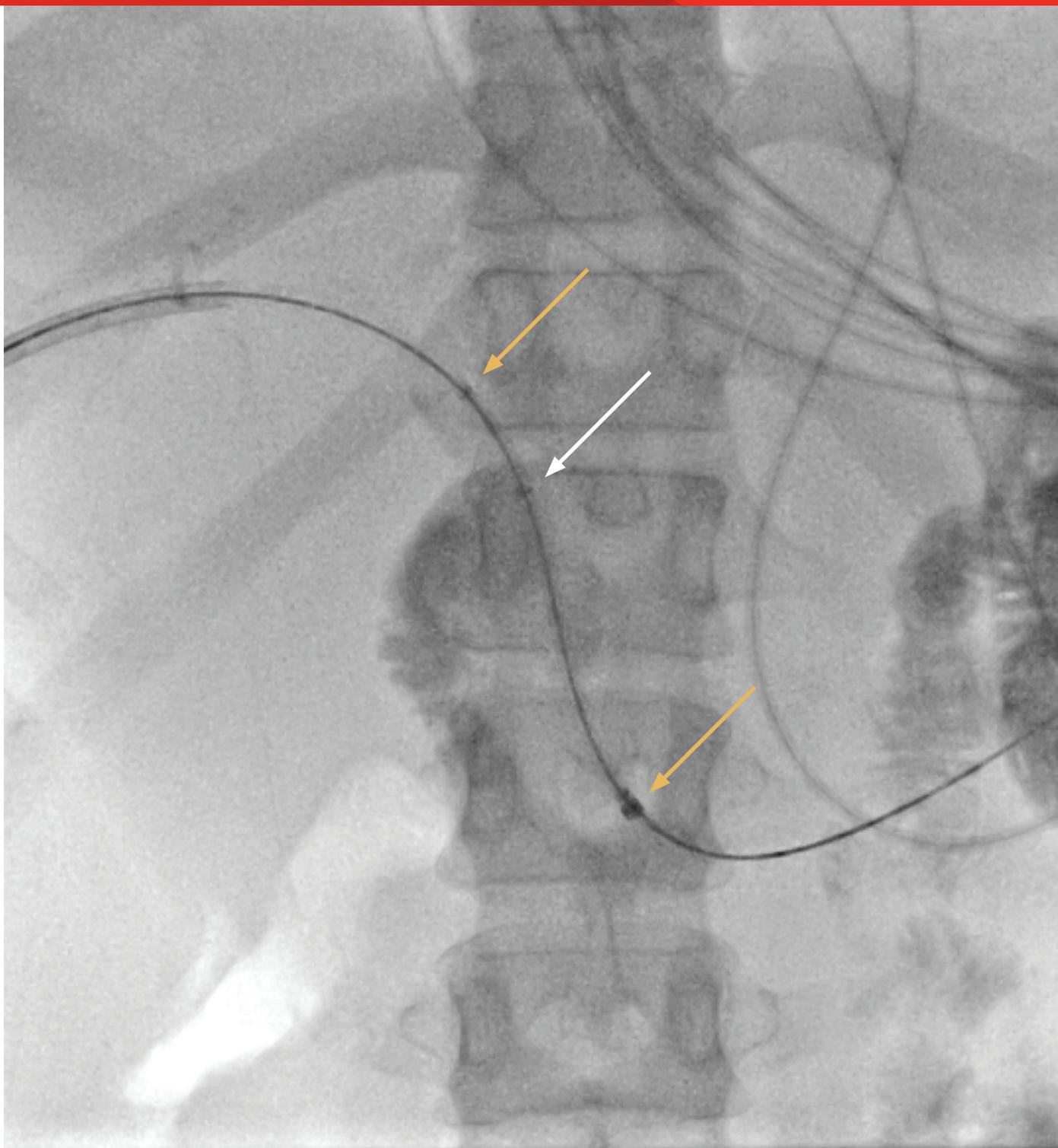


Figure 4: A GORE® VIABIL® Biliary Endoprosthesis with holes shown pre-deployment. Gold arrows show the proximal and distal radiopaque markers on the stent graft. The white arrow shows the third radiopaque marker which delineates the inferior boundary of the holed region of the stent graft.

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- The GORE® VIABIL® Biliary Endoprosthesis with holes was deployed across the cystic duct insertion (*Figure 5*). Initial imaging was done after deployment (*Figure 6*). Post-deployment balloon dilation of the stent graft was done with a 9 mm x 8 cm BOSTON SCIENTIFIC MUSTANG® Balloon Dilatation Catheter along the entire length of the stent graft, including the portion in the duodenum (*Figure 7*).

Figure 5: A cholangiogram was performed, which showed a free drainage of contrast through the stent (gold arrow) into the duodenum and there was complete decompression of the intrahepatic biliary radicals.

