

PREPAST CASE REPORT FORM (CRF)

Insurance number: _____

Name: _____

Date of birth: _____ Age: _____ years

Gender: Male / Female

Date (and time) of admission to the hospital: _____ : _____

I. DAY 0 – ADMISSION:

I/A: Screening:

Inclusion criteria		
Diagnosis of acute pancreatitis:		
- pancreatic type abdominal pain AND	YES	NO
- serum amylase / lipase > 3xULN OR/AND - characteristic findings for pancreatitis on US/CT/MR	YES	NO
Biliary origin:		
- gallstone(s) and/or sludge on imaging OR/AND - dilated CBD (>8 mm if ≤75 yo, >10 mm if >75 yo) OR/AND - ALT > 2xULN and ALT>AST	YES	NO
Patient age ≥18 years	YES	NO
ERCP is possible ≤48 hours from onset of pain	YES	NO
Patient was symptom free during last week	YES	NO
Written informed consent is signed	YES	NO
One „NO” is present = DO <u>NOT</u> INCLUDE!		

Exclusion criteria		
Pregnancy	NO	YES
Alcoholic or post-ERCP pancreatitis or pancreatic cancer	NO	YES
Pain onset >48 hours before ERCP	NO	YES
Liver cirrhosis Child A-C	NO	YES
INR > 1.6 (uncorrectable by the time of ERCP)	NO	YES
Pancreatic fluid collections or necrosis at presentation	NO	YES
Previous sphincterotomy	NO	YES
One „YES” is present = EXCLUDE!		

Acute cholangitis (modified TG13)		
A: Systemic inflammation:		
- fever (>38 °C) and/or shaking AND	YES	NO
- laboratory data: evidence of inflammatory response (WBC <4 or >10 G/l and/or CRP ≥10 mg/l, etc)	YES	NO
B: Cholestasis:		
- jaundice (serum bilirubin ≥34.2 μmol/l) OR/AND	YES	NO
- laboratory data: abnormal LFTs (ALP, GGT, ALT, AST >1.5xULN)		
C: Imaging:		
- biliary dilatation OR/AND	YES	NO
- evidence of etiology (stricture, stone etc)		
One „NO” is present = Acute cholangitis is NOT present = assess cholestasis!		

If acute cholangitis is present = go to RANDOMIZATION, GROUP A!

Cholestasis		
Imaging signs AND (gallbladder stones / sludge OR dilated CBD OR CBD stone)	YES	NO
Elevated liver function tests (LFTs) (ALT, ALP and serum bilirubin >1.5xULN)	YES	NO
One „NO” is present = Cholestasis is NOT present = exclude (GROUP C)!		

If cholestasis is present = go to RANDOMIZATION, GROUP B!

RANDOMIZATION:

All inclusion criteria met + no exclusion criteria present?	YES / NO
If „YES” = RANDOMIZE!	
Acute cholangitis present?	YES / NO
If „YES” = GROUP A	
Cholestasis present?	YES / NO
If „YES” = GROUP B	

Randomization number:

(two-digit centrum-ID - one-letter group identifier - three-digit randomization number)

I/B: Assessment:

Complaints start: _____ hours

❖ **SEVERITY OF PAIN:** 1 (none) to 10 (maximum): _____

Ethanol: Y / N Quantity/day: _____

Medications:

- Azathioprine Y / N
- Opioids: Y / N
- Furosemid: Y / N
- Enalapril: Y / N
- Sulfasalazine: Y / N
- Sulphametoxazole/Trimethoprim: Y / N
- Tetracycline: Y / N
- Steroids: Y / N
- Oral contraceptives: Y / N

Cholecystectomy: Y / N

Past medical history:

- Gallbladder stones: Y / N
- Biliary colic: Y / N
- Pancreatitis: Y / N

ASA group: 1 2 3 4 5

ASA 1 - Normal healthy patient

ASA 2 - Patient with **mild systemic disease** with no functional limitationsASA 3 - Patient with **moderate** systemic disease **with functional limitations**ASA 4 - Patient with **severe** systemic disease that is a constant threat to lifeASA 5 - **Moribund** patient who is not expected to survive another 24 hours with or without surgery**PHYSICAL EXAMINATION:**

