Percutaneous treatment in malignant biliary obstruction: a prospective study

Poster No.: C-2620
Congress: ECR 2015
Type: Scientific Exhibit
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Keywords: Interventional non-vascular, Biliary Tract / Gallbladder, Oncology, Percutaneous, Fluoroscopy, CT, Stents, Cholangiography, Drainage, Obstruction / Occlusion, Multidisciplinary cancer care, Outcomes
DOI: 10.1594/ecr2015/C-2620

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Aims and objectives

Malignant biliary tract obstruction (MBO), due to either primary biliary or non-biliary tract cancer or metastasis to the porta hepatis, is a common clinical problem. Obstructive jaundice in patients with non-biliary tract cancer occurs because of neoplastic infiltration of the common bile duct; other mechanisms may be metastasis to abdominal lymph nodes, hepatoduodenal peritoneum or the liver, infiltration from cholangiocarcinoma (CCA) or gallbladder cancer etc.

Patients with tumors causing biliary tract obstruction are often asymptomatic or have non-specific symptoms until the disease is significantly advanced. Therefore at the time of diagnosis most patients, besides being unfit for surgery, have a very poor prognosis, with a life expectancy of approximately 3-16 months with unresectable CCA [25, 14, 30]; and 1-6 months in patients with MBO due to advanced/recurrent colorectal or gastric cancers [4-6]. To overcome this clinical challenge, several strategies, including percutaneous and endoscopic intervention, adjuvant surgery, adjuvant chemotherapy or radiotherapy, brachytherapy [53] and the multimodality approach [22-23], have been proposed with the hope of extending survival rates.

Treatment in the form of surgical bypass has not been demonstrated to be superior to stenting [15]. Furthermore, stenting procedures resulting in adequate biliary drainage have improved survival. In recent years, endoscopic retrograde biliary drainage (ERBD) has overtaken percutaneous transhepatic biliary drainage (PTBD) as the initial procedure of choice in patients with distal bile duct obstruction [32, 41]. In contrast, the percutaneous approach is considered the treatment of choice for inoperable malignant hilar biliary strictures (Klatskin tumor) [31, 40, and 51].

However, the current use of plastic or metallic stents placed by percutaneous approach, is a well established palliative treatment for decompression of malignant biliary obstruction in patients affected by advanced disease [2, 3, 7-13]. Other less costly alternatives include internal-external percutaneous transhepatic biliary drainage (PTBD), while patients unfit for stent placement, may undergo external biliary drainage.

The objective of our study as an ongoing prospective study is to evaluate the outcomes of percutaneous intervention in patients with malignant biliary obstruction over a 17 month period, comparing our findings with those from previous similar studies [1, 4, 7, 9-10, 14, 16, 29].
Methods and materials

From March 2013 to August 2014, we treated and followed 28 patients with malignant biliary obstruction who were referred to our center for percutaneous decompression of biliary tract.

Patients' Selection Criteria

Patients were selected for percutaneous treatment based on laboratory, radiological, anatomic-pathologic findings, the patients' clinical-status, and co-morbidities. Criteria such as locally advanced disease (meaning unresectable patients) and/or not meeting criteria for surgery, constituted referral for percutaneous treatment. Percutaneous treatment was the only available technique offered to the patients, which constituted a peculiar aspect of our study as compared to other similar studies [1, 4, 7, 9-10, 14, 16, 29].

Patients' Preparation

Patients' fitness for the percutaneous treatment was assessed taking in consideration their coagulation time, findings which were within the generally accepted range.

All patients were treated with broad-spectrum antibiotics. Pain relief was achieved with conscious sedation.

Procedure Selection Criteria

All patients first underwent percutaneous cholangiography for better visualization of the site and extention of the obstruction.

Taking in consideration the patient's life expectancy, stent placement was performed for palliation, otherwise internal-external percutaneous biliary-drainage was performed as a less costly alternative.

