



Implementation of mandatory ERCP registration in The Netherlands and compliance with European Society of Gastrointestinal Endoscopy performance measures: a multicenter database study

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ABSTRACT

Background In 2018, the European Society of Gastrointestinal Endoscopy (ESGE) and United European Gastroenterology (UEG) published quality performance measures for endoscopic retrograde cholangiopancreatography (ERCP). Since January 2016, all endoscopists in the Netherlands have been required to register all ERCP procedures in a nationwide quality registry. This study aimed to evaluate the procedural success rates of ERCP after the implementation of mandatory national registration and to compare these with the ESGE quality performance measures.

Methods This study was conducted with data from a multicenter endoscopy database. Data from 2019 and 2020 were analyzed. The primary outcome was ERCP procedural outcome. ESGE performance measures that could be evaluated were the percentage of successful bile duct cannulations in patients with virgin papillary anatomy; successful stent placement for a biliary obstruction located below the liver hilum; and complete removal of bile duct stones (< 10 mm).

Result In total, 5295 ERCPs performed in 11 centers were included for analysis. The overall procedural success rate was 89.1 %. Successful biliary cannulation in patients with a virgin papilla was 90.3 % in nonacademic and 92.4 % in academic centers. The rates of successful stent placement in patients with a biliary obstruction located below the liver hilum were 97.0 % in nonacademic and 98.2 % in academic centers, and of successful bile duct stone extraction were 97.9 % in both nonacademic and academic centers.

Conclusions The quality of ERCPs performed met five of the six evaluated ESGE performance measures. The 95 % target for successful biliary cannulation in patients with virgin papillary anatomy in academic centers was not met. Mandatory registration provides valuable insight into ERCP performance rates.

Introduction

In recent years, quality assurance of endoscopic retrograde cholangiopancreatography (ERCP) procedures has gained increasing interest from healthcare professionals and patient organizations. This is not without reason, as ERCP nowadays is pri-

marily a minimally invasive therapeutic procedure that is associated with potentially severe complications [1–3]. Significant training and experience are required to maximize procedural success and minimize the complication risks [4].

In 2018, the European Society of Gastrointestinal Endoscopy (ESGE) and United European Gastroenterology (UEG) set up an initiative and published a list of key quality performance meas-

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ures for ERCP and endoscopic ultrasound (EUS) [5]. These performance measures are intended to set a minimum standard for quality and the outcome of ERCP and EUS. Both societies encourage healthcare professionals to implement these performance targets on a national basis.

Quality assurance in ERCP has also gained significant awareness in the Netherlands. Since January 2016, endoscopists in the Netherlands have been required to register several procedural steps and the outcomes of all ERCP procedures in a mandatory nationwide quality registry, using the Rotterdam Assessment Form for ERCP (RAF-E), a self-assessment registry tool that provides insight into ERCP performance [6].

One of the reasons for this mandatory registry was the finding of Ekkelenkamp et al. in 2014 that the overall procedural success rate of ERCP, using the RAF-E, was only 85.8% [7]. Interestingly, since the implementation of the mandatory quality registry, it has been noted that fewer endoscopists perform more ERCPs (unpublished finding), which is likely beneficial with regard to procedural success and quality outcomes.

The current study aimed to evaluate the procedural success of ERCP after the implementation of the mandatory nationwide registry and to determine whether performance measures, according to the ESGE standards, were met.

Methods

Database and data collection

Data was retrieved from a prospectively maintained gastrointestinal (GI) endoscopy database (Trans.IT database; Rotterdam, The Netherlands). All centers participating in the database use a uniform structured tool to report endoscopy findings and all endoscopy reports are then uploaded into the database. The database has recently been described in detail elsewhere [8]. In short, this anonymized multicenter database was initiated in 2012 and currently collects GI endoscopy data from 19 Dutch hospitals (three academic and 16 nonacademic hospitals), distributed over 9 of the 12 provinces of the Netherlands.

The database also automatically creates a RAF-E form based on the findings in the ERCP report and uploads this to the mandatory national registry. The RAF-E includes several items, such as the indication for performing the ERCP, a priori ERCP degree of difficulty (Schutz score), presence of virgin papillary anatomy, outcome of common bile duct cannulation, and procedural success, amongst others [9]. Some endoscopy centers decided to use the Trans.IT database as an intermediary to report ERCPs to the national registry. Other centers report directly to the website of the national registry, in which case a RAF-E form is not created in the Trans.IT database. In the current study, 11 of 19 centers use the Trans.IT database to create a RAF-E form. Therefore, data from 11 centers (two academic, nine nonacademic, distributed over 8 of the 12 provinces in the Netherlands) were available for analysis.

