„Randomized multicenter study on pancreatic duct stenting in disrupted or obstructed ducts in context with endoscopic treatment of pancreatic pseudocysts.“

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Pancreatic duct stenting in patients with pseudocysts?

Pro Stentimplantation:
- Improved long term success by pancreatic duct stenting
  (single transm. drainage vs. simultaneous PD stenting; 97.5% vs. 80%)

Trevino, J Gastro Hepatol 2010
Pancreatic duct stenting in patients with pseudocysts

Contra Stentimplantation:
- Increased rate of recurrence of pseudocyst with combined transpap. /transmural drainage vs. single transmural drainage
  (14/56 vs. 5/60; 25 % vs. 8 %)

Hookey et al., GIE 2006
Rationale of study

- Conflicting data
- Mainly retrospective studies
- No randomised controlled trials available
- High rate of cyst recurrence
Rationale of study

- Classification according to Nealon et al. 2005
  - morphology of pancreatic duct (I – IV)
  - communication with pseudocyst (a / b)
Rationale of study

"Disrupted duct" ➔ communication with pseudocyst ➔ autodigestion ➔ Potential cause of cyst recurrence

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients with cyst recurrence [total]</th>
<th>[%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baron</td>
<td>25/138</td>
<td>18%</td>
</tr>
<tr>
<td>Cahen</td>
<td>5/60</td>
<td>7%</td>
</tr>
<tr>
<td>Binmoeller</td>
<td>5/24</td>
<td>21%</td>
</tr>
<tr>
<td>Hookey</td>
<td>14/56</td>
<td>25%</td>
</tr>
<tr>
<td>Gesamt</td>
<td>49/278</td>
<td>18%</td>
</tr>
</tbody>
</table>
„Randomized multicenter study on pancreatic duct stenting in disrupted or obstructed ducts in context with endoscopic treatment of pancreatic pseudocysts.“
Study – Inclusion criteria

Patients with pancreatic pseudocyst

- at least 6 cm in diameter

plus

- symptoms
- Rapidly increasing in size for > 6 weeks
- Complications (abscess; necrosis; compression, ...)

[Image of ultrasound scan]
Study – Exclusion criteria

- Pregnancy
- Age less than 18 years
- Postoperative status preventing access to papilla
- Allergy to contrast
- Missing written informed consent
- PTT above 1.5-times of normal
- Platelet count < 50,000 /µl
- Pankreatic ascites, fistula (pleural, bronchial, peritoneal, extern)
- Life expectancy less than 2 years
Study outline

Endoscop. cyst drainage
Step I

Duc intact

ERP
Step II

Duct disrupted

Randomization
Step III

Duct stenting

After 3 months:
Re-ERP, stent removal

Clinical follow up:, US, CT/MRT
3, 6, 12 months later
Phone call 24 months later

No stenting
Step I

Transmural, endoscopic cyst drainage:

- Details of technique are left up to participating center
- Cyst drainage is left in situ until complete resolution of cyst is achieved
→ Step II

**Endoscopic retrograde pancreaticography (ERP):**

- Performed within 1 week after cyst drainage
- Duct intact => Follow up; Duct disrupted => Step III

[Diagrams of various types labeled as Type Ia, Ib, IIa, IIb, IIIa, IIIb, IVa, IVb]
Step III

Randomization:

Interventional group

- pancreatic duct stent across the leakage
- additional pancreatic sphincterotomy is left up to participating center
- pancreatic stent will be left in place for 3 months

Control group:

None of these
→ Step IV

Follow up 3, 6 and 12 months later:
- Obligatory: abdominal ultrasound
- Optional: CT-scan, MRI Abdomen, recurrence of cyst?
- Telephone call up 24 months after cyst drainage

Phone call:
- Pain?
- Operation?
- Concomitant disease/medication?
- Diabetes? Exocrine insufficiency?
→ **Endpoints**

- Recurrence of cyst
- Increased diameter of pseudocyst compared to last examination
- Continuous symptoms
- 2 years of follow up
- Pancreatic operation due to other indication
- Death
Calculation of sample size

- Level of significance $\alpha = 0.05$
- Power $> 50\%$

$\Rightarrow$ 28 patients / group

$\Rightarrow$ Randomization of 56 patients

$\Rightarrow$ only 50% „disrupted duct“ $\Rightarrow$ Screening of 112 patients

$\Rightarrow$ Reduced compliance $\Rightarrow$ 120 patients in total
→ Participation

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