

## Preoperative biliary drainage in patients performing pancreaticoduodenectomy : guidelines and real-life practice

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### Abstract

**Background and aim :** Preoperative biliary drainage (PBD) in patients with pancreatic cancer remains debatable. The aim of this study was to analyse the indications for PBD in patients performing pancreaticoduodenectomy (PD) and to evaluate the impact of this procedure on postoperative outcome.

**Methods :** Observational retrospective cohort study of patients undergoing PD for pancreatic cancer. Clinical data and postoperative outcome, namely complications and 90-day mortality, were prospectively collected and compared between patients performing PBD or direct surgery (DS).

**Results :** Eighty-two patients were included: 40 underwent PBD and 42 performed DS. Major complications (27.5% vs 33.3%,  $P=0.156$ ) and 90-day mortality (10% vs 16.7%,  $P=0.376$ ) were similar between the two groups. There was a trend for higher mean total bilirubin in patients with PBD ( $P=0.073$ ). The indication for PBD was suspicion of cholangitis/choledocholithiasis or need to perform neoadjuvant chemotherapy in 24 (60%) patients. In the remaining, elevated bilirubin was probably the only reason to perform PBD. Length of hospital stay was longer in PBD group ( $P=0.003$ ). On multiple logistic regression, 90-day mortality was not related with preoperative bilirubin levels, biliary drainage or its indication, but solely with age (OR 1.15, 95%CI 1.05-1.31,  $P=0.008$ ).

**Conclusions :** PBD is often performed in patients undergoing PD without a formal indication, mainly due to high bilirubin levels. No increased morbidity/mortality was observed but length of hospital stay was prolonged in patients performing PBD. (*Acta gastroenterol. belg.*, 2019, 82, 389-395).

**Key words :** Pancreaticoduodenectomy, Preoperative biliary drainage, ERCP, Guidelines, Real-life practice.

### Introduction

Pancreaticoduodenectomy (PD) remains the only option for cure in non-metastatic patients with malignant periampullary tumours (1). Although the outcome after pancreatic surgery has improved tremendously in the past decades, we can still expect a mortality rate around 5% and a morbidity rate of up to 50%, even in high-volume centres (2). For this reason, optimizing perioperative care in these patients is paramount. Because marked obstructive jaundice has long been considered to increase the risk of developing postoperative complications (3-5), preoperative biliary drainage (PBD), has been incorporated into the standard surgical treatment algorithm of periampullary cancer in many hospitals.

In experimental models, PBD was almost exclusively associated with beneficial results: improved liver function and nutritional status, reduction of decreased systemic endotoxemia, and mortality was significantly reduced in these animal models (6-9). Nonetheless, human studies showed conflicting results. In a prospective randomized controlled trial by van der Gaag *et al.* including 202 patients with total bilirubin lower than 14.6 mg/dL, the authors showed that PBD significantly increased the rate of serious postoperative complications as compared to patients who went for direct surgery (DS) (74% vs 39%; relative risk [RR] 0.54, 95% confidence interval [CI] 0.41-0.71,  $P<0.001$ ) (10). Later, a Cochrane review of six randomized clinical trials evaluating the safety and effectiveness of PBD *versus* DS, found that PBD in patients undergoing surgery for obstructive jaundice was associated with similar mortality (RR 1.12, 95% CI 0.73-1.71,  $P=0.60$ ) but increased serious morbidity compared to DS (RR 1.66, 95% CI 1.28-2.16,  $P<0.001$ ) (11). A more recent case-control study showed that even in patients with total bilirubin above 15 mg/dL, PBD still resulted in increased postoperative morbidity and length of hospital stay (12).

Probably related to the lack of definitive high quality evidence, published guidelines are conflicting. ESGE (13) and ASGE (14) guidelines limit preoperative biliary drainage to patients with cholangitis, possible delay in surgical resection or to those with indication for neoadjuvant therapy, while ESMO guidelines recommend this procedure in patients with bilirubin higher than 14.6 mg/dL (15). Considering that PBD using endoscopic retrograde cholangiopancreatography (ERCP) is not devoid of complications and may delay surgery without anticipated benefits, there is the need to review these recommendations in light of recent and real-life practice reports.

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The aim of the present study was to critically analyse the reasons to perform PBD in patients submitted to PD in our Centre and to evaluate the impact of PBD on the postoperative outcome.

