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# One-stage percutaneous transhepatic biliary stenting for malignant jaundice: a safe, quick and economical option of treatment

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**Abstract. – OBJECTIVE: Patients with proximal malignant jaundices are often diagnosed in an advanced stage and need biliary decompression treatments, such as percutaneous transhepatic biliary drainage (PTBD) and bare metal stenting (BMS), to improve the hepatic function. Whether it is better to perform those two procedures together or in a separate time, it is not well understood. The aim of this study was to investigate the effectiveness and cost-benefit of a combined "one-stage" PTBD/BMS procedure in patients with malignant jaundices.**

**PATIENTS AND METHODS: Forty-five patients with malignant jaundice treated with "one-stage" PTBD/BMS were retrospectively enrolled to evaluate technical success, complications, survival, and length of hospitalization.**

**RESULTS: A full technical success of the procedures was reported for all patients, with only one major complication among 45 treated patients. A better performance in terms of hospitalization rate was achieved by the one-stage procedure compared to the two-stage, also resulting in global saving of costs. A high survival rate was observed at the 3rd and 6th month (97.7% and 86.6%, respectively), with a median overall survival time of 271,58 days.**

**CONCLUSIONS: Our study shows that performing PTBD/BMS as a "one-stage" procedure is useful, safe, and cost-effective with a high percentage of technical success and a similar occurrence of complications compared to the two-stage procedure.**

*Key Words:*
Malignant hilar obstruction, Percutaneous Transhepatic Biliary Drainage (PTBD), Bare Metal Stenting (BMS).

## Introduction

Malignant jaundice occurs when there is a blockage of the biliary tree, either by direct tumor infiltration or by external compression. The most common causes of malignant biliary obstruction are cholangiocarcinoma and adenocarcinoma of the pancreatic head[1]. Other tumors, such as those of gallbladder, stomach, or intrahepatic metastases or metastatic hilar lymph nodes have also been described as a possible cause of jaundice[1].

Approximately 90% of those patients show biliary symptoms, most commonly painless jaundice, while cholangitis may also occur in about 10% of the subjects[2,3]. In all cases, dilatation of the biliary ducts occurs and the bile is not able to correctly flow into the duodenum. Patients with jaundice are usually investigated with laboratory tests and imaging techniques; in all cases, hyper-bilirubinemia is detectable, while the typical onco-marker Carbohydrate antigen (CA) 19-9 may be initially higher or even normal[3-23].

The first diagnostic approach to jaundice is made by ultrasonography, normally demonstrating intrahepatic biliary dilatation with a decompressed distal bile duct; however, a second level imaging investigation is often necessary to better define staging and the underlining cause of the biliary obstruction. For this purpose, multislice computed tomography (MSCT) or magnetic resonance (MR) with cholangiopancreatography (MRCP)[4] may be used, with a high level of sensitivity, specificity (60-69%), and accuracy especially for determining the resectability of the



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lesion[4]. MRCP is the best tool to delineate the intrahepatic extension of the tumor and to diagnose non-malignant causes of hilar obstruction[16]; however, it shows a low accuracy for the evaluation of vascular invasion, which in turn is among the main criteria for a surgical approach[21]. Conversely, when MR and MSCT are performed together, they achieve up to 75% of accuracy to predict resectability[21].

Unfortunately, in a great number of cases, the malignant obstructive jaundice is detected when the disease is already at an advanced stage, and no surgery is indicated[5]. For those patients, biliary decompression treatments are strictly required to improve hepatic function and the effects of anti-tumor therapies[22]. Percutaneous transhepatic biliary drainage (PTBD) and bare metal stenting (BMS) are treatments of choice for malignant obstructive jaundice, in particular of the proximal biliary tract, proving good clinical efficacy with a very limited patient suffering[17,18], high technical/clinical success rate, and lower prevalence of infective complications compared with endoscopy[7,8].

In many studies[9-19], bare metal stents are superior to plastic stents due to longer patency and lower reintervention rates; however, they are often placed 5-7 days after PTBD as a "two-stage" procedure[10,11] to prevent complications, such as cholangitis[12,13].

Since the "two-stage" procedure requires a second hospitalization, patients are more exposed to typical hospital complications, such as infections. This is why performing PTBD and BMS at the same time, as a "one-stage" procedure, may reduce either complications or the length of hospital stay of those patients, possibly improving safety and efficacy[14].

Despite those observations, whether it is better to perform those two procedures together or in a separate time, it is not well understood yet. The aim of our study was then to evaluate the efficacy, safety, and cost/benefit ratio of the "one-stage" procedure for the treatment of malignant hilar obstruction (MHO).

## Patients and Methods

The research included 45 consecutive patients affected by MHO enrolled between January 2014 and December 2016 (Table I).

The inclusion criteria for the study were: (1) patients aged 18-99 years, (2) proximal malignance obstruction level, (3) specific symptoms, such as jaundice and abdominal pain related to biliary obstruction, and (4) unresectable tumors or refusal of the surgical treatment.

The exclusion criteria included: (1) patients with distal obstruction and (2) patients who had undergone previous biliary drainage and/or stent procedures.

The level of obstruction was staged by a second level imaging, such as CT and/or MRCP (Figures 1-3) to identify the biliary duct involvement through Bismuth-Corlette Classification[2] (Figure 4); in all patients a histological assessment, performed by semiautomatic shearing needle 20 Gauge, was also evaluated (Table II). Routine biochemical testing was also available for all patients, and informed consent to perform PTBD and BMS was obtained from all participants.

