Supplementary material

Supplementary Table 1 Experience and training of the study operators.

Experienced operators				
	Total (n = 41)	High-volume (n = 25)	Medium-volume (n = 16)	P value
Lifetime ERCPs performed independently, n (%)				0.906
≤ 100	2 (2,4)	1 (4,0)	1 (6.3)	
101-300	4 (9.8)	3 (12.0)	1 (6.3)	
301-500	2 (4.9)	1 (4,0)	1 (6.3)	
501-1000	2 (4.9)	1 (4,0)	1 (6.3)	
> 1000	32 (78.0)	19 (76.0)	13 (81.2)	
ERCPs performed independently in the last year, n (%)				0.003
< 100	7 (17.1)	5 (20.0)	2 (12.5)	
101-200	20 (48.7)	7 (40.0)	13 (81.3)	
≥ 200	14 (34.1)	13 (52.0)	1 (6.3)	
ERCPs performed independently in the last year, n (%)				0.003
≤ 200	27 (65.9)	12 (48.0)	15 (93.8)	
> 200	14 (34.1)	13 (52.0)	1 (6,2)	
Number of years performing ERCP independently median (IQR)	16 (10-34)	14 (7-25)	17 (13-20)	0.793
The time for ERCP training n (%)				0.756
during residency	13 (31.7)	7 (28.0)	6 (37.5)	
after residency	11 (26.8)	8 (32.0)	3 (18.8)	
Hospital work experience	17 (41.5)	10 (40.0)	7 (43.8)	
Number of tutored ERCPs before independent procedure				0.324
0	4 (9.8)	1 (4.0)	3 (19.0)	
< 50	7 (17.1)	4 (16.0)	3 (19.0)	
50-100	11 (26.9)	7 (28.0)	4 (25.0)	
100-200	8 (19.5)	4 (16.0)	4 (25.0)	
> 200	11 (26.9)	9 (36.0)	2 (12.5)	
Trainees				
	Total (n = 21)	High-volume (n = 12)	Medium-volume (n = 9)	P value
Number of years being in ERCP training				

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median (IQR), year	1.0 (1.0-3.0)	1.0 (1.0-2.0)	1.0 (1.0-3.0)	0.806
Number of ERCP as trainee				0.042
≤ 50	15 (71.4)	6 (50.0)	9 (100)	
50-100	0 (0.0)	0 (0.0)	0 (0.0)	
101-200	3 (14.3)	3 (25.0)	0 (0.0)	
200-300	3 (14.3)	3 (25.0)	0 (0.0)	
Time for ERCP training, n (%)				0.478
During residency	4 (19.0)	3 (25.0)	1 (11.1)	
After residency	4 (19.0)	2 (16.7)	2 (22.2)	
Hospital work experience	13 (62.0)	7 (58.3)	6 (66.7)	

Supplementary material

Supplementary Table 2 Results from univariable analysis for post-ERCP adverse events.*

Variable	Without AEs	With AEs	Univariate regression analysis adjusted for cluster (hospital) effect	
			ORs [95% CI]	*P* value
Center group				
High-volume	544 (92.4)	45 (7.6)	1	
Low-volume	45 (91.0)	16 (9.0)	1.20 (0.42-3.40)	0.72
Age, n (%)				
> 40 years	682 (92.3)	57 (7.7)	1	
< 40 years	23 (85.2)	4 (14.8)	2.10 (0.66-6.43)	0.204
Sex, n (%)				
Female	269 (91.5)	25 (8.5)	1	
Male	437 (92.6)	35 (7.4)	0.83 (0.46-1.37)	0.461
Prior history of pancreatitis				
No	666 (92.2)	55 (7.8)	1	
Yes	39 (90.0)	5 (10.0)	1.52 (0.56-4.14)	0.409
Prior history of ERCP				
Yes	270 (94.4)	16 (5.6)	1	
No	435 (90.8)	44 (9.2)	1.71 (0.64-4.50)	0.281
ASA Classification (reference group, I)				
I	115 (95.8)	5 (4.2)	1	
≥ II	591 (91.5)	55 (8.5)	2.14 (0.96-4.76)	0.062
Indication for ERCP - recurrent/acute/chronic pancreatitis				
Other indications	644 (93.1)	48 (7.1)	1	

