

QUESTIONNAIRE

1. Personal data

1.1 Patient's data

Name: _____

Sex: Male / Female

Date of Birth: _____ Age: _____ Insurance number: _____

Phone number: _____

The patient's study number:

1.2 Doctors' data

DOCTOR No. 1:

Name of the doctor **responsible for the treatment of ABP**: _____

The phone number of the doctor: _____

Institute: _____

DOCTOR No. 2:

Name of the doctor **responsible for the randomization**: _____

The phone number of the doctor: _____

Institute: _____

DOCTOR No. 3:

Name of the doctor **responsible for the operation**: _____

The phone number of the doctor: _____

Institute: _____

DOCTOR No. 4:

Name of the doctor **responsible for the 90 days' visit**: _____

The phone number of the doctor: _____

Institute: _____

Endoscopic sphincterotomy for delay **I**ng
cholecystectomy in mild acute biliary **Y** pancreatitis

2. Inclusion criteria /DOCTOR No. 2/

Patients older than 18 age	YES	NO
Diagnosis of acute pancreatitis (two of them have to be positive) <ul style="list-style-type: none"> - upper abdominal pain - serum lipase or amylase is three times higher of upper limit of normal - characteristic findings of acute pancreatitis on abdominal imaging 	YES	NO
Presence of biliary pancreatitis (one of them has to be true) <ul style="list-style-type: none"> - diagnosis of gallstone or sludge on imaging - the absence of gallstone or sludge with a dilated common bile duct on ultrasound (>8 mm in patients ≤75 years of age or >10 mm in patients >75 years old) - alanine aminotransferase level >2 times higher than normal values 	YES	NO
Mild acute biliary pancreatitis (all of them have to be true) /HAS TO BE DETERMINED AT DISCHARGE OF THE PATIENT/ <ul style="list-style-type: none"> - no peripancreatic fluid collections - no pancreatic necrosis - no persistent organ failure 	YES	NO
ERCP/ES either during the index admission or in the medical history without complication	YES	NO
Written informed consent	YES	NO
One „NO” is present = DO NOT INCLUDE!		

3. Exclusion criteria /DOCTOR No. 2/

American Society of Anesthesiologists (ASA) classification <ul style="list-style-type: none"> - III patients >75 years old - IV, V, VI. Groups 	YES	NO
Acute or chronic cholecystitis during hospitalization	YES	NO
Previous cholecystectomy	YES	NO
Continuous alcohol abuse or chronic pancreatitis	YES	NO
Pregnancy	YES	NO
One „YES” is present = EXCLUDE!		

4. If all inclusions and no exclusion criteria are met, than the physician may indicate the patient to participate in the study. / DOCTOR No. 2/

The treating physician (DOCTOR No. 2) anticipates that the patient can be discharged	YES	NO
No need for analgesics	YES	NO
Declining C-reactive protein levels and <150 mg/l	YES	NO
No evidence of local or systemic complications	YES	NO
The patient has resumed solid oral nutrient	YES	NO
If all YES = RANDOMIZATION /see point 6/		

Date of admission (diagnosis of AP):.....

Date of discharge:

5.1 Anamnesis

History of upper abdominal surgery: Yes / No
 If yes, interventions:.....

 History of biliary colics Yes / No
 History of cholecystitis Yes / No
 Fever Yes / No °C
 Diabetes Yes / No
 Antibiotic therapy during the ABP Yes / No

BMI Weight:___kg, Height:___cm, BMI:___kg/m²

ASA classification (ASA PHYSICAL STATUS CLASSIFICATION SYSTEM)

I. group(Normal healthy patient)	YES	NO
II. group(Patient with mild systemic disease with no functional limitations)	YES	NO
III. group(Patient with moderate systemic disease with functional limitations)	YES	NO

5.2. Laboratory measurements

At discharge after AP:

