

Current status of preoperative drainage for distal biliary obstruction

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Abstract

Preoperative biliary drainage (PBD) was developed to improve obstructive jaundice, which affects a number of organs and physiological mechanisms in patients waiting for surgery. However, its role in patients who will undergo pancreaticoduodenectomy for biliary obstruction remains controversial. This article aims to review the current status of the use of preoperative drainage for distal biliary obstruction. Relevant articles published from 1980 to 2015 were identified by searching MEDLINE and PubMed using the keywords "PBD", "pancreaticoduodenectomy", and "obstructive jaundice". Additional papers were identified by a manual search of the references from key articles. Current studies have demonstrated that PBD should not be routinely performed because of the postoperative complications. PBD should only be considered in carefully selected patients, particularly in cases where surgery had to be delayed. PBD may be needed in patients with severe jaundice, concomitant cholangitis, or severe malnutrition. The optimal method of biliary drainage has yet to be confirmed. PBD should be performed by endoscopic routes rather than by percutaneous routes to avoid metastatic tumor seeding. Endoscopic stenting or nasobiliary drainage can be selected. Although more expensive, the use of metallic stents remains a viable option to achieve effective drainage without cholangitis and reintervention.

Key words: Preoperative drainage; Biliary drainage; Distal biliary obstruction; Pancreaticoduodenectomy; Obstructive jaundice

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Core tip: Because of the postoperative complications, studies have demonstrated that preoperative biliary drainage (PBD) should not be routinely performed in patients who will undergo pancreaticoduodenectomy. PBD may be selectively applied in patients with severe jaundice, cholangitis, or severe malnutrition and in those patients with a relatively long wait before surgery. PBD should be performed through endoscopic routes rather than percutaneous routes to avoid metastatic tumor seeding. Endoscopic stenting or nasobiliary drainage can be selected. Although more expensive, the use of metallic stents remains a viable option to avoid reinterventions.

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INTRODUCTION

Surgical resection is generally considered to be the only curative treatment for patients with periampullary cancer or cancer of the pancreatic head. Obstructive jaundice due to distal biliary obstruction is the most common symptom in such patients. Preoperative biliary drainage (PBD) was introduced in the 1970s to relieve the obstruction and to reverse physiological dysfunction resulting from obstructive jaundice. PBD was previously considered to improve surgical outcomes in patients with malignant distal biliary obstruction who were undergoing curative resection, with many physicians electing to perform PBD in patients who were waiting for surgery^[1]. A number of PBD methods exist, including endoscopic plastic stenting, nasobiliary drainage, metallic stenting, and percutaneous drainage. However, the overall benefit of PBD is currently controversial.

OVERVIEW

In 2002, a systematic review summarized all prospective and retrospective studies published between 1966 and 2001 to evaluate the efficacy of drainage compared with that of direct surgery in patients with malignant obstructive jaundice^[2]. Five randomized controlled studies and 18 cohort studies were analyzed. A meta-analysis of both level I and level II studies found no difference in mortality between patients who underwent PBD and those who underwent surgery without PBD. However, the overall complication rates were significantly and adversely affected by PBD compared with surgery

without PBD; for level I studies, the complication rates of the two approaches were 57% and 42%, respectively, indicating a relative reduction of 15% and an absolute risk reduction of 27% in cases where surgery was performed without PBD. Moreover, the overall hospital stay was prolonged following PBD. That meta-analysis concluded that the benefit of PBD did not outweigh the disadvantages of the drainage procedure and complication rates and that PBD should therefore not be routinely performed. Particularly following the publication of this meta-analysis, the routine performance of PBD was apparently no longer recommended. A multicenter, randomized trial was reported in 2010. van der Gaag *et al*^[3] compared PBD prior to surgery with surgery alone for patients with cancer of the pancreatic head. They concluded that routine PBD in patients undergoing surgery for cancer of the pancreatic head increased the rate of complications. This report corroborated the results of the previous meta-analysis.

However, the above-mentioned studies have some limitations. The meta-analysis published in 2002 is limited by the fact that not all randomized trials are equal in terms of size or quality. The five randomized trials reviewed were relatively poorly designed, with broad eligibility criteria including both distal and proximal cancers, small sample sizes, different interventions (internal and external drainage) and a number of differing surgical resection procedures. These trials reflect the 1970s approach to obstructive jaundice and surgery, as demonstrated by the higher rates of the use of external percutaneous approaches (59%), lower resection rates (16%), and significantly higher rates of perioperative death (12%).

There are also apparent limitations to the report by van der Gaag *et al*^[3]. In that study, the initial rates of endoscopic retrograde cholangiopancreatography (ERCP) failure were 25%, and there were also ERCP-related complications, including pancreatitis, perforation, cholangitis, and bleeding, in 46% of the patients included in the study. Both results appear excessive to us because the majority of studies report rates of approximately 5%-10%^[4,5]. Moreover, these authors only used plastic stents, which have been associated with early stent occlusion following cholangitis in up to 26% of patients.

