Technical Feasibility, Short-Term Patency, Safety, and Efficacy of Percutaneously Delivered Double Pig-Tail Stent for Palliation of Unresectable Biliary Malignancies

Ashish Verma1,*  Ishan Kumar1,*  Pramod Kumar Singh  Tarun Kumar2  Durgatosh Pandey3

1 Department of Radiodiagnosis and Imaging, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India
2 Department of Surgical Oncology, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India
3 Department of Surgical Oncology, Mahamana Pandit Madan Mohan Malviya Cancer Institute, Varanasi, Uttar Pradesh, India

Address for correspondence Ishan Kumar, MBBS, MD, DNB, Department of Radiodiagnosis, Institute of Medical Sciences, Banaras Hindu University, Varanasi – 221005, Uttar Pradesh, India (e-mail: ishanjd@gmail.com).

Abstract

Purpose The aim of this study was to evaluate the technical feasibility, complication rate, and efficacy of percutaneously delivered plastic biliary stent, compared with that of internal–external biliary drainage catheter.

Methods Patients with unresectable malignant biliary obstruction were included who underwent percutaneous transhepatic biliary drainage and double pigtail plastic stenting (DPT-PS) or internal–external biliary drainage catheter in 15 months’ duration.

Results Seventy-seven patients were included in the study who underwent DPT-PS (n = 37) or internal external drainage catheter placement (n = 40). Overall, the technical success rate for percutaneous plastic stenting was 92.5% and technical success rate for primary stenting at the time of initial puncture was 62%. The incidence of fever and hemobilia was similar across the two groups, whereas bile leakage in the perihepatic space and through the skin at puncture site was higher in patients with internal–external drainage catheter. Both the techniques were effective in reducing the bilirubin levels of patients. Re-intervention was done in five patients in DPT-PS and six patients with ring biliary catheter.

Conclusion DPT-PS may be used as a viable cost-efficient alternative for unresectable biliary malignancies with low post-procedure life expectancy

Keywords

► plastic stent
► malignant biliary obstruction
► percutaneous transhepatic biliary drainage

* Ashish Verma and Ishan Kumar are first co-authors as their contribution is equal.

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**Introduction**

Malignant bile duct obstruction (MBO) can be caused by various tumors such as gall bladder cancer, cholangiocarcinoma, pancreatic head tumors, peripancreatic masses and due to extrinsic compression by malignant lymphadenopathy. The most common cancer worldwide is pancreatic cancer, while gall bladder cancer is the most frequent cause in India. The majority of these tumors are unresectable at the time of diagnosis and carries poor prognosis. The accumulation of bile in the intrahepatic biliary channels and resulting jaundice can significantly affect the quality of life, morbidity, and subsequently mortality in these patients. Drainage and decompression of the biliary tree forms an important step in the management of biliary duct obstruction due to malignant causes, especially in non-resectable cases.

Endoscopic biliary stenting (EBS) is the first-line approach to the treatment of MBO, especially in tumors affecting lower CBD and peripancreatic region (Bismuth type I malignant stricture). For hilar obstruction (types II and III), the optimal choice between endoscopic stenting and percutaneous transhepatic biliary drainage (PTBD) is not clearly established. In the endoscopic approach, two types of stents, i.e., self-expanding metallic stent (SEMS) and DPT-PS (PS) can be deployed. SEMS has a significantly longer patency time than DPT-PS but is significantly expensive compared with PS. In the percutaneous approach, three possible drainage techniques can be performed, i.e., (i) percutaneously delivered SEMS, (ii) internal–external ring biliary catheter, and (iii) external drainage PTBD catheter. No study has been performed to evaluate the technical success, and efficacy of percutaneous placement of DPT-PS.

The aim of this study was to evaluate the technical feasibility, complication rate, and efficacy of percutaneously delivered plastic biliary stent, compared with that of internal–external biliary drainage catheter.

**Materials and Methods**

**Subject**

This was a retrospective analysis performed on all patients who underwent percutaneous transhepatic biliary drainage during 15 months from June 2019 to August 2020. The study was approved by the institutional review board of Institute of Medical Sciences, Banaras Hindu University. Patients were included in our study if they fulfilled the following criteria. 

- **a**) Biliary obstruction due to malignant stricture based on pathology or cytology and if they had locally advanced disease based on staging by CT, magnetic resonance imaging, 
- **b**) failed endoscopic stenting attempt, and 
- **c**) nonresectable malignancy. Based on the type of internalization procedure, our study group was divided into two groups.

- **Group A:** Percutaneous placement of double pigtail biliary stent across the malignant stricture due to complete refusal from the patient party for self-expanding metallic stent due to financial constraint refusal in future.

- **Group B:** Percutaneous placement of internal external drainage catheter.

