A vertical red bar is located on the left side of the slide, extending from the top of the main text area to the bottom.

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

M. Ellrichmann; C. Jürgensen; A. Arlt;
A. Fritscher-Ravens

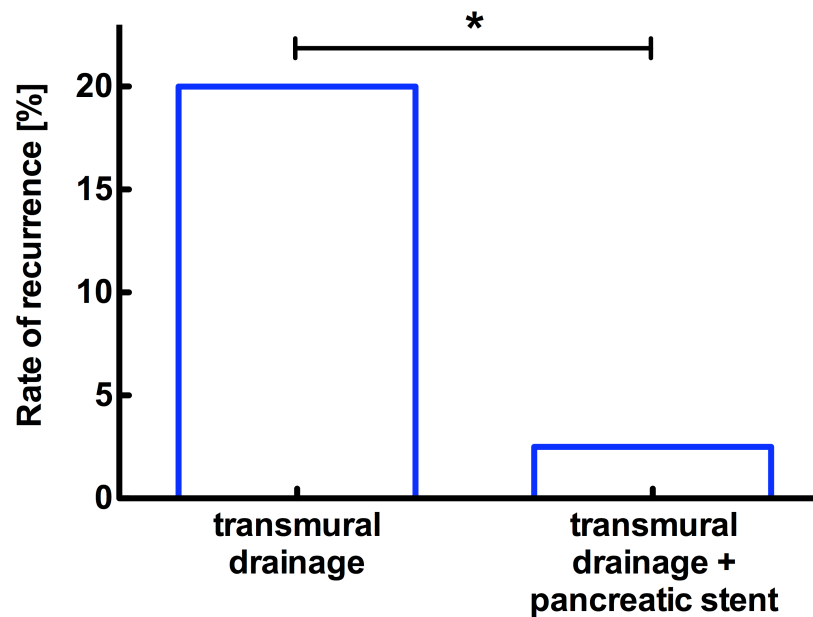
Interdisciplinary Endoscopy
Medical Department I
University Hospital Schleswig-Holstein, Campus Kiel
Germany



→ Pancreatic duct stenting in patients with pseudocysts?

Pro Stentimplantation:

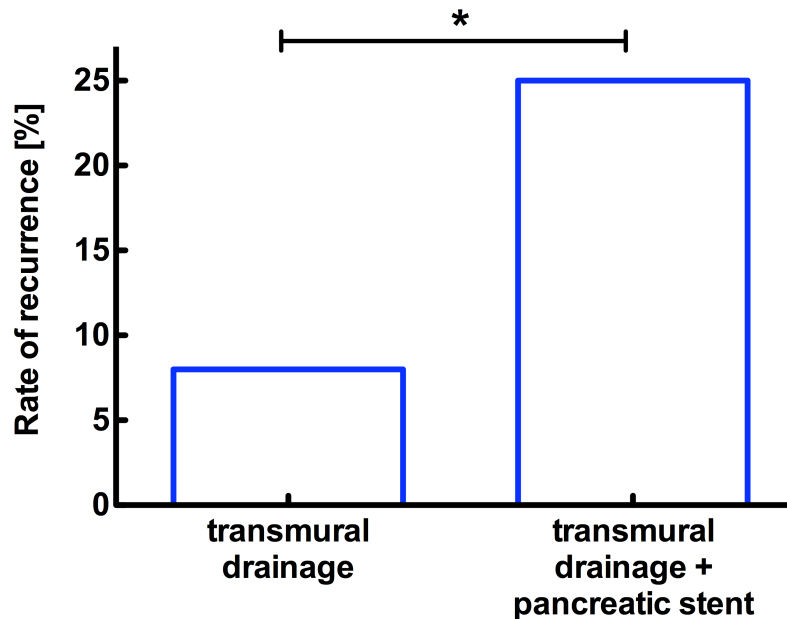
- Improved long term success by pancreatic duct stenting
(single transm. drainage vs. simultaneous PD stenting; 97.5% vs. 80%)



→ 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 %)