Stent selection was patient- and operator-dependant, in accordance with the estimated cost-effectiveness and the expected patients' survival time (preferring metallic stents vs. plastic stents for patients with longer expected prognosis of the disease and vice versa); patients consensus was also an impacting factor (due to the high cost of either stents [especially of the metallic stents] compared to drainage catheter).

When stenting was not possible, patients were drained externally.

Interventional Radiology Procedure
All patients underwent percutaneous cholangiography, which demonstrated the level of neoplastic infiltration of the bile duct, the extension of the malignant stricture (example fig. 1, 8). In accordance with such findings the treatment options were offered to the patient.

The classic interventions in the case of stent placement were attempted as a two-stage procedure, internal-external biliary drainage for 3 weeks followed by stent placement (example fig. 1-7). The main reason was to improve stricture crossing by allowing inflammation reduction during the period of 3 weeks of biliary drainage. Other reasons included giving time for fibrous adhesion creation at the level of percutaneous puncture to avoid a possible biliary peritonitis, and also improvement of jaundice symptoms and the clinical condition of the patients.

Decompression of the bile ducts was confirmed with cholangiography after internat-external biliary drainage placement.

On the second stage (3-weeks later), a percutaneous cholangiogram was performed, followed by placement of the definitive stent along the stricture (example fig. 2-3, 7). Stent insertion was considered successful when deployment of the stent across the stricture was achieved with immediate flow of contrast on the control cholangiography.

Stent placement was considered effective if followed by a fall of 30% of the pre-procedure bilirubin levels within 30 days of the original procedure in our patients, along with improvement in the symptoms of obstructive jaundice.

Stents used were: plastic stents (Wilson-Cook stent double Miller mushroom) and metallic stents (Cook Zilver Metallic stent).

**Patients' Follow Up**

After the procedure, patients were hospitalized for one day and followed up to identify early complications and stent occlusion. The criteria suggested by Cotton et al [20] were used.

Patients were then referred to follow up on a regular basis by the clinician with laboratory tests and ultrasound examination every 3 months, and CT-examinations upon clinical suspect for recurrence etc.

Patients clinical status and preserved stent patency were recorded as confirmed through the improvement of the bilirubin levels.
Fig. 1: Sh.D., 41 year old female, who had previously undergone surgery for right colic flexure carcinoma. Due to the locally advanced disease, the patient's poor clinical conditions, and experience of our center, the patient was referred for percutaneous transhepatic biliary drainage and then was successfully stented with Wilson-Cook stent double Miller mushroom. Fig. 1, Percutaneous Cholangiography before the procedure (obstruction level showed with red arrow).

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Fig. 2: The same patient as in the previous image (fig. 1); plastic stent placement procedure is shown here.

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Fig. 3: The same patient as in the previous images (fig. 1, 2); plastic stent placement procedure is shown here.

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Fig. 6: K. Z., 59 years old male, who had undergone previous surgery for stomach carcinoma, came to our center because of obstructive jaundice owing to disease recurrence. Due to the locally advanced disease, the inability to drain the patient through the endoscopic route and the poor clinical conditions, the patient was referred for biliary drainage. The patient first underwent internal-external biliary drainage (please note that due to the high cost of the procedure he at first refused stent placement).

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Fig. 7: The same patient as in the previous image (fig. 6). Six months after internal-external biliary drainage he experienced cholangitis, pancreatitis (as late complications), subsequently (considering among other factors the life expectancy) the patient underwent metallic stent placement (as shown in this image) which he had previously refused.

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Fig. 8: I.M., 77 years old male, diagnosed with hilar cholangiocarcinoma is depicted in this image and the next one (fig. 8, 9). The patient received a left-sided external drainage due to non accessible right-sided route (fig. 9). He was the only patient with left-sided drainage out of a total of 21 patients who were drained externally.

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Fig. 9: The same patient as in the previous image (fig. 8), left-sided external drainage due to non accessible right-sided route is shown here.

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Results

During the given period, 28 patients suffering from malignant biliary obstruction (MBO) were treated (35 procedures in total, as 7 patients underwent more than one procedure):

# 3 patients underwent percutaneous plastic stent placement (fig. 1-3; see table 1) after the 1st stage biliary drainage (as explained in the materials and methods).

