CASE REVIEW

Successful treatment of high grade distal malignant biliary obstruction of the common bile duct with duodenal stricture

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GORE® VIABIL®
Biliary Endoprosthesis

CASE TAKEAWAYS

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

- Accurately measuring the length of the biliary stricture is highlighted in this case as 3 separate stent grafts as used in this case might not have been required.
- Stent graft migration concerns are mitigated as the anti-migration anchoring fins of the GORE® VIABIL® Biliary Endoprosthesis are designed to reduce the risk of migration.
- The overlap between stent grafts was approximately 1.5 cm.
- Due to the caliber of the stricture, the stiffest wire possible was used to allow for accurate deployment of the stent grafts, converting from the BOSTON SCIENTIFIC Amplatz SUPER STIFF Guidewire to a COOK LUNDERQUIST® Extra-Stiff Wire Guide.
- The conformability of the GORE® VIABIL® Biliary Endoprosthesis was important in this case. The end section of a more rigid stent graft (a stent graft with higher axial force) could have been positioned perpendicular to the wall of the duodenum, potentially leading to duodenal wall erosion[1] or occlusion of the stent, as the stent tends to try to straighten itself.[2]
- The anchoring fins of the last deployed stent were parallel to the wall of the duodenum, thereby mitigating the risk of duodenal erosion or perforation.[1]

Fully covered defeatable anchoring fins

PATIENT CHARACTERISTICS

- **Patient gender:** Female
- **Patient age:** 68
- **Patient condition(s)/diagnosis:** Adenocarcinoma in the head of the pancreas with a distal high grade common bile duct stricture along with a duodenal stricture due to extrinsic compression of the duodenum by the mass within the head of the pancreas.
- **Patient revisions/history:** Originally presented with painless jaundice, endoscopic retrograde cholangiopancreatography (ERCP) was attempted but unable to cannulate the common bile duct, nor was the previous physician able to adequately position the endoscope due to the duodenal stricture (unable to retroflex the scope adequately). After performing percutaneous transhepatic cholangiogram (PTC), an internal-external drainage catheter was placed for decompression of the biliary system. Patient also had a jejunostomy feeding tube due to duodenal stricture.

CASE DETAILS

- **Presenting issue:** Discomfort due to multiple catheter-related complications including occlusions, leakage around the drainage catheter and skin erosion prompting returns to the office every week.
- **Description of treatment approach:** Due to patient's poor quality of life, and since a jejunostomy feeding catheter was in place, it was decided to stent graft the common bile duct through the duodenal stricture so she could drain into the small bowel distal to the duodenal stricture.

PROCEDURE

- In the Interventional Radiology suite, the initial scout image showed the location of a previously placed internal-external biliary drainage catheter. Note the deformation of the pigtail of the catheter due to the duodenal stricture.