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Recurrent/acute/chronic pancreatitis	62 (83.8)	12 (16.2)	2.60 (1.62-4.16)	0.007
Indication for ERCP - obstructive jaundice				
Other indications	452 (94.8)	34 (5.2)	1	
Obstructive jaundice	253 (90.4)	27 (9.6)	1.42 (0.35-1.40)	0.319
Indication for ERCP – altered lab or imaging tests results				
Other indications	467 (93.2)	34 (6.8)	1	
Altered lab or imaging test results	238 (89.8)	27 (10.2)	1.56 (0.91-2.64)	0.11
Indication for ERCP - stones				
Other indications	422 (93.0)	32 (7.0)	1	
Stones	283 (90.7)	29 (9.3)	1.35 (0.79-2.19)	0.267
ERCP difficulty grade				
I	447 (93.1)	33 (6.9)	1	
II/III	259 (90.6)	27 (9.4)	1.77 (0.95-2.10)	0.089
Difficult cannulation				
No	597 (93.3)	43 (6.7)	1	
Yes	109 (86.5)	28 (13.5)	2.16 (1.08-4.34)	0.030
Antithrombotic therapy				
No	478 (92.1)	41 (7.9)		
Yes	192 (91.0)	19 (9.0)	1.21 (0.66-1.93)	0.665
Sedation technique				
Conscious	204 (95.8)	8 (4.2)	1	
Deep/narcosis (intubation)	496 (90.5)	52 (9.5)	2.37 (0.46--12.12)	0.301
Success in deep cannulation				
Yes	682 (92.7)	54 (7.3)	1	

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No	24 (80.0)	6 (20.0)	3.16 (1.42-7.03)	0.005
Number of experts as continuous variable			1.06 (0.85-1.52)	0.373

*Odds ratios estimated for the parameters of the logistic model adjusted for cluster (hospital) effect.

ERCP, endoscopic retrograde cholangiopancreatography; ASA, American Society of Anesthesiologists;

OR, odds ratio; CI, confidence interval.

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<u>**CENTER QUESTIONNAIRE**</u>

Center: _____

Date of compilation: ____ / ____ / _____

No. of hospital beds: _____

Characteristics of the center:

    ☐ Gastroenterology Department with beds ☐ Endoscopy Service ☐ Gastroenterology Unit inside a Medical Department ☐ Gastroenterology Unit inside a Surgery Department

Medical Staff (No.): _____

ERCP operators (No.): _____

Expert ERCP operators (No.): _____

ERCP operators who are Gastroenterologists (No.): _____

Organization of the unit when performing ERCP

The ERCP is performed:

    ☐ In the context of an Integrated Clinical Pathway of the Hospital

    ☐ After evaluation of the clinical case by the ERCP operator

    ☐ The ERCP is performed upon a request from other specialists

Do you use a specific informed consent module for ERCP?   ☐ Yes   ☐ No

If yes, is it obtained:

    ☐ In the department of origin   ☐ Right before the procedure in the ERCP room

Which services are available in your Hospital?:

    ☐ US   ☐ CT   ☐ MR   ☐ EUS   ☐ PTC

Your Endoscopy Unit guarantees ERCP execution:

    ☐ 24-7

    ☐ Everyday, during daytime

    ☐ Only when an endoscopist with experience in ERCP is available

    ☐ Only when the radiology room is available

    ☐ Other: _____

Do you have dedicated nurses for ERCP?   ☐ Yes   ☐ No

Who is your ERCP assistant: ☐ Another physician ☐ A nurse

How many ERCPs were performed in your Center in:

2014: _____ 2013: _____ 2012: _____

Does your Center perform scheduled quality monitoring?:

    ☐ Cannulation percentage

    ☐ Adverse events percentage

    ☐ ERCP repetition percentage

    ☐ Other: _____

    ☐ No

Where is the ERCP performed?:

    ☐ In the endoscopy room, always

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☐ In the radiology room, always

☐ Variable, basing on daytime and conditions of the patient

What type of radiologic equipment do you use?

☐ Digital C-arm X-ray ☐ Analogic C-arm X-ray ☐ Remotely activated system

☐ Angiography system

Do you have an archive of the fluoroscopy images? ☐ Yes ☐ No

If yes: ☐ Printed ☐ Digital ☐ Other:_____

Is the duration of the X-ray exposition recorded? ☐ Yes ☐ No

How is your patient generally sedated?:

☐ Conscious sedation (midazolam +/- pethidine) ☐ Deep sedation (propofol) ☐ General Anesthesia

Anesthesiologist attendance:

☐ An anesthesiologist is always available

☐ An anesthesiologist is partially available (only for a limited number of hours or days)

☐ An anesthesiologist is only availble for critically ill patients

Patient monitoring:

☐ Peripheral pulse oximetry ☐ Capnography ☐ Blood pressure ☐ ECG

Patient assistance after the ERCP:

☐ A recovery room is available

☐ The patient is sent back to the department of origin immediately after the procedure

Post-ERCP pancreatitis (PEP) prophylaxis:

☐ Always ☐ Only for high-risk patients ☐ Never

Which drugs do you use for PEP prophylaxis:

☐ NSAIDS suppository ☐ Gabexate mesilate

☐ Octreotide ☐ Somatostatin ☐ Other:_____

Antibiotic prophylaxis for ERCP:

☐ Always ☐ Only for selected cases, following guidelines indications ☐ Never

Do you have specific protocols for the management of:

☐ ERCP preparation (fasting, prophylaxis, etc)

☐ Antithrombotic therapy

☐ Follow up and therapy after ERCP

☐ Adverse events

Amylase/lipase dosing after ERCP:

☐ Routinely ☐ Only for symptomatic patients

- Timing: ☐1h ☐ 2h ☐ 4h ☐ 6h ☐ 12h ☐ 24h

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<u>**OPERATOR QUESTIONNAIRE**</u>

Center:_____

Operator No.:_____

Date:____/____/_____

Sex: ☐M ☐ F

Age:_____ Year of Degree:_____

Role in the unit:

☐Head of Department ☐Attending physician ☐Contract physician ☐Resident/fellow

☐Other:_____

Education:

☐ Gastroenterologist ☐ Surgeon ☐Medicine Specialist ☐ Other:_____

Permorming ERCP:

☐ Independently ➜ Fill in section A

☐ In training ➜ Fill in section B

SECTION A: EXPERIENCED ERCP OPERATOR

How many years have you been performing ERCP independently?:_____

How old were you when you first performed an ERCP as the first operator?:_____

How many ERCPs have you performed as the first operator?:

☐ <100 ☐ 100-200 ☐ 201-300 ☐ 301-500 ☐ 501-1000 ☐ >1000

How many ERCPs have you performed as the first operator in the last year?:

☐ <100 ☐ 100-200 ☐ 201-300 ☐ 301-500 ☐ 501-1000 ☐ >1000

Where did you learn to perform ERCP?:

☐ During residency/fellowship ☐ After residency/fellowship

☐ In your Hospital ☐ In a separate ERCP center

How many ERCPs did you perform with supervision before performing ERCP independently?:

☐ 0 (self-taught) ☐ <50 ☐ 50-100 ☐ 101-200 ☐ 201-300

What's your opinion on the quality of ERCP training programs?:

☐ There are no training programs, so you have to create your own

☐ There are teaching programs, but they are mainly low quality and/or without a hands-on training

☐ I had the possibility to train in the context of a dedicated program with good supervisors

What are your perfomance measures in ERCP?:

- Native-papilla cannulation success: ☐>90% ☐80-90% ☐<80%

- PEP rate: ☐<5% ☐5-10% ☐>10%

SECTION B: ERCP TRAINEE

How long have you been training in ERCP?:_____

How old were you when you performed your first ERCP with supervision?:_____

How many ERCPs have you performed with supervision?:

☐ <20 ☐ 20- 50 ☐ 51-100 ☐ 101-200 ☐ 201-300 ☐ 301-500 ☐ >500

Where are you learning to perform ERCP?:

☐ Residency/fellowship ☐ After residency/fellowship

☐ In my Hospital ☐ In another Hospital

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What's your opinion on the opportunities for ERCP training?:

☐ There are no training programs, so you have to create your own

☐ There are teaching programs, but they are mainly low quality and/or without a hands-on training

☐ I am attending a dedicated program

What are your perfomance measures in ERCP?:

- Native-papilla cannulation success: ☐>90%   ☐80-90%   ☐50-79%   ☐<50%

- PEP rate: ☐<5%   ☐5-10%   ☐11-20%   ☐ >20%

What's your opinion on the quality of your training program?:

☐ Extremely good, both theory and practice

☐ I have many opportunities to watch procedures, less opportunities to practice

☐ Not good, too little opportunities to watch and practice

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ERCP CRF

Center:_____

Date:___/___/_____

First Operator No.:_____ Second Operator No.:_____

ERCP indication:

☐ Obstructive jaundice ☐ Acute cholangitis ☐ Blood tests anomalies ☐ Documented CBD stone(s)

☐ Acute biliary pancreatitis ☐ Idiopathic/recurrent pancreati ☐ Chronic pancreatitis ☐ Biliary leak ☐ SOD ☐ Iatrogenic biliary stenosis

☐ Biliary stent replacement/removal ☐ Pancreatic stent replacement/removal

☐ Diagnostic ERCP (no definite diagnosis on imaging) ☐ Tissue acquisition ☐ Stenting for a tumor

