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Prospective evaluation of ERCP performance in an Italian regional database study

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ABSTRACT

Background: Prospective studies about endoscopic retrograde cholangio-pancreatography (ERCP) in a community setting are rare.
Aim: To assess success and complication rates of routinely-performed ERCP in a regional setting, and the priority quality indicators for ERCP practice.
Methods: Prospective region wide observational study on consecutive patients undergoing ERCP during a 6-month period. A centralized online ERCP questionnaire was built and used for data storage. Primary quality indicators provided by the American Society of Gastrointestinal Endoscopy (ASGE) were considered.
Results: 38 endoscopists from 18 centers performed a total of 2388 ERCP. The most common indication for ERCP was choledocholitiasis (54.8%) followed by malignant jaundice (22.6%). Cannulation of the desired duct was obtained in 2293 cases (96%) and ERCP was successful in 2176 cases (91.1%). Success and ERCP difficulty were significantly related to the experience of the operator ($p = 0.001$ and $p < 0.001$, respectively). ERCP difficulty was also significantly related to volume centers ($p < 0.01$). The overall complication rate was 8.4%: post-ERCP pancreatitis (PEP) occurred in 4.1% of procedures, bleeding in 2.9%, infection in 0.8%, perforation in 0.4%. Mortality rate was 0.4%. All the ASGE priority quality indicators for ERCP were confirmed.

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Conclusions: The procedural questionnaire proved to be an important tool to assess and verify the quality of routinely-performed ERCP performance in a community setting.

1. Introduction

There are many studies and large series about ERCP mainly performed in academic centers that define both the therapeutic success and complication rate of this procedure [1–4]. Prospective studies with data collected in a community setting are rare [5–7]. The conditions in which endoscopists act in 'real life' are often different from those usually considered in controlled studies. ERCP outcomes can be associated with ERCP volume [8–10], type of the center (community practice and academic centers), operators' skill [6,8,11–13], patients' and/or technical related-risks [1,14,15], complexity of the procedure [16]. In 2006, the American Society of Gastrointestinal Endoscopy (ASGE)/American College of Gastroenterology Task Force on Quality in Endoscopy [17] proposed 5 research questions specifically directed at ERCP in the community, in order to create a comprehensive list of potential quality indicators applicable to the ERCP practice setting and consequently evaluating the skills that must be developed to perform a high quality procedure. In 2015 quality indicators for ERCP were re-evaluated and 5 of them were defined as a priority [18]. Measurement of routine ERCP outcome is a pre-requisite for the development of quality improvement indicators [17,19,20].

The aim of this study was to prospectively evaluate success and post-procedural complication rates of ERCP in a community practice. Furthermore, we aimed to assess the priority quality indicators for such ERCP practice.

2. Patients and methods

2.1. Study protocol

In October 2014, all endoscopists performing ERCP in Lombardia, a region of Italy, were invited to participate in a uncontrolled prospective web-based data collection study. The participants' email addresses were obtained from the Italian Society of Digestive Endoscopy (SIED) and the Italian Federation of Societies of Digestive Diseases (FISMAD) and, in the case of non-members, by contacting the physicians directly. All endoscopists who logged on to a web data base were invited to document their ERCP practice, such as their yearly and lifetime numbers of procedures and center volume before reporting various parameters of each consecutive patient that they submitted to ERCP during a 6-month period, from February 1st to July 1st, 2015. All endoscopists performed ERCP using guidewire as initial method for attempting papillary cannulation, as recommended by European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guidelines [4]. Endoscopists, however, were left free to choose the techniques to gain the access to the common bile duct (CBD) in difficult cases (e.g. the timing and type of precut), and to indicate the preventive measures recommended for post-ERCP pancreatitis (PEP) (rectal NSAIDs and/or pancreatic stenting). The study was designed and coordinated by the University Vita-Salute San Raffaele Gastroenterology and Gastrointestinal Endoscopy Division, appointed by SIED and FISMAD. Approval of the protocol was obtained from the ethics committees in all centers. In each center, informed consent was routinely obtained from all patients undergoing ERCP including data management for scientific purposes. ERCP was planned only for patients staying in hospital for at least 24 h after the procedure. Patients under 18 years of age were excluded. Follow-up patient contact was not scheduled.

