CASE

28 Malignant biliary strictures: covered or uncovered stents?

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Case history

An 87-year-old man presented with moderate melaena in the A&E department of a tertiary care centre. He was not significantly anaemic and he was transferred to a ward with a view to endoscopic examination the following day. His history included bilateral deep vein thrombosis (DVT), spinal stenosis with decompression five years previously, chronic kidney disease (CKD) stage 3 (baseline creatinine value 180μm/L) and hypertension. The endoscopic examination did not detect a bleeding source. The gastrointestinal bleeding was investigated further with a CT scan which revealed dilatation of the common bile duct (16mm) and pancreatic duct (12mm) and the presence of a 3.2cm diameter mass at the head of the pancreas (Figure 28.1).

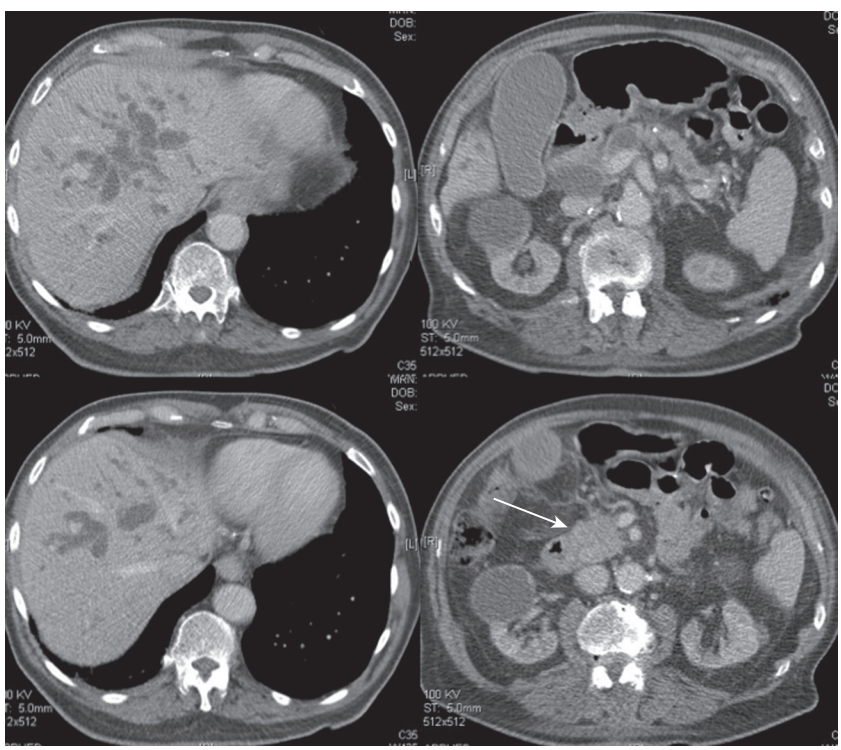

Figure 28.1 CT with IV contrast showing a mass at the head of the pancreas (arrow). There is significant dilatation of the intra- and extra-hepatic ducts and the pancreatic duct.

Learning point CT protocol and characteristics of the of pancreatic adenocarcinoma

When there is suspicion of a tumour at the head of the pancreas a contrast CT scan is required. The timing of image acquisition is critical. The first image set should be acquired during the 'pancreatic phase' (approximately 40–50 seconds) and the second image set during the portal venous phase (90 seconds) [1]. Contrast injection should be performed at a rate of 4–5ml/sec, preferably with low osmolality contrast at an iodine dose of 1.5–2.0mg/kg, and thin slices should be obtained [2].

The lesion is frequently hypodense compared with the background parenchyma on IV contrast-enhanced imaging. It is important to obtain images when the enhancement of the background gland is maximal in order to reveal the attenuation difference between tumour and gland [3]. Secondary findings may include dilatation of the pancreatic duct and the common bile duct (CBD) when the lesion is located in the head of the pancreas.

The case was discussed in the regional hepatopancreatobiliary multidisciplinary meeting and it was decided to perform endoscopic ultrasound-guided fine-needle aspiration (FNA) and endoscopic stent insertion in the distal CBD. FNA confirmed the presence of a pancreatic adenocarcinoma, but endoscopic stent insertion was not feasible and a percutaneous approach was adopted.