Patients who were lost to follow-up after the first month of stent placement, or patients in which internalization could not be performed, were excluded from this study. Also, patients who underwent previous PTBD procedure or endoscopic stenting were excluded. The choice among DPT and ring biliary catheters was decided in discussion with the patients relative based on their preference, ability to come subsequently for follow-ups, financial ability for subsequent exchange of ring biliary catheter with SEMS, etc. Patients who were willing to subsequently afford a SEMS or those who were willing to come for regular follow-up preferred the option of internal external drainage. While the patients who did not want any device externally protruding at the puncture site and those with advanced stage malignancy who could not afford SEMS preferred DPT-PS.

**Technique of Biliary Stenting**

The deployments were done by or under the supervision of a senior interventional radiologist with an experience of 17 years. The initial access to the biliary tree was secured by Seldinger’s technique using a puncture set (Neff-set, Cook Bloomington Inc., Indiana, USA) and ultrasound guidance, via a right subcostal or left subxiphoid approach depending on the anatomy and duct of choice for drainage. A J-tip 0.038” extra stiff wire guide was used to secure the access through the access sheath, over which a 6F vascular sheath was placed. The stricture was negotiated using an assembly of 0.038” straight tip glide wire with a 5F multipurpose catheter through the sheath and once the catheter reached the third part of duodenum, the glide wire was replaced by the stiff wire again (internalization). The hepatic track was dilated up to 8 French using serial fascial dilators, following which the double pigtail 7F DPT-PS was pushed over the wire using the non-tapered end of a 6F fascial dilator to position it across the stricture (primary internalization) (Fig. 1). After placement of the stent, the guidewire was withdrawn proximally to the stent in the intrahepatic biliary duct and a temporary external drainage Malecot’s catheter was placed to maintain access until the proper functioning of the stent was ascertained. In group B patients, 8F or 10F internal external drainage catheter (ring biliary catheter) was placed. In case of an inability to negotiate the stricture in the first attempt, a second attempt was made within a week to negotiate the stricture and place a DPT-PS (secondary internalization) or ring biliary catheter. In cases, where internalization attempt failed, the patient was discharged with 8F external drainage catheter.

**Follow-Up and Outcome Measures**

Assessment of the outcome measures was done at three points-in-time, namely, immediately (within 24 hours) after the procedure, within 3 months (short-term), and within 6 months (long-term). A direct patient contact for assessment by ultrasonography and sampling of sera for bilirubin was performed. Placement of the stent across the stricture.
with its proximal end placed proximal to stricture and a
distal end in the duodenum distal to the ampulla (► Fig. 2).
The efficacy and immediate patency were defined when at
least 30% reduction of serum bilirubin level was noted within
1 to 2 weeks of the procedure. The DPT-PS was considered to
be efficacious and patent in the short term if adequate
decompression of biliary radicals was documented on ultra-
sonography at least twice following the procedure, initially
after the first week, and then within 3 months.

The complications were labeled as being peri-procedure
if the same occurred within the first day of the procedure.
All subsequent complications occurring within the first
week were labeled as post-procedure complications. After
that and until the last available follow-up, the complications
were labeled as short-term complications. Stent occlusion
was defined as elevated liver enzymes, dilatation of the
intrahepatic biliary radicals in which the stent was placed,
and/or the presence of cholangitis. Minor complications
were defined as those who resulted in no additional in-
crease in therapy and was hospitalized for 1 to 2 days for
observation (SIR).6

Results
A total of 92 PTBD procedures were performed within the
study period, of which the follow-up data were available. Of
these, in 15 patients, internalization could not be done and
were excluded from efficacy analysis. Of the remaining 77
patients, 37 patients underwent plastic biliary stenting (group
A), and in 40 patients internal–external drainage was placed
(group B). ►Table 1 summarizes the patient characteristics of
the two groups of this study. In 83% of our patients, biliary
hilum was the site of obstruction and carcinoma of GB was the
cause in 73% of hilar obstruction. Internalization was achieved
in 84% (77/92) cases, out of which primary internalization was
obtained in 59/77 cases (77%) and secondary internalization
was performed after a few days in 23% of cases. Failure to
internalize was most common in hilar cholangiocarcinoma. In
most cases, unilateral procedures were performed and right-
sided system draining the largest segment of the liver and with
favorable anatomy for internalization was preferred. Addition-
al external drainage on the contralateral side had to be
performed in 10 cases due to tumor infiltration of secondary
confluence in the contralateral side.