Registration of procedural indication and procedural outcome were used as an indicator for the completeness of data, with only the years in which at least 90% of the performed ERCPs were completely registered considered for inclusion. This was achieved from 2019 onwards. All ERCP reports of pro-

cedures in the Trans.IT database performed between January 2019 to December 2020 from the 11 centers were analyzed. ERCP reports were included if the indication and procedural outcome of the procedure were in fact registered. ERCP procedures for patients aged younger than 16 years were excluded.

Outcomes and definitions

The primary outcome was the overall procedural outcome, defined as “success” or “failure” of the ERCP, which was identical to the primary outcome measure described in the prospective voluntary evaluation by Ekkelenkamp et al. [7]. The ESGE performance measures that could be analyzed based on outcome findings in the database were: (a) the percentage of successful bile duct cannulations in patients with virgin papillary anatomy (and a biliary indication); (b) the percentage of successful stent placements for a biliary obstruction located below the liver hilum; and (c) complete removal of bile duct stones (stone size < 10 mm). The outcomes of academic centers were compared with those of nonacademic centers.

The ESGE performance measures that could not be analyzed were the percentage of patients with adequate administration of prophylactic antibiotics before ERCP (when indicated) and the rate of post-ERCP pancreatitis, because these data are not included in the nationwide ERCP registry.

Additionally, we evaluated the success of cannulation in patients with a virgin papilla in relation to the type of sedation used and to the American Society of Anesthesiologists (ASA) classification. The type of sedation was categorized into either propofol sedation or general anesthesia in one group, or conscious sedation with midazolam and fentanyl in a second group. The ASA classifications were grouped into ASA classes 1 and 2, and ASA classes 3 and 4.

Statistical analysis

The statistical analysis was based on descriptive analyses, using frequencies (%) for categorical variables, and mean (standard deviation [SD]) for normally distributed continuous variables or median (interquartile range [IQR]) for non-normally distributed continuous variables. Categorical variables were analyzed using the chi-squared test and continuous variables were analyzed using the Mann–Whitney *U* test. A two-sided *P* value of < 0.05 was considered statistically significant.

All data were exported in comma-separated value files (CSV) from the Trans.IT database and imported into SPSS software for statistical analysis (SPSS 25.0; IBM Corp., Armonk, New York, USA).

Ethical considerations

The collection of patient data in the Trans.IT database has been approved by the privacy officer of the Erasmus Medical Center in accordance with the Dutch Personal Data Protection Act. All patient data are anonymously stored in a secure environment and are therefore exempt from formal ethics approval. All included hospitals provided written consent for participation.

► **Table 1** Procedural success rates for the different indications and degrees of difficulty.

	Voluntary registry*		Mandatory registry (2019–2020)	
	n (%)	Procedural success, % (n)	n (%)	Procedural success, % (n)
Indication				
▪ Complete stone extraction from CBD	4388 (51.2)	85.2 (3740)	2439 (46.1)	89.5 (2183)
▪ Endoprosthesis – stenosis of CBD	1829 (21.3)	86.2 (1576)	1021 (19.3)	90.2 (921)
▪ Metal stent insertion – stenosis of CBD	545 (6.4)	87.3 (476)	669 (12.6)	87.4 (585)
▪ Endoprosthesis – bile leakage	292 (3.4)	87.7 (256)	174 (3.3)	93.7 (163)
▪ Therapy for chronic pancreatitis	186 (2.2)	78.5 (146)	243 (4.6)	83.5 (203)
▪ Other	1335 (15.6)	88.0 (1175)	749 (14.1)	88.8 (665)
▪ Total procedures	8575 (100)	85.8 (7360)	5295 (100)	89.1 (4720)
Degree of difficulty				
▪ 1	5676 (66.3)	88.1 (4999)	3162 (60.8)	91.2 (2885)
▪ 2	1989 (23.2)	84.3 (1676)	1444 (27.8)	87.5 (1263)
▪ 3	890 (10.4)	75.2 (669)	595 (11.4)	82.5 (491)

CBD, common bile duct.

* As reported by Ekkelenkamp et al. (2014) [6].