All patients have been treated by PTBD and BMS as a "one-stage" procedure according to the decision taken during our inter-disciplinary meeting as the best current treatment for the patients. Any procedure has been in accordance with the scientific guidelines for palliation of MHO and in accordance with the Declaration of Helsinki. None of the patients or authors received any honorary or economic benefits for participation in this study. The Local Ethics Committee approved the study.

### PTBD and BMS

Prophylactic antibiotics (ciprofloxacin, 200 mg/IV, twice a day) were prescribed 24 h before the procedure and continued for 3 days after in all cases. Analgesics and antiemetics were also

**Table I.** The baseline clinical patient characteristics of one stage procedure group.

| | |
|---|---|
| Sex | 31 M/14 F |
| Age (year) | 74.09 (M 73.1: F: 78.4) |
| TB preoperative (mg/dl) | 18.45 (2.15-34.77) |
| DB preoperative (mg/dl) | 12 (0.76-26.3) |
| WBC (x1000 cell/mm3) | 8.77 (4.23-18.91) |
| Hb (g/1 dL) | 11.13 (7-14.4) |
| TB after 24 h (mg/dl) | 7.54 (0.61-32.73) |
| DB after 24 h (mg/dl) | 6.53 (0.32-17.15) |
| RCP | 6.53 (0.21-27.25) |
| TB 1 month (mg/dl) | 2.02 (0.55-5.32) |
| TB 3 month (mg/dl) | 3.17 (0.6-9.37) |
| TB 6 month (mg/dl) | 4.66 (0.75-16.31) |
| TB 12 month (mg/dl) | 2.64 (0.65-9.7) |
| Hospitalization Time (day) | 12.75 (5-30) |

(M: males; F: females; TB: total bilirubin; DB: direct bilirubin; WBC: white body cells; Hb: Hemoglobin; RCP: Reactive C Protein).

**Table II.** Histological assessment of tumors and sexual prevalence in patients.

| | |
|---|---|
| Hilar cholangiocarcinoma (Klatskin tumor) | 26 M/11 F |
| Colorectal liver metastases | 3 M/1 F |
| Gallbladder tumor | 0 M/2 F |
| Hilar lymph nodes metastases | 2 M/0 F |

administered in saline infusion 30 min before the beginning of the procedure (Tramadol Hydrochloride 50 mg and Metoclopramide 10 mg)[15]. Using an angiographic suite and a digital subtraction X-ray system (Allura Xper FD20; Philips, Eindhoven, the Netherlands), percutaneous transhepatic biliary catheterism was performed after a preliminary ultrasound-guided intradermal injection of 10 ml of lidocaine 1% into site of percutaneous approach. Transhepatic approach was made by a bracket-assisted puncture with a 21-Gauge Chiba needle under ultrasound assistance, with a further injection of 2-5 ml of a 50% solution contrast medium, obtaining initial opacification of the bile ducts. Once the target bile duct was accessed, a 0.018 nitinol guide-wire was advanced into the duct, and a 4 French coaxial system was positioned under fluoroscopic guidance (Figure 5a and 5b). Then, a 7 French valved sheath was replaced inside the hydrophilic 0.035 guide wire to perform cholangiography, to confirm the level of stricture, and to resolve stenosis.

Then, the hydrophilic wire was replaced with a stiffer one, across the 5 French hydrophilic diagnostic catheter, to support interventional proceedings. Conscious sedation was performed by hypnotic and analgesic dose of Propofol 20 mg, during continuous $O_2$ saturation monitoring. Length of stenosis, measured by post-processed semiautomatic analysis software (Philips X-per App, Eindhoven, the Netherlands) and of stenting, were also available (Figure 6). Cholangiography through the sheath after stent deployment was used to assess the stent patency. If the contrast medium did not flow through the stent, an additional coaxial stent was placed. All strictures were subjected to balloon-catheter dilation achieving a good sealing of the stents. If the flow of contrast medium was

