ORIGINAL PAPER

The volume of ERCP per endoscopist is associated with a higher technical success and a lower post-ERCP pancreatitis rate. A prospective analysis

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Study population	Method	Outcomes
Inclusion criteria: • Patients > 18 years. • Biliary ERCP. • Accessible and naïve papilla. Exclusion criteria: • pancreatic ERCP. • Previous biliary ERCP. • No informed consent to be analyzed.	Analysis of the outcomes of biliary ERCP in patients with naïve and accessible papilla on a prospective database. ERCP outcomes along three periods defined by the number of endoscopists performing ERCP in a hospital were compared: 5 (period I); 4 (period II); and 3 (period III).	The increase in the annual volume of ERCP per endoscopist is associated with an improvement in technical success and post-ERCP pancreatitis rates. This improvement is clear when the increase in ERCP burden is greater, although our data point to individual variability between endoscopists.

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Lay summary

This study analyzed how the annual volume of endoscopic retrograde cholangio-pancreatography (ERCP) influences outcomes in a hospital. Three periods were compared in which the number of endoscopists performing this technique was reduced and therefore more ERCP volume was allocated to each endoscopist. We analyzed the outcomes of 2 561 ERCPs in patients with intact papilla and found that the success rate was worse in the period with more endoscopists, while the rate of adverse events and post-ERCP pancreatitis was lower in the period with more endoscopists. The benefit of higher annual ERCP volume was not consistent across all endoscopists. In summary, this study indicates better ERCP outcomes when endoscopists perform a greater number of these techniques.

ABSTRACT

Introduction: conflicting results have been reported regarding the influence of the annual volume of endoscopic retrograde cholangiopancreatography (ERCP) on outcome.

Objective: to evaluate the influence of case volume on ERCP outcomes.

Patients and methods: an analysis of a prospective database was performed, comparing the outcomes of ERCP in three consecutive periods defined by the number of endoscopists performing ERCP: five endoscopists in period I (P1), four in period II (P2) and three in period III (P3). Only patients with biliary ERCP in accessible and naïve papilla were included. Primary variables were cannulation rates and adverse effects (AE). The American Society of Gastrointestinal Endoscopy (ASGE) complexity grades III and IV were considered as highly complex procedures.

Results: a total of 2,561 patients were included: 727 (P1), 972 (P2) and 862 (P3). There were no differences in age and sex between groups ($p > 0.05$). The cannulation rate was significantly higher in P2 and P3: 92.4 % *vs* 93.3 % *vs* 93 % ($p = 0.037$). The AE rate was 13.8 %, 12.6 % and 10.3 % ($p > 0.05$), respectively. The rate of post-ERCP pancreatitis was significantly lower in P3: 8.5 %, 7.3 % and 5 % ($p = 0.01$). The rate of complex procedures was 12 %, 14.8 % and 27 % ($p < 0.0001$), respectively. Two endoscopists participated in all periods and only one had significantly improved outcomes. Cannulation and post-ERCP pancreatitis rates remained significantly better in P3 after adjusting for sex, complexity and endoscopist.

Conclusion: a higher annual volume of ERCP per endoscopist was associated with a higher rate of cannulation and a lower rate of post-ERCP pancreatitis, despite the greater complexity of the procedures. These beneficial effects seem to differ between endoscopists.

Keywords: Cholangiopancreatography. Endoscopic retrograde. Assessment. Outcomes. Activities. Training. Workload. Adverse effects. Biliary tract.

INTRODUCTION

The endoscopic retrograde cholangiopancreatography (ERCP) is a complex therapeutic procedure. It would be expected that the skill of the endoscopist and training influence the outcome, as is the case in highly complex surgical procedures (1,2).