Results

From January 2019 to December 2020, a total of 5671 ERCP procedures were registered by 57 endoscopists in 11 centers (2064 in an academic and 3607 in a nonacademic setting). The median number of ERCPs per endoscopists was 95 in this period (IQR 23–129). Not all endoscopists performed ERCPs during the full study period either because of retirement or starting as a newly registered gastroenterologist. The median number of ERCPs per month per endoscopist, corrected for months of participation, was 4.7 (IQR 3.5–6.3). Of the 5671 ERCPs, 21 ERCPs (0.4%) were excluded because patients were under 16 years of age, 173 (3.1%) because the indication was not registered, and 182 (3.2%) because the procedural outcome was not registered. Therefore, 5295 ERCPs (93.4%) were available for analysis.

The overall procedural success rate was 89.1%. ► **Table 1** shows procedural success according to indication and degree of difficulty as per the classification on the RAF-E form. The ESGE target standards for performance measures and the study outcomes overall and per degree of difficulty are shown in ► **Table 2**.

Successful biliary cannulation in patients with a virgin papilla was achieved in 90.3% of ERCPs in nonacademic centers (ESGE target standard 90%) and in 92.4% of ERCPs in academic centers (ESGE target standard 95%).

Successful stent placement in patients with a biliary obstruction located below the liver hilum was achieved in 97.0% of ERCPs in nonacademic centers (ESGE target standard 95%) and 98.2% of ERCPs in academic centers (ESGE target standard 95%).

Successful extraction of bile duct stones smaller than 10 mm was achieved in 97.9% in both nonacademic centers (ESGE tar-

get standard 90%) and in academic centers (ESGE target standard 95%).

► **Fig. 1** shows the individual endoscopist cannulation rates in patients with a virgin papilla and the number of ERCPs performed in the study period. The rates of successful cannulation in patients with a virgin papilla were not significantly different between ERCPs performed with the patient under general anesthesia or propofol sedation and those under conscious sedation, both for patients with an ASA class of 1 or 2 and those with an ASA class of 3 or 4 (► **Table 3**).

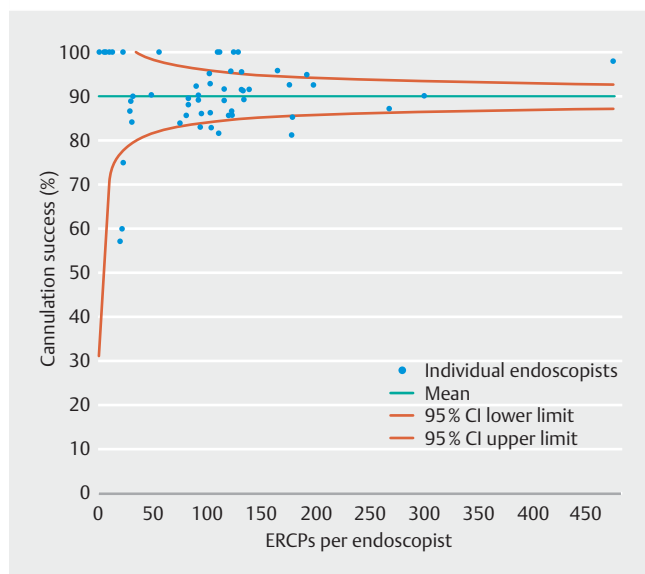
Discussion

In this study, we evaluated whether the ERCP outcome data of 11 Dutch hospitals collected within a mandatory ERCP registration database met the quality performance targets, as defined by the ESGE. We found an overall procedural success rate of 89.1% and five of the six ESGE target standards that could be assessed from the database were met. Successful bile duct cannulation in patients with virgin papillary anatomy was not met in the academic centers, with a rate of 92.4% compared with the required 95%. The target standards were met for successful bile duct cannulation in patients with virgin papilla in nonacademic centers, successful stent placements for an obstruction located below the liver hilum in academic and nonacademic centers, and successful removal of bile duct stones in academic and nonacademic centers. This mandatory registry permits valuable insights into the performance of Dutch gastroenterologists and provides source information to help improve the overall quality of ERCPs.

