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Predicting Native Papilla Biliary Cannulation Success Using a Multinational ERCP Quality Network

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Predicting Native Papilla Biliary Cannulation Success Using a Multinational ERCP Quality Network

by

CHUNYAN PENG

A Thesis submitted to the Faculty of the Medical University of South Carolina in Partial Fulfillment of the Requirements for the Degree Master Science of Clinical Research in the college of Graduate Studies
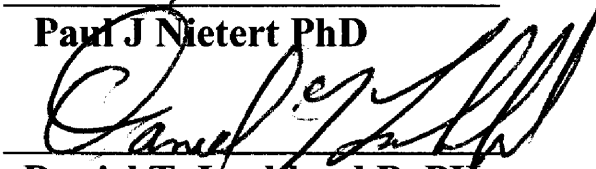
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August 2012

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ACKNOWLEDGEMENTS

I would like to express my deepest gratitude to my mentor, Dr. Romagnuolo, for his excellent guidance, caring, patience, and providing me with an excellent atmosphere for doing research. I would like to thank Dr. Nietert, who helped me in statistical analysis. I would also like to thank Dr. Lackland and Dr. Hulsey for guiding my research. Special thanks go to Dr. Peter B. Cotton, who gave me a lot of significant advice on manuscript writing.

I would like to thank Abha Singh, who is a good friend, was always willing to help and give her best suggestions. I would also like to thank Maritza J Dawkins-Holnes, who gave me a lot of support and assistance in my study and research. I would thank my Chinese friends for helping me in my study and life.

I would thank to my Chinese chief for his support and assistance. Without him, I would not have finished the study successfully. I would like to thank my family members for their supports and encouragements.

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ABSTRACT

CHUNYAN PENG. Predicting Native Papilla Biliary Cannulation Success Using a Multinational ERCP Quality Network. (Under the direction of THOMAS C. HULSEY)

Background and Objective: Success in achieving deep biliary cannulation success in native papillae is an accepted measure of competence in ERCP training and practice. This study aimed to determine the factors associated with native papilla deep biliary cannulation success, with and without precut sphincterotomy.

Methods: A retrospective analysis was conducted in a prospectively collected database. The main outcome was deep biliary cannulation success, with and without precut facilitating access, in non-operated papillae. Multilevel random fixed effect multivariate model was used to control for doctor factor.

Results: 13018 ERCPs were performed by 85 endoscopists between March 2007, and May 2011. Conventional (without precut) and overall (some precut assistance) cannulation rates were 89.8% and 95.6%, respectively. Precut was performed in 876 (6.7%). Conventional success was more likely in outpatients (OR 1.21), but less likely in complex contexts (OR 0.59), sicker patients (ASA grade (II, III/V: OR 0.81, 0.77)), with trainee involvement (OR 0.53), and certain indications (strictures, active pancreatitis). Overall cannulation success (some facilitated by precut) had similar associations, but was more likely with higher volume endoscopists (> 239/year: OR 2.79), endoscopists with efficient fluoroscopy practice (OR 1.72), and less likely with moderate (versus deeper) sedation (OR 0.67).

Conclusion: Success in deep biliary cannulation was high in this self-selected group of endoscopists, but was influenced by both patient and practitioner factors. Patient- and case-specific factors have greater impact on conventional cannulation success, but volume influences overall (including precut-assisted) success; both can be used to select appropriate cases and may help with credentialing guidelines.

INTRODUCTION

Validation of quality metrics in advanced endoscopy is evolving, and predicting quality is an important part of determining training thresholds, credentialing, and recredentialing. Endoscopic retrograde cholangiopancreatography (ERCP) is widely performed at an annual rate of approximately 1 per 1000 population around the world, accounting for approximately 300,000 ERCPs conducted annually in the US. However, it remains one of the most technically demanding and risky endoscopic procedures. Post-ERCP pancreatitis is the most common serious complication (incidence 1% to 7% in unselected patients, up to 10-20% in high risk patients).[1-4] Moreover, ERCP-related mortality is approximately 0.1%, or an estimated 300 deaths/year in the US.[5] [6] Pancreatitis is more likely to occur when cannulation attempts are difficult or unsuccessful. It is thus important to understand the reasons that affect the likelihood of cannulation success.

ERCP is most often indicated for biliary diseases (at least in community practice), so that the rate of successful access to the bile duct has become a key metric of performance. Minimum standards of 80-90% have been proposed in different countries,[7] [8] and wide variations (54%-98%) have been reported.[9-12] This wide variation may be attributable to several factors. Success rates vary among endoscopists, perhaps influenced by annual and lifetime volumes, training, practice conditions, and so on.[13] [14] Surprisingly, they have not been found consistently to be strong independent predictors for success.[15] Technical difficulty of an individual procedure subtype (i.e. the procedure indication and

context) may also contribute.[16] [17] The influence of other candidate factors (e.g. trainee involvement, comorbidity, sedation, and other markers of quality practice) remains largely unknown.