The patient was transferred to the interventional radiology suite and ultrasound (US) confirmed the dilatation of the biliary tree. A left-side approach was decided. US-guided puncture of a left peripheral duct with a Chiba needle (Cook Medical) was performed and a cholangiogram was obtained (Figure 28.2a). A 0.021-inch guidewire was advanced within the central ducts and the needle was exchanged for a 6Fr dilator (NEFF set; Cook Medical) (Figure 28.2b). A 0.035-inch guidewire was then advanced in the common hepatic duct and an 8.5Fr external drain (Ultrathane; Cook Medical) was inserted in order to decompress the biliary tree. The patient was transferred to the ward and IV antibiotics were administered. Two days later a cholangiogram was performed and revealed the presence of multiple filling defects in the CBD due to the presence of multiple clots (Figure 28.3a). The external drain was exchanged over a wire to a 7Fr sheath (CheckFlo; Cook Medical), and the stricture in the lower CBD was crossed using a biliary manipulation catheter (BMC; Cordis Europe) and a hydrophilic guidewire (Glidewire, Terumo Europe). Because of the presence of blood clots an 8.5Fr internal–external drainage catheter was used (Figure 28.3b) and the patient was returned to the ward.

Two days later the patient was transferred back to the interventional radiology suite. A cholangiogram confirmed the decompression of the biliary tree and absence of clots (Figure 28.3c). The external drain was exchanged to a 7Fr sheath and a measuring pigtail catheter was inserted over a wire (Figure 28.4a). Contrast injection confirmed the distance from the cystic duct to the duodenum and a 10 × 100mm partially covered self-expandable metallic stent (Nitinella; ELLA-CS, Czech Republic) was deployed in the distal CBD (Figure 28.4b). A 5Fr access catheter was left in situ and the patient was checked two days later. The control cholangiogram confirmed satisfactory expansion of the stent (Figure 28.4c).

Expert comment

The type of approach adopted for malignant biliary obstruction mainly depends on local expertise. In the majority of the tertiary care centres with experienced endoscopists and interventional radiologists the endoscopic approach should be tried first, and the percutaneous route will usually follow if the failed endoscopic attempt fails. The percutaneous approach is the first approach for patients with a Roux-en-Y loop or when severe oesophageal stenosis is present.

Expert comment

A staged approach with a couple of days interval between each stage may be necessary in some cases, particularly when sepsis or bleeding occurs. If a stent is inserted when blood clots are present it may become occluded; therefore clots should be removed from the bile tree before stent deployment.

Evidence base Plastic and metallic stents

A recently published meta-analysis included ten randomized trials and 785 patients, of whom 392 received a metal stent and 393 a plastic stent [4]. The results showed that metal stents were associated with significantly longer stent patency, fewer re-interventions, and longer patient survival times.

Learning point Biliary stents in malignant biliary strictures

Biliary stents are used in malignant disease for the palliative treatment of malignant jaundice. Plastic stents were initially used, but were rapidly replaced by self-expandable metallic stents. However, bare metallic stents tend to become occluded as a result of tumour in-growth, and therefore covered metallic stents have been developed and integrated into clinical practice.