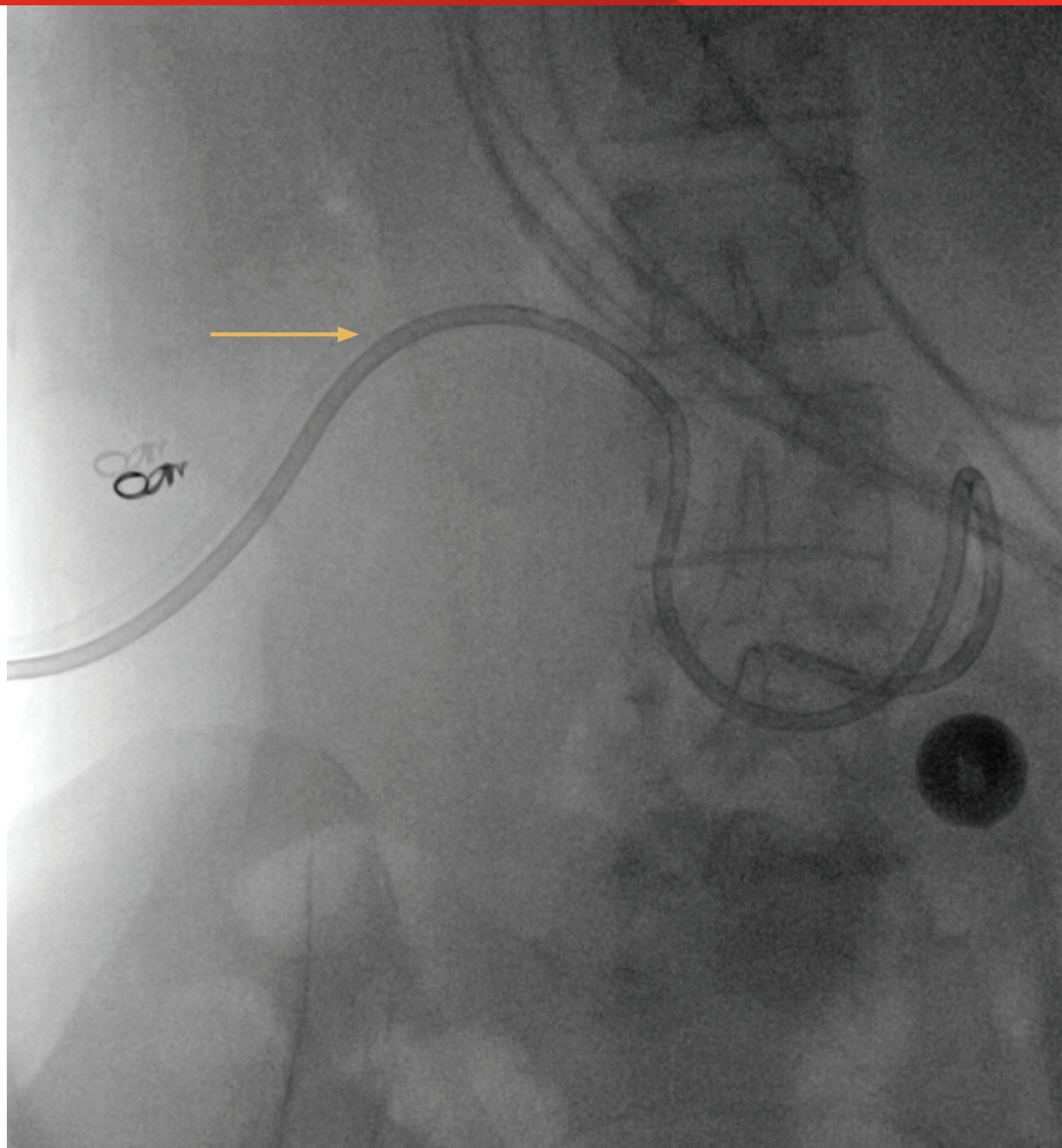

Figure 1: X-ray scout image showing internal-external biliary drainage catheter (gold arrow).

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- A guidewire was placed through the internal-external drainage catheter, and the catheter was removed over the wire.
- A sheath was placed at the catheter entrance site, and a cholangiogram was performed to better delineate the common bile duct stricture.

Figure 2: Initial cholangiogram after drain removal demonstrating occluded common bile duct stricture (gold arrow). The cystic duct appears highly tortuous.

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- A marking pigtail catheter was used to measure the length of the stricture as accurately as possible. The length was also measured using the measurement tool of the angiography unit itself.
- Accurate measurement of the length was difficult for 2 reasons: (1) the duodenal stricture was causing reflux of contrast into the first portion of the duodenum and into the stomach, and (2) the stiff guidewire straightened the entire system making it difficult to measure using the angiography unit.
- Three stent grafts were ultimately required to extend into the "unstrictured" portion of the duodenum (distal third portion to fourth portion).