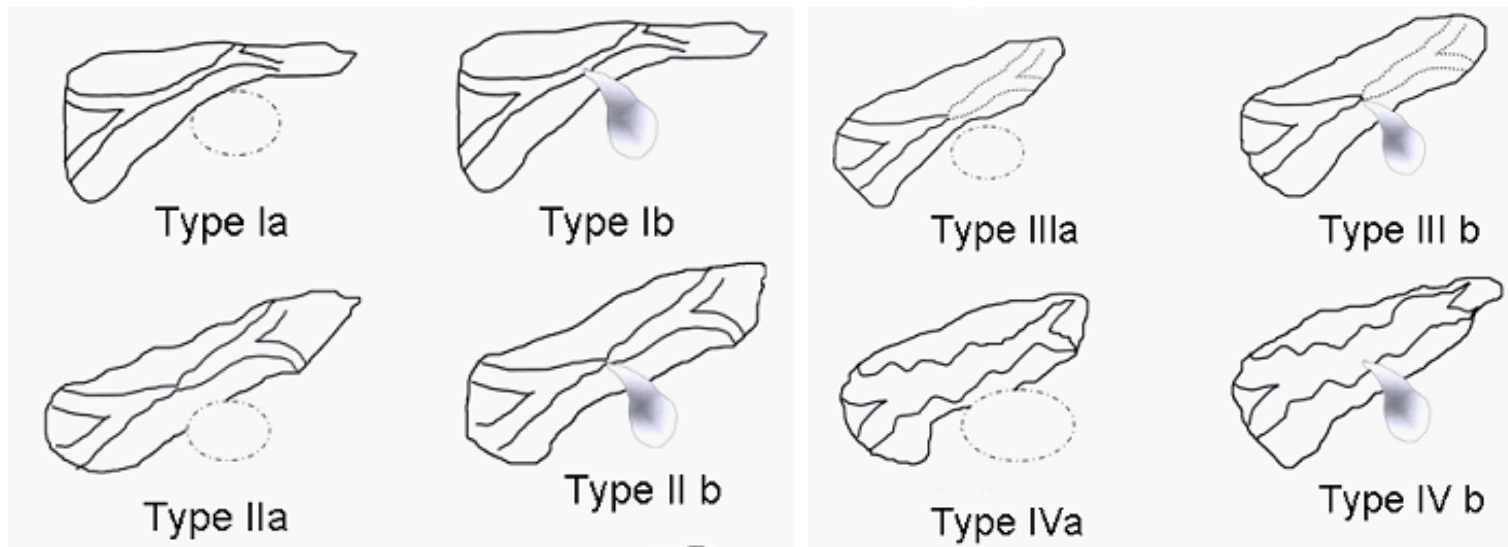


→ Rationale of study

- 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

Study	Patients with cyst recurrence [total]	[%]
Baron	25/138	18 %
Cahen	5/60	7 %
Binmoeller	5/24	21 %
Hookey	14/56	25 %
Gesamt	49/278	18 %

„Disrupted duct“ → communication with pseudocyst → autodigestion
 → Potential cause of cyst recurrence