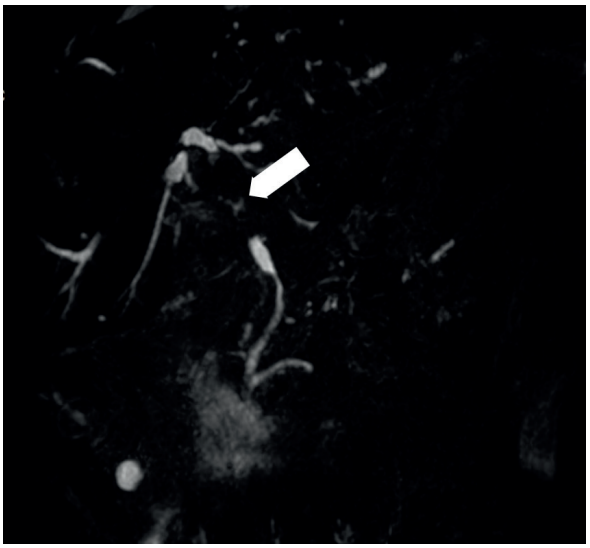


**Figure 2.** MRCP: main biliary duct stenosis (*big arrow*).

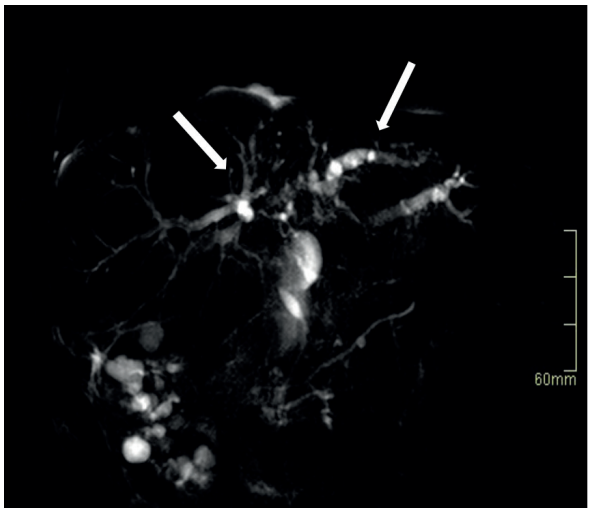



**Figure 1.** MRCP study of biliary system shows dilation of biliary ducts (*small arrow*).

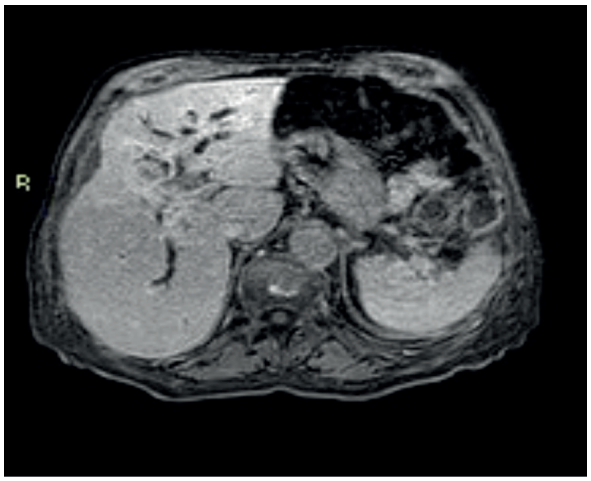



**Figure 3.** MR T1 late contrast phased axial shows the dilation of intrahepatic biliary ducts (*small arrow*).


**Figure 4.** Original drawing of the Bismuth-Corlette classification of malignant biliary obstruction[2].

satisfactory, the vascular sheath was removed, and an 8.5-10 French external-internal drainage just below the duodenal papilla was placed (Figure 7) to proceed with saline lavage for 48 h.

### *Statistical Analysis*

All variables are summarized as mean or indicated as minimum/maximum value. Categorical variables are summarized as percentages. Variables were compared between the two patients' groups by the Bartlett test. *p*-value <0.05 was considered statistically significant.

## Results

45 consecutive patients (31 males, mean age 74±16) with MHO, enrolled between January 2014 and December 2016, were treated with PTBD and BMS. The baseline clinical characteristics of those patients are summarized in Table I.

Primary cholangiocarcinoma was present in 37 patients (22 Bismuth type I, 9 type II, 6 type III, and 1 type IV carcinomas). The main clinical presentation was jaundice, which occurred in 43 patients. Anorexia and poor clinical conditions were also present in 30 patients, while abdominal pain and pruritus were observed in 15 patients. Pre-procedural cholangitis was observed in 11 patients.

Pathological diagnoses were confirmed using percutaneous or transluminal biopsies in 42 patients (Figures 8, 9, and 10).

Every patient received chemotherapy after final diagnosis, while 6 patients were lost during the follow-up period.

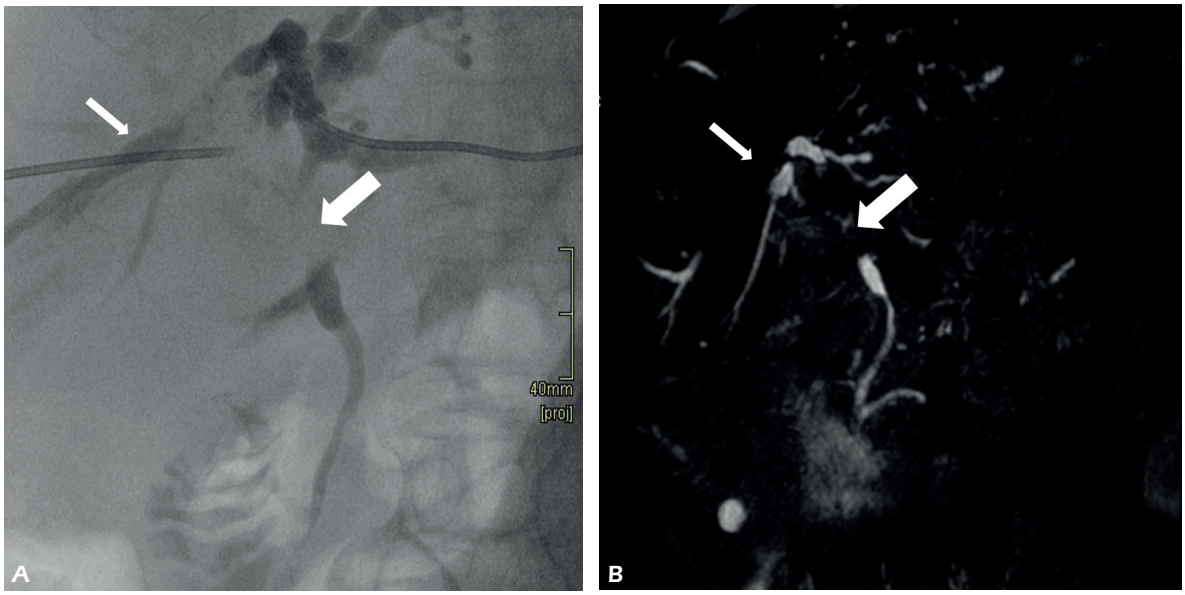



**Figure 5.** ***A-B***, Percutaneous transhepatic cholangiography (8a) and MRCP study of biliary system (8b), they show similar pattern of main biliary duct stenosis (*big arrow*) and dilation of biliary ducts (*small arrow*).