Training is an objective factor determined by the annual volume of ERCP and its influence has been analyzed in different studies with contradictory results and it continues to be a controversial issue (3,4). Most of these studies are multicenter and compare the results of hospitals with a high and low volume of ERCP. These comparisons present biases that can influence the result (5). Clinical training, personality, common sense, patience, perseverance and even prior rest are subjective factors depending on the endoscopist that can compensate for a lack of skill and can be decisive (1,5). Some are circumstantial and mean that the same endoscopist can offer a variable level of skill in different situations (5). Moreover, experience of the nurse team, periprocedural patient management, the type of sedation or the devices used can become biases that are difficult to analyze. Moreover, there is indirect evidence that training is important. Endoscopists with a higher volume of ERCP are more comfortable performing precut (6), their outcomes are progressively improved (7), administer lower radiation doses (8), place prophylactic pancreatic stents more frequently and enjoy more the procedure (6).

Considering this background, the aim of this study was to evaluate the influence of training, measured as the annual case volume on ERCP outcomes. This evaluation was made in a single hospital and for the same endoscopists during a period of time in which the volume of annual ERCP per endoscopist was significantly increased, limiting the influence of the aforementioned subjective biases.

MATERIAL AND METHODS

The study inclusion time, from September 2013 to June 2020, was divided into three periods based on the number of endoscopists who performed ERCP in our unit. The first period (P1) was from September 2013 to September 2015 with five endoscopists. The second period (P2) was from October 2015 to January 2018 with four endoscopists. In January 2018, the number of endoscopists was reduced to three, extending this third period (P3) until June 2020.

All ERCP performed at our center were collected in a prospective database. A retrospective analysis of this database was performed, comparing the outcomes of the ERCP during the three study periods. The following inclusion criteria were defined: patients > 18 years old with an accessible papillary area and naïve papilla undergoing biliary ERCP who gave their consent to be analyzed. The exclusion criteria were patients that underwent pancreatic ERCP, previous biliary ERCP and patients who did not sign the informed consent.

The following parameters were evaluated: cannulation rate, primary technical success, final technical success and

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adverse effects (AE) rate. Demographic variables, therapeutic maneuvers performed during ERCP and the degree of complexity of ERCP according to the American Society of Gastrointestinal Endoscopy (ASGE) classification (9) were recorded. Grades III and IV of this classification were considered as highly complex procedures.

Successful cannulation was defined as deep insertion of the guidewire into the bile duct. Primary technical success was defined as completion of the necessary treatment to ensure bile duct patency after ERCP. Final technical success was achieved when the biliary pathology was completely resolved during ERCP. AE were defined and evaluated according to the ASGE classification (10).

Only two endoscopists participated in all three periods. At the beginning of the study, the previous experience in ERCP of these two endoscopists was eleven years and more than 1,000 ERCP (endoscopist 1); and five years and more than 500 ERCP (endoscopist 2). Regarding the experience of the other endoscopists, two had more than 18 years of experience in ERCP, both with more than 2,000 ERCPs performed. Another endoscopist had one year of experience performing ERCP when the study started. Finally, a sixth endoscopist began his training at the beginning of P3.

All ERCP were performed under sedation or general anesthesia at the discretion of the anesthesiologist. During ERCP, the endoscopist was assisted by two nurses from a group consisting of ten nurses, which remained stable throughout the study.

The prophylactic maneuvers recommended by international guidelines were performed (11-14). In January 2015, the administration of 100 mg of rectal indomethacin was systematically established in our unit, in all patients without contraindications. Before January 2015, indomethacin was administered at the endoscopist's discretion.

Quantitative variables are shown with descriptive statistics. Success, cannulation and AE rates were compared using the Chi-squared or Fisher's test. The probability of success, cannulation and AE was modeled using multivariate logistic regression, providing adjusted odds ratios (OR) together with their 95 % confidence intervals (CI) for the three periods considered. The SPSS program, version X, and the level of significance was considered to be $\alpha = 0.05$. The study was approved by the Ethics Committee for Medical Research of our center and registered in clinicaltrials.gov (NCT04705740).

RESULTS

A total of 4,156 ERCPs were performed in our Endoscopy Unit during the study period. Of these, 1,389 were excluded due to previous sphincterotomy, 295 due to pancreatic ERCP and 123 for inaccessible papillary area. Finally, 2,561 ERCP were included in the study: 727, 972 and 862 in P1, P2 and P3, respectively. Therefore, all these ERCPs were biliary, with an accessible papillary area and naïve papilla.