Table 1
Grading of difficulty of ERCP.[a]

Grading 1 = standard	- Biliary sphincterotomy - Biliary stones <10 mm - Stents for distal biliary stenosis
Grading 2 = advanced	- Biliary stones >10 mm - Stents for proximal biliary stenosis - Benign biliary stenosis
Grading 3 = tertiary	- Post Billroth II gastrectomy - Intrahepatic biliary stones - Pancreatic therapy

[a] By Cotton [16].

2.2. Data collection

After ERCP, each endoscopist prospectively recorded patient and procedure-related data on a detailed web-based data collection form, which was checked by an external party to the study monitor who guaranteed the anonymity of the data source and assessed the completeness of data entry. The database contained more than 150 variables including patient demographics, clinical and technical (ERCP details) data, admission type (urgent or elective ERCP), diagnosis, sedation type (deep sedation using propofol or moderate sedation using benzodiazepines and opioids), length of hospital stay and in-hospital complications. More than one indication or procedure could be listed, as applicable.

2.3. Definitions

Success was defined as cannulation and visualization of the desired duct as well as the achievement of the therapeutic/diagnostic target.

ERCP difficulty was classified as standard, advanced and tertiary according to Cotton criteria [16] (Table 1).

ERCP complications were defined and graded according to the consensus criteria proposed by Cotton et al. in 1991 [21]: mild = unplanned hospital stay of 2–3 nights; moderate = 4–10 nights; severe ≥ 10 nights or intensive care or surgery.

2.3.1. Risk factors for post-ERCP pancreatitis

We considered as clinical and/or technical risk factors for PEP those reported in Table 1 of ESGE guidelines [14].

2.3.1.1. Volume centers. Volume centers were divided into three groups based on the number of ERCP that they declared to perform per year: centers with less than 100 ERCP per year were arbitrarily defined "low-volume" centers, those with 100–250 ERCP per year were defined "medium-volume" centers and those with more than 250 ERCP per year "high-volume" centers.

2.3.1.2. Operators' expertise. Operators' expertise was defined on the basis of both the total number of procedures performed career-long and the number currently done per year. As reported by Dutch authors [5], the current ERCP volume per year among endoscopists was graded as follows: less than 50, from 50 to 100, from 100 to 150 and more than 150 procedures per year. A "low-grade" experience was defined as a career-long total performance of less than 200 procedures and/or current number less than 50 per year [3].

Table 2
Indications for ERCP (overall 2388 procedures).

Indication	No.	%[a]
Extrahepatic lithiasis	1365	57.2
Jaundice	639	26.8
Suspected malignant secondary biliary stenosis	352	14.7
Cholangitis	277	11.6
Suspected malignant primary biliary stenosis	172	7.2
Suspected benign biliary stenosis	143	6.0
Substitution of biliary stent	141	5.9
Acute pancreatitis	135	5.7
Chronic pancreatitis	48	2.0
Post-surgical biliary leak	47	2.0
Suspected Ampulloma	47	2.0
Intrahepatic lithiasis	42	1.8
Recurrent acute pancreatitis	33	1.4
Pancreas divisum	16	0.7
Substitution of pancreatic stent	7	0.3
Drainage of pseudocyst	3	0.1

[a] Percentages add up to more than 100% because a given procedure could have more than one indication.

The participation in the study of trainees performing ERCP in "high volume" centers was considered.

2.3.1.3. Type of sedation. Deep sedation with propofol was done in all cases by an anesthesiologist; where the anesthesiologist was absent, a moderate sedation using traditional medications (benzodiazepine and opioids) was done.

2.3.1.4. Quality indicators. We adopted the benchmarks first established by ASGE 2006 [17] and later reviewed and updated [18] when five priority quality indicators for ERCP were identified.