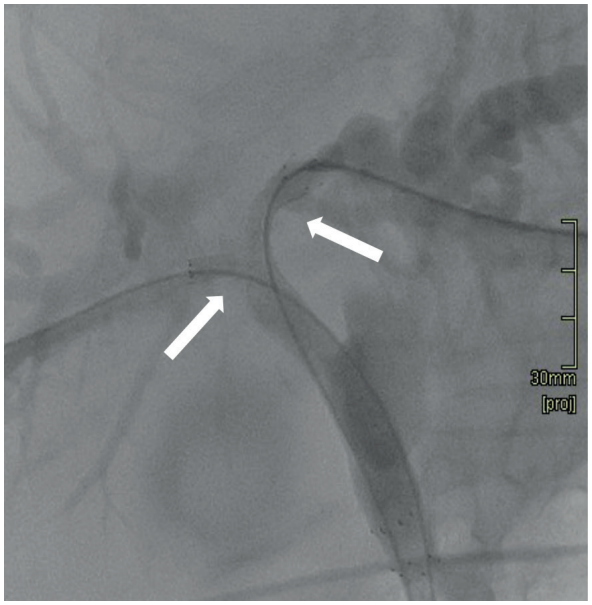



**Figure 6.** Percutaneous transhepatic double stenting with bare metal stents (arrows).

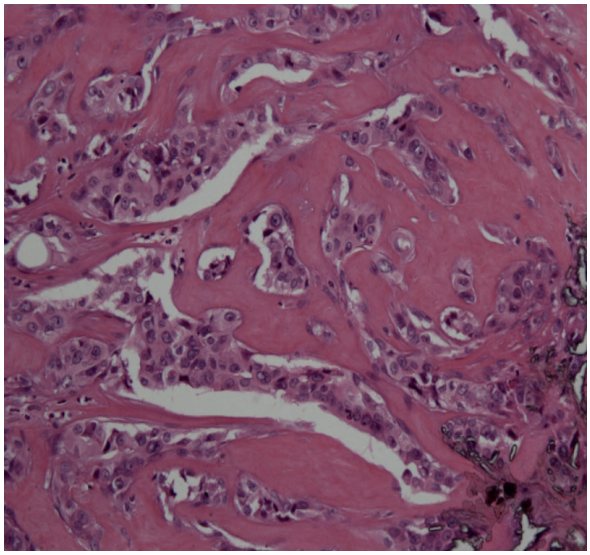


**Figure 8.** Scleroialin tissue infiltrated by neoplastic cells of an intrahepatic cholangiocarcinoma. Hematoxylin and Eosin staining (original magnification x 200).

### *Procedure Success*

The main endpoint of our retrospective study was the efficacy and safety of one-stage procedure in terms of technical success and complication rate. Technical success was achieved in 100% of patients. Every patient received an ultrasound transhepatic approach through the right access (40 subjects), the left access (1 subject), or the bilateral accesses (4 subjects). The mean duration of the combined treatment was 38 min (range 20-57 min). Thirty-eight patients received monolateral biliary stenting, while 7 subjects underwent a Y-configuration stenting. The distal stent was placed above the duodenal papilla to avoid ascendant cholangitis in all patients except for 6 in whom it was placed across the duodenal papilla. Every patient received temporary external-internal drainage (8-10 Fr) with the tip below the duodenal papilla. During the hospital stay, a successful reduction of total bilirubin level was achieved in 43 of 45 patients, while PTBD was maintained for about 6.4 days (3.5-9.3 days).

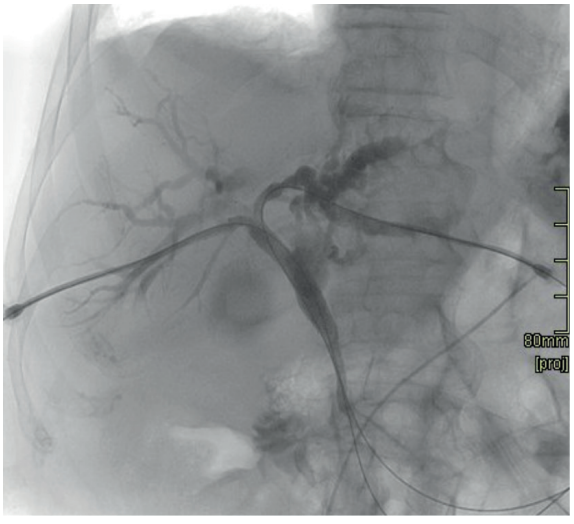



**Figure 7.** Bilateral percutaneous transhepatic cholangiography after double bare metal stenting.

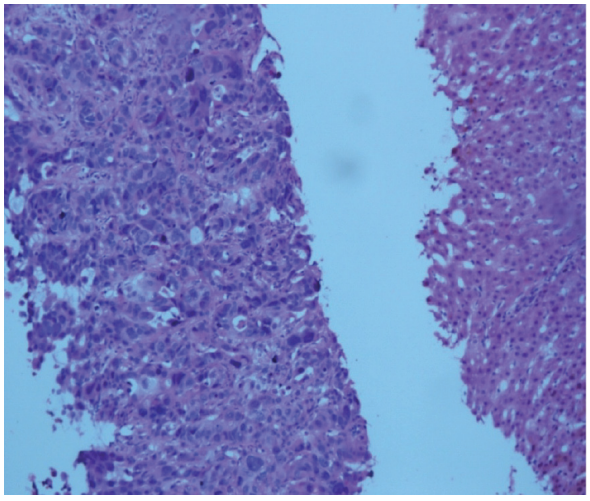


**Figure 9.** Poorly differentiated mucinous cystic cholangiocarcinoma in liver biopsies. Hematoxylin and Eosin staining (original magnification x 200).