Technical Success
DPT-PS was attempted in 40 cases while in 3 cases, the stent
did not cross the stricture over the stiff wire and an internal–
external catheter was placed in these patients. Out of the 37
patients, primary stenting was performed at the time of
initial puncture in 23 patients and the overall technical
success rate for primary stenting was 62%, whereas in group
B, 75% of cases underwent primary internalization and the
overall technical success rate for primary internalization was
64% (59/92). In one patient in group A, the DPT-PS migrated
proximally during the deployment. Hence, the technical
success rate for DPT-PS was 90% (36/40).
Table 1 Patients’ characteristics of two groups of this study

<table>
<thead>
<tr>
<th></th>
<th>Group A:</th>
<th>Group B:</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DPT-PS</td>
<td>ring biliary</td>
<td></td>
</tr>
<tr>
<td>Gender (M:F)</td>
<td>14:23</td>
<td>16:24</td>
<td>30:47</td>
</tr>
<tr>
<td>Mean age (y)</td>
<td>54</td>
<td>55</td>
<td>54</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carcinoma GB</td>
<td>22</td>
<td>25</td>
<td>47</td>
</tr>
<tr>
<td>Hilar cholangioca</td>
<td>9</td>
<td>8</td>
<td>17</td>
</tr>
<tr>
<td>Mid/distal CBD carcinoma</td>
<td>4</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Pancreatic carcinoma</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Malignant lymphadenopathy</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Level of obstruction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hilar</td>
<td>31</td>
<td>33</td>
<td>64</td>
</tr>
<tr>
<td>Mid</td>
<td>4</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Low</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Site of PTBD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>25</td>
<td>27</td>
<td>52</td>
</tr>
<tr>
<td>Left</td>
<td>12</td>
<td>12</td>
<td>24</td>
</tr>
<tr>
<td>Both</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Additional external drainage</td>
<td>3</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Time of internalization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary internalization</td>
<td>29</td>
<td>30</td>
<td>59</td>
</tr>
<tr>
<td>Secondary staged internalization</td>
<td>8</td>
<td>10</td>
<td>18</td>
</tr>
</tbody>
</table>

Safety

Table 3 summarizes the major and minor complications in two groups. The overall incidence of complication within 1 week in DPT-PS was 13.5% (n = 5) (Table 2). There was no mortality within 1 month in patients included in the study directly attributed to the procedure. The incidence of fever and hemobilia was similar across the two groups, whereas bile leakage in the perihepatic space and through the skin at puncture site was seen in group B. Out of the patients reporting for short-term follow-up, stent occlusion with IHBRD and cholangitis was seen in five patients in each group. Puncture site bile leak was higher in group B (n = 6) compared with group A (n = 1). Stent migration into the bowel was noted in two patients in group A and two patients in group B had accidentally removed ring biliary catheter.

Efficacy and Short-Term Patency

Table 3 summarizes the preprocedure and post procedure bilirubin levels at ~1 to 2 weeks after the procedure. Both

Table 2 Short- and long-term efficacy of the PTBD procedures amongst three groups

<table>
<thead>
<tr>
<th>Complications</th>
<th>Group A (n = 37)</th>
<th>Group B (n = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postprocedure complication (within 1 wk)</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Fever</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Bleeding from drain lasting &gt; 24 hours</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Bile leakage through skin</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Perihepatic bile leakage/biliary peritonitis</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Short-term complication (3 months follow-up)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent occlusion and cholangitis</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Puncture site bile leakage</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Stent migration/dislodgement</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Perihepatic bile leakage/biliary peritonitis</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Death</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 3 Short- and long-term efficacy of the PTBD procedures amongst three groups

<table>
<thead>
<tr>
<th>Serum bilirubin (mg/dL)</th>
<th>Group A (n = 37)</th>
<th>Group B (n = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–5</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5–10</td>
<td>6</td>
<td>21</td>
</tr>
<tr>
<td>10–15</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>15–20</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>&gt;20</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Decompression of IHBRD (USG)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 week</td>
<td>33/37</td>
<td>40/40</td>
</tr>
<tr>
<td>2–3 months</td>
<td>27/35</td>
<td>29/37</td>
</tr>
<tr>
<td>Repeat/additional intervention required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 1 month</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1–3 month</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>
techniques were effective in reducing the bilirubin levels of the patients. Persistent decompression of the biliary system was seen in 76% of patients with DPT-PS and 78% in patients with internal external drainage catheter. Re-intervention was done in five patients in group A and 6 patients in group B.

**Discussion**

Malignant biliary obstruction with obstructive jaundice usually results in a poor outcome with a 1-year survival rate of 5 to 22% with only 10 to 15% of the patients qualifying for tumor resection at the time of diagnosis.\(^1\) Following an initial unsuccessful attempt of endoscopic biliary decompression, most centers consider PTBD. While a DPT-PS is the standard device used with the endoscopic approach, PTBD is typically followed up by the placement of a SEMS or a ring biliary internal–external drainage catheter.\(^4\) The present analysis demonstrates that DPT-PS shows similar technical success and efficacy performance of in a specific sub-set of patients who opt against a more expensive SEMS device while understanding their post-procedure life expectancy.

