

**Endoscopic versus percutaneous biliary drainage for resectable
pancreatic head cancer with hyperbilirubinemia and
impact on pancreaticoduodenectomy: A prospective cohort study**

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Protocol

Introduction

Currently, pancreatoduodenectomy is the only curative treatment for patients with periampullary malignant tumors, such as pancreatic adenocarcinoma, distal cholangiocarcinoma, and duodenal neoplasms. The use of preoperative biliary drain (BD) for all jaundiced patients eligible for pancreatoduodenectomy has been called into question by the results of several studies, including 1 multicenter randomized clinical trial (RCT) (1) as well as several retrospective studies (2–4) and meta-analyses (5,6), in which preoperative BD failed to demonstrate any reduction in postoperative complication rates. However, most authors agree that preoperative BD should be performed on patients presenting with cholangitis; on patients who have very high levels of bilirubin (some authors suggest above 15–17 ml/dl); on patients who have borderline resectable neoplasms requiring neoadjuvant therapy; or in centers where the waiting list for the surgical procedure is long (7,8). Effective, albeit temporary, resolution of malignant biliary obstruction can be achieved by either percutaneous BD or endoscopic drain, which in turn may be either endoscopic retrograde cholangiopancreatography (ERCP) or nasobiliary drain (9). The merits of selecting one method over the other for patients awaiting pancreatoduodenectomy remain controversial due to potential procedure-related or postoperative complications. Despite being the first preoperative BD method employed to treat preoperative jaundice, percutaneous BD has been overmatched by endoscopic drain. However, in the current literature, it is difficult to find reasons that justify this preference.

Aim of the work

The aim of this prospective study is to compare postoperative complications in patients who will undergo pancreatoduodenectomy after either percutaneous or endoscopic preoperative BD, to determine which method is preferable in the preoperative management of such patients.

Patients

Sixty patients with resectable pancreatic cancer with high total bilirubin level more than 10 mg/dl and symptomatic jaundice, as cholangitis, intense pruritis, coagulopathy, severe nausea or anorexia, admitted to Gastro-intestinal Surgery Unit, Faculty of Medicine, Alexandria University, Egypt. Those with metastatic or locally advanced disease and those unfit for major surgery and anesthesia will be excluded.

Methods

All patients will be subjected to the following:

- Thorough history taking as regards symptoms of obstructive jaundice: pain, pruritis, coagulopathy and nausea.
- Complete physical examination:
 - General examination for fitness of surgery i.e. vital signs, severity of jaundice, anemia, malnutrition and dehydration.
 - Local abdominal examination: abdominal distension,
- Investigations:
 - Laboratory:
 - Routine: complete blood picture, fasting blood sugar, urea and creatinine.
 - Liver functions: prothrombin time, albumin, bilirubin (total and direct)
 - Liver cell integrity: AST, ALT, alkaline phosphatase.
 - Tumor marker: CA 19.9
 - Viral hepatitis markers
 - Imaging:
 - Ultrasound abdomen: diameter of CBD, intrahepatic biliray dilatation, condition of the liver, liver metastasis, ascites.

- Computed tomography of the abdomen/pelvis with oral and intravenous contrast: site, length, number, enhancement pattern of the tumor, relation to superior mesenteric vessels.

Patients will be randomly subdivided into two equal groups:

- The first group (group A) will be managed by endoscopic retrograde cholangiopancreatography (ERCP), endoscopic sphincterotomy with insertion of plastic stent 10 Fr under general anesthesia.
- The second group (group B) will be managed by Percutaneous Trans-hepatic Drainage (PTD) by interventional radiologist under local anesthesia. Either external or internal-external drainage technique will be performed according to the preference of the interventional radiologist,

For each method, the technical and clinical success rates will be observed by the improvement of liver functions and decrease in bilirubin after drainage.

Within 2 weeks, each patient in each group will undergo Pancreaticoduodenectomy (whipple operation) with triple anastomosis. Intra-operatively, technical difficulties as well as culture sensitivity from the catheter or stent will be recorded.

Patients will be closely observed in the immediate and early post-operative period for the occurrence of potential complications and mortality:

Complication of the operation:

- General: deep venous thrombosis, chest infection
- Specific: bleeding, leak, intra-abdominal collection

Complications of endoscopic drainage:

- Pancreatitis, cholangitis
- Wound infection
- Chest infection
- Intra-abdominal collection and abscess
- Renal insufficiency

Complications of percutaneous trans-hepatic drainage:

- Bleeding
- Biliary leak/fistula
- Pseudoaneurysm
- Cholangitis, sepsis
- Liver abscess
- Catheter occlusion and Misplacement

Follow up for quality of life issues, catheter-site tumor recurrence.

Results

The results obtained will be recorded, tabulated and statistically analyzed in the view of the aim

Discussion

The results of the work will be analyzed in view of achievement of the aim, their significance and comparison with other available studies will be discussed.

References

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