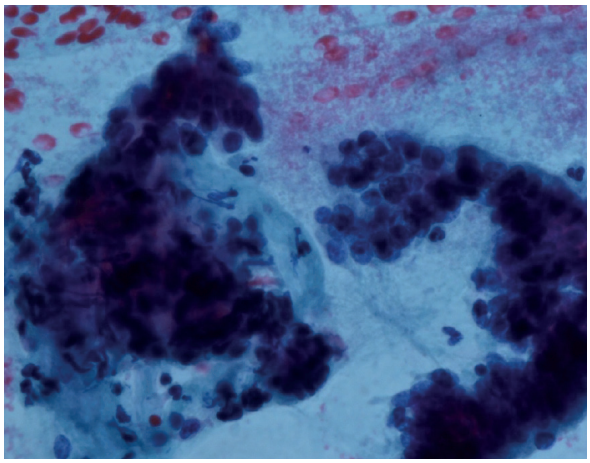


**Figure 10.** Cytologic smears showing papillary groups of epithelial neoplastic cells with huge nuclei with prominent nucleoli. Hematoxylin and Eosin staining (original magnification x 400).

### Complications

Among major complications, only a case of severe haemobilia, which did not require a surgical approach, was observed. Other minor complications were fever up to 72 h (6 of 45 patients), abdominal pain up to 72 h (3 of 45 patients), and cholangitis (1 of 45 patients).

### Survival

The second endpoint of the study was the overall survival (OS) and laboratory test improvement, such as serum bilirubin levels performed within 48 h, as well as 1, 3, and 6 months after stent placement (Tables III-V).

The overall survival rate was: 97.7% after 3 months, 86.6% after 6 months, and 28.9% after 12 months, with a median overall survival (OS) of 271,58 days (59-424 days) and with an intra-stent tumor growing modal time of 305 days.

### Cost-Benefit Ratio

The third endpoint of the study was to determine the cost/benefit ratio of the one-stage procedure in terms of complication and hospitalization days.

Medium hospitalization time was 12.75 days (5-30 days), lower than a two-stage procedure, which requires the same time, plus 5.2 (range 2-9) days[11] of interval between procedures.

There is a statistical trend between total bilirubin level reduction rate in the first 24 h (Bil Delta/24 hour) and the hospitalization time, as estimated by Pearson correlation (Table III and Figure 11). The statistically significant shorter hospital stays observed for the one-stage compared to two-stage procedure group, as analyzed

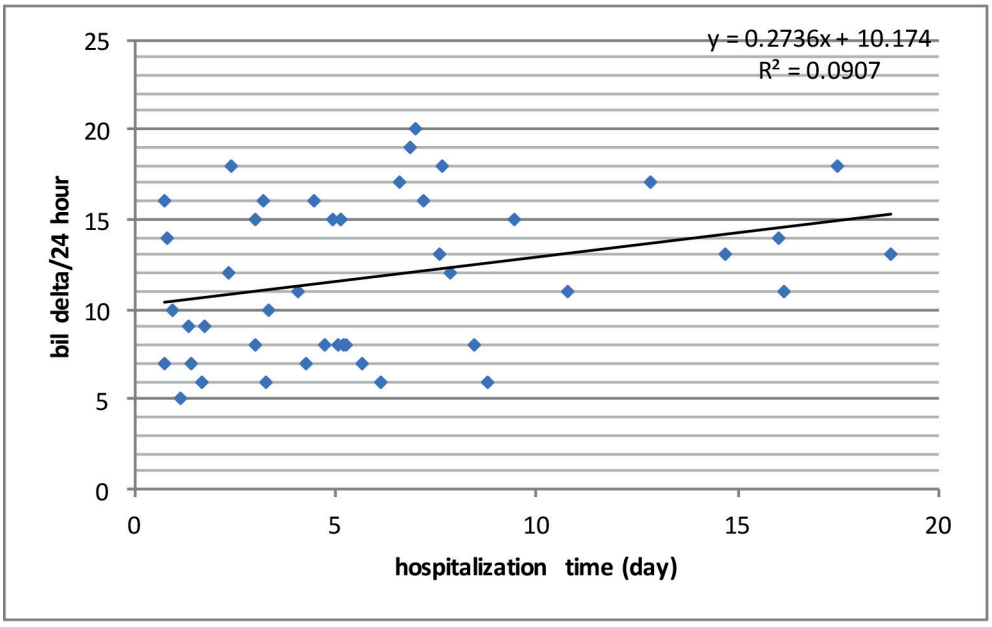



**Figure 11.** Statistical correlation between total bilirubin level reduction rate in the first 24 h (Bil Delta/24 h) and the hospitalization time, estimated by Pearson correlation analysis.

**Table III.** Baseline laboratory tests and serum bilirubin levels before and after stent placement at 24 h and hospitalization time of two-stage procedure group.

