Percutaneous transhepatic biliary drainage (PTBD): re-stent rate, morbidity and mortality and the Hull Risk Stratification for PTBD

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Purpose

Percutaneous transhepatic biliary drainage (PTBD) is effective in the management of biliary obstruction [1, 2].

In patients with obstructive jaundice, PTBD and/or stenting plays an important role in the overall management of patients with benign and malignant biliary disease.

Drainage or stenting of an obstruction can relieve symptoms and restore serum biochemistry to normal.

PTBD is an invasive technique and has associated complications. These include bleeding, infection and bile leak. Procedure related death is reported as 0.6%-5.6% [3-6].

- The aim of this study was to assess outcomes and complications of PTBD in a large group of patients.
- It also sought to identify the re-occlusion rate following stent deployment and factors associated with this complication.
- A secondary aim was to assess long-term survival data in patients treated by this technique. Risk stratification is suggested to predict those patients who are less likely to benefit from PTBD and stenting.

Methods and Materials

Consecutive patients with biliary obstruction managed by PTBD were included.

All cases were performed by one of two consultant interventional radiologists between July 2002 and July 2009 (JEIC and ORB).

A definitive diagnosis was made in all cases either from surgical specimens or biopsy (percutaneous, endoscopic or endobiliary).
Patient history, biochemical data from the time of and following intervention, the radiological data base, procedural records, and pathological and clinical follow-up were reviewed.

Data collected included patient demographics, history and chronic disease status, details of the procedure, technical success, site of the lesion, approach site, complications, histological diagnosis, follow up imaging and intervention, and clinical details before death. Biochemical data at the time of the procedure and week following the procedure included, haemoglobin (Hb), white cell count (WCC), platelets (plts), prothrombin time (PT), activated prothrombin time (APTT), urea, creatinine, c-reactive protein (CRP), bilirubin, alkaline phosphatase (ALP), aspartate transaminase (ALT) and albumin. All patient records were reviewed retrospectively from the initial procedure until death.

Technical success was defined as gaining access to the biliary system, performing successful drainage and/or stenting with resolving jaundice.

Complications were grouped into immediate (occurring <24 hours from the procedure) early (occurring from 24 hours to 30 days from the procedure) and late (occurring >30 days from the procedure).

30-day mortality was calculated.

Procedural mortality was defined as death attributed to the procedure.

Pre procedure imaging with abdominal ultrasound and computed tomography was performed in all patients. Magnetic Resonance Cholangiopanreatography (MRCP) was performed in complex cases for interventional planning.

**Procedural technique**

**External biliary drainage**

Patients presenting with obstructive jaundice due to suspected malignancy (+/- cholangitis) undergo external biliary drainage. This relieves jaundice and sepsis and decreases the risk of hepato-renal failure.

**Biliary stenting and endobiliary biopsy**
Patients with inoperable disease who are not considered suitable for surgical resection are considered for chemotherapy and require a tissue diagnosis. Forceps biopsy (Endojaw, Olympus, USA) is performed prior to stent placement and samples placed in a formalin pot. The obstruction is stented with either a Wallstent (Boston Scientific, Galway, Ireland) or Nitinella (Ella CS, Hradec Kralove, Czech Republic) uncovered metal stent. The distal end of the stent is placed across the ampulla.

Re-intervention

Stents occasionally block due to either biliary sludge or tumour recurrence resulting in recurrent jaundice. Recurrent tumour growth can be either through the interstices of the stent or overgrowth of the proximal or distal ends. PTBD can be repeated with coaxial metal stent placement with or without balloon dilatation, as appropriate.

Statistical Evaluation

Statistical analysis was performed with SPSS (SPSS, Chicago, Ill) and Chi-squared tests and multivariate logistic regression analysis were performed. A $p$ value of <0.05 was considered to indicate a significant difference.

Results

Between July 2002 and July 2009 a total of 948 procedures were performed on 704 patients.

The 704 patients can be considered in 3 main groups (Fig. 1)

In total there were 345 male (49%) and 359 female (51%) patients.

The mean age was 70.1 years and ranged from 48-96 years.