Three other meta-analyses have concluded that PBD does not reduce post-operative mortality and complications in cases of malignant obstructive jaundice and that PBD in patients undergoing surgery for obstructive jaundice is associated with increased serious morbidity; however, these studies included proximal obstruction in addition to distal obstruction^[6-8]. Based on another meta-analysis of studies that evaluated the use of PBD in patients who were waiting for pancreaticoduodenectomy, the use of PBD increased postoperative wound infection rates, with no overwhelming evidence that PBD either promoted or protected against other complications. However, a limitation of this report was the lack of comparison between percutaneous transhepatic biliary

drainage (PTBD) and endoscopic drainage^[9]. Although no study has yet equally randomized comparable patients according to the level of obstruction and PBD method used, and the results of the previous studies remain controversial, all reported meta-analyses have concluded that PBD should not be performed routinely where possible.

PATIENTS FREQUENTLY UNDERGO PBD BEFORE SURGICAL CONSULTATION

A significant issue with PBD has been the use of the technique before surgical referral or consultation. The first and largest population-based study of patients with pancreatic cancer undergoing pancreaticoduodenectomy at a single institution found that 77% of 2573 patients who were referred to a surgeon already had a stent in place^[10]. This result was consistent with previous studies reporting prior stent placement rates of 42%-79%^[11-14].

The report concluded that the use of preoperative biliary stenting doubled between 1992 and 2007 despite evidence suggesting that stenting was associated with increased perioperative infectious complications. The performance of PBD prior to surgical consultation can be associated with significant delays in the time to operate in many cases. Therefore, patients waiting for pancreaticoduodenectomy should ideally be carefully treated following discussion between surgeons and endoscopists regarding the necessity of PBD^[10].

There are three remaining questions: (1) How do we select patients who are suitable for PBD? (2) What is the appropriate PBD method with minimum complications? and (3) How do we reduce the complications associated with PBD?

HOW DO WE SELECT PATIENTS WITH DISTAL BILIARY OBSTRUCTION WHOSE HEALTH ORGANIZATION ARE SUITABLE FOR PBD?

Preoperative drainage should be performed after consideration of the following factors^[15,16]: (1) The period of time from diagnosis to anticipated surgery; (2) The presence of an urgent indication for biliary drainage; that is, acute cholangitis, severe pruritus, or severe obstruction with very high bilirubin levels; (3) The functional status of the patient. Many patients are in poor status in terms of nutrition due to obstructive jaundice, which is expected to improve with PBD; and (4) The plan for neoadjuvant chemotherapy or chemoradiation for locally advanced or borderline resectable cancer, where PBD may prevent hepatotoxicity from chemotherapeutic agent.

In 1999, Povoski *et al.*^[17] reported that PBD was the only factor associated with postoperative infection and postoperative death. Bacterobilia was thought to develop in some patients with biliary stents due

to postoperative ascending colonization^[18]. Although some reports discourage the use of PBD in cases of distal biliary obstruction^[19-24], a recent Cochrane Review found that PBD in patients with resectable pancreatic cancer and periampullary cancer undergoing surgery was associated with a similar mortality rate, but an increased incidence of serious morbidity, compared with patients who did not undergo PBD^[25]. Recent studies have reported the effect of selective biliary drainage on perioperative morbidity and mortality in patients undergoing pancreaticoduodenectomy^[26,27]. Jagannath *et al.*^[26] reported that a positive bile culture in patients with drainage was associated with stent complications and duration of stenting and that uncomplicated stenting was not associated with increased rates of serious morbidity or mortality. Coates *et al.*^[27] also concluded that the morbidity and mortality associated with PBD may not be as significant as previously reported due to recent refinements in endoscopic techniques and improvements in perioperative management.

WHAT IS THE OPTIMAL PBD METHOD WITH MINIMAL COMPLICATIONS?

One of the largest prospective randomized trials, performed in the United States by Pitt *et al.*^[28], concluded that PTBD does not reduce operative risk, increases hospital cost and is therefore not recommended. In contrast, a recent study reported that PTBD was superior to endoscopic drainage from the perspective of cost-effectiveness; however, the lower cost was related to those patients who were initially subjected to endoscopic drainage and later changed to PTBD^[29]. It is also important to determine which method is safer in terms of the long-term survival of patients with resectable distal cancer. Two recent retrospective studies revealed that patients with resectable pancreatic cancer who underwent PTBD had significantly worse survival than patients who underwent endoscopic biliary drainage (EBD)^[30,31]. Strom *et al.*^[30] reported that patients with PTBD had an even worse 5-year survival of just 3%, whereas patients who underwent EBD and patients without PBD had 5-year survival rates of 24% and 32%, respectively. The result was almost identical to the results reported by Murakami *et al.*^[31]. The major underlying cause of this finding is thought to be metastatic tumor seeding along the PTBD sinus tract.