☐ Papillectomy ☐ Other:_____

Previous surgery:

☐ Cholecystectomy ☐ Billroth I ☐ Billroth II

☐ GEA ☐ Whipple procedure ☐ Roux-en-Y

☐ Other: _____

Previous ERCP: ☐ Yes ☐ No

If yes:

☐ Biliary sphincterotomy already performed ☐ Pancreatic sphincterotomy ☐ Minor papilla sphincterotomy ☐ Biliary stent in place ☐ Pancreatic stent in place

☐ Other:_____

ERCP difficulty:

☐ Grade 1 ☐ Grade 2 ☐ Grade 3

ERCP characteristics (Table 1, A-V) which grade difficulty:_____

Risk factors:

☐ Suspected S.O.D. ☐ Female sex ☐ Previous pancreatitis

☐ Age < 40 ☐ Other:_____

Antithrombotic therapy: ☐ Yes ☐ No

ASA score (table 2): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Investigations performed prior to the ERCP:

☐ Clinical evaluation/blood tests ☐ Abdominal US ☐ CT scan

☐ MRCP ☐ EUS ☐ Other (if relevant):_____

Place of execution of the ERCP:

☐ Endoscopy room ☐ Radiology room ☐ Operating room ☐ Other:_____

Sedation:

☐ Conscious sedation ☐ Deep sedation (propofol) ☐ General anesthesia

Anesthesiologst attendance: ☐ Yes ☐No

PEP prophylaxis: ☐ Yes ☐No

If yes:

- Drug:_____

- Timing: ☐ Before the ERCP ☐ At the end of the procedure

- Why?:

☐Routine administration ☐Risk factors present ☐Long/difficult procedure

Antibiotic prophylaxis: ☐ Yes ☐No

If yes:

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- Timing: ☐ Before the ERCP   ☐ At the end of the procedure
- Why?:
  - ☐ Routine administration
  - ☐ Patient characteristics (age, sex, comorbidities)
  - ☐ Long/difficult procedure or incomplete drainage

Procedure duration (from scope insertion to scope extraction):_____min

Fluoroscopy duration: _____min

If a trainee was involved, what is the estimated percentage of his/her contribution to the procedure:

     ☐ 0%   ☐ < 25%   ☐ 26-50%   ☐ 51-75%   ☐ 76-99%   ☐ 100%

Procedure success

	Task	Success	Partial successo	Unsuccessful
1	The duodenum was reached	☐		☐
2	The papilla was identified	☐		☐

3	CBD deep cannulation
	Wire-guided sphincterotome
	    ☐ Yes ☐ No
	Difficult cannulation:
	  - Precut: ☐ Yes ☐ No
	
	  - Trans-pancreatic sphincterotomy:
	    ☐ Yes ☐ No
	
	  - DGW technique:
	    ☐ Yes ☐ No
		☐		☐

4	Pancreatic duct cannulation: Desired: ☐ Yes ☐ No	☐		☐
5	Biliary sphincterotomy	☐		☐
6	CBD stone exctraction <1cm	☐	☐	☐
7	CBD stone exctraction >1cm	☐	☐	☐
8	Distal CBD stenting	☐		☐
9	Hilum stenting	☐	☐	☐
10	Biliary brushing/biopsy	☐		☐
11	Pancreatic brushing/biopsy	☐		☐
12	Stricture dilation	☐	☐	☐
13	Pancreatic sphincterotomy	☐		☐
14	Pancreatic duct stone extraction	☐	☐	☐
15	Therapeutic pancreatic stent	☐		☐
16	Prophylactic pancreatic stent	☐		☐
17	Minor papilla cannulation	☐		☐
18	Minor papilla sphincterotomy	☐		☐
19	Minor papilla stenting	☐		☐
20	Biliary manometry	☐		☐

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21	Pancreatic manometry	☐		☐
22	Papillectomy	☐		☐
23	Other:_____	☐		☐

Accessories/devices used:

	Accessory/device	Quantity	Non-disposable	Short-wire
1	ERCP catheter		☐	☐
2	Guidewire		☐	☐
3	Sphincterotome		☐	☐
4	Pre-wired sphincterotome		☐	☐
5	Cystotome		☐	
6	Pre-cut needle knife		☐	☐
7	Stone extraction ballooon		☐	☐
8	Basket		☐	☐
9	Lithotriptor		☐	☐
10	Brushing catheter		☐	☐
11	Biliary dilation balloon		☐	☐
12	Inflating device			
13	Biliary dilation catheter		☐	☐
14	Pre-mounted biliary plastic stent			☐
15	Biliary plastic stent			☐
16	Plastic stent introduction kit		☐	☐
17	Pre-mounted pancreatic plastic stent		☐	☐
18	Pancreatic plastic stent			☐
19	Nasobiliary drainage tube		☐	☐
20	Nasopancreatic drainage tube		☐	☐
21	Self-expandable biliary stent ☐ Fully covered ☐ Partially covered ☐ Uncovered			
22	Self-expandable pancreatic stent			☐
23	Biopsy forceps		☐	☐
24	Cholangioscopy			
25	Other:_____			