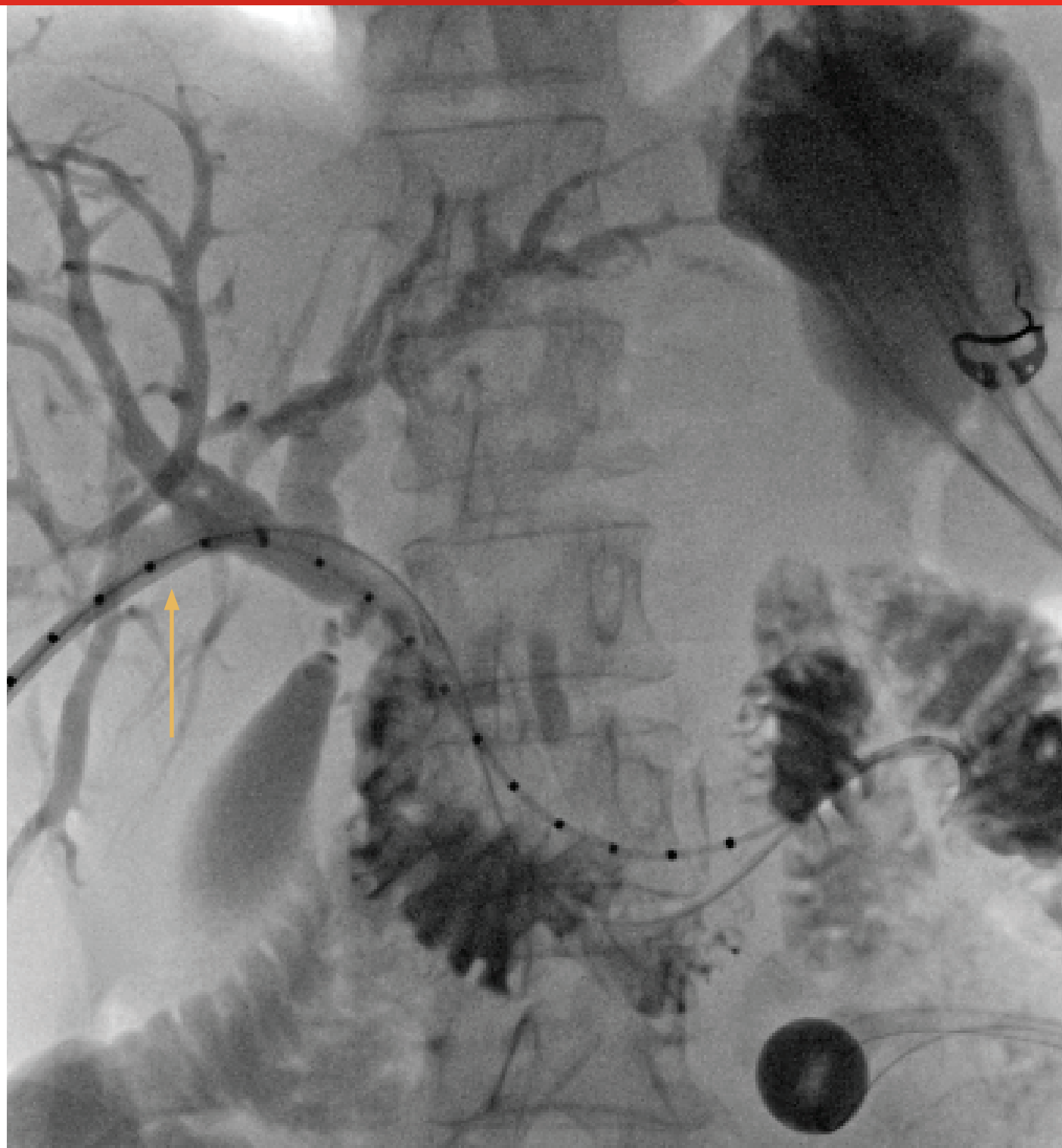

Figure 3: A pigtail catheter with markers (gold arrow) was used to confirm necessary length.

