ERCP registry

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Hand-out

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Dániel Pécsi

Áron Vincze

https://tm-centre.org

https://ercp.tm-pte.org

Aim of the ERCP registry

The aim of the ERCP Registry is to prospectively collect and monitor success rate, adverse event rate and other quality indicators of endoscopic retrograde cholangio-pancreatography (ERCP). At this moment we are waiting for Hungarian centres to join and to upload data into the registry. We would like to encourage international centres to participate in the registry at a later phase. The registry will allow monitoring continuously the quality indicators for each individual endoscopists and centres. We aim to determine those factors which influence the success and risk of intervention and to monitor the efficacy of different prophylactic and therapeutic measures. Consequently, those aspects where changes are needed could be identified and acted upon with the help of the registry. Trainee endoscopists could also be monitored during the training phase to follow their learning curve and to determine the number of interventions needed to reach individual competency. At this moment the evidence is limited in this respect and current recommendations are based mostly on expert opinion.

The quality and outcome of ERCP could be continuously improved by the detailed analysis of the above-mentioned parameters. We could get reliable prospectively collected data on multiple aspects of biliopancreatic interventions to see our current practice and benchmarking will be also possible at individual, institutional and national level with the implementation of the ERCP Registry. Our patients will hopefully benefit from the identification and correction of weak points in our current practice and the cost-effectiveness might be improved parallelly. The register also might aid future prospective observational and interventional clinical trials.

Áron Vincze (vincze.aron@pte.hu)

Dániel Pécsi (pecsi.daniel@pte.hu)

1. Upload of patient data

1) **Healthcare ID number, name, birthdate, gender** are compulsory fields.

Attention! It is important to fill these fields without error! Only central modification is available after saving.

Race: Caucasian / Roma / Afroamerican / Indian / Asian / Other: *(not compulsory)*

2) **Who signed the consent form?:** means the consent to the ERCP examination, not the registry.
In the case of missing consent form to the registry for any reason, no data upload is permitted!

Solution:

<u>If the consent is not signed for some reason, the patient could be called and be informed about the registry. Consent forms should be mailed to them</u>

3) **Weight, height measurements:** if possible measure the patients, if that is not possible rely on data from the wards!

4)Alcohol consumption: equals how many units of alcohol?

Guide to volumes:

1 dl beer (4.5 vol. %) = ~3.5 g alcohol

1 dl wine (12.5 vol. %) = ~10 g alcohol

1 dl spirits (50 vol. %) = ~40 g alcohol

5) **Smoking:** based on the questionnaire

Code of the examining doctor: **important to mark it, because after saving it could only be modified centrally!**

2. Indication and planned intervention

2A) Planned or emergency examination

- **Planned exam:** e.g. elective stent exchange
- **Emergency exam:** with emergency indication (e.g. acute cholangitis)

→ in work hours or during on-call hours?

2B) Indication of ERCP: *indications accepted by ASGE*

Obstructive jaundice: if there are no signs of cholangitis

Cholangitis: jaundice could be present, however, cholangitis is the primary indication in that case

Disease of the biliary ducts: biliary stones and strictures

Disease of the pancreatic ducts: Wirsungolithiasis belongs here

Suspicion of pancreatic malignancy, if other imaging techniques were not unequivocal or normal

Pancreatitis with unknown etiology: diagnostic indication, should be avoided

Others: we should always try to select the indications above, however, if it is not possible here you can write free text (this will be centrally reviewed)

2C) Indication of the therapeutic intervention

Implementing EST: why did we do an EST? If there are more than one indications, you can write it in the point 2C by free text.

Biliary stone

Stenosis of the papilla / SOD

Insertion of a biliary stent

Dilatation of a biliary stricture

Sump sy.

Choledochocele

Carcinoma of the papilla of Vater, if surgery is not an option

Facilitation of the cannulation of the pancreatic duct

Insertion of a biliary stent: why did you implant a biliary stent? If there are more than one indications, you can write it in the point 2C by free text.

