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Research Article

# Endoscopic Biliary Drainage of Biliopancreatic Tumors (about 270 Cases)

**Samir Mrabti*, Ahlam Benhamdane, Jihane Bennas, Meryem Amine, Tarik Addajou, Reda Berrida, Sara Sentissi, Ilham El Koti, Fedoua Rouibaa and Hassan Seddik**

*Hepato-Gastro-Enterology Department II of Military Training Hospital Med V in Rabat- Morocco*

***Corresponding Author:** Samir Mrabti, Hepato-Gastro-Enterology Department II of Military Training Hospital Med V in Rabat- Morocco.

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## Abstract

**Background:** Endoscopic biliary drainage remains the main palliative treatment for biliopancreatic cancers.

The objective of our study was to analyze the results of this drainage technique, as well as the various associated success and failure factors.

**Materials and methods:** From January 2002 to September 2023, 270 patients with neoplasic biliary stenosis were included in the study. Patients were divided into 3 groups: Group A for patients with proximal cholangiocarcinoma, Group B for patients with pancreatic cancer, and Group C for patients with a gallblader cancer. Only technical success was analyzed. This success was defined as the placement of biliary stent covering the entire stenosis. The factors studied were sex, age, type of cancer, location and appearance of the stenosis, endoscopic dilation of the stenosis before placement of the stent and finally the presence or absence of duodenal stenosis in case of a pancreatic cancer.

**Results:** The mean age was 64+/-11.2 years. The sex ratio M/F was 1.5. Overall technical success rate was 80%. The analysis according to the type of cancer showed that the success rate was better in pancreatic cancer (81%) compared to cholangiocarcinoma (77%); this diffence wasn't sigificant in group C which included few patients this rate was 83% .

**Conclusion:** Palliative endoscopic biliary drainage is an effective method in biliopancreatic cancers. In our study, the important factors associated with success are low located stenosis, the prior dilation of the stenosis and the absence of duodenal stenosis.

**Keywords:** Biliary Cancer; Pancreatic Cancer ; Gallbladder Cancer ; Endoscopic Retrograde Cholangiopancreatography

## Introduction

Biliopancreatic cancers are common pathologies in current practice, and their incidence has been increasing for several years. These are cancers with a poor prognosis. The diagnosis of these neoplasms is generally made at an advanced stage and is based on imaging and histology.

Due to late diagnosis, most biliopancreatic tumors are subject to palliative treatment and make any curative surgical treatment impossible. This treatment is based on surgical diversions, endoscopic biliary drainage and percutaneous drainage allowing complete remission of jaundice and its complications with less post-interventional morbidity and mortality.

In this context, endoscopic biliary drainage techniques have received particular attention as an effective and safe therapeutic option, which may improve the patient's quality of life compared to the more invasive nature of surgery and/or percutaneous transhepatic biliary drainage approaches.

Currently, endoscopic retrograde cholangiopancreatography (ERCP) remains the cornerstone and technique of choice for endoscopic biliary drainage. Its widespread use and high success rate, especially in expert hands, make it an effective method for biliary drainage.

However, in case of failure or inaccessibility of cannulation, ultrasound-guided endoscopic biliary drainage techniques have become second-line options. They have emerged as second-line options with comparable clinical outcomes. Our aim is to present the results of endoscopic biliary drainage in the palliative treatment of biliopancreatic cancers in our department, as well as the different factors associated with its failure or success.

## Materials and Methods

This is a retrospective descriptive and analytical study carried out in our department, between January 2002 and October 2023.

### Inclusion criteria

We included all patients with neoplastic biliary stenosis of the biliary-pancreatic junction (perihilar cholangiocarcinoma, pancreatic cancer and calculocancer) and who benefited from endoscopic biliary drainage as part of palliative treatment.

### Exclusion criteria

- Resectable biliary-pancreatic cancer in operable patients
- Patients whose files are not usable due to missing data.
- Patients with distal cholangiocarcinoma or papillary tumor
- Patients with benign biliary stricture or biliary stricture secondary to extrinsic compression of the biliary tract by locoregional extension of a tumor other than pancreatic or biliary tract cancer.