# 5 patients underwent internal-external percutaneous biliary drainage (fig. 6, 10, 11-12; see table 1), from whom 1 patient underwent metallic stent placement due to late procedure related complications (fig. 6-7). Please note that in the latter case, it was the patients' choice in the 1st place to chose internal-external biliary drainage (fig. 6) over stent placement, then after procedure related complications occurred the patient accepted to undergo metallic stent placement (fig. 7).

# 21 patients were drained externally (fig. 8-9; see table 1), in 5 of these patients the stricture could be crossed, but they refused any further technique (mainly due to the cost of the other procedures). 3 patients underwent a 2nd procedure due to external drain tube occlusion.

# Only 1 patient underwent left sided external biliary drainage, due to inability to access the right biliary tract for decompression (fig. 8-9).

In summary, the level of obstruction was defined as perihilar in 21 patients (in 3 pts the infiltration extended up to the common bile duct [CBD]) and as distal in 7 patients.

2 out of the 21 patients (pts) with perihilar biliary obstruction underwent percutaneous biliary stent placement (PBSP), 4 were eligible for stent placement but refused either PBSP or internal-external percutaneous transhepatic biliary drainage (PTBD). While the others underwent internal-external PTBD, or external biliary drainage alone when crossing of the stricture was not possible (see table 1 for detailed results).

2 out of 13 patients with distal biliary obstruction underwent PBSP, in both of these patients the stricture extended up to the CHD; 1 patient was eligible for stent placement but refused either PBSP or internal-external biliary drainage. While the others underwent internal-external PTBD, or external biliary drainage alone when crossing of the stricture was not possible (see table 1 for detailed results).
<table>
<thead>
<tr>
<th>Level of Obstruction</th>
<th>No. pts</th>
<th>Patients' Eligibility</th>
<th>Procedures</th>
<th>Total Procedures per Level of Obstruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perihilar(^1)</td>
<td>18</td>
<td>6 pts eligible for PBSP</td>
<td>2 out of 6 pts underwent PBSP&lt;br&gt;4 out of 6 pts refused &amp; underwent external drainage</td>
<td>2 pts with PBSP&lt;br&gt;#15 pts external drainage</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7 pts eligible for external drainage ##</td>
<td>7 pts underwent external drainage</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 pts eligible for internal-external PTBD #</td>
<td>4 pts refused &amp; underwent external drainage</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 pts underwent internal-external PTBD</td>
<td>1 pts with internal-external PTBD</td>
</tr>
<tr>
<td>Distal(^2)</td>
<td>10</td>
<td>3 pts eligible for stent placement</td>
<td>2 pts underwent PBSP&lt;br&gt;1 pts refused, and underwent external drainage</td>
<td>2 pts with PBSP&lt;br&gt;#6 pts with external drainage</td>
</tr>
</tbody>
</table>
Patients with perihilar biliary obstruction included:

- 14 patients with hilar obstruction (at the level of either right / left hepatic biliary duct or/and the common hepatic duct (CHD)), in 1 of these patients the infiltration extended up to the level of common bile duct (CBD);
- 6 patients with obstruction at the level of CHD from which in 3 of these patients the infiltration extended up to the CBD).

Patients with distal biliary obstruction: 7 patients (obstruction at the level of the CBD).

Mainly due to the cost-effectiveness of internal-external PTBD in comparison to percutaneous transhepatic stent placement (PTSP). See materials and methods for further details.

Mainly because the stricture couldn't be crossed. See materials and methods for further details.

In our series, most of the patients suffered MBO due to cholangiocarcinoma (see table 2 for detailed results).

