Preoperative drainage is always indicated in malignant CBD strictures

PRO

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Malignant biliary obstruction: preoperative drainage

**Background**

- Jaundice is associated with high perioperative morbidity and mortality
- Preoperative drainage may reverse the pathophysiological disturbance (e.g. hepatic synthetic and clearance function, mucosal intestinal barrier function)
Malignant biliary obstruction: preoperative drainage

Cochrane Database Systematic Review

- 4 RCT`s on PTCD, 1 RCT on endoscopic drainage
- 320 patients
- Drainage vs no drainage:
  - No difference in mortality
  - Higher morbidity (endoscopy study)
  - Longer hospitalisation
  - Increased costs
- However: poor quality of the included trials

Wang Q, Cochrane Database Syst Rev 2008; 16(3): CD005444
Malignant biliary obstruction: preoperative drainage

RCT in patients with pancreatic head cancer

Obstructive jaundice
Bilirubin: 2.3 – 14.6 mg/dl

Preoperative drainage

Surgery after 4 – 6 weeks
Surgery alone within 1 week

Primary outcome:
Serious complications within 120 days

Van der Gaag NA, NEJM 2010; 362:129-37
**Malignant biliary obstruction: preoperative drainage**

**RCT in patients with pancreatic head cancer**

<table>
<thead>
<tr>
<th></th>
<th>Drainage</th>
<th>No drainage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>102</td>
<td>94</td>
</tr>
<tr>
<td>Successful drainage</td>
<td>94 %</td>
<td></td>
</tr>
<tr>
<td>complication rate</td>
<td>46 %</td>
<td></td>
</tr>
<tr>
<td>Surgery related complications</td>
<td>47 %</td>
<td>37 %</td>
</tr>
<tr>
<td>Serious complications</td>
<td>74 %</td>
<td>39 %*</td>
</tr>
<tr>
<td>Procedure related mortality</td>
<td>9 %</td>
<td>4 %</td>
</tr>
</tbody>
</table>

* P < 0.001

Van der Gaag NA, NEJM 2010; 362:129-37
Malignant biliary obstruction: preoperative drainage

RCT in patients with pancreatic head cancer
Van der Gaag NA, NEJM 2010; 362:129-37

Limitations

• Exclusion of patients with a bilirubin level of ≥ 14.6 mg/dl

• Compared to previous trials on endoscopic biliary stenting:
  - High initial failure rate (25 %)
  - Frequent need (30 %) for early stent exchange
  - High incidence of secondary cholangitis (26 %)
  - High rate of other ERCP related complications
    panncreatitis 7%, perforation 2%, bleeding 2%
  - High rate of benign or unresectable disease (39 %)
Malignant biliary obstruction: preoperative drainage

Surgical concepts for patients with pancreatic head cancer
Survey among 102 German surgical centers

Criteria for non-resectability

Arterial infiltration
- Common hepatic artery: 70%
- SMA: 85%
- Celiac trunk: 86%

Portal vein infiltration: 18%

Extrapancreatic tumor manifestation: 70%

Preoperative endoscopic drainage in patients with a bilirubin level of ≥ 15 mg/dl

Yes: 54%
No: 43%

Langenbecks Arch Surg 2011; 396:223-9
Malignant biliary obstruction: palliative drainage

Distal biliary obstruction
Metaanalysis

SEMS vs plastic prosthesis (7 RCT`s)

- Reduced risk of recurrent biliary obstruction at 4 months (OR 0.4) or prior to death/end of study (OR 0.5)
- No difference: success, complications, mortality

Moss AC, Cancer Treat Rev 2007; 33: 213-21
Malignant biliary obstruction: preoperative drainage

Partially covered SEMS as a bridge to surgery
Malignant biliary obstruction: preoperative drainage

Partially covered SEMS as a bridge to surgery regardless of resectability

<table>
<thead>
<tr>
<th>Patients</th>
<th>27</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic cancer</td>
<td>23</td>
</tr>
<tr>
<td>Others</td>
<td>4</td>
</tr>
</tbody>
</table>

| Median time between stenting and surgery | 32 days |

<table>
<thead>
<tr>
<th>Complications</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Migration</td>
<td>2</td>
</tr>
<tr>
<td>Tissue overgrowth</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Whipple procedure</th>
<th>9 (33 %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palliative approach</td>
<td>18 (67 %)</td>
</tr>
<tr>
<td>Median f/u post-surgery</td>
<td>210 days</td>
</tr>
</tbody>
</table>

Pop GH, Surg Endosc 2011; 25:613-8
Malignant biliary obstruction: preoperative drainage

SEMS as a bridge to pancreaticoduodenectomy (PD) in patients with resectable pancreatic cancer

<table>
<thead>
<tr>
<th>Patients</th>
<th>79</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous plastic stents</td>
<td>70 %</td>
</tr>
<tr>
<td>Neoadjuvant RCTx</td>
<td>95 %</td>
</tr>
<tr>
<td>Median time between stenting and surgery</td>
<td>120 days</td>
</tr>
<tr>
<td>SEMS related difficulties during PD</td>
<td>0</td>
</tr>
<tr>
<td>30-day morbidity rate</td>
<td>33 %</td>
</tr>
<tr>
<td>30-day mortality rate</td>
<td>0 %</td>
</tr>
</tbody>
</table>

Singal AK; Dig Dis Sci 2011; Jul 13 (Epub ahead of print)
Malignant biliary obstruction

Indications for preoperative biliary drainage

Obligatory

• Delay in surgery
• Neoadjuvant RCTx / CTx
• Cholangitis
• Bilirubin level of $\geq 15$ mg/dl

Investigational: SEMS in all jaundiced patients

• Options to postpone surgery
• Low risk of secondary cholangitis
• No adverse effect in case of PD
• Adequate palliative biliary drainage in case of irresectability