2.4. Statistical analysis

Data is presented as means ± standard deviations and frequency values. Group differences and significant association in the incidence of each variable were assessed using t-tests and one-way anovas, and chi-square tests, respectively. All differences and associations were considered significant at a two-sided P value less than 0.05. Variables with a p value <0.1 in the univariate analysis were all included in a forward stepwise multiple logistic regression. Data was analyzed using the SPSS system software (IBM Analytics).

3. Results

23 out of 45 contacted centers accepted to participate in this study, and 18 of them actively collected data. During the established 6-month period, a total of 2388 ERCP procedures were performed by 38 different operators. 474 (19.9%) ERCP were performed in 6 low-volume centers, 729 (30.5%) in 7 medium-volume centers and 1185 (49.6%) in 5 high-volume centers. 1051 ERCP (44%) were done in deep sedation, the remaining 1337 in moderate sedation. Elective procedures accounted for 2124 (88.9%), urgent procedures for 264 (11.1%). 76.1% of the ERCP were grade 1 difficulty, 18.9% grade 2 and 5% were grade 3. The papilla was native in 1765 (73.9%) cases, already cut (previous sphincterotomy) in 623 cases (26.1%). The most common indication for ERCP was suspected or effective choledocholithiasis that accounted for 57.2% of all procedures, followed by malignant jaundice (22.6%) (Table 2). Mean duration of procedures was 33 minutes (±19.6 SD; range: from 20 to 170 min). Even if slightly shorter, 27 min (±18.6 SD; range: from 20 to 155 min), mean duration of procedures was ostensibly not significantly reduced by the presence of an anesthesiologist (p = 0.8). The presence of an anesthesiologist, however, was significantly higher in high volume centers (20.6%, 13.4% and 66%, p < 0.01), and in the case of higher ERCP difficulty (43.8%, 41.2% and 58.8%, p < 0.01). The most common finding at ERCP was choledocholithiasis in 1309 procedures (54.8%). Purely diagnostic procedures were 69 (2.9%). Among therapeutic procedures, biliary sphincterotomy was performed in 1490 (62.4%) cases, pancreatic sphincterotomy in 46 (1.9%), precut sphincterotomy in 259 (10.8%), placement of biliary stent in 751 (31.4%) and placement of therapeutic pancreatic stent in 60 (2.5%) cases; prophylactic pancreatic stents were placed in 62 (2.6%) cases. A difficult cannulation [4] was observed in 425 procedures (17.8%). Precut sphincterotomy was mainly performed in cases of difficult cannulation (89.6%).

3.1. Efficacy

Technical success of the procedure was obtained in 2176 (91.1%) cases. The success rate of biliary cannulation was 94.9% in presence of native papilla and 99.2% with prior sphincterotomy (p < 0.01).

3.1.1. Volume centers

Cannulation and technical success rates were not significantly different according to volume centers (95.3%, 96.5%, 95.9%, p = 0.6; 90%, 91.6%, 91.2%, p = 0.6, respectively). However, there was a significant association between the grading of difficulty of the procedures and volume centers (i.e. rates of tertiary procedures according to centers volume 2.9%, 3.4% and 6% respectively, p < 0.01). No significant differences in hospital stay length (mean ± SD) and volume of the centers were observed: 2.7 ± 2.1 days in low-volume centers, 2.9 ± 2.8 days in medium-volume centers and 2.9 ± 2 .8 days in high-volume centers (p = 0.5).

3.1.2. Operators' expertise

8.1% of procedures (n = 194) were done by operators with ERCP volume <50 per year, 15.9% of procedures (n = 380) were done by operators with ERCP volume 51–100 per year, 25.8% of procedures (n = 617) were done by operators with ERCP volume 101–150 per year, 50.1% of procedures (n = 1197) were done by operators with ERCP volume >150 per year, 15.3% of which (n = 183) were started by trainees. The success rate of the procedures was significantly related to the experience of the operator (87.2%, 89.7%, 88.5%, 93.1%, p = 0.001). Furthermore, there was a significant association between the operators' expertise and the rates of more difficult procedures (p < 0.001) (Fig. 1). ERCP success was not influenced by the presence of trainees (rate of successful procedures performed by expert operators plus trainee vs expert alone was 90.2% and 93.1%, respectively; p = 0.5).