There were no differences between the different periods with regard to the distribution by sex (50.5 % *vs* 46.4 % *vs* 40.6 % female; p = 0.36) or in the mean age (71.4 ± 15.8 *vs* 71.5 ± 15.6 *vs* 72.8 ± 15.5, p = 0.1). The reason for the indication of ERCP according to the ASGE classification is shown in table 1.

Table 1. *Reasons for the indication of ERCP classified by the ASGE degree of complexity during the three periods*

		P1	P2	P3	Total
Grade I	Biliary cannulation	49	11	65	125
Grade II	Stone extraction < 1 cm	434	587	355	1,376
	Biliary fistula	6	18	20	44
	Extrahepatic stricture	150	210	189	549
Grade III	Stone extraction > 1 cm	58	97	191	346
	Cholangioscopy	3	7	2	12
	Hilar tumors	19	35	24	78
	Sphincter of Oddi disfunction	7	4	5	16
Grade IV	Intrahepatic stones	0	2	1	3
	Ampullectomy	0	0	1	1

ERCP: endoscopic retrograde cholangiopancreatography; ASGE: American Society of Gastrointestinal Endoscopy.

There were no significant differences regarding cannulation rate or global AEs, with significant differences in terms of primary technical success and final technical success (Table 2). The incidence of post-ERCP acute pancreatitis was significantly lower in P3. In multivariate analysis, a significant tendency to gradually present a lower proportion of post-ERCP pancreatitis was observed (7.895, p = 0.005).

The degree of complexity of the ERCP increased significantly throughout the inclusion period, which was high in 12 % *vs* 14.8 % *vs* 27 % of patients, respectively, with significant differences when comparing P3 with P1 and P2 (p < 0.0001).

Two endoscopists participated in all periods (Table 3). Both endoscopists significantly increased their ERCP case volume. Endoscopist 1 significantly improved their cannulation, primary and final technical success rates as the case volume increased. On the contrary, overall AE and post-ERCP pancreatitis rates did not significantly improve. Regarding the therapeutic maneuvers performed by endoscopist 1, the performance of sphincterotomy increased (75.2 % *vs* 91.2 % *vs* 89.5 %; p < 0.001) and the performance of sphincteroplasty decreased (12.4 % *vs* 3.7 % *vs* 5.4 %; p = 0.003), with no differences in the rest of the therapeutic maneuvers performed. The proportion of highly complex ERCP performed by endoscopist 1 increased progressively: 16.8 % *vs* 20.5 % *vs* 31.4 % (p = 0.004).

Endoscopist 2 had no significant differences in cannulation rate, AEs, or post-ERCP pancreatitis. Primary technical success was stable and final technical success was significantly higher in P2. There were no differences in the performance of sphincterotomy (76.1 % *vs* 76.9 % *vs* 79.2 %, p = 0.73) or biliary sphincteroplasty (25.7 % *vs* 20.8 % *vs* 24.2 %, p = 0.51).

Table 2. *Cannulation rate, technical success, AE and therapeutic maneuvers performed during ERCP*

	P1	P2	P3	p
Cannulation rate	92.4 %	93.3 %	93 %	0.77
Primary technical success	92.2 %	95.1 %	92.5 %	0.02
Final technical success (2,561 patients)	81 %	90.9 %	87 %	< 0.0001
Global final technical success (4,156 patients)	74,2 %	85.4 %	81.6 %	< 0.0001
Overall adverse effects	13.8 %	12.6 %	10.3 %	0.10
Pancreatitis	8.5 %	7.3 %	5 %	0.01
Perforation	1.5 %	0.9 %	0.4 %	
Bleeding	1.5 %	2.5 %	2.9 %	
Cholangitis/bacteremia/sepsis	1.3 %	1.5 %	0.9 %	
Cholecystitis	0.4 %	0.3 %	0.3 %	
Other	0.02 %	0.1 %	1 %	
Death	0.8 %	0.2 %	0.9 %	
Biliary sphincterotomy	83.3 %	85.4 %	84.7 %	0.51
Needle knife fistulotomy	5.4 %	5.1 %	4.9 %	0.90
Sphincteroplasty	17.5 %	14.8 %	12.8 %	0.03
Plastic biliary stent	17.2 %	14.7 %	14.4 %	0.24
Uncovered self-expandable metallic stent	5.4 %	6.8 %	6.5 %	0.46
Covered self-expandable metallic stent	5.8 %	10.3 %	10.7 %	0.001
Prophylactic pancreatic stent	10.2 %	19.7 %	19.2 %	< 0.0001