### Materials and methods

We conducted a retrospective study of patients with periampullary malignant disease undergoing PD between 2012 and 2017 at our Centre, which is one of the five Reference Centres for Pancreatic Surgery in Portugal. All patients were operated by the same surgeon (RM).

Patients were identified from a prospective database which included 461 patients discussed in multidisciplinary meetings during this period. Patients' demographic and clinicopathologic characteristics were collected prospectively including age, gender, laboratory values prior to PBD and/or surgery [total bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and  $\gamma$ -glutamyltransferase (GGT)], common bile duct (CBD) diameter on abdominal ultrasound, computed tomography or magnetic resonance imaging, final pathological diagnosis, time elapsed since diagnosis to surgery, estimated blood loss, duration of surgery, postoperative complications, need for reintervention or hospital readmission, length of hospital stay and mortality. For patients undergoing PBD, indications for insertion of biliary stent, technical and clinical success, procedure-related complications and mortality and time to surgery were also recorded.

#### Preoperative Biliary Drainage

Preoperative biliary drainage was performed by ERCP with plastic stent or, more recently, with self-expandable metal stent (SEMS) placement (Fig. 1). Percutaneous transhepatic cholangiography with biliary drainage (PTCD) was used as rescue option in case of failed ERCP. Clinical indication to perform PBD was critically extracted from electronic charts. Leucocytosis, elevated C-reactive protein and prescription of blood cultures in febrile patients were accepted as clinically suspected cholangitis. For suspected choledocholithiasis we followed the criteria defined by ASGE (16) using the

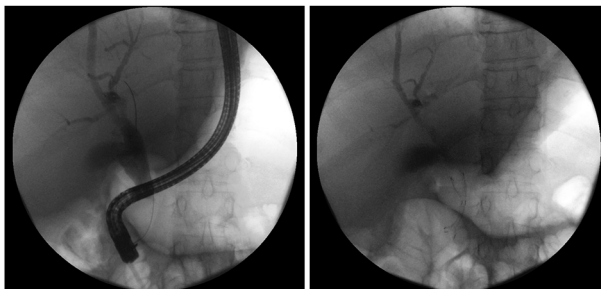


Figure 1. — Endoscopic retrograde cholangiopancreatography with metal stent placement in a patient with pancreatic adenocarcinoma.

value of total bilirubin, CBD diameter and/or presence of CBD stone on abdominal ultrasound.

Biliary drainage was defined as successful if total bilirubin level decreased by 50% or more by the time of surgery. Complications were defined as those leading to new symptoms, characterized by acute pancreatitis, perforation, obstruction and stent migration. A new stent was placed if signs of inadequate bile drainage, obstruction or migration developed.

#### Surgery

Surgical procedures consisted of classical pancreaticoduodenectomy with antrectomy in all patients. Standard lymphadenectomy was routinely performed. If the tumor infiltrated into the portal vein or superior mesenteric vein, a segmental or lateral resection of the vein was performed in order to achieve a R0 resection. A standardized two-layer, end-to-side, duct-to mucosa pancreaticojejunostomy was performed. Distal to the pancreatic anastomosis an end-to-side hepaticojejunostomy was made. Closed-suction drains were placed anterior and posterior to the pancreatic and biliary anastomosis. A nasogastric tube was routinely placed intraoperatively to enteral nutrition on the first postoperative day. Postoperative complications were defined according to the Clavien-Dindo classification (17) and categorized as minor (grade I-IIIa) and major (grade IIIb-V). A grade V complication was defined as death during the hospital stay or within 30 days of surgery.

#### Statistical analysis

All continuous variables were described as mean and standard deviation or median and range while categorical variables were expressed as frequency and proportions. Differences in mean continuous variables with a normal distribution were analysed using an independent Student t-test and one-way ANOVA. The other continuous variables were compared using the Wilcoxon Mann-Whitney test and Kruskal Wallis test. To explore univariate associations in the distribution of categorical data, the Chi-square test or Fisher's exact test was used as appropriate. On multiple logistic regression, major complications and 90-day mortality were used as dependent variables, since we considered these variables as the most clinically relevant. In respect to major complications we only considered grade IIIb to IVb since patients with grade V complications were included in 90-day mortality. Variables with P-value < 0.25 on simple logistic regression or that were considered clinically relevant were selected to a multiple logistic regression. For continuous variables cubic spline graphs and Wald test of linearity were used to assess linearity of the logit in the predictor. Variable selection was performed with a both stepwise analysis. Multiple logistic regression was used to determine the effect estimates, which are presented as odds ratio (OR) and 95% confidence intervals (CI). A

P-value < 0.05 was considered statistically significant. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 23 and R software.