—→ Study

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

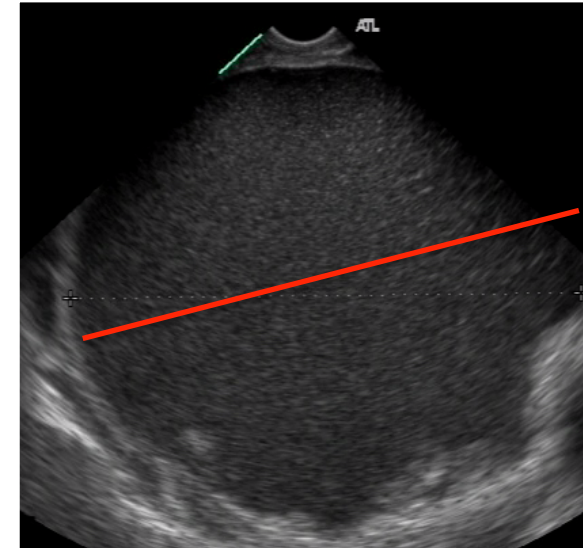
→ Study – Inclusion criteria

Patients with pancreatic pseudocyst


- at least 6 cm in diameter

plus

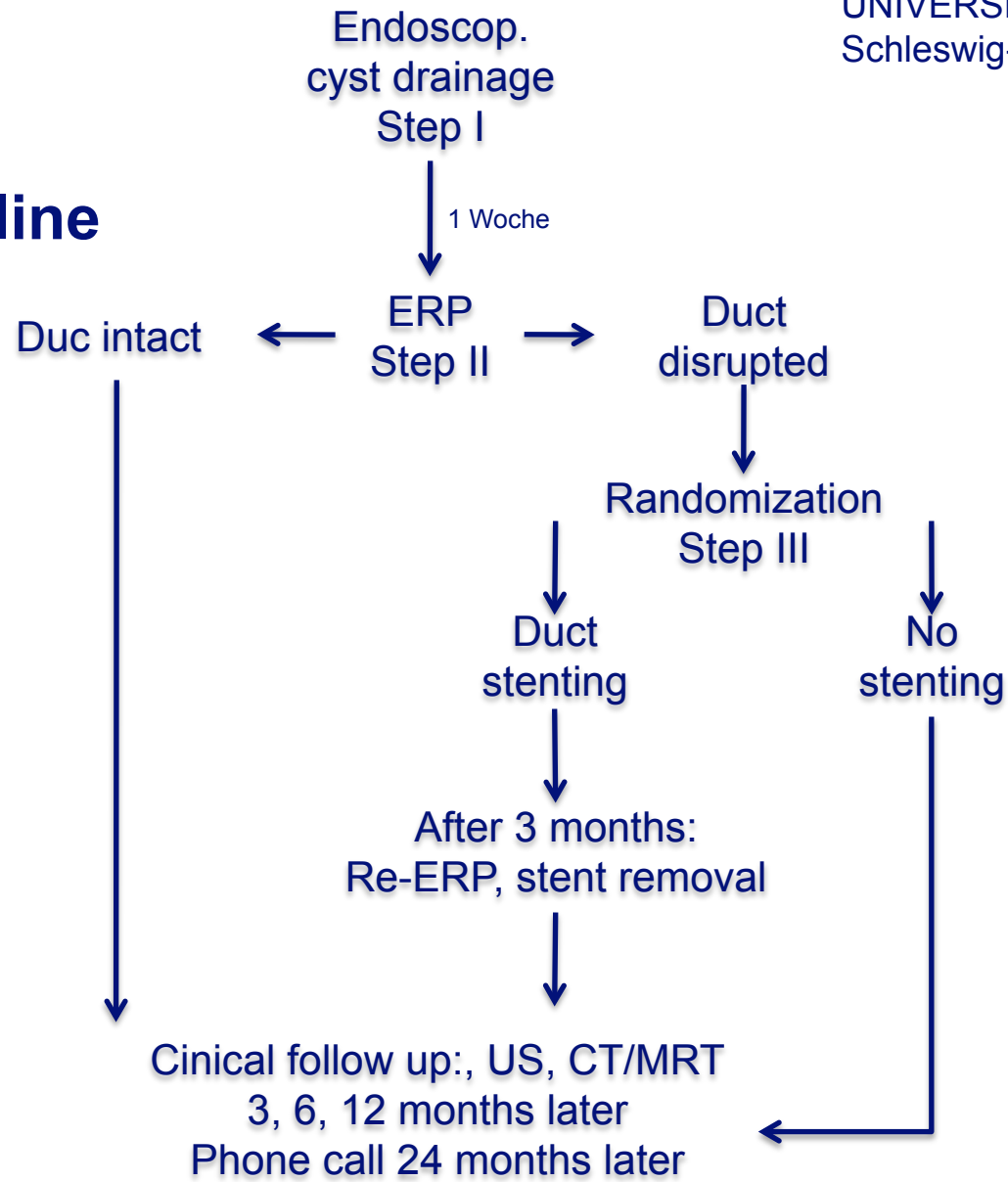
- symptoms
- Rapidly increasing in size for > 6 weeks
- Complications (abscess; necrosis; compression, ...)