3.2. Complications

The overall complication rate was 8.4% (200 out of 2388 ERCP). 10 patients (0.4%) died because of cardiopulmonary events (n = 5), biliary sepsis (n = 3) and pancreatitis (n = 2). The frequencies and severity of main complications are shown in Table 3.

3.2.1. Volume centers

There was not a significant association between overall complications and center volume (p = 0.1): centers with less than 100 ERCP per year had 10.6% of complications, centers with 100–250 ERCP per year had 6.6% of complications, centers with more than 250 ERCP per year had 8.8% of complications.

3.2.2. Operators' expertise

In the same way, there was not a significant association between rates of overall complications and operators' experience (p = 0.6): 10.8%, 8.2%, 7.8% and 8.4% in hands of operators performing <50 ERCP per year, 50–100 ERCP per year, 100–150 ERCP per year and more than 150 ERCP per year, respectively.

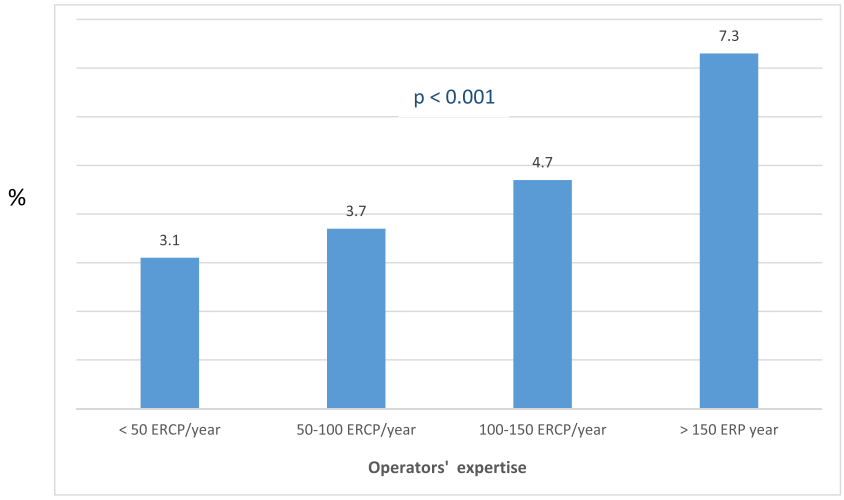

Fig. 1. Rates of grading 3 ERCP according to operators' expertise.

Table 3
Complications' frequency and severity.

Complications	Total no. (% of total ERCP)	Mild no. (%)	Moderate no. (%)	Severe no. (%)
Overall	200 (8.4)	161 (80.5)	21 (10.5)	18 (9)
Pancreatitis	98 (4.1)	89 (90.8)	1 (1)	8 (8.2)
Bleeding	66 (2.9)	51 (77.3)	15 (22.7)	0 (0)
Infection	20 (0.8)	13 (65)	4 (20)	3 (15)
Perforation	8 (0.4)	5 (62.5)	1 (12.5)	2 (25)
Others[a]	8 (0.4)	3 (37.5)	0 (0)	5 (62.5)

[a] Cardiopulmonary and miscellaneous complications.

Overall complications were not significantly higher in patients who underwent urgent rather than elective ERCP (8.2% in election vs 9.5% in urgency; p = 0.4) except for cardio-pulmonary complications which occurred more frequently in urgent rather than elective ERCP (0.8% vs 0.3%, p = 0.02).

Even if a slight tendency of minor complications was observed in the presence of an anesthesiologist (7.3% vs 9.2%), this effect was not statistically significant (p = 0.1).