### Intervention methods

Our patients were subject to a well-established operating sheet to collect the various data

- Demographics: Age and sex of patients
- Diagnosis (Cholangiocarcinoma, pancreatic cancer, calculocancer)
- Type of imaging: CT/MRI
- The location of the stenosis
- The appearance of the stenosis
- Presence or absence of duodenal stenosis (pancreatic cancer)
- Dilation of the stenosis during ERCP
- Type of prosthesis used
- Immediate success or failure of drainage

The patients were divided into 3 groups

- **Group A** for patients with perihilar cholangiocarcinoma.
- **Group B** for patients with pancreatic cancer.
- **Group C** for patients with calculocancer.

All ERCPs were performed under general anesthesia with intubation, by an experienced endoscopist.

### Evaluation methods

We evaluated only the technical success (immediate) which is defined as the placement of plastic or metal prostheses covering the entire stenosis and exceeding it proximally and distally, draining at least 50% of the segments.

The other factors studied were

- Sex,
- Age,
- Type of imaging (CT or MRI)
- Location and appearance of the stenosis
- The presence or absence of a duodenal stenosis (pancreatic cancer)
- Whether or not endoscopic dilation of the stenosis was performed before placement of the prosthesis.
- Type of prosthesis placed.

### Statistical methods

- The data were analyzed using SPSS software. Quantitative variables were expressed as means ± standard deviation and analyzed using the Student t test, qualitative variables were expressed as percentages and numbers and analyzed using the Chi-square test.

Factors associated with the overall success of endoscopic biliary drainage were studied using a binary logistic regression model in univariate and multivariate analysis.

A value of $p < 0.05$ was considered statistically significant.

## Results

### Epidemiological data

### Age

- The mean age of our patients was 64 ± 11.2 years with extremes ranging from 25 to 93 years.
- The sixth decade was the most represented in our series.

### Sex

Our series was characterized by a male predominance with a sex ratio (M/F) estimated at 1.5.

### Diagnostic data

### Etiological diagnosis

In 270 patients, biliary stricture was due to:

- Perihilar cholangiocarcinoma (group A) in 93 cases, or 35%
- Pancreatic cancer (group B) in 147 cases, or 54%
- Calculocancer (group C) in 30 cases, or 11%

### Type of imaging

- 17.4% of patients had a abdominal scan
- 82.6% of patients had an bili magnetic resonance imaging (MRI)

### Therapeutic data

### Dilation of the stricture

Thirty-seven percent of patients had a dilation of the stricture before the placement of biliary prostheses.

### Therapeutic success

The overall success was 80%.

The comparative study of the success rates observed in the 3 groups did not show any significant difference. (p = 0.712)

### Factors associated with failure and success

In univariate and multivariate analysis, and by adjusting for the parameters studied concerning the 3 groups of our study (the type of biliopancreatic cancer : group A, B and C, the location of the stenosis, the appearance of the stenosis, the presence of a duodenal stenosis in the case of pancreatic cancer, the practice or not of an endoscopic dilation of the stenosis before the implantation of the prosthesis and the type of prostheses).

The predictive factors for failure of biliary drainage were: the presence of duodenal stenosis in pancreatic cancer while the presence of low bile duct stenosis and endoscopic dilatation of the stenosis before insertion of the prosthesis were predictive factors for the success of biliary drainage.

Indeed, the presence of low bile duct stenosis and endoscopic dilatation of the stenosis before insertion of the prosthesis reduced the risk of failure by 66% (OR = 0.338, p = 0.028) and 76% (OR = 0.240, p = 0.005), respectively; while the presence of duodenal stenosis multiplied this risk by 8.4 (OR = 8.4, p = 0.001).

In order to refine our results, we studied the factors associated with the failure of biliary drainage within each group of the study

Concerning the group, only the appearance of the stenosis on imaging was predictive of failure in univariate and multivariate analysis while the dilation of the stenosis before the placement of the prosthesis was rather a predictive factor of success.