Blood pressure: _____ / _____ Hgmm

Heart rate: _____ / min

T axill.: _____ °C

Resp. freq.: _____ / min

Abdominal tenderness: Y / N

Abdominal guarding: Y / N

COMORBIDITY:

- diabetes mellitus Y / N
- hypertension Y / N
- myocardial infarction or stroke or periferial vascular disease Y / N
- heart failure Y / N
- Please mark severity:
 - NYHA I.
 - NYHA II.
 - NYHA III.
 - NYHA IV.
- chronic kidney injury (renal failure) Y / N
- hyperlipidaemia Y / N

BMI:

Patient height: _____ m

weight: _____ kg

BMI (kg/m²): _____

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ABDOMINAL ULTRASOUND ON ADMISSION (1.):

Gallbladder:

- Stones: yes - sludge - none

Bile ducts:

- Intrahepatic bile duct dilatation: mild – moderate – severe
- CBD diameter: _____ mm or N/A
- CBD stones: _____ Y / N or N/A

Pancreas:

- visible / not visible
- Pancreas oedema: _____ Y / N
- inhomogeneity: _____ Y / N
- pancreas enlargement: _____ Y / N
- Peripancreatic fluid collection: _____ Y / N
- Pancreatogen ascites: _____ Y / N

IV. FLUIDS:

Before ERCP: _____ ml

First 24 hours: _____ ml

Type of solution: _____ crystalloid / colloid

Laboratory tests:			
WBC		bilirubin	
Hgb		AST	
Htk		ALT	
blood sugar		GGT	
UN		AP	
Creatinie		Amylase	
Na		or lipase	
K		CRP	
Ca		Procalcitonine	

Respiratory check:O₂ saturation _____ breath rate _____**Blood gas (Astrup):**ONLY if O₂ sat is below 90% OR the breath rate is above 20/minpH _____ PaO₂ _____**ORGAN FAILURE:**Marshall score ≥ 2 for at least one of three organ systems:

Y / N

Marshall scoring system	Score				
Organ system	0	1	2	3	4
Respiratory (PaO ₂ /FiO ₂)	> 400	301-400	201-300	101-200	≤ 100
Renal (serum creatinine, $\mu\text{mol/l}$)*	≤ 134	135-169	170-310	311-439	> 439
Cardiovascular (sytolic BP, mmHg)**	> 90	< 90 Fluid responsive	< 90 Not fluid responsive	< 90, pH < 7.3	< 90, pH < 7.2
<i>For non-ventilated patients, the FiO₂ can be estimated from below:</i>					
Supplemental Oxygen (l/min)	FiO₂	*A score for patients with pre-existing chronic renal failure depends on the extent of further deterioration of baseline renal function. No formal correction exists for a baseline serum creatinine $\geq 134 \mu\text{mol/l}$ or $\geq 1.4 \text{ mg/dl}$ **Off inotropic support. For patients with the need for inotropic catecholamine support, a Marshall score of 2 is appointed for cardiovascular system and dependent on the pH a Marshall score of 3 or 4 can be appointed			
Room air	21%				
2 - 3	25%				
4 - 5	30%				
6 - 8	40%				
9 - 10	50%				

SIRS:

SIRS	
Heart rate >90/min	YES
Core temperature <36 °C or >38 °C	YES
WBC <4 or >10 G/l	YES
Respiratory rate >20/min	YES
SIRS present if ≥ 2 „YES”	

BISAP:

BISAP score	1 point for each:
Urea nitrogen >25 mg/dl	YES
Impaired mental status	YES
SIRS present	YES
Age >60 years	YES
Pleural effusion present	YES
Sum of points	

II. ERCP

Name of endoscopist: _____

Date: _____ Time: _____:_____ Hours after admission: _____

Duration of procedure: <15 min 15-30 min >30 min
(scope insertion to extraction)

Premedication: Y / N	Butylhyoscine:	Y / N
	Nalbuphin:	Y / N
	Midazolam:	Y / N
	Fentanyl:	Y / N
	Dolargan:	Y / N

Other (please specify name and dose):