Amylase(U/l)		Hematocrit(%)	
Lipase(U/l)		Hemoglobin(g/l)	
Gamma GT(U/l)		Kreatinine(umol/l)	
White blood cell(G/l)		eGFR	
ASAT/GOT(U/l)		CRP(mg/l)	
INR(U/l)		Alkaline phosphatase(U/l)	

5.3. Pancreatic imaging /At discharge after AP/

5.3.1 Abdominal Computed Tomography: yes/no

Modified CTSI Score (0-10):

Please NOTE! Abdominal CT is compulsory when the patient is discharged

- **CTSI:**

CTSI Score: (I) Normal pancreas 0 point, intrinsic pancreatic abnormalities with or without inflammatory changes in peripancreatic fat 2 points, Pancreatic or peripancreatic fluid collection or peripancreatic fat necrosis 4 points **(II)** Necrosis absent 0 Points, < 30% necrosis 2 Points, > 30% necrosis 4 points **(III)** presence of extrapancreatic findings 2 points.

MAXIMUM OF: 10 points

- **Pancreas Size:**

- Normal
- Partially enlarged (body AP diameter is over 2 cm and/or head AP diameter is over 2,5 cm, none exceeds 3 cm)
- Definitely enlarged (any part over 3 cm AP diameter)

- Largest diameter of peripancreatic **fat infiltration** cm

- **Peripancreatic fluid:**

- none
- present
- Large pseudocyst(s)

- Size of peripancreatic fluid or pseudocyst: cm

- **Necrotizing area** (nonenhancement):

- Largest diameter of necrosis area cm
- Location of necrosis:
- Type: patchy / full width
- Estimated necrosis: 0%, < 30% , 30% - 60%, > 60%

- **Wirsung** dilatation: YES / NO (yes, diametermm)

- Distant **abdominal fluid:**

- Small amount (hard to see, less than 2 cm in lesser pelvis, less than 1 cm around liver/spleen)

- Moderate amount (easy to see, but without pelvic or abdominal distension)
- Large amount with abdominal/pelvic distension
- **Pleural effusion:**
 - none
 - one sided:..... (AP diameter cm)
 - Both sides, L - cm, R.....cm
- **Extrapancreatic findings:**
 - Inflammation (Cholecystitis, Duodenitis, etc.) location:
 - Cholecystolithiasis
 - Choledocholithiasis
 - Signs of bowel ischaemia
 - Bowel distension, ileus
 - Venous thrombosis
 - Pseudoaneurysm
 - Parenchymal organ involvement, define:
 - none

Other Description:

.....
.....
.....
.....

5.4. Characteristics of AP

Date of diagnosis (admission).....

Date of EST:.....

Date of discharge:

6. Randomization / DOCTOR No. 2/

The patient will be randomized by an internet randomization module in the following 2 groups:

- Randomization:
- A.** Early cholecystectomy (within 6 days after discharge)
 - B.** Delayed cholecystectomy (between 45 and 60 days after discharge)

Please circle the relevant group after randomization:

A or B

Please inform the patient concerning the **1)** Date for imaging examination and blood measurements before the operation, **2)** Date for the operation, **3)** Date for the 90 days visit

7. Operation /responsibility of DOCTOR No. 3/

Date of operation:

Length of days between discharge and operation:

If the operation is not in the time period described in point 6 please provide the reason:

7.1 Anamnesis (between discharge after ABP and operation)

Acute pancreatitis - Upper abdominal pain - Serum lipase or amylase is three times higher of upper limit of normal - Characteristic findings of acute pancreatitis on cross-sectional abdominal imaging	YES	NO
Biliary pancreatitis - Diagnosis of gallstone or sludge on imaging - Dilated common bile duct on ultrasound (>8 mm in patients ≤75 years old or >10 mm in patients >75 years old - Alanine aminotransferase level >2 times higher than normal values	YES	NO
Cholecystitis A. Local signs of inflammation: 1) Murphy's sign; 2) RUQ mass/pain/tenderness. B. Systemic signs of inflammation: 1) Fever; 2) Elevated C-reactive protein; 3) Elevated white blood cell count. C. Imaging findings characteristic of acute cholecystitis Final diagnosis 1) One item in A and one item in B are positive; 2) C confirms the diagnosis when acute cholecystitis is suspected clinically	YES	NO
Biliary colics Upper abdominal pain (either right upper quadrant or epigastric pain) lasting at least 30 minutes, according to the Rome criteria	YES	NO
Cholangitis 1) Serum total bilirubin level >40 μmol/l (>2.3 mg/dl) and/or dilated common bile duct (>6 mm) on transabdominal or endoscopic ultrasound or computed tomography; 2) Temperature >38.5°C.	YES	NO
Organ failure 1) Respiratory: PaO ₂ ≤60 mmHg (SaO ₂ ≤ 90%) or need for mechanical ventilation; 2) Cardiovascular: systolic blood pressure <90 mmHg or need for catecholamine support; 3) Renal: creatinine level >177 μmol/l after rehydration or need for hemofiltration or hemodialysis (not including pre-existent renal failure).	YES	NO
Mortality	YES	NO

If any of the answers is **YES** please provide the dates:

Except mortality, all of the above mentioned diseases can occur multiple times.
Please provide details for all events separately.

Other reasons for hospitalization:

Endoscopic sphincterotomy for delay **I**ng
cho**L**ecystectomy in mild acute biliar **Y** pancreatitis

7.2 Laboratory measurements (no more than 24h before the operation)

Amylase(U/l)		Hematocrit(%)	
Lipase(U/l)		Hemoglobin(g/l)	
Gamma GT(U/l)		Kreatinine(umol/l)	
White blood cell(G/l)		eGFR	
ASAT/GOT(U/l)		CRP(mg/l)	
INR(U/l)		Alcaline phosphatase(U/l)	

If the patient is in group A, and the operation is performed within 24h after the blood samples are taken during the discharge of the patients, NO ADDITIONAL BLOOD SAMPLE HAS TO BE TAKEN. Please copy the values from 5.2.

7.3 Pancreatic imaging

7.3.1 Abdominal ultrasonography:

- **Visualization:**
 - o Good, complete (head at least partially visualized, body and neck well visualized, tail: partially visualized)
 - o Partially, incomplete (only body or only head visualized)
 - o Poor, non-diagnostic
- **Size:**
 - o Normal
 - o Partially enlarged (body AP diameter is over 2 cm and/or head AP diameter is over 2,5 cm, none exceeds 3 cm)
 - o Definitely enlarged (any part over 3 cm AP diameter)
- **Peripancreatic fluid:**
 - o none
 - o present
 - o Large pseudocyst(s)
- Size of peripancreatic fluid or pseudocyst: cm
- **Pancreas homogeneity:**
 - o Homogenous
 - o Inhomogeneous, includes area(s) of low echogenicity
 - o Inhomogeneous, includes calcifications
- In case of circumscribed low echogenicity area, it's sizecm
- **Wirsung** dilatation: YES / NO (yes, diametermm)

Other Description:

.....

7.3.2 Abdominal Computed Tomography: yes/no
Modified CTSI Score (0-10):

- **CTSI:**

CTSI Score: (I) Normal pancreas 0 point, intrinsic pancreatic abnormalities with or without inflammatory changes in peripancreatic fat 2 points, Pancreatic or peripancreatic fluid collection or peripancreatic fat necrosis 4 points **(II)** Necrosis absent 0 Points, < 30% necrosis 2 Points, > 30% necrosis 4 points **(III)** presence of extrapancreatic findings 2 points.
MAXIMUM OF: 10 points

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- Largest diameter of peripancreatic **fat infiltration** cm

- **Peripancreatic fluid:**

- none
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- Size of peripancreatic fluid or pseudocyst: cm

- **Necrotizing area** (nonenhancement):

- Largest diameter of necrosis area cm
- Location of necrosis:
- Type: patchy / full width
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- **Wirsung** dilatation: YES / NO (yes, diametermm)