## Results

During the study period, 128 patients were referred for biliopancreatic surgery. After excluding patients undergoing PD for benign/pre-malignant disease (n=29) and for metastasis of renal cell carcinoma (n=2), patients who performed distal pancreatectomy (n=10) and multivisceral resection due to other primaries (n=5), we ended up with 82 patients with malignant disease undergoing PD in whom PBD was an option (Fig. 2). In the final population, 47 (57.3%) were male with a mean age at surgery of  $69.1 \pm 10.5$  years. Median time of follow-up was 9 (0-46) months. Overall, the incidence of postoperative complications was 61% (n=50): 25 patients (30.5%) had minor complications and 25 (30.5%) had major complications. Ninety-day mortality was 13.4% (n=11): five patients died from septic postoperative complications, four from hemorrhagic shock, one from ischemic stroke 40 days after surgery and one patient was lost to follow-up and the cause of death is unknown. If we exclude patients older than 80 years old (n=10), 90-day mortality was 8.3% (6/72).

A total of 40 patients (48.8%) underwent PBD and 42 (51.2%) went for DS.

### 1. Preoperative Biliary Drainage

Indications for PBD are shown on Table 1. Unquestionable reasons for PBD such as suspicion of cholangitis or choledocholithiasis and indication to perform neoadjuvant chemotherapy were present in 24 (60%) patients. In the remaining 16 patients, critical review of prospectively collected data could not disclose any other reasons for PBD except for elevated bilirubin; in this group 68.8% (11/16) of patients had preoperative bilirubin higher than 15 mg/dL.

Table 1. — Indications for preoperative biliary drainage (N=40)

Neoadjuvant chemoradiotherapy	7
Suspicion of choledocholithiasis	8
Suspicion of cholangitis	9
No formal indication	16

In all patients the first attempt of biliary drainage was performed with ERCP (n=40). In one patient stent placement was not attempted since the procedure was being performed for suspected choledocholithiasis but a periampullary tumor was diagnosed during ERCP. Two other patients performed percutaneous drainage after failed ERCP. As such, a biliary stent was successfully placed in 82.1% (32/39) patients. In the remaining 7 patients we were unable to cannulate the common bile duct due to tumor infiltration.

Of the 32 patients who underwent stent placement, 29 received plastic stent and three a self-expandable

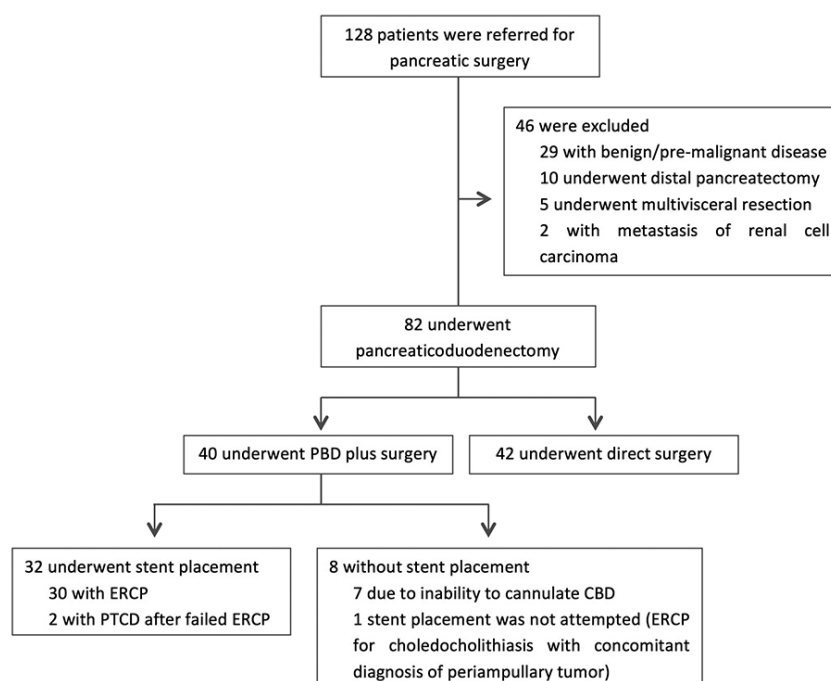


Figure 2. — Diagram of patients included.