PEP prevention was done in 515 patients overall (21.6%): in 453 (19%) using rectal NSAIDs (100 mg diclofenac or indomethacin immediately before or after ERCP), in 62 (2.6%) using a pancreatic stent either alone in 48 cases or in combination with NSAIDs in 14.

3.2.3. *Risk factors for complications*

9 out of the 12 ESGE patient- and procedure-related risk factors [5] were significantly associated with PEP according to the univariate analysis (Table 4), the following four at the multivariate analysis: previous PEP (p < 0.01) contrast injection into the MPD (p < 0.01), pancreatic guidewire passages >1 (p = 0.048) and pancreatic sphincterotomy (p = 0.04).

443 (97.8%) of the 453 patients who received rectal NSAIDs prophylaxis and all the 62 patients who received pancreatic stenting presented at least one clinical or technical risk factor for post ERCP pancreatitis.

PEP rates did not differ between patients who underwent or not underwent NSAIDs (3.8% vs 5.1%, p = 0.1) or pancreatic stenting (2.9% vs 3.9% p = 0.5). ERCP volume per centers and operators' expertise were not significantly associated with PEP (4.7%, 3.2%, 4.5% p = 0.2 and 6.2%, 3.2%, 3.7%, 4.3% p = 0.3, respectively).

The risk of developing PEP was significantly associated with the ERCP difficulty; (3.6%, 5.1%, 8.4%; p = 0.01); in particular, it was significantly higher in tertiary as opposed to standard procedures (OR 2.47; 95% CI 1.23–4.96; p = 0.01).

Table 4
Clinical and technical risk factors associated with PEP according to univariate analysis.

Clinical risk factors for PEP	p-Value
Previous PEP	<0.01
SOD type II and III	<0.01
Technical risk factors for PEP	**p-Value**
More than 10 attempted cannulation	<0.01
More than one passage of GW[a] in MPD[b]	<0.01
Injection of MPD	<0.01
Precut	<0.01
Pancreatic sphincterotomy	<0.01
Failure of complete biliary stone removal	<0.01
Native papilla	<0.01

[a] GW, guidewire.
[b] MPD, main pancreatic duct.

Normal caliber of CBD (p < 0.01) and precut (p = 0.03) were two risk factors independently associated with bleeding. Low rates of post-procedural perforation (0.4%) or infection (0.8%) made the evaluation of related risk factors impossible.

3.3. *Quality indicators*

All the ASGE priority quality indicators for ERCP were confirmed in this study, as shown in Table 5.

4. Discussion

This is the first Italian study evaluating ERCP practice in a regional setting. Table 6 summarizes and compares our results with those of three multicenter studies performed in other European countries.

Table 5
Priority quality indicators according to ASGE.[a]

	%	Performance ASGE target (%)
Frequency with which ERCP is performed for an appropriate indication and documented	98	>90
Rate of deep cannulation of the duct of interest in patients with native papilla without surgical altered anatomy	95.9	>90
Success rate of extraction of common bile duct stones >1 cm in patients with normal bile duct anatomy	96.6	>90
Success rate for stent placement for biliary obstruction in patients with biliary obstruction below the bifurcation in patients with normal anatomy	93.4	>90
Rate of post ERCP pancreatitis	4.1	N/A

N/A, not available.
[a] By Adler et al. [18].

Table 6
Comparison between the main results of this study and previous studies performed in Europe.

Authors	Year of pubblication	Region	No. of participating centers	No. of endoscopists	No. of exams	Success rate	Complications rate
Ekkelenkamp et al. [5]	2014	Netherlands	61	171	8575	85.8%	N.D.
Kapral et al. [6]	2008	Austria	28	89	3132	84.8%	12.6%
Williams et al. [7]	2007	UK	66	190 74 trainees	5264	70.4%	5.1%
Mariani et al. [present study]	2019	Lombardy (region of Italy)	18	38	2388	91.1%	8.4%

The overall ERCP quality of this study could be considered as good, since all the five ASGE priority quality indicators [18] were fulfilled. However, some considerations have to be made about operators' performance and patients' care: these goals must be object of corrective measures that would guaranty and further improve routine ERCP performance.