Benign stricture
Malignant stricture
Stricture of unknown nature
Fistula
Post-operative bile leaking

Non-removable, large biliary stone

<u>Other therapeutical interventions</u>:

Dilatation of a stricture

Balloon dilatation the papilla

Insertion of nasobiliary drain

Drainage of pancreatic pseudocyst

Sampling from the pancreatic duct

Sampling from the biliary duct

Ampullectomy

Cholangioscopy

Pancreatoscopy

Pancreatic stent implantation: only therapeutical, prophylactic pancreatic stents should not be marked here

Other biliary or pancreatic therapeutic interventions: free text entry, always look for the options above!

Any remarks concerning the points above should be written down here in the free text entry field!

3. ASA score: based on comorbidities and general state

I. Normal healthy patient

II. Patients with mild systemic disease: e.g. hypertension

III. Patients with severe systemic disease: e.g. severe form of heart failure

IV. Patients with severe systemic disease that is a constant threat to life: e.g. end-stage heart failure

V. Moribund patients who are not expected to survive without the intervention: e.g. in septic shock

4. Aggregation inhibition and/or anticoagulation treatment

aspirin:	what dose, discontinued Y/N, if yes, how many days ago
clopidogrel:	what dose, discontinued Y/N, if yes, how many days ago
prasugrel:	what dose, discontinued Y/N, if yes, how many days ago
NOAC:	what dose, discontinued Y/N, if yes, how many days ago

K-vitamin antagonists: what dose, discontinued Y/N, if yes, how many days ago
LMWH: what dose, discontinued Y/N, if yes, how many days ago

You should write the **active component of the drug** and the **brand name**, too! Dosing is not compulsory, however, the **date of discontinuation is essential!**

5. Coagulation disorder: **if there is , here you can mark**

INR value: ___, correction happened Y/N, if yes (what, how much) FFP (number of units), Vitamin K (dose, mg/day)/ Prothrombin complex/

Platelet count: ___, have correction happened (what, how much) /Platelet concentrate (units)/Thrombopoetin

Known haemophilia: Y/N, have correction happened (what, how much) Factor VIII concentrate (units)

Other: under clopidogrel effect!

6. Sedation and pharmacological prophylaxis

6A: Sedation:

Vigilant sedation: active component of drug, dose (pl. Fentanyl, Midazolam)

Propofol sedation: only dose is needed

Other: general anaesthesia with other drugs

Patient monitoring during the examination: important, document it in the patient documentation, too!

Use of antidote: pl. Anexate (flumazenil), Narcan (naloxone)

6B: PEP pharmacological prophylaxis: **PPS is at point 11!**

Indomethacin suppository (100 mg / ___ mg) before exam / after exam

Diclofenac suppository (100 mg / ___ mg) before exam / after exam

6C: Antibiotic prophylaxis: did it happen? Type of antibiotics, indication?

Patients with PSC!!!

7. Time of the examination: *time measurements according to the clock!*

A. Beginning of the exam (time and date) (e.g. 2017.10.01. 08:02:35)
B. Duodenoscope in cannulating position: e.g. 08:03:31
C. Deep biliary access: e.g. 08:07:54
D. End of the exam: e.g. 2017.10.01. 08:20:24

D. Fluoroscopy time: mm: ss; write radiation dose also, if available
Radiation dose: Gy

Findings: free text field: it is important for further quality checks!

8. Anatomy

Operated stomach (BI, BII, total gastrectomy, Whipple, Roux-en-Y bariatric operation)

Deformity (pylorus / bulbus / postbulbar duodenum): more could be selected!

Stenosis (pylorus / bulbus / postbulbar duodenum): more could be selected!

Vater papilla and orifice

Normal / Lacerated orifice (previous stone exit) / Fistula / Impacted stone in the papilla / Neoplasia / /

Other (_____): free text entry

Previous EST Y/N, if yes: adequate / stenotic

Juxtapapillary diverticulum Y/N, if there is

Visible orifice Y/N

Position of the papillary tract: on the edge of the diverticulum / in the diverticulum

Sampling Y/N (if there was sample taking from the papilla or its surroundings. Biliary citology, biopsy are signed elsewhere) by free text

9. Cannulation

A. Biliary cannulation:

Yes: successful biliary cannulation
No: no attempts to biliary access were made e.g. in the cases of severe anatomic deformations
Unsuccessful: after multiple attempts no successful biliary access, however, if precut papillotomy was made, here you should choose yes, even if biliary access was not successful, because of the precut points below!