The global final technical success is also shown for all the ERCPs performed during the inclusion period. ERCP: endoscopic retrograde cholangiopancreatography; AE: adverse events.

Prophylactic pancreatic stent placement was significantly lower in P1 (4.6 % *vs* 20 % *vs* 12.8 %; p < 0.0001). The proportion of highly complex ERCP performed by endoscopist 2 also increased significantly (11 % *vs* 12.4 % *vs* 22.3 %; p < 0.0001).

P3 includes the learning curve outcomes for a third endoscopist. The cannulation rate (86.9 % *vs* 94.7 % *vs* 96 %, p < 0.0001), primary technical success (86.8 % *vs* 94 % *vs* 95.3 %, p < 0.0001) and final technical success (84 % *vs* 84.2 % *vs* 91.2 %, p = 0.009) were significantly lower for this endoscopist 3 *vs* endoscopist 2 *vs* endoscopist 1, respectively. This effect did not change after multivariate logistic regression analysis.

In the multivariate analysis, the influence of the case volume of ERCP was maintained when analyzing the primary technical success, final technical success, overall AE and post-ERCP pancreatitis rates, which was adjusted for sex, complexity of ERCP and participation of the endoscopist in training. In P2, a significantly higher primary technical success rate was obtained compared to P1 (OR = 1.6, 95 % CI = 1.106-2.451, p = 0.014). Final technical success was significantly higher in both P2 (OR = 2.408, 95 % CI = 1.805-3.213, p < 0.0001) and P3 (OR = 1.750, 95 % CI = 1.290-2.374, p < 0.0001). The post-ERCP pancreatitis rate was significantly lower in P3 (OR = 0.639, 95 % CI = 0.414-0.986, p = 0.04). No significant differences were observed in the rate of cannulation or the overall rate of AE.

DISCUSSION

The annual volume of ERCP is an objective parameter that represents the training of the endoscopist. There are studies in which endoscopists with a higher annual volume of ERCP have a greater technical success (7), a lower rate of AE (15,16) or both (3,17-19). However, there are also studies that do not show these associations (4,20,21). According to a meta-analysis including 59,437 procedures performed by high-volume endoscopists, the OR for technical success was 60 % higher

Table 3. *ERCP outcomes from the only two endoscopists who participated throughout the whole study*

Endoscopist	Period	n	Cannulation rate	Primary technical success	Final technical success	AE	Post-ERCP pancreatitis
Endoscopist 1	P1	113	89.4 %	92.9 %	77.9 %	11.5 %	5.3 %
	P2	326	95.4 %	98.2 %	94.8 %	12 %	5.2 %
	P3	353	96 %	95.2 %	91.2 %	8.2 %	3.4 %
	p		0.01	0.02	< 0.001	0.243	0.456
Endoscopist 2	P1	109	93.6 %	92.7 %	80.7 %	13.8 %	9.2 %
	P2	251	92 %	94.4 %	90.8 %	12 %	8.4 %
	P3	265	94.7 %	94 %	84.2 %	15.5 %	8.7 %
	p		0.468	0.8	0.01	0.5	0.9

ERCP: endoscopic retrograde cholangiopancreatography; AE: adverse events.