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DEFINITIONS

1. ERCP difficulty grade

	Diagnostic	Therapeutic
Grade 1: standard	**A.** Selective deep cannulation **B.** Biopsy and citology	**C.** Biliary sphincterotomy **D.** Stones <1cm **E.** Stents for biliary leaks **F.** Stents for low tumors **G.** Prophylactic small pancreatic stents
Grade 2: advanced	**H.** Billroth II diagnostics **I.** Minor papilla cannulation	**L.** Stones >1cm **M.** Hilar tumor stent **N.** Benign biliary stricture
Grade 3: tertiary level	**O.** Sphincter manometry **P.** Whipple/Roux-en-Y **Q.** Intraductalendoscopy	**R.** Billroth II therapeutics **S.** Intrahepatic stones **T.** Pancreatic therapies **U.** Ampullectomy **V.** Pseudocyst drainage

2. ASA score

ASA score	Definition
1	A normal healthy patient Examples: Healthy, non-smoking, no or minimal alcohol use
2	A patient with mild systemic disease Examples: Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
3	A patient with severe systemic disease Examples: Substantive functional limitations; One or more moderate to severe diseases; Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.
4	A patient with severe systemic disease that is a constant threat to life Examples: Recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC,

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		ARD or ESRD not undergoing regularly scheduled dialysis
5		A moribund patient who is not expected to survive without the operation Examples: Ruptured abdominal/thoracic aneurysm, massive trauma

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ADVERSE EVENT(S) CRF

Center: _____

ERCP Operator No.: _____

AE date: ___/___/_____

ERCP date: ___/___/_____

AEs (always evaluate one week after the procedure to define severity)

	AE	Mild	Moderate	Severe or fatal
1	Acute pancreatitis	☐	☐	☐
2	Bleeding	☐	☐	☐
3	Cholangitis	☐	☐	☐
4	Perforation after sphincterotomy	☐	☐	☐
5	Duodenal wall perforation	☐	☐	☐
6	Cardiopulmonary AE	☐	☐	☐
7	Other: _____	☐	☐	☐

DEFINITIONS

- **AE definition**

AE	Mild	Moderate	Severe
Bleeding	Clinically defined (not only endoscopically). Hb drop <3g; Transfusions not necessary	Transfusion of ≤4 units of pRBC. Angiography or surgical intervention not needed	Transfusion of ≥5 units of pRBC or angiography or surgery
Perforation	Possible or mild leak of liquid or contrast; conservative management ≤ 3 days	Definite perforation, conservative management, 4-10 days	Medical therapy >10 days or percutaneous treatment or surgery
Acute pancreatitis	Abdominal pain, amylase /lipase x3 which normalize within 24 h. Hospitalization or 2-3 days prolongation of hospitalization	4-10 days hospitalization	Hospitalization >10 days or necrotic pancreatitis, pseudocyst, surgery or percutaneous intervention
Infection (cholangitis)	>38°C for 24-48 h	Sepsis and >3 days hospitalization or percutaneous or endoscopic intervention	Septic shock or need of surgery
Basket impaction	Basket freed spontaneously or by endoscopic intervention	Percutaneous intervention needed	Need of surgery

Gravity is defined by length of hospitalization: < 3 days: mild; 4-9 days: moderate; 10 days or any ICU hospitalization or surgery: severe

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OUTCOME CRF

Center:_____

Operator No.:_____

Date of ERCP: ___/___/_____

Date of outcome:___/___/_____

1-month outcome:

- Patient is asyimptomatic: ☐ Yes ☐ No
- ERCP was repeated: ☐ Yes ☐ No

  If yes:

    ☐ Management of sequelae of the procedure: (specify)_____

    ☐ Recurrent disease

    No. of repeated ERCPs:_____

- A new hospital admission was required: ☐ Yes ☐ No

    If yes:

    ☐ For ERCP AEs

    ☐ For the management of recurrent disease

    ☐ For ERCP-unrelated causes

- Need of surgery: ☐ Yes ☐ No
- Patient died: ☐ Yes ☐ No

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