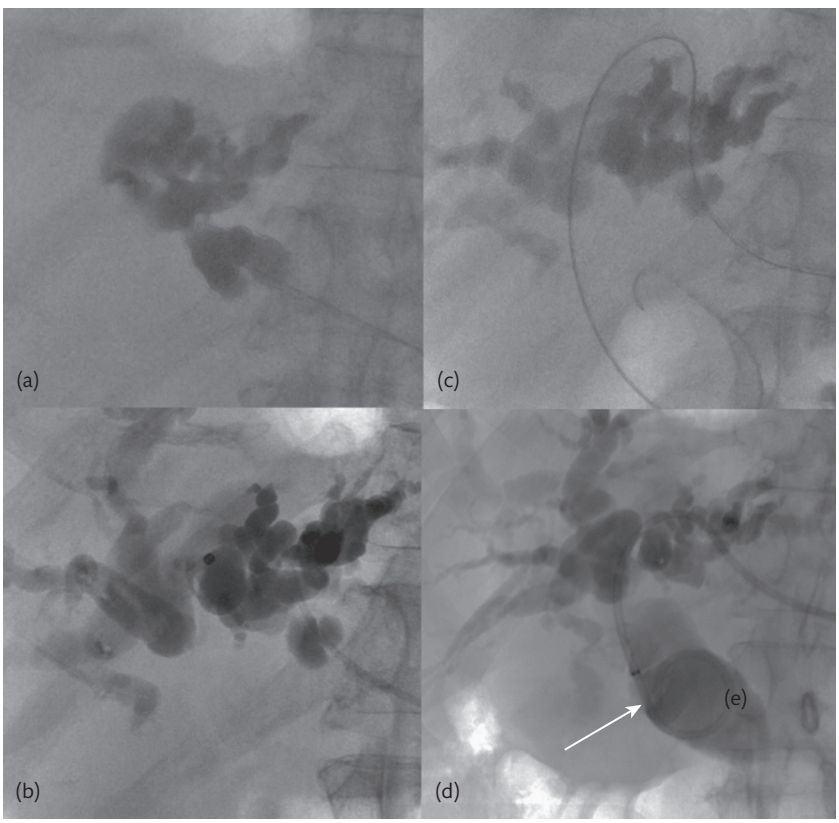

Figure 28.2 (a) Cholangiogram performed from a left-side puncture confirms biliary duct dilatation. (b) This is followed by opacification of the rest of the biliary tree, and (c) a guidewire is advanced in the CBD. (d) An external drain (arrow) is advanced over the wire in the CBD.

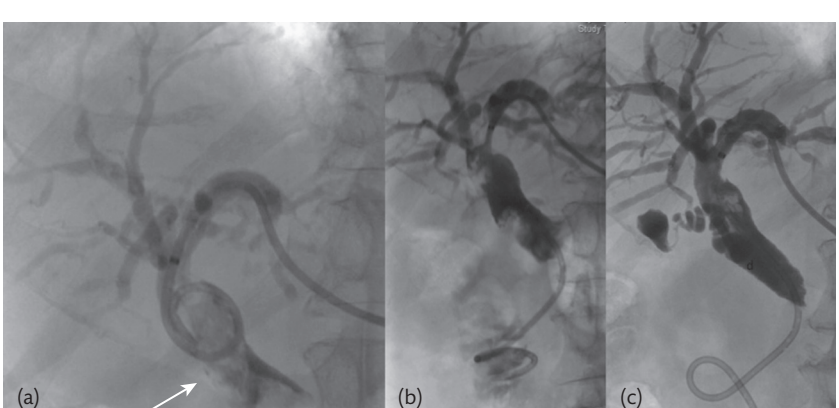

Figure 28.3 (a) Cholangiogram through the external drain reveals the presence of filling defects due to clotted blood (arrow). (b) The external drain was internalized. (c) Two days later filling defects were significantly reduced.

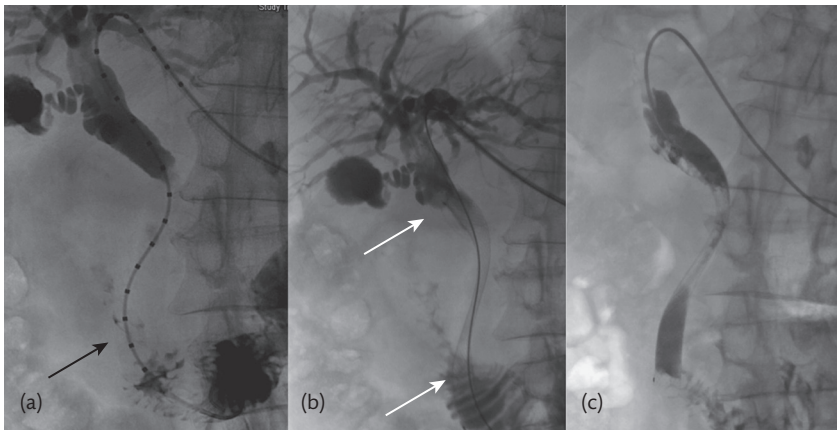

Figure 28.4 (a) The drain was exchanged for a metric pigtail catheter (black arrow) in order to measure the distance from the cystic duct to the duodenum. (b) A covered stent was deployed in the stenotic area. (c) Cholangiogram obtained two days later confirming satisfactory stent expansion and contrast run-off towards the duodenum.