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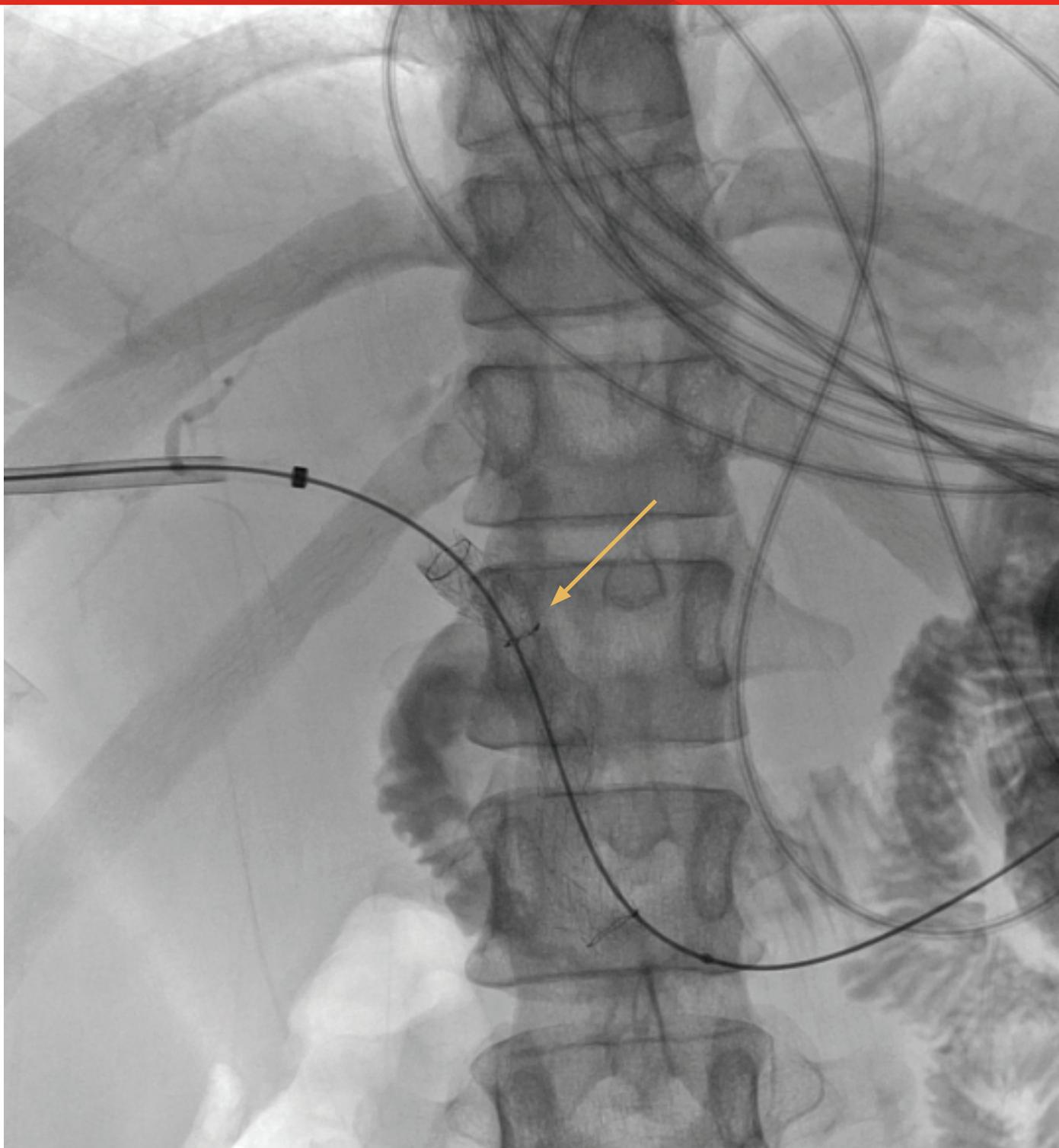




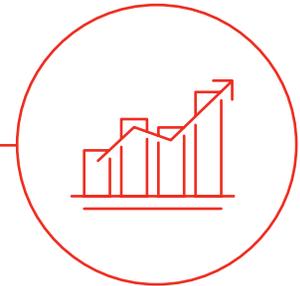
Figure 6: Balloon dilatation of the stent graft with inflated balloon shown within the stent graft.



Figure 7: View of the fully dilated GORE® VIABIL® Biliary Endoprosthesis showing wide patency of the common bile duct and stent graft.

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RESULTS



- Patient bilirubin rapidly normalized over the next 3 days.
- Patient's pain resolved over the next 2–3 days. Patient's pruritis resolved also over the next 2–3 days.
- Patient discharged home 4 days after the procedure.
- On clinic follow up 2 weeks later, patient stated her quality of life was substantially improved after removal of the internal-external biliary drainage catheter and placement of the GORE® VIABIL® Biliary Endoprosthesis.
- Patient had no further hospital admissions due to biliary obstruction.
- Although the patient's quality of life drastically improved after the GORE® VIABIL® Biliary Endoprosthesis placement, she succumbed to her progressive malignant disease 3 months later.

The outcomes and observations reported are based on individual case experience and the patients treated. The steps described here may not be complete and are not intended to be a replacement for the *Instructions for Use* or the education, training and professional judgment of health care providers (HCP). HCPs remain solely responsible for making decisions about patient care and the use of medical technologies.

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