Difficult biliary canulation: > 5 attempts / > 5 mins

CBD diameter: _____ mm

Stone impacted in papilla **Y / N**CBD stones: **Y / N**

Number: _____ Size: _____ mm

Sludge in CBD: **Y / N**Papillary oedema: **Y / N**Duodenal oedema: **Y / N**Lacerated orifice: **Y / N**Juxtapapillary diverticulum: **Y / N**Number of pancreatic guidewire manipulation: **0 / 1 / ≥2**Pancreatic injections **Y / N**Pancreatic acinarization: **Y / N**Pancreas divisum: **N/A / Y / N**Successful PD stent if attempted: **Y / N**

PD stent implanted: 5 F 3 or 5 cm

PD stent outer end: pigtail / straight

Biliary EST:

Conventional sphincterotome: **Y / N**Precut papillotomy: **Y / N**• Precut with needle knife: **Y / N**• Longitudinal precut: **Y / N**• Fistulotomy: **Y / N**Need for additional procedure NB drainage: **Y / N**CBD stent: **Y / N**Lithotripsy: **Y / N**Balloon dilation: **Y / N**

Other (please specify): _____

Schutz degree of difficulty : 1 2 3 4 5**Grade 1: Simple diagnostic ERCP**

(standard diagnostic cholangiogram)

Grade 2: Simple therapeutic ERCP

(standard biliary sphincterotomy, removal of 1-2 small CBD stones (<1 cm), nasobiliary catheter)

Grade 3: Complex diagnostic ERCP

(diagnostic cholangiogram, Billroth II anatomy, biliary cytology)

Grade 4: Complex therapeutic ERCP(More than 2 or large ≥ 1 cm CBD stones, cystic duct stone removal, CBD dilation or stenting)**Grade 5: Very advanced ERCP**

(precut BS, stone removal with ML, intrahepatic stone removal, Billroth II anatomy)

Subjective difficulty:

Assessed?: Y / N

Subjective difficulty of ERCP: 1 (very simple) to 10 (extremely difficult): _____**ERCP COMPLICATIONS**

Bleeding: Y / N

Severity: Mild / Moderate / Severe

Endotherapy:

Injection Y / N (injected material: _____ volume: _____ ml)

Other Y / N (specify: _____)

Perforation: Y / N

Type (or Stapfer classification): _____

Bleeding as a complication of ERCP (Cotton classification):**"mild"**: Hb decreases less than 3 g/dL, no transfusion necessary**"moderate"**: transfusion of ≤ 4 RBC units, no surgery nor arteriography**"severe"**: transfusion of at least 5 RBC units or surgery or angiographic intervention**Perforation as a complication of ERCP (Stapfer classification):****"type I"**: duodenal perforation (lateral or medial wall) / endoscope related**"type II"**: periampullary / sphincterotomy related**"type III"**: ductal or duodenal perforations because of endoscopic instruments**"type IV"**: guidewire related perforation with presence of retroperitoneal gas in imaging

III. 24 HOURS AFTER ERCP

Intensive care unit Y / N

Blood pressure: _____ / _____ Hgmm

Heart rate: _____ / min

T axill.: _____ °C

Antibiotics: Y / N

Intent: Profilactic / therapeutic

Specify name and dose: _____

Indication: _____

SIRS assessed?: Y / N

SIRS present?: Y / N

Organ failure assessed?: Y / N

Organ failure present?: Y / N

❖ **SEVERITY OF PAIN:** 1 (none) to 10 (maximum): _____**GLASGOW PROGNOSTIC SCORE (WITHIN 48 HOURS):**

SCORE	VALUE	YES
Age	>55 years	
pO ₂ (arterial)	<8 kPa (60mmhg)	
Albumine	<32 g/l	
Calcium	<2 mmol/l	
WBC	>15 x10 ⁹ /l	
LDH	>600 U/l	
Glucose	>10 mmol/l (no diabetic hx)	
Urea	>16 mmol/l	
Pancreatitis is severe if Glasgow score ≥ 3!		