PD denotes pancreaticoduodenectomy, PBD preoperative biliary drainage, ERCP endoscopic retrograde cholangiopancreatography, PTCD Percutaneous transhepatic cholangiography with biliary drainage, and CBD common bile duct.

short metal stent. Median stent length was 6 (4-9) cm and median diameter was 10 (7-10) French for plastic stent and 10mm for all metal stents. Seven stent-related complications (17.5%) were recorded: one proximal migration and six occlusions. These patients repeated ERCP 1 to 3 times and a new plastic stent was placed in 5 cases and a metal stent in two. No procedure-related death was recorded. Mean time between biliary drainage and surgery was  $26.1 \pm 36.9$  days, excluding seven patients who underwent neoadjuvant chemotherapy. Of the remaining 33 patients, 10 performed PBD and were operated during the same hospitalisation. Whenever possible, patients were discharged to recover at home and readmitted for surgery. Although the numbers are small, comparing patients with plastic and metal stents, no differences were observed in respect to stent-related complications (24.1% vs 0%,  $P=0.629$ ), postoperative complications (75.9% vs 33.3%,  $P=0.184$ ), 90-day mortality (10.3% vs 0%,  $P=0.999$ ), need for repeated laparotomy (27.6% vs 0%,  $P=0.555$ ) and hospital readmission at 90 days (18.5% vs 0%  $P=0.999$ ).

## 2. Direct Surgery

Direct surgery was performed in 42 (51.2%) patients. Of these, 33 had total bilirubin levels lower than 15 mg/dL and 9 had values above that threshold. We analysed the outcomes in these two groups. No differences were observed in postoperative complications (57.6% vs 44.4%,  $P=0.707$ ), 90-day mortality (15.2% vs 22.2%,  $P=0.631$ ), estimated blood loss ( $460.0 \pm 234.9$  mL vs  $550 \pm 332.9$  mL,  $P=0.685$ ), need for repeated laparotomy (30.3% vs 11.1%,  $P=0.403$ ), length of hospital stay ( $16.5 \pm 12.9$  days vs  $14.4 \pm 7.6$  days,  $P=0.651$ ) and hospital readmission at 90 days (24.1% vs 12.5%  $P=0.655$ ). Time between diagnosis and surgery was substantially lower in those with total bilirubin above 15 mg/dL ( $21.8 \pm 34.9$  vs  $2.6 \pm 3.6$  days,  $P=0.002$ ).

## 3. Preoperative Biliary Drainage versus Direct Surgery

Table 2 shows demographic and clinical characteristics in patients who performed PBD and DS. There were no differences in age and gender distribution of patients with PBD and those who went for DS. There was a trend towards higher mean value of total bilirubin in PBD group as compared to DS group ( $11.6 \pm 8.0$  mg/dL vs  $8.6 \pm 6.8$  mg/dL,  $P=0.073$ ), as well as ALT, AST, ALP and GGT ( $P<0.05$ ). Estimated blood loss was lower in patients with PBD ( $426.0 \pm 371.7$  mL vs  $483.3 \pm 259.8$  mL,  $P=0.003$ ). Table 3 shows postoperative outcomes in patients with and without PBD. Length of hospital stay was longer in PBD group ( $21.9 \pm 11.9$  days vs  $16.0 \pm 11.9$  days,  $P=0.003$ ). No differences were observed between both groups in respect to other parameters namely postoperative complications, 90-day mortality, need for reintervention and hospital readmission within 90 days after initial discharge.

Considering only patients with bilirubin concentration higher than 15 mg/dL ( $n=22$ ), and comparing the outcome of those submitted to PBD ( $n=13$ ) and DS ( $n=9$ ), no significant differences were observed in intraoperative blood loss ( $321.4 \pm 121.9$  mL vs  $550.0 \pm 332.9$  mL,  $P=0.129$ ), postoperative complications (61.5% vs 44.4%,  $P=0.666$ ), 90-day mortality (15.4% vs 22.2%,  $P=0.999$ ), need for reintervention (25.0% vs 11.1%,  $P=0.603$ ), length of hospital stay ( $21.9 \pm 12.5$  days vs  $14.4 \pm 7.6$  days,  $P=0.082$ ) and hospital readmission (8.3% vs 12.5%,  $P=0.999$ ).

