Preoperative biliary drainage – better stents in specialised centres are needed

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A recent trial concluded that preoperative biliary drainage (PBD) in patients with pancreatic head cancer increases complications but is unlikely to change clinical practice. The difference in the outcomes reported was because of excessive complications in the PBD group using plastic stents. We argue that these patients need treatment in regional pancreatic cancer centres using low-occlusion metal stents.

It is common practice that patients with obstructive jaundice caused by a tumour in the head of the pancreas undergo preoperative drainage of the biliary tree. This enables partial resolution of the physiological impairment of the liver parenchyma secondary to biliary obstruction, and allows easier logistical planning for both preoperative staging and surgery. Until now, the collective evidence could neither support nor refute preoperative biliary drainage (PBD) for patients with obstructive jaundice needing surgery.[1]

The recent Dutch multicentre trial reported by van der Gaag et al.[2] concluded that routine PBD in patients undergoing surgery "for cancer of the pancreatic head" increases the rate of complications. Patients with serum bilirubin >250 μmol/l were excluded as presumably all of these individuals had preoperative endoscopic stenting. The study was not blinded; 202 patients deemed to be resectable by preoperative staging using CT were randomised to surgery within one week of diagnosis (n=94) or PBD for up to six weeks before surgery (n=102). The trial opened in November 2003 and closed in June 2008. The primary endpoint was the rate of serious complications within 120 days of randomisation. In the final analysis, the mean time to surgery was 1.2 weeks for the early surgery group and 5.2 weeks for the PBD group. 74% of patients in the PBD group had serious complications versus 39% of patients in the early surgery group. However, the outcomes following surgery in both groups including major complications, hospital stay, readmission rates and mortality were similar. Thus the difference lay in the complication rates associated with the biliary stenting.

While the quality of the trial itself was satisfactory, we contend that the setting almost certainly predicted the outcome. The stenting was probably performed mostly in district general hospitals, although this is not specifically reported by the authors. Remarkably, antibiotic prophylaxis was left to local policy, while all patients undergoing laparotomy received perioperative antibiotics. Moreover, the use of plastic stents undoubtedly contributed

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to the outcome. The 46% complication rate following biliary stenting (perforation, bleeding and cholangitis) was far in excess of that which could be reasonably expected. The initial procedural failure rate was 25%, and in these cases percutaneous transhepatic stenting was employed, which is known to have a high complication rate (the number of percutaneous stents actually used was not reported). Most studies report an initial stent failure rate of around 5%–10% and a similar range for serious complications.[3,4]

Overall, stent occlusion accounted for more than half of the episodes of cholangitis, which occurred in 26% of patients who underwent endoscopic stenting, and necessitated a second endoscopic procedure in one third of these patients. This is almost certainly related, in part, to the routine use of plastic stents rather than short, non-foreshortening, self-expanding metal stents that are associated with a very low rate of occlusion and hence a minimal rate of acute cholangitis.[5] Indeed, the authors of the Dutch study themselves recognise this point, although only within the context of neoadjuvant treatment.

The authors also decided to include eight regional hospitals in addition to the five academic centres in order "to provide operating-room capacity to ensure that early surgery could be performed as required by the protocol".[2] Although each of the participating hospitals performed at least 10 resections of cancer of the pancreatic head per year, these would still be regarded as relatively low-volume hospitals and may account for the rather poor surgical results.

Resection was performed in only 67% of patients in the early surgery group and 56% in the PBD group, although it is noted that the authors relied entirely on CT for staging and apparently did not use laparoscopy or serum CA 19–9 levels.[6]

Surgery-related complications occurred in 37% of patients in the early surgery group and in 47% of patients in the PBD group. Furthermore, repeat laparotomy was required in 14% and 12% of patients in the early surgery group and PBD group, respectively. Death from any cause occurred in 13% of patients in the early surgery group and in 15% of patients in the PBD group. These mortality figures are excessive by any consideration and again emphasise the need to focus pancreatic cancer oncological management including surgery in regional high-volume cancer centres.[7-10] In addition, there is recent evidence that dramatically reducing the level of bilirubin preoperatively may actually improve survival in the medium-term follow up period.[10]

There are further criticisms of this study. The body-mass index, which is an adverse risk factor, was significantly higher in the PBD group compared with the early surgery group (25.2±3.9 vs 24.0±3.1, P=0.03); however, this imbalance might be due to the relatively small patient numbers in the trial.

The title of the article, "Preoperative biliary drainage for cancer of the head of the pancreas",[2] is itself probably a misnomer. It is not at all clear from the text whether the 95% of patients in the early surgery group and the 90% of patients in the PBD group who had "adenocarcinoma" actually all had pancreatic ductal adenocarcinoma. In fact, it seems that the study population probably comprised patients with periampullary cancer, and therefore also included patients with ampullary and bile duct cancers (both of these groups normally have significantly better interventional outcomes than individuals with pancreatic ductal adenocarcinoma). If this were so, the results are even harder to interpret.

We conclude that this study is unlikely to change the routine use of PBD as there might be specific needs for preoperative staging beyond CT[6] as well as neoadjuvant therapy. The focus needs to turn to patients undergoing endoscopic stent insertion in regional pancreatic cancer centres, and the need to use more modern, short, non-foreshortening, self-expanding metal stents with a low occlusion rate.[3–5]

Details of the references cited in this article can be accessed at www.cancerworld.org

Practice point

Preoperative biliary drainage before surgery in patients with tumours in the head of the pancreas using plastic stents is associated with a high incidence of complications due to stent occlusion.

Surgical outcome was unaffected by preoperative relief of jaundice in the context of unselected centres with a high postoperative morbidity and mortality.

Consideration should now be given to using low-occlusion, modern, short, non-foreshortening, self-expanding metal stents with a low complication rate.

This will provide a logistical advantage enabling more considered preoperative staging, the potential to use neoadjuvant therapy, and planning of surgery.

The study indicated rather poor results from both stenting and surgery, reinforcing the benefit of undertaking these procedures in high-volume regional pancreatic cancer centres.

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