| SEX | AGE (years) | TB (mg/dL) | CB (mg/dL) | WB (x 1000) | Hb (g/dL) | TB POST 24 H (mg/dL) | DB POST 24 H (mg/dL) | RCP | HOSP (days) |
|---|---|---|---|---|---|---|---|---|---|
| F | 76 | 28.09 | 20.4 | 6.4 | 11.7 | 25.47 | 14.19 | 8.2 | 21 |
| F | 78 | 13.48 | 8.81 | 5.2 | 14.4 | 10.63 | 6.59 | 11.9 | 20 |
| F | 87 | 20.47 | 15.32 | 9.9 | 10 | 15.21 | 9.72 | 10 | 25 |
| F | 80 | 12.45 | 8.52 | 8.4 | 13.8 | 11.6 | 6.55 | 14.2 | 14 |
| M | 60 | 34.75 | 22.7 | 17.3 | 12.6 | 27.91 | 16.95 | 13.4 | 11 |
| M | 79 | 17.99 | 9.71 | 7 | 10.9 | 13.89 | 7.89 | 11.87 | 13 |
| M | 66 | 18.53 | 10.38 | 8.9 | 14 | 15.7 | 9.66 | 15.2 | 22 |
| M | 79 | 29.88 | 19.32 | 17 | 11 | 25.76 | 15.6 | 9.9 | 19 |
| F | 84 | 15.5 | 10.2 | 8.8 | 12.9 | 11.87 | 8.67 | 11 | 12 |
| F | 74 | 12.75 | 9.78 | 11.8 | 10.7 | 10.1 | 8.1 | 12.2 | 18 |
| F | 86 | 22.05 | 15.72 | 8.2 | 11.2 | 9.22 | 5.81 | 10.4 | 12 |
| F | 48 | 26.3 | 16.72 | 9.5 | 14.1 | 23.23 | 14.99 | 9.82 | 21 |
| F | 88 | 6.25 | 4.32 | 5.8 | 12 | 5.2 | 3.9 | 11.64 | 23 |
| M | 80 | 30.76 | 19.86 | 12.7 | 11.8 | 14.72 | 8.18 | 9.2 | 18 |
| M | 81 | 10.42 | 7.23 | 11.8 | 9.6 | 8.1 | 5.96 | 11.8 | 15 |
| M | 64 | 22.8 | 12.15 | 6.2 | 10.9 | 14.05 | 6.86 | 10.18 | 15 |
| M | 55 | 17.13 | 11.01 | 7 | 8.9 | 14.8 | 9.8 | 12.2 | 17 |
| F | 67 | 21.97 | 15.68 | 9.9 | 12.7 | 16.8 | 13.7 | 7.39 | 14 |
| F | 62 | 10.85 | 8.11 | 13.7 | 13.2 | 7.27 | 4.75 | 14.8 | 19 |

by the Bartlett test (Figure 12), could also exert a positive effect on the intra-hospital infection risk.

## Discussion

Our study shows that PTBD/BMS performed as "one-stage" procedure is safe and cost-effective in patients with malignant jaundice. Also, it shows a similar prevalence of efficacy and complications than the "two-stage" procedure, as reported by Inal et al[24].

In all patients, percutaneous transhepatic biliary access was performed by combined ultrasound and fluoroscopic technique, with a thin needle and a low X-ray patient exposure. Ultra-