(OR = 1.6; 95 % CI = 1.2-2.1; P 1⁄4 .001) and the OR for AEs was 31 % lower (OR = 0.7; 95 % CI = 0.5-0.8; P 1⁄4 .001) compared with low-volume endoscopists (17). No influence was shown on the rate of post-ERCP pancreatitis or mortality.

In a prospective multicenter study including 1,191 patients, the outcomes were analyzed based on the annual volume of ERCP greater or less than 200 (16). A lower rate of AE (24.7 % *vs* 17.5 %; p = 0.003), post-ERCP pancreatitis (12 % *vs* 6.8 %; p = 0.004) and hemorrhage (14.5 % *vs* 10 %; p = 0.018) was reported for endoscopists with a higher volume of ERCP. In multivariate analysis, the low annual ERCP volume was associated with a higher post-ERCP pancreatitis rate.

In our study, we analyzed the influence of the annual volume on the outcome of ERCP for seven years. The volume of ERCP in our hospital remained stable with 600-700 procedures per year. After a series of organizational changes, we went from having five endoscopists doing ERCP to four and three, with a gap of approximately two years. By reducing the number of endoscopists, they went from having a low to a high annual volume of ERCP. The technical success rate was significantly worse when ERCP was performed by five endoscopists, whose annual volume was lower. The cannulation or global AEs rates did not improve with the post-ERCP pancreatitis rate. The incidence of post-ERCP pancreatitis could have been influenced by other factors such as the administration of rectal indomethacin. In our unit, this measure was established around the middle of P1. However, there was no difference in incidence between P1 and P2, which seems to rule out a related bias.

The complexity of ERCP in our unit has gradually increased over the last few years. This has already been described, especially in high-volume centers (4,6,17). In fact, several authors recommend that more complex ERCPs should be referred to high-volume centers (6,22). This may lead to a bias when comparing high and low-volume centers, by centralizing the more complex ERCP in high-volume centers. Despite this, endoscopists in these centers are more comfortable performing high-risk techniques such as precut and use prophylactic pancreatic stents more frequently (6). In our study, despite this increase in complexity, the outcomes of the procedure significantly and progressively improved.

When analyzing the results of the two endoscopists who participated in the three periods of the study, the influence of the previously mentioned subjective biases was reduced, since we assume these factors remain unchanged as they were the same endoscopists. Improvement in the results was verified by increasing the annual volume of ERCP for endoscopist 1. This is not attributable to a learning curve, since he was the most experienced. He went from doing a total of 113 biliary ERCPs with naïve papilla during P1 to 353 in P3. This caused his cannulation, primary and final technical success rates to improve significantly.

This effect was not seen for endoscopist 2, with no improvement in any of the parameters despite significantly increasing the volume of ERCP performed. This could support the idea that the benefit of increasing the annual volume would be significant from a minimum level of annual ERCP that has been described in 300 procedures (23). This limit will probably vary between endoscopists depending on subjective factors.

Our study has several limitations. It is a retrospective analysis using a prospective database, which may lead to bias. Nevertheless, the retrospective design also has advantages when the individual results of a procedure are analyzed, by avoiding the Hawthorne effect (24). In any case, the data collection was carried out in a systematic way, minimizing these biases. A second limitation is the participation of an endoscopist in training. This worsened the outcomes during P3 and may be the reason that more definitive conclusions comparing P3 and P2 cannot be made.

In addition, the main strength of the study remains in avoiding subjective biases by analyzing ERCP outcomes with different case volumes in the same hospital with the same endoscopists. Another strength of the study lies in the high number of patients included, despite being a highly selected patient population: biliary ERCP, with accessible papillary area and naïve papilla.

In conclusion, the increase in the annual volume of ERCP per endoscopist is associated with an improvement in technical success and post-ERCP pancreatitis rates. This improvement is clear when the increase in ERCP burden is greater, although our data point to individual variability between endoscopists. This would support the establishment of reference centers and endoscopists that accumulate more experience for the performance of the more complex ERCPs (17). It would even support a greater accumulation of experience in a specific endoscopist within the same unit who could tackle the more complex ERCP procedures with a better expectation of results.

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