In this study, diagnostic ERCP accounted for only 2.9%, a rate that is adequately in line with the increasing availability of MRCP and, mainly, EUS and the consequent recommendation to reserve ERCP for only therapeutic aims. Appropriate indication is a well-established pre-procedure priority quality indicator. In 95% of cases, ERCP confirmed the diagnosis of choledocholithiasis, the most frequent ERCP indication. Jaundice in a patient suspected of having malignant biliary obstruction was the second most frequent indication for ERCP. However, since questionnaire did not report if an early surgery was already planned or not, ERCP could have been non-indicated, although in current clinical practice preoperative biliary decompression by stenting is frequently performed. Biliary cannulation was successful in 94.9% of ERCP in presence of native papilla, a higher rate in comparison to that reported in some other studies [5–7]. Although all endoscopists used guidewire as initial method for attempting papillary cannulation, they were free to use short- or long-wire technique or, in cases of difficult cannulation, timing and type of the secondary techniques to enter the CBD. X-ray exposure time was not recorded.

4.1. Volume centers

We did not find any significant difference in the cannulation and ERCP success and the ERCP center volume. However, a significant higher rates of difficult procedures (advanced or tertiary) where observed in centers with a larger ERCP volume. This is an important finding that seems to show good health care policy decision making and resource utilization for patients undergoing ERCP in our region. These results confirm those observed in a previous Italian multicenter study [9] in which high-volume centers had a significantly greater number of difficult procedures and case mix. On the contrary, this study did not confirm that patients undergoing ERCP at high-volume centers have a shorter length of hospital stay compared to those undergoing this procedure at low-volume centers [10].

4.2. Operators' expertise

The current study confirms that ERCP volume per operator is associated with ERCP success. Results showed that a yearly volume of more than 150 ERCP was associated with a significantly higher rate of procedural success than that of <50 ERCP. These results are in accordance with some studies [6,8,13] that showed a good ERCP success and outcome when the yearly volume per operator is >200 ERCP, and in disagreement with others [12]. The arbitrary cutoff levels used in this study to assess the operator volume are similar to those considered in the Dutch study [5] in which a yearly volume of ≥50 ERCPs was significantly associated with a lower risk of procedural failure. However, as already suggested in this last study, the strong association between lifetime number of ERCPs and yearly volume of ERCP performed per operator, underline that the experience of the operator seems an important variable to ensure ERCP quality rather than the number of procedures per year. A process of professional approval of each operator is crucial because it allows certification of technical expertise and retention of privileges other than the management capability of patient problems.

4.3. Complications

While ERCP success was associated with endoscopists' experience, complications were not. Significantly higher rates of difficult procedures in the hands of more skilled endoscopists may be the reason of such a result. The overall rate of complications (8.4%) was within the range (from 4 to 15.9%) shown in other studies [6,7,22], although it is a difficult comparison, as complication rates vary widely in the literature because of differences in study design, patient population and definitions of complications. The rate of PEP (4.1%) was lower than the average rate of 5–7% seen in most observational and retrospective studies [15–24], that of bleeding (2.8%) was surprisingly higher [1,2,21,22,24], although in 75% of cases was graded as mild and in none of them severe. Anyway, this rate of post-procedural bleeding is still high considering the lack of data on delayed bleeding. In all cases a controlled ERBE electrosurgical generator was used for sphincterotomy but without a pre-established standardization of the current setting.