Evidence base Covering material for biliary stents

In attempts to reduce tumour in-growth several covering materials have been tested with various stents:

- Gore-Tex with biliary Gianturco–Rösch Z-stents [5]
- 0.015mm thick polyurethane with Wallstents [6–8]
- 0.015mm thick polyurethane with Strecker stents [9]
- 0.035mm thick polyurethane membrane with Gianturco–Rösch Z-stents and spiral Z-stents [10]
- 0.030mm thick polyurethane membrane with Niti-S stents [11]
- 0.040–0.050mm thick polyurethane with Wallstents [12]
- 0.050–0.060mm polyurethane membrane with diamond stents [13]
- 0.010mm expanded PTFE/FEP with nitinol stents [14–17]

Discussion

In order to reduce tumour in-growth and re-intervention rate, with the aim of increasing the quality of life of oncological patients, covered stents with a large variety of designs and covering materials have been developed in the last two decades.

In the case described here a stent partially covered with silicone was used as a palliative measure for a patient with pancreatic cancer. The rationale of this approach is to obtain the longest possible patency period and avoid another episode of jaundice during the course of the patient's life that would interrupt chemotherapy and require a new procedure and potentially another stent. This is supported by two prospective randomized comparisons of covered and uncovered biliary stents in patients with pancreatic cancer and cholangiocarcinoma [18,19].

Evidence base Prospective multicentre clinical comparison of bare versus covered stents for patients with pancreatic adenocarcinoma and cholangiocarcinoma [18,19]

- Prospective single-arm two-centre studies.
- In the first study [18], 60 patients with Bismuth type I cholangiocarcinoma (36 men and 24 women, age range 46–78 years) were randomized.
- Technical success was 100% for both groups.
- Minor early complications were noticed in 13.3% of the bare-stent group and 10% of the patients of the covered-stent group.
- The mean follow-up period was 212 days (45–675 days). The 30-day mortality was zero for both groups. The median survival time was 180.5 days for the bare-stent group and 243.5 days for the covered-stent group. The mean patency rates were 166 days for the mesh stent and 227.3 days for the covered stent. Stent dysfunction occurred in nine patients in the bare-stent group after a mean period of 133.1 days, and forceps biopsy revealed tumour in-growth in 88.8% of these. Dysfunction also occurred in four patients in the covered-stent group after a mean period of 179.5 days due to tumour overgrowth in two patients and sludge in the other two. Tumour in-growth occurred exclusively in the mesh stent group. A cost analysis showed no difference in the overall costs for the two groups.
- In the second study [19], 80 patients with pancreatic adenocarcinoma (53 men and 27 women with an age range of 41–79 years, mean 62.7 years) were randomized into a bare-stent group and a covered-stent group.
- Technical success was 100% in both groups.
- Early complications were observed in 10% of the bare-stent group and 12.5% of the covered-stent group. Median follow-up time was 192 days (range 104–603 days). The 30-day mortality was zero for both groups. The median survival time was 203.2 days for the bare-stent group and 247 days for the covered-stent group which was not statistically significant. The mean primary patency was 166 days for the uncovered stents and 234 days for the covered stents (p <0 .05). Dysfunction, which was due to tumour in-growth in 91.6% of cases, occurred in 12 patients in the bare-stent group after a mean period of 82.9 days. Dysfunction, occurred in four patients in the covered-stent group after a mean period of 126.5 days and was due to tumour overgrowth in two patients and sludge in the other two. A cost analysis showed no difference in the overall costs for the two groups.

As reported in previous studies [5,6], migration has always been a problem with covered stents. The use of anchoring fins in a partially covered stent with an uncovered portion decreases the rate of distal migration and therefore of dysfunction of the endoprosthesis.

Complications may occur when covered stents are used, particularly when the cystic duct is covered. In the case described here a measuring pigtail catheter was used to measure the exact distance from the cystic duct drainage point to the duodenum in order to avoid coverage of the cystic duct, which may lead to cholecystitis.

Covered stents may be able to prevent ingrowth, but they are unable to prevent overgrowth, i.e. growth of tumour at the proximal end of the stent. In order to prevent overgrowth an uncovered proximal extension can be integrated with the covered stent.

Expert comment

In cases of cholangiocarcinoma the cystic duct is probably infiltrated by tumour, and may be covered without problems. Similarly, in cases of pancreatic carcinoma the pancreatic duct can be covered without risk of pancreatitis.

Final word from the expert

Covered stents are part of the management of patients with malignant biliary disease. However, their use should be restricted to patients where survival will be long enough to obtain a benefit, i.e. more than three months. Anatomical considerations are required in order to avoid obstructing the cystic or intrahepatic ducts, and an uncovered extension should be integrated in the design of future covered stents in order to reduce the rate of overgrowth.

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