Superficial cannulation Y/N, if yes guidewire / papillotom / cannula / injecting contrast material (more could be selected)
Deep cannulation Y/N if yes guidewire / papillotom / cannula
Precut papillotomy Y/N if yes papillotom / needle knife from the orifice /needle-knife fistulotomy)

Besides a pancreatic guidewire with: guidewire / papillotom / cannula

Beside a pancreatic stent with: guidewire / papillotom / cannula

Transpancreatic sphincterotomy alone / with needle knife precut / with papillotomy

Rendezvous technique

Failed (biliary duct did not opacify): choose yes, in the cases of precut, but no successful biliary access!

Did the pancreatic duct appear? Y / partially / N: important point!

Guidewire / papillotom / cannula insertion into the pancreatic duct N / 1x / multiple times: important point for difficult biliary cannulation!

B. Cannulation of the pancreatic duct through the major papilla

Yes/No/Unsuccessful;
As the biliary cannulation, in case of unintended pancreatic cannulation mark yes!

Superficial cannulation Y/N
if yes by guidewire / papillotom / canula / injecting contrast material
Deep cannulation by guidewire / papillotom / cannula
Precut papillotomy/needle knife from the orifice / needle-knife fistulotomy
Failed (pancreatic duct did not show): only in cases of intentional cannulation!

C.Cannulation of the pancreatic duct through the major papilla

Yes/No/Unsuccessful;

Superficial cannulation Y/N
if yes by guidewire / papillotom / canula / injecting contrast material

Deep cannulation by guidewire / papillotom / cannula
Precut papillotomy/needle knife from the orifice/needle-knife fistulotomy
Failed (pancreatic duct did not show): only in cases of intentional cannulation!

Extravasation of contrast material:

Submucosal
Other (____): biliary duct leakage or cystic stump

10. Findings of the cholangiography and pancreatography

A. Biliary duct:

Normal: to 5 mm
Pathological: >5mm, stone, stenosis, pus, sludge etc.
St. post cholecystectomiam normal: to 10 mm
St. post cholecystectomiam pathological: >10 mm, stone, stenosis, pus, sludge.etc.
Did not appear: unsuccessful cannulation or other reason (e.g. severe suprapapillary stricture) cholangiography is not evaluable

Dilation (largest diameter in mm)

Caliber irregularity

Biliary stone (size (mm), number, location: lower/ middle / upper third / hilar / right or left intrahepatic)**Sludge**

Pus

Stricture of the biliary tract

localization: lower/ middle / upper third / hilar / right or

left intrahepatic

benign / malignant / unknown nature

Sampling: cytology / biopsy / culture

Bile leak (localization) lower/ middle / upper third / hilar / right or left intrahepatic**?**

B. Pancreatic duct: in case of normal appearance, no other questions

Normal: to 3 mm
Pathological: >3 mm, caliber irregularities, stones, stricture etc.
Did not appear

Dilation (largest diameter in mm)

Caliber irregularity

Wirsungolithiasis

Stricture localisation: head / body / tail
length (in mm) benign / malignant / unknown
nature
sampling: citology / pancreas juice
Pseudocyst filling form the duct
localisation: head/body / tail (in mm)

11. Terápia A. Sphincterotomy Y/N:

Precut papillotomy by papillotom / needle knife from the orifice/needle knife fistulotomy/transpancreatic sphincterotomy(septotomy)
Traditional
Repapillotomy
Pancreatic sphincterotomy
Double sphincterotomy

B. Dilatation Y/N

Balloon dilatation of the papilla (extent of dilatation(mm), balloon size (mm))
Stircture dilatation (balloon / bougie, extent of dilatation (mm), balloon size(mm))

C.Stone extraction Y/N: if there is a stone extraction attempt, but no biliary stones are not found, here it should be marked!