**Table 2. Causes of malignant biliary obstruction in our pts**

*(in order of decreasing approximate frequency)*

<table>
<thead>
<tr>
<th>Cause</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholangiocarcinoma</td>
<td>18 patients</td>
</tr>
<tr>
<td>Pancreas Head Carcinoma</td>
<td>6 patients</td>
</tr>
<tr>
<td>Stomach Carcinoma</td>
<td>2 patients</td>
</tr>
<tr>
<td>Gallbladder Carcinoma</td>
<td>1 patient</td>
</tr>
</tbody>
</table>

(64%)
Colon Carcinoma 1 patient (4%)

# In relation to complications, only 1 patient experienced early complications and mortality due to persistence of the preprocedure hepatorenal insufficiency and died within 3 days of the procedure (see table 3).

Late-complications were recorded in only 1 patient (table 3). These late complications consisted mainly of cholangitis and pancreatitis. Afterwards the patient underwent metallic stent placement with resolution of the symptoms and improvement in clinical status (fig. 6-7).

No other patient experienced early or late complications. 3 patients are still in follow-up, 3 patients didn't show up for routine-check.

<table>
<thead>
<tr>
<th>Table 3. Complications Rate in 28 pts</th>
</tr>
</thead>
<tbody>
<tr>
<td>All complications</td>
</tr>
<tr>
<td>Late</td>
</tr>
<tr>
<td>Early</td>
</tr>
</tbody>
</table>

#Resolution of complications was recorded after metallic stent placement.

##Patient was hospitalized for hepatorenal insufficiency (level of bilirubin up to 40mg/dl), which was present prior of the procedure and persisted after the procedure. Subsequently the patient died within 3 days of the procedure.

# In relation to the success of the percutaneous procedures, accurate drainage was achieved in all patients in whom the stricture was crossed successfully (pts who underwent internal-external PTBD or PTSP), with decompression of the biliary tract in all of them, as noticed by an initial gradual decrease of bilirubin levels; and a fall of 30%
of the initial bilirubin levels was recorded one month from the procedure in all of these patients. A significant improvement of patients' clinical status was recorded, as well.

# Average-survival-time was 8 months for patients who underwent PTSP (4 pts in total). 2 patients are still in the follow up process.

These findings were similar to that recorded in previous studies; thus similar studies have shown that in patients with CCA, percutaneous stent placement has been successful in 69-97%, with a 30-day mortality of 0-24%; while mean survival time is 3-23 months [2, 3, 7-13]. Percutaneous stent placement has shown useful in achieving biliary decompression and also in improving hepatic function [4, 21], making it possible for patients to undergo chemotherapy safely, as chemotherapeutic agents are often implicated in causing liver damage.

# Percutaneous biliary drainage is one of the most challenging procedures performed by interventional radiologists. Contraindications to PTBD and stent placement are relatively few but might include severe coagulopathy or ascites [42]. All of our patients were eligible for percutaneous treatment.

The reported technical success rate of percutaneous transhepatic cholangiogram / PTBD has between 90-95% [16, 33-35]. Related periprocedure mortality rates of 0.7 to 8.6% have been reported [16, 34]. Only 1 patient who underwent external biliary drainage in our series died due to hepatorenal insufficiency. Drainage-related complications such as hemorrhage, acute sepsis and pleural transgression can occur during the catheter placement [56-62], and delayed complications such as pericatheter bile leak, catheter dislodgement, catheter obstruction with or without cholangitis, and tumor spread along the catheter tract have been described [16, 35-39, 56-62]. None of our patients experienced procedure-related complications and had preserved stent patency (fig. 3-5, 7), with no signs of cholangitis.

In 3 patients previously treated with external biliary drainage, catheter obstruction was recorded at a later time and thus patients subsequently underwent a second procedure (external biliary drainage) with good outcomes in fall of bilirubin level and improvement of patients' clinical status.

In all these patients who underwent external biliary drainage or internal-external PTBD, a gradual decrease of the bilirubin levels was recorded with improvement of the clinical status, apart from the one above mentioned patient who due to hepatorenal insufficiency and extremely high bilirubin levels, didn't undergo a significant decrease of the levels of bilirubin.