Multiple logistic regression analysis was performed to explore the effect of independent variables on postoperative outcome: major complications (grade IIIb-IVb) and 90-day mortality. In respect to major complications (IIIb-IVb), no risk factors could be identified namely demographic factors, preoperative total bilirubin levels, PBD or its indication and duration of surgery. Predictors of 90-day mortality data are shown

Table 2. — Demographic and clinical characteristics of patients with and without PBD\*

	PBD (N=40)	Direct surgery (N=42)	P-value
Age – years	70.0 ± 9.2	68.3 ± 11.6	0.469
Male gender – no. (%)	23 (57.5)	24 (57.1)	0.974
Total bilirubin – mg/dL†	11.6 ± 8.0	8.6 ± 6.8	0.073
Alanine aminotransferase – U/L†	189.5 ± 109.3	137.4 ± 140.6	0.004
Aspartate aminotransferase – U/L†	310.8 ± 199.1	202.1 ± 172.3	0.006
Alkaline phosphatase – U/L†	582.8 ± 324.0	416.3 ± 406.9	0.003
γ-glutamyltransferase – U/L†	1344.9 ± 829.9	866.9 ± 1051.6	0.002
Pathological diagnosis – no. (%)‡			
Pancreatic ductal AC	23 (57.5)	27 (64.3)	0.338
Papilla of Vater AC	12 (30)	8 (19.0)	
Distal CBD AC	4 (10)	2 (4.8)	
Pancreatic NET	1 (2.5)	4 (9.5)	
Duodenal AC	0 (0)	1 (2.4)	
Time between diagnosis and surgery – days	56.4 ± 88.9	17.6 ± 31.9	0.003
Blood loss – mL	426.0 ± 371.7	483.3 ± 259.8	0.003
Operative time – minutes	223.5 ± 166.2	198.6 ± 218.9	0.259

\* PBD refers to preoperative biliary drainage. Plus-minus values are means ± standard deviation. † Total bilirubin and other biochemistry analyses refers to levels before preoperative biliary drainage or preoperative levels in patients who underwent direct surgery. ‡ AC refers to adenocarcinoma, NET to neuroendocrin tumor, CBD to common bile duct.

Table 3. — Outcomes of patients with and without PBD\*

	PBD (N=40)	Direct surgery (N=42)	P-value
Postoperative complications – no. (%)	27 (67.5)	23 (54.8)	0.237
Minor (I-IIIa)	16 (40)	9 (21.4)	0.156
Major (IIIb-V)	11 (27.5)	14 (33.3)	
90-Day mortality – no. (%)	4 (10.0)	7 (16.7)	0.376
Need for repeated laparotomy – no. (%)†	9 (23.1)	11 (26.2)	0.745
Postoperative hospital stay – days	21.9 ± 11.9	16.0 ± 11.9	0.003
Hospital readmission at 90 days – no. (%)‡	5 (13.5)	8 (21.6)	0.359

\* PBD refers to preoperative biliary drainage; Plus-minus values are means ± standard deviation. † Excluded one patient who died intra-operatively. ‡ Excluded eight patients who died during hospital stay after surgery.

Table 4. — Analysis of factors associated with 90-day mortality\*

	Simple Logistic Regression		Multiple Logistic Regression	
	Odds Ratio (95% CI)	P-Value	Odds Ratio (95% CI)	P-Value
<i>CONTINUOUS VARIABLES</i>				
Age – years	1.14 (1.04-1.27)	0.009	1.15 (1.05-1.31)	0.008
Total bilirubin – mg/dL†	1.04 (0.96-1.12)	0.300	Excluded	
Operative time – minutes	1.00 (0.99-1.02)	0.210	1.01 (0.99-1.03)	0.130
<i>CATEGORICAL VARIABLES</i>				
Female	1.12 (0.29-4.07)	0.860	Excluded	
Preoperative biliary drainage	0.57 (0.14-2.07)	0.400	Excluded	
Indication for PBD	0.69 (0.09-3.31)	0.670	Excluded	

\* PBD refers to preoperative biliary drainage; 95% CI - 95% Confidence Interval. † Total bilirubin refers to preoperative levels (for those patients who underwent preoperative biliary drainage, it refers to bilirubin after biliary drainage).

in Table 4. On simple and multiple logistic regression age was the only factor associated with increased 90-day mortality (OR 1.15, 95% CI 1.05-1.31, P=0.008). The receiver-operator characteristic (ROC) curve plotted for this model, where the dependent variable was 90-day mortality and independent variables were age and surgery duration, showed a good power of discrimination [area under the curve (AUC) of 0.816] (Fig. 3).