Unfortunately, the questionnaire did not ask whether patients were under anticoagulant therapy, the length of incision performed, nor the pre-procedure use of aspirin that are reported to

be risk factors for bleeding [2,25,26]. Precut and not-dilated CBD were independently associated with bleeding complication. Precut has been associated with increased incidence of bleeding in other studies [3,27]. Reported complication rates of precut range from 2.6% to as high as 20% [4,14,15,28,29] and are mainly due to PEP when performed in case of difficult cannulation. In our study, precut was often done only after more than 10 or >5 min cannulation attempts and it was not asked in the questionnaire which precut technique was used. The delayed timing and the quite high overall rate of precut (10.8%) used to gain CBD access, could explain the high rates of post-ERCP bleeding observed in this study. Among the independent risk factors for PEP we would like to stress the risk induced by repeated passages of the wire into the MPD [14,30], as shown in this study. Despite the wire assisted cannulation technique being safer than the contrast technique to reduce the risk of PEP [4], attention has to be paid when the wire enters the MPD, limiting its gentle progression to the cephalic portion of the duct.

The rate of post-ERCP infection was less than 1% and it is consistent with the available literature data [21,22,24–26]. Further, the presence of the anesthesiologist to allow a deep sedation with propofol had no benefit on the rates of overall complications. Controversial data is shown in literature at this regard [31–33]. However, it is commonly accepted that high quality ERCP is obtained under deep sedation [34]. In our study, the positive effect on ERCP efficacy in the presence of the anesthesiologist could have been counterbalanced by the significantly higher presence of the anesthesiologist in the most difficult procedures, i.e. those mainly performed in high volume centers. Cardiopulmonary problems may arise from medications used for sedation and analgesia [33]. In patients undergoing ERCP, propofol has shown the same efficacy and safety as conventional moderate sedation, with fewer associated hypoxemic events [35–37]. In the present study, complications, particularly cardio-pulmonary adverse events, were significantly higher in patient who underwent urgent rather than elective ERCP, independent of the presence of deep sedation. It is likely that patients who underwent urgent ERCP had worse clinical conditions but its measurement (ASA classification, for example) was not scheduled.

4.4. Quality indicators

Despite all the five ASGE priority quality indicators [18] have been confirmed in this study, some limitations have to be reported. We have already commented about the opportunity to dispose of adequate documentation to establish whether an indication for ERCP is appropriate. Deep sedation was done in only 44% of patients and although it did not seem to effect ERCP success, this rate is too low for acceptable comfort and safety of patients, especially of those with some comorbidities and undergoing complex endoscopic procedures. The rate of NSAIDs either alone or in combination with pancreatic stent for the prophylaxis of PEP, 21.6% and 2.6%, respectively, was very low. ESGE and ASGE guidelines recommend the routine use of rectal NSAIDs in all patients and pancreatic stent for those at high-risk [14,26]. A possible reason for non-use was the perception of a low incidence of PEP in non NSAID and/or pancreatic stent users. However, even if PEP rate was in the range usually reported in literature, the use of NSAIDs prophylaxis and/or pancreatic stent at least in patients at high risk of such a complication may further increase the quality and efficiency of ERCP practice. Finally, only 51.1% of the contacted centers accepted to participate in the study, 40% actively. Most of the non-responders were non-expert operators working in small ERCP volume centers. It is possible that relatively inexperienced operators are unlikely to publish their data, even though, as in the case of this study, a blind data analysis is ensured. This is an important issue because it is always advisable to measure our results against others, as a first step to improvement, and to compare them with the benchmarks to evaluate if the quality indicators are fulfilled [18,38].

In conclusion, even if this prospective uncontrolled community practice-based ERCP study shows that success, safety, and main quality indicators are consistent with the available literature data, further efforts have to be made to improve our territorial routine ERCP performance and how it is carried out. Based on the data of the present study we suggest an improvement in the ERCP performance as follows: (a) in the pre-procedural phase, carefully evaluating the indication for the ERCP, by means of a multidisciplinary approach in the most difficult cases, considering the possibility of addressing them to the most expert operators or to the highest ERCP volume centers, with the aim of cost-saving; (b) in the procedural phase, assuring deep sedation of all patients, doing PEP prevention by using rectal NSAIDs in all patients, at least in those at high-risk, and supporting the ongoing training of the trainees; (c) in the post-procedural phase recording the results and complications, and reviewing, periodically, the quality indicators in the assessment programs.

Conflict of interest

None declared.

Appendix A. Participating co-investigators

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