Indeed, the tight appearance of a stenosis multiplies the risk of failure by 2.9; while the dilation of the stenosis before the placement of the prosthesis increases the success by 87%.

Concerning group B, the presence of a duodenal stenosis was a predictive factor of failure in univariate and multivariate analysis while the location of the stenosis at the level of the lower common bile duct was a factor associated with success.

In fact, low bile duct stenosis reduces the risk of failure by 78%, while the presence of duodenal stenosis multiplies this risk by 44.

For group C, the tight aspect of the stenosis was a predictive factor for biliary drainage failure in univariate and multivariate analysis, while dilatation of the stenosis before stent placement was associated with success. That said, the tight aspect of the stenosis multiplies the risk of failure by 2.23, while dilatation of the stenosis before stent placement reduces this risk by 78%.

## Discussion

### Indications for drainage

### Cholangiocarcinoma and calculocancer

### Preoperative temporary drainage [1]

The objective of endoscopic drainage of cholangiocarcinoma preoperatively is threefold: to relieve hepatic biliary congestion (and hepatocyte distress), to restore the presence of bile in the digestive tract (and thus reduce the risk of bacterial translocation) and to reduce icteric cholestasis (to treat possible pruritus and protect renal function and especially to avoid cholangitis).

The European Society of Digestive Endoscopy (ESGE) through the latest published guideline has retained as indications for preoperative biliary drainage [2]

- Cholangitis
- Severe jaundice (bilirubin > 300µmol)
- Neoadjuvant chemotherapy or radiochemotherapy.
- Delayed surgery
- Right hepatectomy considered
- Volumetric modulation (portal embolization): drain the future remaining liver

Preoperative temporary drainage most often uses self-expandable covered metal prostheses or plastic prostheses.

The time required between biliary drainage and surgery is not defined. It lasts as long as it takes to allow blood levels of bilirubin and transaminases to return to normal or almost normal values.

### Palliative biliary drainage

Drainage in the event of biliary obstruction is the first step in therapeutic management. It is urgent in the event of cholangitis. It is essential if normal bilirubin levels are required before chemotherapy.

It must be entrusted to a center with expertise in interventional biliary endoscopy and radiology. Cholangio-MRI is the examination of choice for planning the placement of drain (s) or prosthesis (es).

Palliative biliary drainage prolongs patient survival. Drainage should be as anatomically complete as possible. It should focus on functional areas. The iatrogenic risk should be minimized and should therefore include perioperative antibiotic therapy and concern any area opacified during cholangiography [3].

The ESGE recommends that biliary drainage of perihilar cholangiocarcinoma should be performed by endoscopic retrograde cholangiopancreatography (ERCP) rather than percutaneously or surgically [2].

## Pancreatic cancer

Preoperative biliary drainage

The indications for preoperative biliary drainage should be selective, as it increases the morbidity of surgery and can lead to serious complications such as necrotizing pancreatitis, and can sometimes definitively contraindicate curative surgery [4]. Before curative surgery, biliary drainage is indicated in cases of jaundice associated with the following conditions [5]

- Severe hyperbilirubinemia (threshold between 250 and 300 µmol/l-Grade C)
- Angiocholitis
- Renal failure related to hyperbilirubinemia
- Need to postpone surgery (operability assessment, renutrition, neoadjuvant chemotherapy) (expert opinion).

The endoscopic retrograde approach should be preferred because of its lower immediate morbidity [6], the absence of excess risk of peritoneal carcinomatosis and the possibility of confirming the diagnosis by biopsy. Short metal stents ≤ 6 cm should be preferred to long stents and plastic stents [7].

## Palliative biliary drainage

In palliative situations, biliary drainage is indicated in the event of symptoms and retrograde endoscopic treatment using a biliary prosthesis should be chosen as first-line treatment.

According to the 2019 National Cancer Institute recommendations, the retrograde endoscopic approach is recommended as first-line treatment in 2019 (Grade B) by placing a metal stent preferably over a plastic stent [6-8].