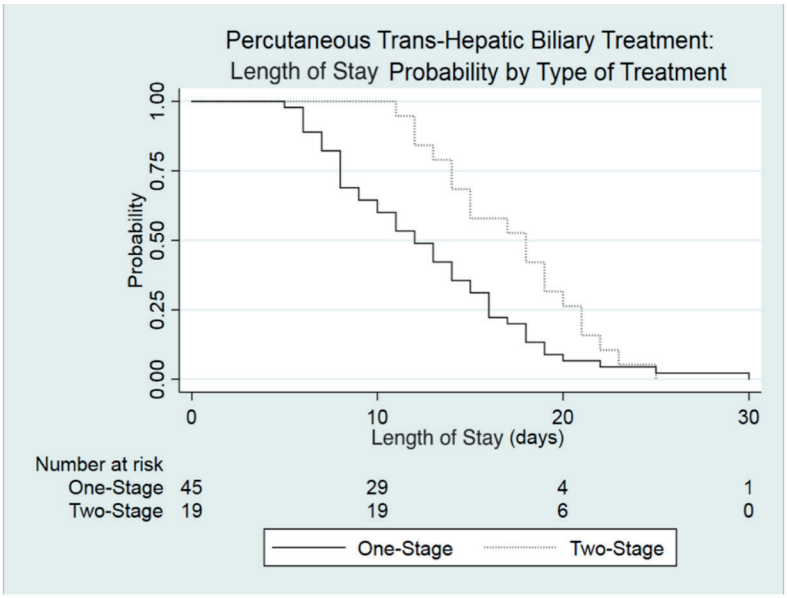



**Figure 12.** Hospital stay probability for the one-stage and the two-stage group after percutaneous procedures.

**Table IV.** Overall survival distribution rate.

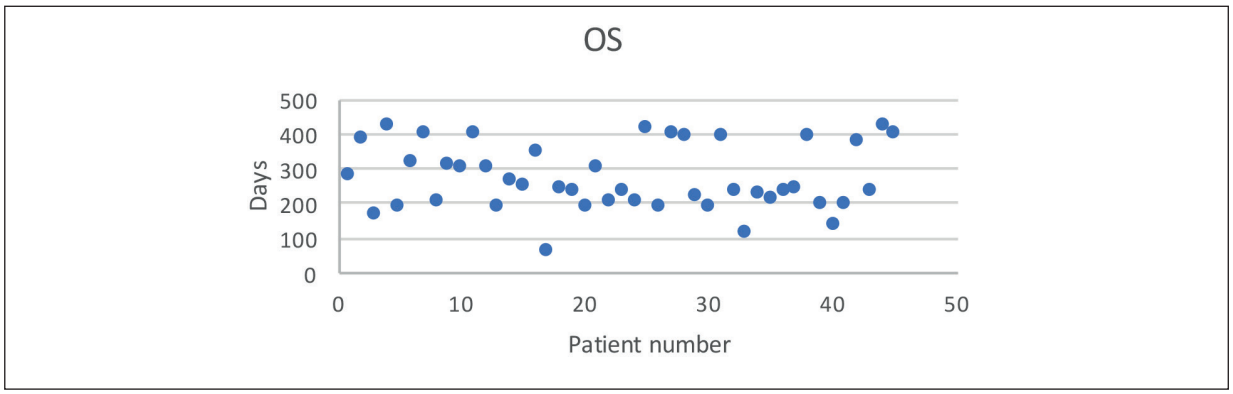
| SEX | AGE (years) | TB (mg/dL) | CB (mg/dL) | WB (x 1000) | Hb (x 1000) | TB POST 24 hour (mg/dL) | DB POST 24 hour (mg/dL) | RCP (mg/dL) | TB 1 (mg/dL) | TB 3 (mg/dL) | TB 6 (mg/dL) | TB 12 (mg/dL) | HOSP (days) | OS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| F | 76 | 28.09 | 20.4 | 6.4 | 11.7 | 10.57 | 5.19 | 1.12 | 2.3 | 2.5 | 2.6 | 3.5 | 18 | 277 |
| F | 78 | 13.48 | 8.81 | 5.2 | 14.4 | 6.63 | 3.89 | 6.5 | 1.4 | 1.5 | 1.5 | 1.8 | 19 | 385 |
| F | 87 | 20.47 | 15.32 | 9.9 | 10 | 15.21 | 14.03 | 4.4 | 4.5 | 9.3 | 14.8 | na | 8 | 164 |
| M | 74 | 6.15 | 3.64 | 9.1 | 10.5 | 2.87 | 1.72 | 14.21 | 1.7 | 1.9 | 2.1 | 2.7 | 6 | 424 |
| M | 80 | 2.45 | 1.52 | 8.4 | 13.8 | 1.66 | 1.52 | 0.77 | 1.5 | 1.7 | 8.5 | na | 14 | 190 |
| M | 60 | 34.75 | 22.7 | 17.3 | 12.6 | 15.93 | 8.95 | 7.62 | 2.23 | 2 | 2.1 | na | 13 | 318 |
| M | 79 | 17.99 | 9.71 | 7 | 10.9 | 13.52 | 7.8 | 5.6 | 2.1 | 1.5 | 1.5 | 2.18 | 16 | 402 |
| M | 66 | 18.53 | 10.38 | 8.9 | 14 | 22.78 | 14.16 | 8.35 | 5.32 | 3.16 | na | na | 9 | 206 |
| M | 79 | 16.13 | 10.3 | 17 | 11 | 8.27 | 5.36 | 4.14 | 1.32 | 1.43 | 1.53 | na | 12 | 310 |
| M | 64 | 2.15 | 0.76 | 8.4 | 11.1 | 1.44 | 0.6 | 8.4 | 0.76 | 0.86 | 1.53 | na | 7 | 305 |
| M | 84 | 15.5 | 10.2 | 7.6 | 10.5 | 7.08 | 4.09 | 9.88 | 2.2 | 1.5 | 1.5 | 1.9 | 8 | 398 |
| M | 68 | 4.75 | 2.71 | 13.3 | 11.2 | 3.63 | 1.85 | 1.66 | 1.2 | 1.6 | 1.87 | na | 5 | 305 |
| F | 86 | 22.05 | 15.72 | 8.2 | 11.2 | 9.22 | 5.81 | 4.2 | 2.7 | 8.2 | 14.8 | na | 17 | 189 |
| F | 48 | 26.3 | 16.72 | 9.3 | 11.4 | 23.23 | 14.99 | 0.21 | 2.35 | 3.06 | na | na | 15 | 265 |
| F | 78 | 26.67 | 17.81 | 7.6 | 10.2 | 3.66 | 1.95 | 2.92 | 1.9 | 5.3 | 12 | na | 8 | 250 |
| F | 88 | 6.25 | 4.32 | 5.8 | 12 | 3.87 | 1.88 | 1.01 | 0.89 | 0.89 | 1.75 | na | 18 | 350 |
| F | 83 | 26.47 | 15.75 | 5.7 | 10.4 | 10.3 | 6.21 | 3.3 | na | na | na | na | 11 | 28 |
| M | 68 | 20.94 | 13.15 | 8.5 | 8.9 | 15.32 | 13.06 | 8.27 | 1.32 | 1.86 | 2.3 | na | 7 | 240 |
| F | 90 | 22.18 | 17.21 | 7.8 | 9.9 | 14.53 | 9 | 6.96 | 1.2 | 1.9 | 13.2 | na | 18 | 191 |
| M | 80 | 30.76 | 19.86 | 12.7 | 11.8 | 14.72 | 8.18 | 4.28 | 1.86 | 9.3 | 14.8 | na | 14 | 190 |
| M | 81 | 10.42 | 7.23 | 11.8 | 9.6 | 4.3 | 2.98 | 5.1 | 2 | 1.5 | 2 | na | 6 | 305 |
| M | 64 | 22.8 | 12.15 | 6.2 | 10.9 | 14.05 | 6.86 | 0.84 | 2.55 | 3.6 | na | na | 6 | 149 |
| M | 55 | 17.13 | 11.01 | 7 | 8.9 | 15.8 | 10.12 | 27.25 | 1.35 | 1.78 | 1.82 | na | 9 | 212 |
| M | 67 | 21.97 | 15.68 | 9.9 | 12.7 | 16.81 | 1.83 | 6 | 4.53 | 9.7 | 14.8 | na | 8 | 200 |
| F | 62 | 10.85 | 8.11 | 13.7 | 13.2 | 3.27 | 1.75 | 17.08 | 1.4 | 1.4 | 1.5 | 1.67 | 13 | 415 |
| M | 75 | 30.42 | 15.97 | 4.31 | 10.7 | 25.31 | 15.97 | 3.63 | 4.1 | 9.32 | 16.31 | na | 15 | 192 |
| M | 53 | 15.72 | 9.31 | 12.8 | 13.3 | 14.81 | 8.95 | 2.63 | 1.83 | 1.5 | 1.54 | 1.98 | 10 | 402 |
| F | 80 | 5.3 | 3.72 | 10.3 | 10.4 | 0.61 | 0.32 | 7.84 | 0.75 | 1.22 | 1.56 | 2.88 | 8 | 390 |
| M | 66 | 6.65 | 4.73 | 7.59 | 11.3 | 5.29 | 3.11 | 12.2 | 1.32 | 1.86 | 2.3 | na | 7 | 198 |
| M | 83 | 25.21 | 17.24 | 18.91 | 11 | 14.43 | 8.9 | 17.96 | 3.67 | 7.94 | 16.1 | na | 11 | 189 |
| M | 45 | 21.27 | 14.36 | 7.03 | 12 | 26.33 | 16.53 | 13.9 | 1.4 | 1.5 | 1.5 | 2.1 | 25 | 390 |
| F | 85 | 7.38 | 4.57 | 10.23 | 7 | 4.06 | 2.32 | 2.3 | 1.37 | 1.6 | 2.1 | na | 10 | 235 |
| M | 91 | 22.83 | 14.86 | 9.43 | 10.7 | 15.62 | 9.58 | 7.81 | 3.87 | 9.37 | na | na | 16 | 116 |
| M | 85 | 24.4 | 16.05 | 10.09 | 8.7 | 9.72 | 9.72 | 5.23 | 1.82 | 1.86 | 2.13 | na | 13 | 190 |
| M | 90 | 32.5 | 19.07 | 8.56 | 12.1 | 28.28 | 17.15 | 12.5 | 1.73 | 1.86 | 1.97 | na | 14 | 213 |
| M | 70 | 9.68 | 5.63 | 10.98 | 8.7 | 11.67 | 7.3 | 5.2 | 0.95 | 1.26 | 1.75 | na | 30 | 199 |
| M | 75 | 11.24 | 7.9 | 4.49 | 10.7 | 6.16 | 3.67 | 6.89 | 1.42 | 1.51 | 1.59 | na | 8 | 211 |
| M | 84 | 16.72 | 11.91 | 6.16 | 12.2 | 15.97 | 8.86 | 5.9 | 1.55 | 1.6 | 1.75 | 1.78 | 16 | 390 |
| F | 81 | 23.53 | 15.41 | 4.23 | 10 | 14.09 | 7.29 | 2 | 1.94 | 1.5 | 1.56 | na | 20 | 169 |
| F | 76 | 19.95 | 13.17 | 6.28 | 11.5 | 13.35 | 7.6 | 8.08 | 4.76 | 10.3 | na | na | 22 | 135 |
| M | 75 | 14.62 | 9.29 | 6.57 | 9.3 | 11.44 | 7.12 | 10.55 | 0.55 | 1.23 | 6.43 | na | 16 | 149 |
| M | 56 | 12.76 | 7.06 | 5.6 | 12.3 | 7.66 | 4.11 | 0.52 | 0.55 | 0.6 | 0.75 | 9.7 | 19 | 380 |
| M | 82 | 34.77 | 26.3 | 6.15 | 10.5 | 30.74 | 18.2 | 3.2 | 1.4 | 1.5 | 1.5 | na | 11 | 177 |
| M | 77 | 15.7 | 10.3 | 5.58 | 11.9 | 13.4 | 8.22 | 2.77 | 1.9 | 1.6 | 1.6 | 1.6 | 12 | 423 |
| M | 60 | 34.4 | 22.08 | 6.98 | 14.1 | 32.73 | 20.73 | 3.1 | 1.8 | 1.4 | 1 | 0.65 | 6 | 398 |