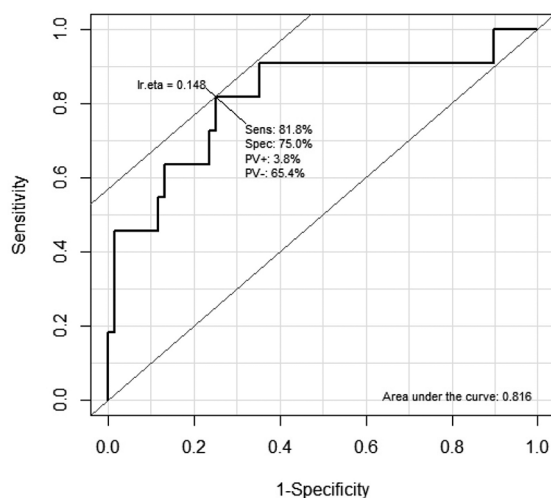


Figure 3. — Receiver-operator characteristic (ROC) curve using treatment 90-day mortality as dependent variable and age and surgery duration as independent variables. Sensibility : 81.8% ; Specificity : 75% ; Positive predictive value (PV+) : 3.8% ; Negative predictive value (PV-) : 65.4% ; Area under the curve (AUC) : 0.816.

## Discussion

Surgical resection is the only option for cure in patients with non-metastatic periampullary tumors of the pancreas and periampullary tumors (1). Although the long term prognosis of these patients remain dismal, it has improved significantly during the last decades probably related to better selection of patients, use of neoadjuvant chemotherapy in patients with borderline resectable tumors and more aggressive surgery with vascular resections whenever necessary. Nevertheless, even in high volume centres this surgery is still associated with significant morbidity and mortality (2).

ERAS guidelines for perioperative care aim at reducing complication rates, enhance functional recovery and, as a result, reduce length of hospital stay (18). ERAS guidelines for pancreatic surgery were published in 2012 (19). In respect to performing or not PBD, the authors analysed the results of five meta-analyses (20-24) and two randomized controlled trials (10,25) not included in the meta-analyses. The authors concluded that although there was a trend towards decreased postoperative morbidity in patients undergoing PBD, the increased risk of procedure-related complications counterbalanced this possible benefit. In a seminal paper, van der Gaag *et al.* showed that these results hold true for patients with total bilirubin level lower than 14.6 mg/dL (10). This threshold was later used in ESMO guidelines and in a review of PBD in periampullary tumors as a criteria to consider biliary drainage (15,26). However, the fact that van der Gaag *et al.* did not include patients with higher levels of

bilirubin, does not mean that these patients benefit from PBD. In fact, a case-control study published in 2014, found that even in patients with bilirubin level above 15 mg/dL, PBD was associated with increased morbidity and length of hospital stay (12). The decision of delaying surgery in patients with periampullary cancer to perform PBD, which is a procedure not devoid of complications and with unclear benefit in this context, probably needs to be revisited.

In the present study we observed that 49% of patients with periampullary malignant disease received preoperative biliary drainage. Critical review of electronic charts showed that unquestionable reasons to perform PBD such as suspicion of cholangitis or choledocholithiasis and/or need to perform neoadjuvant chemotherapy were present in 24 (60%) patients only. There was a trend for higher bilirubin in patients submitted to PBD as compared to those who went for DS which is in line with previous studies reporting that severe obstructive jaundice *per se* still remains a frequent indication to include ERCP in the preoperative management of these patients (27,28). In our study we also observed that the majority of patients who went straight to surgery had preoperative bilirubin levels under 15 mg/dL, in agreement with ESMO guidelines (15,19).