In the event of failure of the retrograde endoscopic approach, an approach guided by endoscopic ultrasound should be used in preference to the percutaneous approach (Grade C). No recommendation between a covered metal stent and an uncovered metal stent can be made (Grade A).

With regard to pancreatic cancer in our series, palliative biliary drainage concerned 45% of cases of locally advanced pancreatic cancer and 55% of cases of inoperable metastatic cancer.

## Biliary drainage by plastic prosthesis vs. metal prosthesis Cholangiocarcinoma and calculocancer

Uncovered metal prostheses are permeable for longer than plastic prostheses, particularly in the absence of liver metastases and for a tumor size < 3 cm and a subhilar location. Uncovered hilar metal prostheses should be strictly reserved for palliative treatments.

According to some authors, the placement of a unilateral metal prosthesis on a hilar tumor obstacle could be as effective as bilateral placement provided that more than 50% of the liver volume is drained [7-9].

Several meta-analyses have compared the effectiveness of plastic prostheses and metal prostheses in the treatment of cholangiocarcinoma; these meta-analyses have shown different results. All these studies showed favorable patency in the metal graft group [9], but better overall survival in the metal graft group was demonstrated in only half of the meta-analyses [10-14].

Only one meta-analysis showed lower rates of cholangitis and a reduction in the need for reinterventions for patients who received metal grafts [13,14]. Metal graft drainage has been shown to be associated with lower overall failure rates (OR 0.43; 95% IC: 0.27-0.67), lower rates of graft stenosis (OR 0.28; 95%IC: 0.19-0.39), and lower reintervention rates (OR : 0.59; 95%IC: 0.28-0.90; I2 = 76.4%) [15,16].

In view of the results demonstrated in these different studies, metallic prostheses are chosen as first-line treatment in endoscopic biliary drainage of perihilar cholangiocarcinoma.

In our series, for perihilar cholangiocarcinoma and calculocancer, uncovered metallic stents 10 or 12 cm/8 or 10 mm were used in 62% of patients, while 15% of patients benefited from drainage by plastic prosthesis (since their life expectancy was judged to be less than 4 months), the rest of the patients did not benefit from biliary drainage given the failure of retrograde catheterization.

### Pancreatic cancer

In palliative situations, biliary drainage is indicated in the event of symptoms (cholangitis, pruritus, bilirubin levels incompatible with palliative chemotherapy) and a retrograde endoscopic approach using a metallic prosthesis should be chosen as first-line treatment.

No recommendation between covered and uncovered metal prosthesis can be made, unless the diagnosis is not confirmed at the time of biliary drainage. In this case, an extractable covered prosthesis is preferable, despite a higher risk of migration. In our study, 70% of our patients benefited from biliary drainage by uncovered metal prosthesis of 6cm or 8cm/10mm, while 11% of patients were drained using plastic prostheses (life expectancy < 4 months).

## Results

The success of endoscopic treatment varies in the literature between 50% and 100%. The overall success of biliary drainage in our study was 80%, which is consistent with the results in the literature. However, this success differs from one cancer to another depending on its location.

For cholangiocarcinoma, a study carried out by A.M Kuelen [17] in., *et al*. in 2022 in 161 patients who benefited from endoscopic biliary drainage for palliative purposes showed a success rate of 77%. In our study, the success rate was 77%.

Three studies [18-20] focused on the endoscopic treatment of pancreatic cancers, showing that the success of endoscopic treatment was greater than 70%, including that carried out by Paik., *et al*. in 2018, which included 61 patients and concluded a success rate of 77%. In our study, this success rate was 81%.

As for calculocancer, the success of endoscopic drainage in the literature varies between 75% and 91%. A systematic review including 72 studies published by Mohan [21]., *et al.* in 2020 concluded an endoscopic drainage success rate of 83%, which represents the same success rate in our study.

In the literature, there are few studies that have evaluated the predictive factors for immediate failure of endoscopic biliary drainage in biliopancreatic cancers. The most recent was conducted by B. C. Martins., *et al.* [22] in 2023 having concluded that only the anatomical classification of Bismuth influenced the success rate, that Bismuth IV multiplied the risk of failure by 5.