**Technical feasibility:** The endoscopic approach is preferred in cases of low malignant strictures, opinions are divided in the management of malignant hilar stricture (Bismuth–Corlette type ≥ 2). Studies indicate that biliary drainage in these patients may be achieved by percutaneous route with a higher success rate and lower complication.\(^12\) The placement of DPT-PS was feasible in all cases where it was attempted (n = 37) via the percutaneous route, the misplacement in one of the initial cases was due to the telescoping of the leading end of the stent pusher into the lagging end of the stent. This technical flaw may be due to the fact that the retrograde biomechanical force offered by the stricture to the forward movement of the stent during percutaneous placement would be more than that encountered during the endoscopic approach, keeping in mind that all these were strictures where endoscopic negotiation was not feasible. Kesava et al.\(^16\) used a “push-retain-pull” technique to deploy a PS with terminal flap mechanism using a fascial dilator through a larger bore sheath advanced until the duodenum. Though many centers prefer the two-staged or three-staged procedure with an attempt to negotiate the stricture made only after adequate biliary decompression has been achieved,\(^15\) we routinely attempt crossing of the stricture at the first instance, which allows shorter hospital stay.\(^17,18\)

**Patency and efficacy:** Though DPT-PS has been used as a standard option for endoscopic biliary decompression, experience regarding the use of this device in patients of Bismuth types III and IV strictures is limited to small series and single reports.\(^16\) The patients having Bismuth III/IV obstructions especially due to gall bladder carcinoma usually have a delayed clinical presentation in comparison to type I/II strictures. The chronic biliary stasis is liable to cause biliary concentration and intra-stent encrustation, responsible for most of the occlusions of DPT-PS.\(^18\) In the present cohort, the maximum follow-up was until 3 months with a documented efficacy and patency rate being 67%. Further, the reported average patency of DPT-PS (endoscopically delivered) is ~80 days similar to our cohort, as opposed to 117 days for the SEMS. The present analysis substantiates the notion that a DPT-PS is a cost-efficient solution for biliary decompression in patients with low 1-year survival as opposed to a more expensive SEMS,\(^8\) even when delivered through percutaneous access. Another study including nonresectable gall bladder malignancies, the stent patency, complication rate, re-intervention required and the overall survival time was comparable between endoscopically placed SEMS and DPT-PS.\(^11\) Moreover, DPT-PS should be the preferred choice in patients, in which the decision for resection or palliation has not been made because removal of SEMS is not possible.

**Safety:** Postprocedure complications were comparable in both groups. The complications associated with the percutaneous deployment of SEMS have been described to be < 2\%\(^18,19\) compared with 0.13% for DPT-PS in our study. In short term, stent migration is more common with DPT-PS (n = 2 in the present cohort) compared with SEMS, which epithelialize once positioned and rarely migrate. This low migration rate (0.05%) in our study as compared with that described hitherto for DPT-PS placed via endoscopic access may be ascribed to the biomechanical difference between the holding capacity of type III/IV as opposed to type I/II strictures and not due to the access of delivery. The occlusion rate in our cohort was unexpectedly and paradoxically low when compared with available data for endoscopically deployed DPT-PS as the biliary stasis was more chronic in our cohort. The puncture site bile leak noted in one patient was due to the inadvertently delayed persistence of the external indwelling catheter, which was removed at 7 weeks. Internal–external stent is associated with a major disadvantage in the form of morbidity because of catheter management and pericatheter leak, which can cause skin infection and ulceration.\(^19\) Another possible disadvantage of the internal–external catheter is reflux of duodenal content into biliary channels due to lower pressure in the collecting bag leading to a high infection rate in up to 53% of cases.\(^20\) SEMS is known to compress the pancreatic duct with the incidence of pancreatitis being 6%\(^12\) which was not encountered in any case of our cohort. DPT-PS is better tolerated by the patient because there is lesser risk of infection and leak from the puncture site.

This analysis was however limited by the fact that there was a lack of adequate follow-up beyond 3 months. Second, a direct randomized comparison with SEMS delivered via percutaneous route was not done as most patients after being explained about the prognosis of disease and success of DPT-PS preferred the same due to financial reasons. Our results however remained comparable to those mentioned in the literature for SEMS delivered via a percutaneous approach.

In conclusion, the present analysis affirms the use of the percutaneous approach to deliver DPT-PS for biliary decompression and reduction of liver enzymes, with reasonable technical success, efficacy, patency, and safety. DPT-PS carries significantly lesser risk of stent-induced morbidity than internal–external drainage and it may be used as a viable cost-efficient alternative for unresectable biliary malignancies with low postprocedure life expectancy.
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