Dormia
Balloon
Mechanical lithotripsy
Biliary duct without stones after extraction: Y/N

D. Biliary stent I/N

Previous stent: Previous stent: Y/N, if yes: migration N/proximal/distal; removal Y/N
Inserted stents
- Number/ size/ position of plastic stents (CBD, CBD and left intrahepatic / CBD and right intrahepatic)
- Covered/ uncovered, size, position (transpapillary / suprapapillary; CBD, CBD and left intrahepatic / CBD and right intrahepatic) metal stent)

E. Pancreatic stent Y/N

Prophylactic (size (Fr, mm), type: inner flap, outer flap, outer pigtail)
Previous stent: Y/N, if yes: migration N/proximal/distal; removal Y/N
Therapeutic pancreatic stent (size (Fr, mm), type: inner flap, outer flap, outer pigtail)

F. Nasobiliary drain / nasocystic drain

G. Special interventions

Papillectomy
Cholangioscopy
Pancreatoscopy
Intraductal US
Other (free text entry): e.g. *biliary lavage could be written here*

H. Failed therapeutic intervention:

patient intolerance/anatomic reason/instrumental or accessor failure/other (*more could be selected)*
Comment: (free text input)

12. Further therapeutic/diagnostic recommendations

infusion: Y/N, if yes e.g. Ringer lactate, 1500 ml (infusion before ERCP could also be marked here)

per os feeding: Y /N, if yes normal/fat free/only fluid

antibiotics: Ceftriaxone/Ciprofloxacin/Amoxicillin-clavulanic acid/other:

free text entry: e.g***. combinations: ceftriaxon+metronidazol.***

Continuation of anticoagulant / antiplatelet therapy: date

laboratory measurements: CBC, amylase, CRP, bilirubin, LFTs (more could be selected) date:…….

further imaging: CT/MRI/ EUS *(*more could be selected*)*

interventional radiology / surgical consultation *(*more could be

selected*)*

13. Complication and their management

A. Immediate (occurring during the examination or immediately after) Y/N

Bleeding:
Type of endoscopic hemostasis: epinephrin / thermocoagulation / clip / other
Did the bleeding stop? Y/N

Perforation
(by guidewire / periampullary / far from the ampulla)
retroperitoneal / intraperitoneal air Y/N
Treatment (surgery?/free text)

Cardiorespiratory (hypotension / arrhythmia / hypoxia)

Therapy: complication needing intervention e.g.
hypoxia: satO2 82%, O2 2l/min

B. Late (after the examination – within 2 weeks)

Hemorrhage Y/N
Time of detection
Time of the endoscopic examination
Type of hemostasis (epinephrin / thermocoagulation / clip / other)

Did it stop? Y/N

Need for transfusion? Y/N, if yes, what (Packed RBC/ FFP/Whole blood?) and how many units (units)

Perforation Y/N (guidewire / periampullary / far from the ampulla)
Time of detection
retroperitoneal/intraperitoneal air (Y/N) checkbox?
Treatment……..

Pancreatitis Y/N
Previous PEP? Y/N
Mild / moderate / severe

Cholangitis
Time of detection
Treatment……..

Cholecystitis
Time of detection
Treatment……

C.30-day follow up **important point! please, fill out the attached 30-day follow-up sheet!**

Mortality Y/N
if yes, date:
is it connected to the examination (e.g. PEP) Y/N
After discharge was there a need for emergency /gastroenterological/surgical treatment

D. Severity of complications: **do not forget about this point!**

Mild: resulted in the termination of the examination, needs consultation, discharged within 3 days

Moderate: need for respiratory support during conscious sedation, 4-10-day hospital stay, 1-daycare in ICU, transfusion, repeated endoscopy, intervention radiology

Severe: more than 10-day treatment in hospital, more than 1-day stay in ICU, surgery, permanent damage

Fatal

14. Difficulty of the examination

A. Based on objective parameters (modified Schutz – ASGE):

endoscopist scores after the exam!