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- A 10 mm diameter x 6 cm length partially fenestrated GORE® VIABIL® Biliary Endoprosthesis with holes was deployed, and a cholangiogram showed a static column of contrast with no flow into the duodenum and no decompression of the intrahepatic biliary radicals.
- Post-deployment dilation was performed with a 9 mm x 80 mm BOSTON SCIENTIFIC MUSTANG® Balloon Dilatation Catheter.
- The marking pigtail catheter was reintroduced over a guidewire and extended through the initially placed stent graft in a repeat attempt to accurately size the stricture for another stent to extend the first stent and bypass the stricture.

Figure 4: A GORE® VIABIL® Biliary Endoprosthesis 10 mm x 6 cm with holes was deployed (gold arrow). Notice no decompression of hepatic ducts and contrast stasis within stent graft persists.

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- A 10 mm diameter x 4 cm length GORE® VIABIL® Biliary Endoprosthesis without fenestrations (holes) was deployed overlapping the initially deployed stent by 1.5 cm.
- Post-deployment dilation was again performed with a 9 mm x 80 mm BOSTON SCIENTIFIC MUSTANG® Balloon Dilatation Catheter. Repeat cholangiogram was then performed.
- A persistent static column of contrast was again visualized within the overlapping stent grafts with no decompression of the intrahepatic ducts and with no spillage of contrast into the distal duodenum.

Figure 5: A second GORE® VIABIL® Biliary Endoprosthesis (10 mm x 4 cm) was deployed (gold arrow).

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- A third GORE® VIABIL® Biliary Endoprosthesis was deemed necessary. A 10 mm x 4 cm GORE® VIABIL® Biliary Endoprosthesis was considered appropriate but, due to the lack of hospital inventory, the next highest size available was used — 10 mm x 6 cm. The stent graft was deployed and dilated post-deployment with the 9 mm x 80 mm BOSTON SCIENTIFIC MUSTANG® Balloon Dilatation Catheter. This stent graft overlapped the previously placed stent graft by approximately 1.5 cm.

Figure 6: A third GORE® VIABIL® Biliary Endoprosthesis (10 mm x 6 cm) was deployed (gold arrow).

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- After deployment of the third stent graft, immediate drainage of contrast into the fourth portion of the duodenum occurred. There was immediate reduction in the size of the intrahepatic biliary radicals.