The main advantage of endoscopic drainage over percutaneous intervention is the avoidance of skin and liver puncture in patients with underlying coagulopathy and the avoidance of tumor seeding along the catheter track. ERCP with biliary drainage has become the first line technique for the treatment of distal biliary obstruction. In addition, ERCP is considered a diagnostic tool in many countries due to the clinical importance of biopsy material or cytology. However, only a few studies have evaluated the safety and efficacy of each method of endoscopic drainage for malignant distal

biliary obstruction. To the best of our knowledge, our study was the first to compare endoscopic biliary stenting (EBS) with endoscopic nasobiliary drainage (ENBD) for PBD in patients with malignant distal biliary obstruction^[32]. No significant differences in the overall rate of catheter-related complications, the rate of tube dysfunction, or the median interval from PBD to the time of tube dysfunction were observed between the two groups. Adequate endoscopic PBD was achieved in all patients on the first attempt, and all patients underwent surgery following a successful PBD. Symptoms such as cholangitis and obstructive jaundice resolved within 7 d after the drainage was placed in all patients. Two major complications occurred: one case of cholangitis and another of perforation due to endoscopic sphincterotomy were observed in patients in the EBS group, both of whom recovered following conservative treatment. Another retrospective study demonstrated that EBS increased the rates of wound infection because of a high incidence of cholangitis prior to operative intervention and should, therefore, be avoided^[33]. In that study, ENBD had no effect on complication rates. However, this finding required further analysis due to the small number of patients included in this study.

Several studies have reported the utility of self-expanding metallic stents (SEMSs)^[15,34,35]. Singal *et al.*^[34] demonstrated that SEMSs provide excellent patency, with cholangitis occurring in < 5% cases after 4 wk; does not affect surgical technique; and results in minimal postoperative complications in patients waiting to undergo pancreaticoduodenectomy. In a study of 29 patients with pancreatic cancer, Decker *et al.*^[35] reported no preoperative intervention in the group that received SEMS placement, and up to 40% of the group that underwent plastic stenting required reintervention. The other two studies comparing plastic and metallic stents for internal drainage found no significant difference in either the overall or serious complication rates between SEMSs and plastic stents^[36,37]; however, Haapamäki *et al.*^[37] concluded that the significantly higher price of SEMSs restricts their use to selected cases. A number of recent studies have recommended the use of SEMSs in patients who are candidates for neoadjuvant chemotherapy or chemoradiation with obstructive jaundice and resectable or borderline resectable pancreatic cancer^[15,38,39]; however, the small number of prospective studies available means this conclusion remains unreliable.

Another type of stent is completely contained within the bile duct without one end extending to the duodenum. This stent is called an inside stent and is expected to prevent the reflux of intestinal contents into the bile tree. Inside stents have been mainly used for proximal bile duct strictures. Fewer early complications, such as ascending cholangitis, and ease of performing reinterventions were reported^[40,41]. Although few reports have evaluated using inside stents for distal biliary obstruction, the latest report demonstrated their efficacy for PBD in biliary tract cancer^[42]. Kobayashi *et al.*^[42]

retrospectively compared the postoperative complications in two groups and reported that morbidity rates were 34.3% (11/32) in the conventional stent group and 24.0% (6/25) in the inside stent group. The limitation of the report was that they included not only patients with distal obstruction but also those with proximal obstruction; additionally, they did not include patients with pancreatic cancer^[42].

Rerknimitr *et al.*^[43] observed that the different types of drainage were used in previous analyses; therefore, the patient groups who underwent internal or external drainages were not homogeneous.

Further randomized studies are needed to determine the optimal method of PBD for distal biliary obstruction.

HOW TO REDUCE POSTOPERATIVE INFECTION?

Despite many recent studies that have concluded that PBD is not associated with increased postoperative infection^[44-48], the possibility of preoperative cholangitis caused by tube dysfunction after preoperative drainage remains. Sudo *et al.*^[49] revealed that the susceptibility of biliary microorganisms to antibiotics was the only independent risk factor for postoperative infections in the largest detailed bacteriologic analysis of intraoperative bile cultures corresponding to PBD procedures using data collected from 254 patients who were undergoing pancreaticoduodenectomy. That study found that perioperative antibiotics covering bile contamination may prevent infectious complications following pancreaticoduodenectomy in patients with and without PBD.

In addition to preoperative cholangitis, drainage duration may also impact patient outcomes through the development of preoperative complications. In general, a minimum of 4-6 wk of PBD is advised. An overly long drainage duration may increase infectious morbidity. Son *et al.*^[50] reported that a PBD duration of < 2 wk, which was associated with lower rates of preoperative drainage-related complications, was more appropriate in severely jaundiced patients with periampullary cancer. However, the optimal duration in that study may not be appropriate because the study did not strictly distinguish between the different PBD methods. The optimal drainage time will continue to be a controversial issue because neoadjuvant chemotherapy and chemoradiation are currently considered for locally advanced or borderline resectable cancer.

CONCLUSION

The majority of authors believe that PBD should not be routinely performed in patients with malignant distal obstruction due to a possible effect on preoperative complication rates. However, preoperative drainage may be selectively applied in patients with severe jaundice, concomitant cholangitis, or severe malnutrition and in patients who must wait for a relatively long time

before surgery. To avoid complications, PBD should be completed with endoscopic stenting or nasobiliary drainage. Although the cost is significantly higher, metallic stenting can be utilized in patients waiting for surgery for more than 4 wk. Further randomized studies are required to determine the optimal PBD method for distal biliary obstruction.

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