Grade 1	Deep cannulation of the desired duct; sampling of the major papilla; Removal/ replacement of a biliary stent
Grade 2	Biliary stone removal < 10 mm; treatment of bile leak; treatment of an extrahepatic benign and/or malignant stricture; prophylactic pancreatic stent
Grade 3	Biliary stone removal > 10 mm; cannulation of the minor papilla / treatment; removal of a proximally migrated stent; intraductal imaging, biopsy, FNA; treatment of acute or recurrent pancreatitis; treatment of pancreatic stricture; pancreatic stone removal < 5 mm; treatment of hilar tumors; treatment of benign biliary strictures at hilum or intrahepatically; SOD
Grade 4	Removal of a proximally migrated pancreatic stent; intraductal treatment; pancreatic stone removal, impacted and/or > 5 mm; intrahepatic stones; pseudocyst drainage, necrosectomy; ampullectomy, Whipple or Roux-en-Y bariatric surgery after ERCP

B. Subjective judgement

1-10 scale? (1: very easy – 10: very difficult)

Crucial points:

1) It is crucial to score the severity of complications!
2) Please, upload the text of the ERCP findings!
3) Radiation dose should always be reported!
4) Weight and height measurements could be acquired from the data of the ward
   Time of examinations should be noted as the time according to the clock.
5) Do not leave empty fields, if there is no data choose N/A instead.
6) Please make further management recommendations and mark it!
7) The objective and subjective difficulty should be assessed by the endoscopist!
8) Do not forget to report complications!
9) 30-day follow up is essential, please, call your patient to assess late occurring adverse events!

Results from the ERCP registry

Quality indicators (ASGE 2014)	Grade of recomm.	Perfor-mance target	Mea-sured rate
Documented appropriate indication	1C+	>90%	**100%**
Informed consent is obtained / documented	1C	>98%	**96.5%**
Patient monitoring during sedation is performed	3	>98%	**97.2%**
Doses and routes of medications are documented	3	>98%	**99.5%**
Immediate adverse events are documented	3	>98%	**100%**
Deep cannulation of the ducts of interest in patients with native papilla and unaltered anatomy	1C	>90%	**93.8%**
CBD stones <1 cm without stricture are extracted	1C	>90%	**94.6%**
Stent placement for biliary obstruction below bifurcation	1C	>90%	**98.2%**
Rate of post-ERCP pancreatitis	1C	N/A	**1.5%**
Rate and type of perforations	2C	≤0.2	**1.25%***
Rate of clinically significant bleeding after sphincterotomy	1C	≤1	**0.9%**
Frequency with which patients are contacted at or greater than 14 days to detect adverse events	3	>90%	**76.3%**

DEVELOPMENT OF ERCP REGISTRY FOR QUALITY CONTROL AND BENCHMARKING

(presented as a poster at UEGW 2017 Barcelona)

Aim: Monitoring the efficacy and safety of invasive endoscopic procedures is crucial. One of the primary aims of our registry is to monitor relevant outcome data of ERCP.

Methods: Hungarian experts in ERCP were invited at the initiation of the registry for discussion and consensus. A web-based case report form (https://ercp.tm-pte.org/) was developed and tested from January 2017 at our department.

Results: ERCP related data of consecutive patients were collected prospectively after approval by the Scientific and Research Ethics Committee and after informed consent from the patients. The data from the first 400 procedures of 301 patients were analyzed to demonstrate the usability of the registry. Difficult biliary access was observed in 56 of 207 (27.1%) cases with native papilla, and 48 (85.7%) of them had successful biliary access at the first ERCP. Successful biliary cannulation was achieved in 93.8% of all procedures where the papilla was reached. Immediate complications were observed in 43 cases (10.75%), 21 of them (5.25%) were bleeding (19 mild (4,75%) and 2 (0,5%) moderate severity), hypoxia occurred in 18 cases (4.5%, all mild). Post-ERCP pancreatitis developed in 6 patients (1.5%, 4 mild, 2 moderate). Cholangitis was observed in 4 cases (1%), while late bleeding only in 2 cases (0.5%, moderate severity).Follow up was conducted 30 days after the ERCP by a telephone call and/or reviewing health care documentation to observe long-term outcome in 231 patients (76.3%). 16 patients (6.9%) died during this period, but only 1 (0.4%) death was related to the procedure (due to unresolved cholangitis in Klatskin tumor). All other quality indicators can be monitored by using the ERCP registry.

Conclusions: The ERCP registry is an essential tool for measuring quality indicators. The universal usage will allow benchmarking at individual, institutional and national level and will help in quality improvement. Effectivity, safety and impact on different pancreatobiliary disorders will be also measurable.

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Taking discoveries to patients' benefit