(TB: Total Bilirubin; DB: Conjugated Bilirubin; WB: white bodies; Hb: hemoglobin; RCP: Reactive C Protein; HOSP: Hospitalization time; OS: Overall survival; na: not available)

sound-guided hepatic access reduced also the risk of bleeding[24].

Through this technique, the technical success of 100% was reached both for monolateral and bilateral access. The duration of the procedures was very acceptable, ranging from 20 to 57 min and well-tolerated by all patients. Bleeding was observed in only 1 patient, while the other complications, such as fever, pain, and cholangitis were similar to those reported by Mansour et al[23] where the same procedures were performed. On the other hand, in our series, stent placement above the

**Table V.** Baseline laboratory tests and serum bilirubin levels before and after stent placement at 48 h and 1, 3, and 6 months, hospitalization time and overall survival in days after treatment.




duodenal papilla did not expose to a greater risk of cholangitis, differently from what reported by other studies[25-29]. This could be explained by the placement, in our patients, of temporary external-internal drainage below the papilla, facilitating contrast medium and bile flow through the duodenum.

Notably, we have observed an OS rate very high for the first 6 months (Figure 12), with a mean of 271,58 days, and an intra-stent tumor growing modal time of 305 days (Table V). Chemotherapy treatment was then performed in relation to the clinical status of our patients[25].

Mean hospitalization time is lower when performing a "one-stage" procedure compared to the "two-stage", remarking the importance of combining those two techniques in our patients. This time saving may reduce further hospitalization, as well as exposure to hospital infections[14], rather than having a positive economic impact on the management of patients with MHO.

## Conclusions

One-stage PTBD/BMS procedure instead of performing the same procedures into separate times is safe and cost-effective for the majority of MHO patients. Also, it is well-tolerated and it may allow to reduce length of hospitalization and intra-hospital infection risk. Further prospective studies are now needed to validate our results.

### Conflict of Interests

The Authors declare that they have no conflict of interests.

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