Another study concerning bilateral drainage in cholangiocarcinoma carried out in 2017, showed that there was a positive correlation between the angle formed by the axis of the first released prosthesis and the other hepatic duct to be catheterized and the failure rate, in fact an angle greater than 49.7° is a predictive factor for failure of bilateral biliary drainage [23].

In other studies such as that carried out by J.K Wiggers., *et al*. [24] in 2015 a bilirubin level greater than 88mg/l was demonstrated as a factor associated with failure, since the latter is correlated with the importance of the stenosis. Other predictive factors of failure have been found in the literature, including: the presence of duodenal stenosis, papillary invasion in pancreatic cancer and an inaccessible papilla, particularly in the case of gastric surgery (Billroth type I anastomosis).

### Predictive factors of success

The predictive factors of success of biliopancreatic endoscopic biliary drainage in the literature have been analyzed in several studies, Vienne A., *et al.* [25] found through a retrospective study including 107 patients carried out in 2011 that drainage of more than 50% of the liver, most often bilateral drainage, was associated with a better success rate of endoscopic drainage of tumor hilar stenoses (OR 4.5, p = 0.001).

Other studies have considered the primary nature of malignant biliary stricture and dilatation of the stricture before placement of the biliary prosthesis as predictive factors for the success of palliative and curative endoscopic treatments. In our study, the presence of a stricture at the level of the lower bile duct and endoscopic dilatation of the stricture before placement of the prosthesis were predictive factors for success.

### Complications

### Early complications

Early complications occur from the end of the procedure to 30 days after drainage in 5% of patients. They are distributed as follows: biliary infection (1 to 8.2%), pancreatitis (3.5 to 9.7%), bleeding (23%), perforation (6%), early migration of prostheses (3%) [26].

### Biliary infection

Post-ERCP biliary infection is a serious complication that is fatal in 1% to 8.2% of cases and can be prevented by complete biliary drainage [27,28]. Biliary infection [28] can be in the form of

- **Cholangitis (0.5 to 3%):** it is due to malposition of the prosthesis with ineffective drainage, early displacement or migration, early obstruction (clots, tumor buds, sludge).
- **Acute cholecystitis (0.5 to 5.2%):** it is favored by tumor invasion of the cystic duct. In this case, avoid severe gallbladder opacification during retrograde cholangiography.

The use of sterile equipment allows the patient to be contaminated only by his commensal flora and avoids nosocomial infections by multiresistant germs (pseudomonas aeruginosa). It also seems useful to reduce the number of manipulations [29].

### Pancreatitis

Post-ERCP acute pancreatitis is the most common and unpredictable complication of biliary endoscopy. Its frequency is 3.5 to 9.7%, depending on the thresholds of hyperlipaemia used for diagnosis [30].

Recent ESGE recommendations target rectal administration of nonsteroidal anti-inflammatory drugs for procedures with low risk of post-ERCP pancreatitis and prophylactic placement of pancreatic stents in high-risk conditions, including biliary sphincterotomy, biliopancreatic cannulation, and the simultaneous presence of several risk factors for post-ERCP pancreatitis [31].

### Hemorrhage

Post-ERCP hemorrhage has been suggested to be related to the sphincterotomy and not to the stent [32]. On the other hand, a study showed that it was more frequent in cases of hemostasis disorders and that it was not linked to the taking of aspirin or non-steroidal anti-inflammatory [33]. Their frequency is less than 0.3 to 9.6%. It is immediate in 90% of cases and exceptionally gives rise to delayed symptomatic hemorrhage [34].

### Duodenal perforation

This is a rare complication, its frequency is approximately 0.08 to 0.6% [35].

### Late complications

As for late complications (after 30 days), they occur in 9 to 37.5% [36,37].

### Prosthesis dysfunction

### Late obstruction of the prosthesis

The occlusion of the endoprosthesis is caused by sludge (in plastic endoprostheses) or by tumor growth or proliferation (metal prosthesis).