- Distant **abdominal fluid:**

- Small amount (hard to see, less than 2 cm in lesser pelvis, less than 1 cm around liver/spleen)

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- **Pleural effusion:**
 - none
 - one sided:..... (AP diameter cm)
 - Both sides, L - cm, R..... cm
- **Extrapancreatic findings:**
 - Inflammation (Cholecystitis, Duodenitis, etc.) location:
 - Cholecystolithiasis
 - Choledocholithiasis
 - Signs of bowel ischaemia
 - Bowel distension, ileus
 - Venous thrombosis
 - Pseudoaneurysm
 - Parenchymal organ involvement, define:
 - none

Other Description:

.....
.....
.....
.....

If the patient is in group A, and the operation is performed within 24h after the imaging is performed during the discharge of the patients, NO ADDITIONAL IMAGING EXAMINATION HAS TO BE ORDERED. Please copy the details from 5.3.

7.4. Characteristics of the Operation

The difficulty of cholecystectomy (10 – hard, 5 – average difficulty):

1	2	3	4	5	6	7	8	9	10

Conversion to open cholecystectomy:	Yes / No
The length of the operation (min): _____	
Days spent in hospital after cholecystectomy: _____	
Intenziv unit care:	Yes / No
Mortality:	Yes / No
Haemorrhage, reintervention needed:	Yes / No
No iatrogenic perforation of the gallbladder	Yes / No
Common bile duct (CBD) injuries	Yes / No
Bile leakage	Yes / No
Sub-hepatic abscess	Yes / No

8. Visit 90 days after discharge / DOCTOR No. 4/

The visit has to be completed +/- 7 days (between 83 and 97 days after discharge)

Date of the visit:

Length of days between discharge and visit:

8.1 Anamnesis (between the operation and visit)

Acut pancreatitis - Upper abdominal pain - Serum lipase or amylase is three times higher of upper limit of normal - Characteristic findings of acute pancreatitis on cross-sectional abdominal imaging	YES	NO
Biliary pancreatitis - Diagnosis of gallstone or sludge on imaging - Dilated common bile duct on ultrasound (>8 mm in patients ≤75 years old or >10 mm in patients >75 years old - Alanine aminotransferase level >2 times higher than normal values	YES	NO
Cholecystitis A. Local signs of inflammation: 1) Murphy's sign; 2) RUQ mass/pain/tenderness. B. Systemic signs of inflammation: 1) Fever; 2) Elevated C-reactive protein; 3) Elevated white blood cell count. C. Imaging findings characteristic of acute cholecystitis Final diagnosis	YES	NO

1) One item in A and one item in B are positive 2) C confirms the diagnosis when acute cholecystitis is suspected clinically		
Biliary colics Upper abdominal pain (either right upper quadrant or epigastric pain) lasting at least 30 minutes, according to the Rome criteria	YES	NO
Cholangitis 1) Serum total bilirubin level >40 µmol/l (>2.3 mg/dl) and/or dilated common bile duct (>6 mm) on transabdominal or endoscopic ultrasound or computed tomography; 2) Temperature >38.5°C.	YES	NO
Organ failure 1) Respiratory: PaO ₂ ≤60 mmHg (SaO ₂ ≤ 90%) or need for mechanical ventilation; 2) Cardiovascular: systolic blood pressure <90 mmHg or need for catecholamine support; 3) Renal: creatinine level >177 µmol/l after rehydration or need for hemofiltration or hemodialysis (not including pre-existent renal failure).	YES	NO
Mortality	YES	NO

If any of the answers **YES** please provide the dates:

Except mortality, all of the above mentioned diseases can occur multiple times. Please provide details for all events separately.

Other reason for hospitalization:

SIGNATURES:

Doctor No.1.....

Date:.....

Doctor No.2.....

Date:.....

Doctor No.3.....

Date:.....

Doctor No.4.....

Date:.....