The mean survival time of patients treated with internal-external PTBD or external drainage in previous studies has been recorded as 87.3 days [29]. In our series the mean survival time was relatively higher mainly due to the fact that some of the patients treated
with PTSP or PTBD were in a good clinical status and were fit for stent placement, but refused it due to the cost of the procedure, thus the prognosis of such patients was already better than of those in the other published series. 3 patients are still in follow-up, while 3 patients did not show for their routine medical checkup.

There has been some uncertainties on the choice of plastic or metallic stents for the optimal percutaneous or endoscopic palliation of patients with nonresectable malignant biliary obstruction [24]. Plastic stents have some advantages, including: less expense, technically easy insertion, and relatively easy removal and exchange when stent occlusion or malfunctions occur, but they have limited patency due to their narrow lumen and a higher chance of clogging because of the longer length of the stent. Comparative trials have shown that plastic stent patency is significantly prolonged by the use of larger caliber stents [35-39]. Metallic stents have been shown to be more cost-effective when placed, with fewer reinterventions needed and fewer hospital stay and costs in patients with longer life expectancies [33, 47], whereas plastic stents are superior for patients with life expectancies of 6 months or less [31, 51]. The long-term patency of metallic stents, on the other hand, is not good, with high occlusion rate by 6 months [48-50], other major limiting factors is that they may be difficult to remove and greater cost relative to plastic stents, that is another reason why plastic stents are more cost-effective in patients with poor life expectancy [51]. Although there are no clear data in the literature, the temporary use of plastic stents may be preferable also in cases of obstructive lesions that may respond to chemotherapy/radiotherapy (for e.g. lymphoma), in patients who have hilar lesions with multiple isolated biliary segments, or in patients whose histological diagnosis has yet to be made [31, 33, 47, 51]. Plastic stents were used in both of our patients with preserved stent patency and optimal palliation. More data are needed to show important comparative results in using plastic over metallic stents for percutaneous treatment of MBO, as we continue gathering data in the years to come our results will be more statistically significant. Also, 2 out of 4 patients treated with PTSP are still in follow-up.

There has been discussions regarding the use of one or multiple stents (unilateral versus bilateral) for the optimum approach. It is well known that only 25% of the liver volume requires drainage for adequate palliation of obstructive cholestasis in order to see improvement in biochemical parameters [32]. As previously shown, to achieve good percutaneous palliation, a single biliary stent in one functional liver lobe for unilateral drainage can provide adequate palliation in the majority of patients with hilar biliary malignancy. All of our patients were treated with only one stent or catheter placement.

A number of prognostic factors have been proposed as to the expected life expectancy. While survival rates depend on a wide range of factors, generally speaking cases that did not experience improvement of their liver functions after biliary stent placement had poor prognoses [6]. This may be due to the fact that most of these patients do not benefit
from the subsequent chemotherapy. In a few reports patients who improved their hepatic function after stent placement, and received subsequent chemotherapy after complete resolution of jaundice, survived longer [4-6]. We hereby emphasize that most of the studies confirm that life expectancy is mostly related to the underlying disease causing MBO [55], than to the success of the stent placement procedure. Thus, in our patients we noticed that younger patients, with better performance status, without lung metastasis, and who were chemo-naive seem to live longer, but further data in the years to come are needed.

In patients with CCA, the topographic classification has major prognostic value, too. In Western countries, approximately 60-70% of cases of CCA were reported to be hilar CCA (Klatskin tumor) [25-26, 14, 29], and these patients with hilar or intrahepatic CCA had worse clinical outcomes than those with distal CCA [26-27, 28-29]. Our patients with hilar CCA also had worse outcomes than the patients with non hilar MBO or with MBO due to other reasons than CCA.

It is clear that symptoms of obstructive jaundice can significantly impair quality of life. Apart from attempts to extend survival, the main goal of PTSP in unresectable patients with MBO is palliation, with relief from obstructive jaundice, pruritis, cholangitis, pain and quality of life improvement [15, 31, 54]. Our patients, after successful PTSP or PTBD or external biliary drainage reported relief of symptoms and a stable clinical condition. These findings are similar to that reported in previous series [4, 6, 54].