► **Table 2** Target standards for the ESGE performance measures and outcomes for the different degrees of difficulty in academic and nonacademic centers.

	n	Target standard, %	Success, % (n)			
			Overall	Schutz 1	Schutz 2	Schutz 3
Successful biliary cannulation in patients with a virgin papilla						
▪ Nonacademic (n = 9)	2007	90	90.3 (1813)	91.2 (1291)	90.9 (430)	72.1 (62)
▪ Academic (n = 2)	473	95	92.4 (437)	92.0 (275)	93.0 (120)	92.7 (38)
Appropriate stent placement biliary obstruction, after successful biliary cannulation						
▪ Nonacademic (n = 9)	694	95	97.0 (673)	99.1 (453)	93.2 (178)	93.1 (27)
▪ Academic (n = 2)	791	95	98.2 (777)	98.4 (421)	97.8 (310)	100 (36)
Bile duct stone extraction, <10 mm						
▪ Nonacademic (n = 9)	1313	90	97.9 (1286)	97.9 (1286)	–	–
▪ Academic (n = 2)	190	95	97.9 (186)	97.9 (186)	–	–

ESGE, European Society of Gastrointestinal Endoscopy.



► **Fig. 1** Individual endoscopist cannulation rates for patients with a virgin papilla and number of endoscopic retrograde cholangiopancreatographies (ERCPs) performed. CI, confidence interval.

This is the first study that has reported on the procedural outcomes of ERCP in the Netherlands since the implementation of the nationwide mandatory quality registry in 2016. A previous study by Ekkelenkamp et al. that was based on voluntary registration, including approximately 50% of all ERCP procedures performed in the Netherlands in 2014, reported an overall procedural success rate of 85.8% [7]. In the current study, the overall procedural success rate was higher at 89.1%. Although a direct comparison is difficult to make, it is at least reassuring that, despite mandatory registration, results have numerically improved. It is therefore tempting to speculate

► **Table 3** Cannulation outcomes in patients with a virgin papilla for the different sedation types and ASA classifications.

	n	Common bile duct cannulation success, % (n)
ASA classification 1 or 2		
▪ Propofol	928	92.0 (854)
▪ Midazolam + fentanyl	526	92.6 (487)
ASA classification 3 or 4		
▪ Propofol	667	88.3 (589)
▪ Midazolam + fentanyl	141	89.4 (126)

ASA, American Society of Anesthesiologists.

that as a consequence of the implementation of the mandatory registry, endoscopists performing ERCPs are more conscious and critical about their own performance. This may be reflected by the observation that, compared with the study of Ekkelenkamp, currently fewer endoscopists perform more ERCPs in the majority of Dutch centers.

We aimed to compare our results with the ESGE quality performance measures, which were published in order to improve the outcome and quality of endoscopy. The current study is the first to investigate whether the ESGE quality performance measures for ERCP procedures are being met in daily clinical practice. The results show that monitoring of the ESGE quality performance measures is not only feasible but also provides valuable insight into the performance level of individual endoscopists, centers, and ultimately a country.

Our results for successful biliary stenting and stone extraction were comparable to an Austrian nationwide benchmarking program, in which 28 of 140 ERCP sites participated. Biliary stenting was successful in 97.8% vs. 97.0%–98.2% in our study

and stone extraction in 98.6% vs. 97.9% in our study [10]. In the current study, the target standard of successful biliary cannulation in patients with a virgin papilla in academic centers was not met, with 92.4% compared with the 95% target. In this regard, it is important to take into consideration that the ESGE has stated that the quality of the evidence used to develop the target measure for biliary cannulation was graded as low. Further evaluation is needed as to whether the target standard of 95% for expert centers is realistic, taking into consideration that potentially more primarily failed and difficult ERCPs are referred to academic centers, for which sometimes more advanced selective cannulation techniques are required.

Compared with our study, the successful cannulation rate in patients with a virgin papilla was found to be lower in a study from the UK (84% vs. 90.3%–92.4%) [11]. A nationwide study from Sweden [12] and a multicenter study from Norway, including 11 hospitals [13], reported common bile duct cannulation rates of 92% and 91.1%, respectively, but these studies did not report selectively on cannulation rates in patients with a virgin papilla. The ERCP outcome data for the nine nonacademic centers in the current study are in line with a study from the USA that reported on ERCP outcomes from eight community hospitals [2].