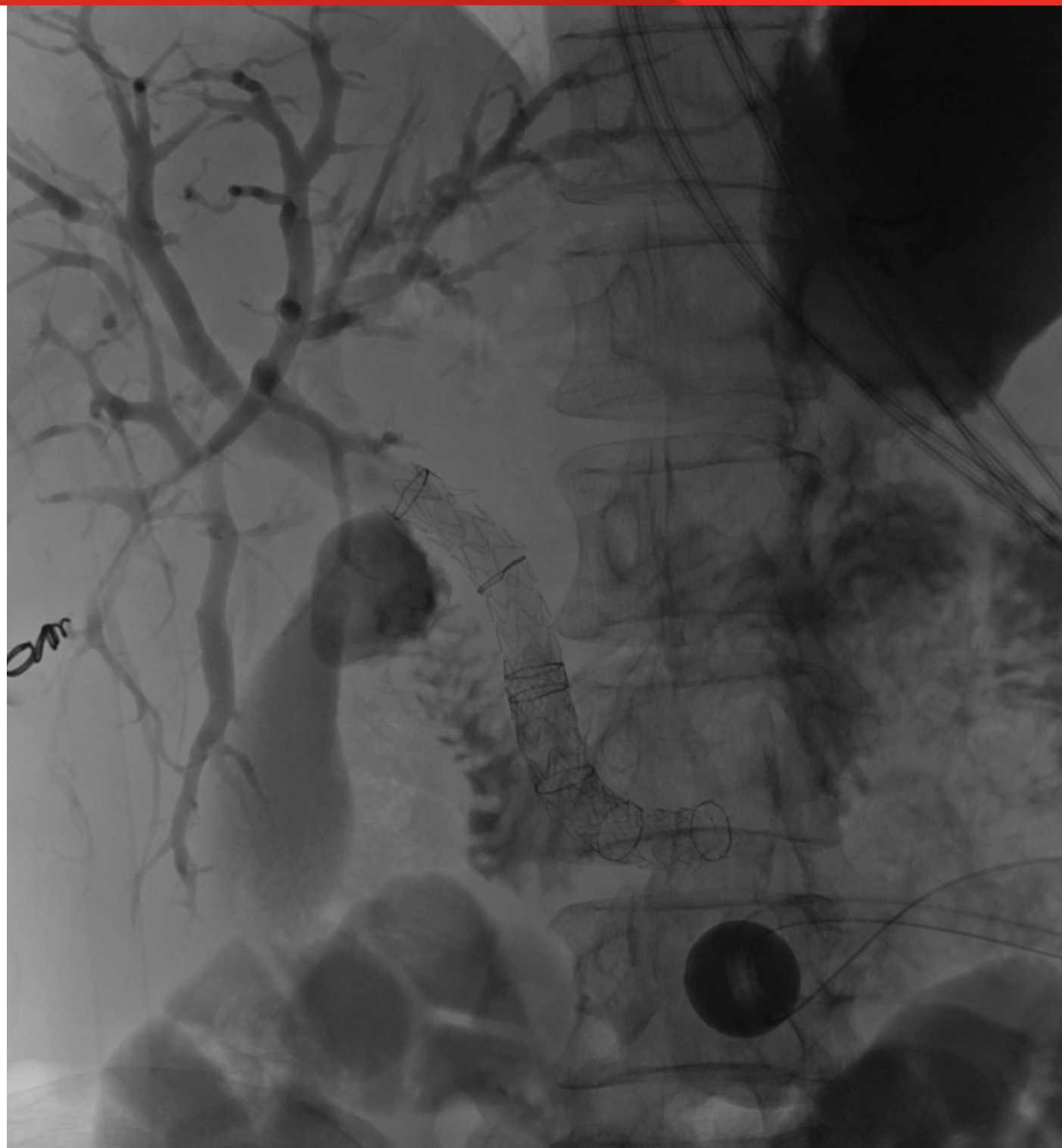

Figure 7: Following deployment of the third stent graft, drainage of contrast through the stent graft occurred into the duodenum along with reduction of biliary radical size.

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RESULTS

- The internal-external biliary drainage catheter was successfully converted into 3 overlapping internal-external stent grafts as an outpatient procedure. The patient was sent home the same evening after post-procedural monitoring for approximately 3 hours due to the amount of sedation administered.
- During clinic follow-up with the patient the next day, she was already feeling much better. By 2 days post procedure, she returned to normal activities of daily living, which she was not able to do for several months prior to this internal stenting procedure.
- At no point while using the internal-external drainage catheter was patient's serum bilirubin elevated because the external catheter had been draining externally into a bag. This procedure was done to improve that patient's quality of life.
- After conversion from the drainage catheter to the internal stent grafts, the patient's quality of life markedly improved. She had no further issues of biliary drainage after stent graft conversion and had no further hospital admissions or outpatient visits due to catheter-related complications or impaired biliary drainage.

At follow-up appointments the patient was noted to maintain a good quality of life for 7 months after stenting, until she succumbed to disease progression.

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.

References

1. Bakhru MR, Foley PL, Gatesman J, Schmitt T, Moskaluk CA, Kahaleh M. Fully covered self-expanding metal stents placed temporarily in the bile duct: Safety profile and histologic classification in a porcine model. *BMC Gastroenterology* 2011;11:76.

2. Isayama H, Mukai T, Itoi T, *et al*. Comparison of partially covered nitinol stents with partially covered stainless stents as a historical control in a multicenter study of distal malignant biliary obstruction: the WATCH study. *Gastrointestinal Endoscopy* 2012;76(1):84-92.

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