In summary, plastic stent placement for biliary drainage has evolved over the past three decades and has established itself as an important treatment modality in the management of patients with malignant obstructive jaundice. For an effective percutaneous biliary drainage, the selection of the appropriate stent according to the patient's condition and anatomical position is important. Also, acknowledgement and understanding of the advantages, disadvantages, and complications according to each type of stents are needed. Palliative therapeutic strategies should be made on an individual basis such as the experience of the center, patient condition, or surrounding medical curriculum. Multidisciplinary tumor boards with participation of medical oncologists, gastroenterologists and interventional radiologists must be where the decision is made.
Fig. 1: Sh.D., 41 year old female, who had previously undergone surgery for right colic flexure carcinoma. Due to the locally advanced disease, the patient's poor clinical conditions, and experience of our center, the patient was referred for percutaneous transhepatic biliary drainage and then was successfully stented with Wilson-Cook stent double Miller mushroom. Fig. 1, Percutaneous Cholangiography before the procedure (obstruction level showed with red arrow).

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**Fig. 2:** The same patient as in the previous image (fig. 1); plastic stent placement procedure is shown here.

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Fig. 3: The same patient as in the previous images (fig. 1, 2); plastic stent placement procedure is shown here.

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Fig. 4: The same patient as in the previous images (fig. 1-3) three months from plastic stent placement, confirming its patency. In this image and the next one (fig. 4, 5), enhanced abdominal computed tomography (CT) examination (as requested from the medical oncologist) is shown including CT scans at two different levels, where the presence of the plastic stent (red arrows) is noticed and its extension from the distal common bile duct (fig. 4) to the right hepatic duct in the next image (fig. 5).

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Fig. 5: The same patient as in the previous images (fig. 1-4). In this image the presence of the plastic stent (red arrows) is noticed in the right hepatic duct, as it extended from the distal common bile duct (previous image, fig. 4).

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Fig. 6: K. Z., 59 years old male, who had undergone previous surgery for stomach carcinoma, came to our center because of obstructive jaundice owing to disease recurrence. Due to the locally advanced disease, the inability to drain the patient through the endoscopic route and the poor clinical conditions, the patient was referred for biliary drainage. The patient first underwent internal-external biliary drainage (please note that due to the high cost of the procedure he at first refused stent placement).

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**Fig. 9:** The same patient as in the previous image (fig. 8), left-sided external drainage due to non accessible right-sided route is shown here.

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Fig. 10: B.Q., 83 years old male, diagnosed with cholangiocarcinoma at the distal portion of the common bile duct (red arrow). He received an internal-external biliary drainage; over-passing of the obstructed segment is shown here. The patient had significant decrease of bilirubin levels after the procedure, he is still on follow up.

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Fig. 11: S.S., 76 years old male. Fig. 12, 13, Coronal T2WI MRI image demonstrates hilar cholangiocarcinoma (red arrow) infiltrating the bile ducts with resulting intrahepatic bile duct dilatation. The next image (fig. 13) shows subsequent right sided internal-external biliary drainage.

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**Fig. 12:** The same patient as in the previous image (fig. 12). Right sided internal-external biliary drainage is shown here (white arrow).

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Conclusion

Percutaneous plastic stenting and drainage is a treatment of choice in carefully selected patients with hilar malignant biliary obstruction due to advanced or recurrent biliary and non-biliary tumors, with significant improvement in the quality of life, as a successful technique in extension of the survival time.

Percutaneous drainage and stenting were shown to be important lines of treatment in carefully selected patients with malignant biliary obstruction, particularly in those unfit for surgery and/or other treatment options, with good outcomes well beyond simply relieving the obstructive jaundice. Reasonable survival with good palliation is a common outcome and most patients do not require further interventions.

Our findings replicated previous similar studies [1, 4, 7, 9-10, 14, 16, 29] to a certain extent, considering that these results are our initial results as a prospective ongoing study.
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References