A notable finding in our study was the low cannulation rate in nonacademic centers for cases with a Schutz 3 difficulty score (72.1%). It should be noted however that this finding is based on only 62 procedures and that more evidence is needed to establish whether this observation holds true. However, we believe this is an excellent example of the strength of a national registry, giving the opportunity to detect these trends and making it possible to intervene on both a personal and national level. Further actions, such as additional training of endoscopists in nonacademic centers or maybe centralizing the more difficult ERCP cases in academic centers, should be explored. The funnel plot provided in ► **Fig. 1** is another example of the strength of a national registry and shows how the national registry permits the identification of low performing endoscopists who may benefit from additional training in ERCP.

An additional finding of our study was that cannulation rates in patients with a virgin papilla were similar whether the ERCP was performed with the patient under general anesthesia or propofol sedation, or under conscious sedation with midazolam and fentanyl, regardless of the ASA classification. A prospective nationwide study from Sweden that reported on the impact of sedation types on cannulation rates in patients with a virgin papilla, in a total of 31 001 ERCP procedures, found a statistically significant difference based on the type of sedation, with a cannulation success rate of 89.0% for propofol sedation vs. 86.7% for midazolam sedation, although this small difference seems to carry limited clinical relevance [14].

The Trans.IT database was chosen for this project because it currently offers more transparency than the national database, which is a key strength of this study. The national registry only registers procedures that are submitted to the registry and does not record how many ERCPs are actually performed in each center. The Trans.IT database includes all ERCP procedures performed in a center and an overview of the quantity of data

registered for each procedure. This allowed us to control for the completeness of data for all ERCP procedures performed within a certain time period, which is not possible with the national database. We attempted to minimize bias by analyzing only the time period in which at least 90% of the performed ERCPs were completely registered. As such, the outcomes of our study are a reliable representation of everyday clinical practice. This is however a Dutch study, which makes it potentially difficult to generalize our results. For example, in the Netherlands, it is common practice that gastroenterologists perform endoscopic procedures, such as ERCP, in combination with direct patient care management in both an inpatient and outpatient setting. The median number of 95 ERCPs per endoscopist during the study period may suggest that further concentration of ERCP procedures should be considered, as other studies have shown that endoscopists may benefit from higher yearly volumes of ERCPs to achieve core skills [15].

The limitations of this study that need to be addressed are firstly the fact that this is not a strictly nationwide report. Although the 11 centers included in the current study are distributed over eight of the 12 provinces in the Netherlands and represent both academic and nonacademic centers, it is not certain that the outcomes from these 11 centers is representative of the whole of the Netherlands. Nonetheless, more than 5000 ERCPs were included, which amounts to approximately 12.5% of the total number of ERCPs performed in the Netherlands in this period. Second, not all centers participating in the Trans.IT database could be included, because eight of the 19 participating hospitals registered ERCPs in the Trans.IT database without using the RAF-E form.

Third, not all years during which the reporting of ERCPs was mandatory were included. Owing to start-up problems and the time required to train endoscopists to correctly register ERCPs during the first years of the national registry, a sizeable percentage of ERCPs were not registered completely (registration rates for procedural indications and outcomes of 63.1% and 56.0%, respectively, in 2017 vs. 95.4% and 93.7%, respectively, in 2019). Registration problems occurred not only in the Trans.IT database but were seen also on a nationwide level in the national registry. We believe that including these years with low registration rates could have potentially induced bias and therefore we decided to exclude these years from the analysis. A correct registration in these years would have allowed us to perform a time-trend analysis and to assess whether procedural success increased each year during mandatory registration. Finally, not all ESGE quality performance measures could be evaluated because the RAF-E form that is currently used does not include information on antibiotic prophylaxis or post-ERCP pancreatitis.

In conclusion, the Dutch national mandatory centralized registry of ERCP reporting offers the opportunity to evaluate and improve the quality of ERCP. Comparison with the ESGE quality performance measures is feasible and showed that the overall quality of ERCP in Dutch ERCP centers is high. Five out of six ESGE quality performance measures were achieved successfully, but the 95% target for successful biliary cannulation of a virgin papilla in academic centers was not met.

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Competing interests

M.J. Bruno has provided consultancy for and has received support for industry- and investigator-initiated studies from Boston Scientific and Cook Medical; and has received support for investigator-initiated studies from Pentax Medical, Mylan, and ChiRoStim. R.J.T. Ouwendijk has received research grants from Janssen Netherlands, and the Cool-singel Foundation. P.D. Siersema has received research grants from Norgine, Pentax, MicroTech, Yakult and Motus GI; and is on the advisory board of Motus GI and Boston Scientific. The remaining authors declare that they have no conflict of interest.

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