The approach for PTBD was left sided in 13 cases (1.5%), right sided in 860 (90.5%) and bilateral in 75 cases (8%). The histology of the obstructing lesions is listed in Table 1.
Table 1: Histological diagnosis

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Percentage</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gall bladder Carcinoma</td>
<td>1%</td>
<td>7</td>
</tr>
<tr>
<td>Cholangiocarcinoma</td>
<td>20%</td>
<td>141</td>
</tr>
<tr>
<td>Pancreatic carcinoma</td>
<td>48%</td>
<td>338</td>
</tr>
<tr>
<td>Benign Disease</td>
<td>10%</td>
<td>71</td>
</tr>
<tr>
<td>Metastatic Disease</td>
<td>20%</td>
<td>140</td>
</tr>
<tr>
<td>Neuroendocrine</td>
<td>1%</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>704</td>
</tr>
</tbody>
</table>

The location of the obstructing pathology is described in Table 2.

Table 2: Location of obstructing lesion.

<table>
<thead>
<tr>
<th>Location</th>
<th>Percentage</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left or Right hepatic duct</td>
<td>2%</td>
<td>14</td>
</tr>
<tr>
<td>Common hepatic duct</td>
<td>8%</td>
<td>56</td>
</tr>
<tr>
<td>Hilum</td>
<td>5%</td>
<td>35</td>
</tr>
<tr>
<td>Proximal CBD</td>
<td>16%</td>
<td>114</td>
</tr>
<tr>
<td>Mid common CBD</td>
<td>11%</td>
<td>77</td>
</tr>
<tr>
<td>Distal CBD</td>
<td>55%</td>
<td>387</td>
</tr>
<tr>
<td>Anastomosis</td>
<td>1%</td>
<td>7</td>
</tr>
<tr>
<td>Ampulla of Vater</td>
<td>2%</td>
<td>14</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>704</td>
</tr>
</tbody>
</table>

PTBD plus/minus stenting

Only patients with malignant disease were considered for stenting and therefore groups 2 and 3 were included in this part of the analysis (Fig. 1: 633 patients and 872 procedures).

There were 8 (<1%) technical failures giving a technical success rate of (98.5%). These included 2 stent malfunctions and 6 cases where we were unable to cross the obstruction.
Re-intervention for stent blockage

Re-interventions for blocked stents were required in 91 (13%) patients. The mean stent patency in this group was 174.8 days with a range of 9-276 days.

A high bilirubin (p<0.001), high urea (p<0.001), high WCC (p<0.02) and post procedure cholangitis (p=0.032) were also predictors of stent blockage.

The rate of decrease of bilirubin, urea and creatinine over the first week post stent insertion was not related to subsequent blockage or failure (p=>0.05).

Complications

All patients were included in the analysis of complications from Fig. 1.

There were a total of 97 (10%) complications associated with the PTBD.

There were 53 (6%) immediate complications (<24 hours). Independent predictors for immediate complications were:

- low albumin (#30g/dl versus >30g/dl, p=0.004, OR 2.4
- low Hb (#11d/dl versus >11g/dl, p=0.034, OR 2.2
- concurrent stent insertion (stent insertion versus no stent insertion, p=0.017, OR 2.9
- high CRP (#50mg/L versus <50mg/dl, p=<0.001, OR 2.7
- high WCC (#14x10^9/L versus <14x10^9/L, p=0.011, OR 2.8

There were 23 (2.5%) early complications (1-30 days). Independent predictors for early complications were:

- high bilirubin level (#300mmol/L versus <300mmol/L, p=<0.001, OR 1.8
- high urea (#12mmol/L versus <12mmol/L, p=<0.001, OR 1.2
- high WCC (#14x10^9/L versus <14x10^9/L, p=0.014, OR 1.9
- high ALT (#150iu/L versus <150iu/L, p=0.041, OR 1.4

There were 21 (2%) cases of late complications (>30 days). Independent predictors for late complications were:

- high bilirubin (#300mmol/L versus <300mmol/L, p=0.049, OR 1.1
• high urea (#14x10^9/L versus <14x10^9/L, OR 1.1, p=0.024,

A diagnosis of diabetes (p=0.004) was also associated with late complications. There were no cases of clinical pancreatitis. Endobiliary biopsy did not result in complication increase (n = 119, p=0.54).