- In plastic biliary prostheses, obstruction occurs by biliary sedimentation, after a period of 3 to 4 months. This complication is the main limitation of plastic prostheses used in the palliative treatment of jaundice due to neoplastic stenosis of the main bile duct. Often revealed by a recurrence of jaundice or by cholangitis, it requires replacement of the latter after endoscopic extraction (loop, forceps or Soehendra extractor) [38].

In metal biliary prostheses, obstruction can occur by two mechanisms

- Either by tumor progression which obstructs the prosthesis through the mesh, or its upper pole when they are covered,
- Or by precipitation of bile as in plastic prostheses. This complication is treated by the placement of a plastic endoprosthesis or a second expandable prosthesis in the lumen of the obstructed metal prosthesis.

When the mechanism is tumor invasion, it is possible to perform destruction by electrocoagulation, prior to the placement of the second prosthesis inside the first obstructed prosthesis. This electrocoagulation can be done without any risk with an argon plasma electrocoagulation probe at 60-70 watts of power [39].

### Prosthesis migration

A migration of the prosthesis can occur, either inside the bile duct favoring the occurrence of cholangitis or biliary perforation, or towards the duodenum, and migrate into the intestine [40].

According to ESGE data, migration phenomena are described for 5% of partially covered plastic and metal prostheses, 1% of uncovered metal prostheses and 20% of covered metal prostheses [41].

Displacement, whether early or late, can be prevented by the use of lug prostheses. Treatment consists of replacing the prosthesis more adequately. When the displacement consists of an ascension of the prosthesis in the bile duct: it is then sometimes difficult to recover it, especially if it exceeds the stenosis [29].

### Others

- **Prosthesis fracture:** This is a rare complication that probably depends on the material used [29]. It occurs late after placement (3 to 8 months), at the base of the spurs and seems to be favored by migration [42].

- **Cholecystitis:** Neoplastic invasion of the cystic duct and the gallbladder are the main risk factors for acute cholecystitis, particularly in the case of a metal prosthesis. Cholecystitis must be treated on a case-by-case basis either by cholecystectomy or by percutaneous drainage of the gallbladder in fragile patients [31].

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### Endoscopic vs. percutaneous biliary drainage

Endoscopic biliary drainage has been performed much more than percutaneous drainage in the context of biliopancreatic cancers. Several meta-analyses [43-46] have been conducted and have concluded that endoscopic biliary drainage has not shown any significant advantages over percutaneous drainage.

The latter has allowed to obtain a better therapeutic success rate and a lower incidence of complications including cholangitis, however no difference was found concerning 30-day mortality and pancreatitis.

In practice, it is advisable to choose between endoscopic and percutaneous drainage, depending on the location of the stenosis, the indication and the interest of drainage (in the context of neoadjuvant or palliative treatment) and the level of experience in the different centers.

Generally percutaneous drainage is performed in patients with perihilar cholangiocarcinoma infiltrating the intrahepatic biliary branches contraindicating or making endoscopic drainage impossible or ineffective.

## Conclusion

Biliopancreatic drainage represents an appropriate therapeutic means for biliopancreatic cancers that have a poor prognosis; thus reducing the occurrence of complications and allowing patients to undertake a good quality of life.

However, endoscopic drainage remains a challenge for endoscopists and requires a specialized team capable of offering a variety of interventions depending on the location of the biliopancreatic stenosis, the presentation of the disease, and the life expectancy of the patients.

In our study, which included 270 observations, we tried to elucidate the factors associated with the success or failure of drainage, and we concluded that the predictive factors for failure of biliary drainage were: the tight aspect of the stenosis and the presence of duodenal stenosis in pancreatic cancer, while the presence of a stenosis of the lower bile duct and endoscopic dilatation of the stenosis before the placement of the prosthesis were predictive factors for the success of biliary drainage.

By integrating these factors into patient management, it is possible to optimize the results of endoscopic biliary drainage for patients with biliopancreatic tumors, thus opening the way to more targeted and effective strategies in the field of interventional gastroenterology.

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