IV. 48 HOURS AFTER ERCP:

Intensive care unit Y / N

Nutritional assessment:

- oral feeding can be restarted? Y / N
- enteral feeding needed? Y / N
 - NJ Y / N
 - NG Y / N
- other forms of feeding? Y / N
 - please specify: _____

PHYSICAL EXAMINATION:

Blood pressure: _____ / _____ Hgmm

Heart rate: _____ / min

Temperature: _____ °C

Resp. freq.: _____ / min

Bowel sounds absent – diminished – normal

Abdominal tenderness Y / N

Abdominal guarding Y / N

Laboratory tests:			3.
WBC		Amylase	
Hgb		CRP	
Htk		Creatinine	

SIRS:

SIRS	
Heart rate >90/min	YES
Core temperature <36 °C or >38 °C	YES
WBC <4 or >10 G/l	YES
Respiratory rate >20/min	YES
SIRS present if ≥2 „YES”	

ORGAN FAILURE:Marshall score ≥ 2 for at least one of three organ systems:

Y / N

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Marshall scoring system	Score				
Organ system	0	1	2	3	4
Respiratory (PaO ₂ /FiO ₂)	> 400	301-400	201-300	101-200	≤ 100
Renal (serum creatinine, μmol/l)*	≤ 134	135-169	170-310	311-439	> 439
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2 - 3	25%	<i>**Off inotropic support. For patients with the need for inotropic catecholamine support, a Marshall score of 2 is appointed for cardiovascular system and dependent on the pH a Marshall score of 3 or 4 can be appointed</i>			
4 - 5	30%				
6 - 8	40%				
9 - 10	50%				

V. 72 HOURS AFTER ERCP:

Intensive care unit Y / N

SIRS assessed?: Y / N

SIRS present?: Y / N

Organ failure assessed?: Y / N

Organ failure present?: Y / N

❖ **SEVERITY OF PAIN:** 1 (none) to 10 (maximum): _____**ABDOMINAL ULTRASOUND (2.):**

Gallbladder:

- Stones: yes - sludge - none
- Pericholecystic fluid: Y / N

Bile ducts:

- Intrahepatic bile duct dilatation:mild – moderate – severe
- CBD diameter: _____ mm or N/A
- CBD stones: Y / N or N/A

Pancreas:

- visible / not visible
- Pancreas: oedema: Y / N
- inhomogeneity: Y / N
- pancreas enlargement: Y / N
- Peripancreatic fluid collection: Y / N
- Pancreatogen ascites: Y / N

Peripancreatic fluid collection: Y / N

VI. 72 – 96 HOURS AFTER ERCP:

ONLY IF:

- *severe ABP*
- *fail to respond conservative treatment*
- *clinically deteriorating*

Abdominal CT scan (3-5 days): - performed? Y / N

Performed _____ hours after randomization

Balthazar score: A / B / C / D / E

A: Normal

B: "intrinsic pancreatic changes"

C: "Intrinsic and extrinsic pancreatic changes, Mild inflammatory changes of the peripancreatic soft mass"

D: "Extrinsic pancreatic changes with more than one pancreatic fluid collection"

E: "Multiple or extensive extrapancreatic fluid collections or abscess"

% of necrosis (no contrast enhancement): none / <33% / 33-66% / > 66%

Local complications: Y / N

Systemic complications: Y / N

VII. OVERALL OUTCOME

Total length of stay: _____ days (ICU length of stay: _____ days)

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Organ failure: no / temporary / persistent

Multi organ failure: Y / N

Severe organ failure: Y / N

> requiring (tick appropriately):

- mechanical ventilation
- cardiac support (vasopressors)
- haemodialysis

Systemic complications: Y / N

(tick appropriately)

- Shock
- Sepsis
- Renal failure
- ARDS / respiratory failure
- Heart failure / hypotension
- DIC / coagulopathy
- Hypocalcaemia
- Hyperglycaemia / diabetes mellitus
- Ascites

Local complications: Y / N

(tick appropriately)

- Acute peripancreatic fluid collection without tendency of spontaneous resolution
- Pancreatic pseudocyst
- Acute necrotic collection
- Walled off necrosis
- Necrosis / infected necrosis / phlegmone
- Ileus
- Fistula
- GI bleeding
- Pseudoaneurysm

Mortality: Y / N Date of death: _____

Cause of death: _____

Antibiotics: Y / N

Specify: _____

(name: active substance: dose (gram, milligram, etc.).....)

if fluid: concentration (e.g. 10%, 1g/2ml, etc.)..... how many times/day

type of administration:..... indication:

Jejunal feeding: Y / N

CT score: _____

Max. CRP: _____

Surgery: Y / N

Specify: _____