The procedure related mortality was 18 (2%). These included 11 cases of sepsis, and 7 cases of pneumonia secondary to pleural effusions post procedure. Multivariate analysis revealed this was related to:

• pre-procedure presence of ascites (ascites present versus no ascites, p=0.04, OR 2.4
• high CRP (#50mg/L versus <50mg/dl, p=0.010, OR 2.7
• high WCC (#14x10^9/L versus <14x10^9/L, p=0.02, OR 2.6

A new Risk Stratification Score for PTBD

Using the data from multivariate regression analyses we propose a scoring system to identify which patients are more likely to suffer from immediate and early complications and procedural mortality (Table 3).

Table 3: The Hull Risk Stratification system for PTBD: a) The risk scoring system. The immediate risks have been given a score of 2 and the early risks a score of 1, and; b) the complications and mortality associated with the corresponding score from our cohort.

<table>
<thead>
<tr>
<th>IMMEDIATE RISK Factors</th>
<th>EARLY RISK Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin (&lt;30 g/dl) or Ascites = 2</td>
<td>Urea (&gt;12 mmol/l) = 1</td>
</tr>
<tr>
<td>WCC (&gt;14 x10^9/L) = 2</td>
<td>Bilirubuin (&gt;300 mmol/L) = 1</td>
</tr>
<tr>
<td>CRP (&gt;50 mg/L) = 2</td>
<td>ALT (&gt;150 iu./L) = 1</td>
</tr>
<tr>
<td>Proceed direct to stent = 2</td>
<td></td>
</tr>
<tr>
<td>Hb (&lt;11 g/dl) = 2</td>
<td></td>
</tr>
</tbody>
</table>

a) Maximum score = 13, minimum score = 0.

The immediate risk factors score 2 points as they had an odds ratio (OR) of between 2 and 2.9 from the multivariate regression analysis. On the whole these factors can also be modified prior to the procedure. A high WCC and CPR can be reduced with antibiotics. A low Hb can be transfused. Ascites can be drained.
The early risk factors were given a value of 1 point as their OR was between 1 and 1.9 from the multivariate regression analysis. Furthermore, these factors can only be modified with the drainage procedure and therefore they do not alter immediate patient management. Whilst a high urea is potentially modifiable in some patients it is not in those with renal impairment and was only significantly related to early complications.

If a risk factor (i.e. WCC) was associated with more than one complication (i.e. immediate and early complications) then the highest OR was used, for example, WCC and immediate complications OR=2.8 and early complications OR=1.9.
% of total mortality 2% (n=90)

% of patient group as a whole (n=704)
b)

Images for this section:

**Group 1:** Benign Disease – PTBD only
- 71 patients
- 77 procedures

**Group 2:** Malignant Disease – PTBD as primary procedure
- 320 patients
- 467 procedures (147 subsequent stents inserted)

**Group 3:** Malignant Disease – PTBD and stent as primary procedure
- 313 patients
- 404 procedures (91 re-stents)

**Fig. 1:** Patient Groups
Conclusion

PTBD and stenting offers a safe and effective method in providing palliative treatment for patient with biliary obstruction. Discussion and consensus at multidisciplinary meetings will dictate the best definitive treatment for such patients.

Percutaneous biliary intervention has an important role in the management of patients with malignant biliary obstruction with a view to improving their quality of life, irrespective of their suitability for surgical intervention.

The proposed risk stratification score should allow clinicians to time PTBD more appropriately, delay stent insertion and also highlight patients who require closer follow-up, making PTBD and stenting a safer procedure.

Using this new stratification scoring system it has been possible to demonstrate the increased complications and mortality associated with the medium and high-risk patients (Table 3). Adopting this scoring system before PTBD and stenting should mean high-risk patients can be identified and treated to decrease their risk of complications and/or mortality before the procedure.

If a patient is high risk (Score 10-13) before stent placement we would advocate PTBD only and a delay in stent placement until the patient risk stratified score is lower. This will usually mean percutaneous drainage of biliary sepsis and fluid resuscitation, with possible ascitic drain placement.

The high proportion of patients suffering from complications and higher mortality in the medium and high-risk groups is dramatic. There is a smaller increase in 30-day mortality in these higher risk groups, which is partly explained by the severity of the underlying diagnosis in many cases. Further prospective evaluation of this system is however warranted.

References


Personal Information