Preoperative biliary drainage may result in adverse events, eventually delaying or precluding a potentially curative resection (29). In our Centre, two patients with distal cholangiocarcinoma and pancreatic head cancer developed severe pancreatitis after ERCP which precluded curative surgery in both cases. These two patients were not included and analysed in the present series as they were not operated. In the present study 17.5% (7/40) of patients needed to repeat ERCP due to stent migration or occlusion. Although plastic stents were placed in the majority of patients and the numbers are far too small to draw conclusions, postoperative outcome tended to be worse in patients with plastic stent. This is in line with a recent study by JAMG Tol *et al.* who observed that metal stents are associated with a better outcome compared in with plastic stents (30). In this study, PBD performed with a fully covered self-expandable metal stent (FCSEMS) was compared with the plastic stent cohort by van der Gaag *et al.* Stent-related complications rates were significantly lower in the FCSEMS group (6% vs 30%,  $P=0.003$ ). Overall complications including PBD and surgical complications were higher in patients who had undergone PBD with plastic stent (74%) compared with 51% and 39% in the FCSEMS and early surgery groups, respectively.

Even in the absence of adverse events from ERCP, several studies suggest that the rate of postoperative adverse events after pancreaticoduodenectomy is higher when a preoperative ERCP is performed (10,31-33) possibly related to stent-induced inflammation. In our study, although postoperative length of hospital stay was significantly prolonged in patients performing PBD, no differences in postoperative complications or

90-day mortality were observed in patients undergoing PBD as compared to those who went for DS. Thus, despite potential complications of PBD, if the latter is performed in patients with clear and formal indications such as suspicion of cholangitis, choledocholithiasis and/or need to delay surgery, the benefits most probably outweigh the risks and in such cases a metal stent should be preferred. In contrast, the use of PBD without a strict criteria, namely in those patients with a high value of preoperative bilirubin as the sole reason for PBD, may contribute to increase postoperative morbi-mortality without any anticipated benefits. Anticipation of surgery is certainly the best option in this group of patients.

In what concerns patients with bilirubin higher than 15 mg/dL, 13 underwent PBD and 9 DS. No differences were observed in postoperative outcome whether the patients underwent DS or received PBD. Time between diagnosis and surgery in patients with total bilirubin higher than 15 mg/dL and who went for DS was only 2.6 days, which probably reflects the priority that is given to these patients in terms of anticipating surgery. Although this refers to a small number of patients, it is a good example on the unjustified concerns that surgeons feel on operating a patient with very high bilirubin level without prior PBD.

Finally, simple and multiple logistic regression analysis showed that age is an important factor influencing postoperative outcome. It may be debatable whether octogenarians should be referred to PD. As western population ages, it is increasingly recognized that chronological age should not, by itself, be a contraindication to more invasive and high risk procedures namely PD. In the present study 90-day mortality increased from 8% to 13% when we include patients aged 80 years or more. This increased risk should certainly be discussed with the patient and his relatives but we definitely need functional markers of frailty which might be helpful in these decisions.

Our study has some limitations, namely its retrospective nature. Considering that we had an observational study running, most data analysed were prospectively collected. Also, numbers are too small especially when we stratify patients according to PBD and DS or bilirubin level. However, in the present study more important than drawing conclusions about the impact of PBD in the outcome of these patients, is to conclude that in a real-life scenario physicians often include ERCP in the «routine» management of these patients, especially in those patients with high bilirubin level sometimes forgetting the potential and severe complications of this procedure. ESGE and ASGE guidelines do not attach their recommendations to the value of total bilirubin as opposed to ESMO guidelines which use the cut off of 14.6 mg/dL to decide whether PBD should, or not, be considered. Since PBD is an invasive procedure, with potentially serious complications, ours and other centres reports on their experience are important, as they may contribute to a better understanding on the best approach

for these patients and to make different societies guidelines more uniform.

The strength of the present study is that it shows real-life practice. The indications for PBD were critically and exhaustively reviewed and all patients were treated by the same institutional group and operated by the same surgeon.

In our opinion, the decision to perform preoperative biliary drainage needs to be extensively discussed between gastroenterologists, surgeons and oncologists and must be individualized for each patient, objectives of PBD should be defined and total bilirubin value by itself should not interfere with that decision. If biliary drainage is clearly indicated then a metal stent should be preferred.

### Conflict of interest

The authors have no conflicts of interest to declare.

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