→ Study – Exclusion criteria

- 
- A vertical red bar is positioned on the left side of the slide, extending from the top of the list area to the bottom.
- 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 / μ l
 - Pankreatic ascites, fistula (pleural, bronchial, peritoneal, extern)
 - Life expectancy less than 2 years

→ Study outline



→ Step I

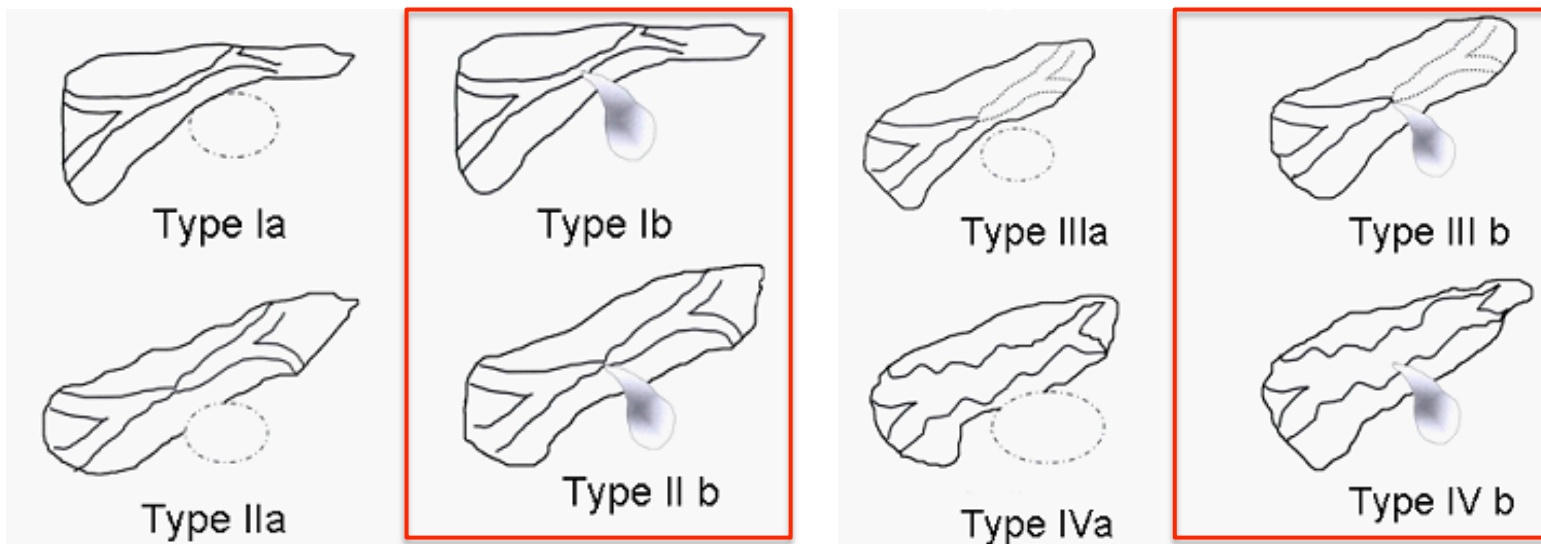
Transmural, endoscopic cyst drainage:

- 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



→ **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 $> 50\%$

⇒ 28 patients / group

⇒ Randomization of 56 patients

⇒ only 50% „disrupted duct“ ⇒ Screening of 112 patients

⇒ Reduced compliance ⇒ 120 patients in total

→ Participation

Contact info:

Dr. M. Ellrichman

mark.ellrichmann@uk-sh.de

PD Dr. A. Arlt

aarlt@1med.uni-kiel.de

Prof. Dr. A. Fritscher-Ravens

fri.rav@btopenworld.com

Schittenhelmstr. 12

24105 Kiel

Tel: 0431-597-2075 (Zentrale)

www.uk-sh.de