An option when standard cannulation attempts fail is to perform a "pre-cut" sphincterotomy to facilitate access. This may increase risk in inexperienced hands, but meta-analyses of randomized trials concluded that precut appears safer than persistence; 18 as such, precut-assisted cannulation should not necessarily be regarded as "failure". Cannulation is generally easy after a prior sphincterotomy, or after a biliary stent has been placed; therefore, even though this has not consistently been done in the existing literature, it would seem preferable to consider only unoperated or "native" papillae for this metric.

In this context, data gathered in the context of a unique multinational ERCP quality network, were used to investigate the predictors for native papilla biliary cannulation success (with and without "precut") using multilevel logistic regression analyses.

REVIEW OF LITERATURE

Endoscopic retrograde cholangiopancreatography (ERCP) is an endoscopic technique in which a specialized side-viewing upper endoscope is inserted into the duodenum, allowing instruments access to the bile duct and pancreatic duct. Both ducts drain into a single orifice surrounded by a circular muscle (the Sphincter of Oddi), in the second part of the duodenum, approximately 10 cm past the stomach. For biliary indications (the majority of community ERCP), the challenge is to selectively cannulate the bile duct while avoiding the pancreatic duct. Selective biliary cannulation rate is used as the main measure of competence in ERCP during training, and quality of an ERCP endoscopist in practice, and should be over 80%, with rates over 90-95% achievable in expert hands. "Conventional" cannulation success is generally defined as cannulation achieved without cutting one's way into the duct (so-called "precut"); precut is a more advanced technique, but is successful 70-90% of the time at achieving cannulation ultimately.[19-21] It was originally thought that it increases the pancreatitis risk after an ERCP, but meta-analysis of randomized trials of early precut vs persistent cannulation have shown that it is likely the difficulty of cannulation that increases the risk rather than the precut itself.[4] Nevertheless, many community ERCPists are not trained to precut safely.

Over the past 40 years, ERCP has developed from a diagnostic to a predominately therapeutic tool in a variety of biliary and pancreatic disorders. It is widely performed annually around the world at a rate of approximately 1 per 1000 population, accounting for approximately 300,000 ERCPs conducted annually in the US. Yet, it remains one of

the most technically challenging and risky procedures. Post-ERCP pancreatitis is the most common and dreaded complication. Failed or difficult cannulation also predicts a higher rate of post-ERCP pancreatitis.[9] [22] Meanwhile, the reported ERCP-related mortality is approximately 0.1% (or 1 in 1000 cases), accounting for an estimated 300 deaths per year in the US.[5] [6] To avoid repeat procedures (or rescue procedures, such as percutaneous drainage or surgery), and to decrease the rate of failed cannulations, both of which increase risk, the American Society for Gastrointestinal Endoscopy recommends a biliary cannulation success rate of > 80% as a benchmark for competence in ERCP.[7] This is a global issue, and the British society of gastroenterology highlighted the community variation in ERCP in a nation-wide audit recently.[10]

However, even in experienced hands and with advanced techniques, some patient's biliary ducts cannot be accessed under certain circumstances. The reported rates of successful biliary cannulation vary widely. This may be attributable to several factors, including variation of endoscopist experience, variation in case-mix, variation in definition of success (allowing precut or not), and the denominator (all cases, or just native papilla cases). First of all, it is likely that the endoscopist's case volume is one important factor that can influence biliary cannulation success rate. One study about learning curve for deep biliary cannulation showed that the successful cannulation rate increased from 43% at the beginning of training to >80% after 350 to 400 supervised procedures.[23] Another study from Austria indicated that modest case volume (endoscopists performing >50 ERCPs per year) was associated with significantly higher deep cannulation success.[24] However, interestingly, a recent study from the US

community hospitals found no significant association between cannulation success and physician procedure volume or years of experience with a median of 50 ERCP/yr.[15] One possible explanation for this discrepancy might be non-uniform thresholds for high-and low-volume caseload. What's more, once competence is achieved, it is not clear that high caseloads for the endoscopist are required to maintain high biliary cannulation success. In addition, hospital volume and technical difficulty may also contribute as factors predicting cannulation success in a few reports.[14 16 17] Nevertheless, most of these above studies have focused primarily on the risk factors for the complications of therapeutic ERCP, rather than cannulation success. Many of the studies did not carefully stratify the results by the patients who had native papillae (i.e. no prior cut of the orifice ("sphincterotomy") or stent placed across their papilla – both of which dramatically increase the chance of success). Furthermore, other predictors for cannulation success (e.g. indication, trainee involvement, comorbidity) remain elusive and need further investigations. Lastly, the cutpoints for endoscopist experience and volume in prior analyses have been quite arbitrary, without a formal threshold analysis to quantitatively or qualitatively determine appropriate categorizations.

MATERIALS AND METHODS

Materials

Database

The data were retrieved from the ERCP Quality Network database, which was a web-based voluntary registry of prospectively entered, consecutive, self-reported, anonymous data from a variety of ERCP practices worldwide. We included ERCP procedures submitted between March 28, 2007, and May 18, 2011. Our study cohort was cleaned and restricted to cases with native papillae. It was further restricted to the physicians contributing more than 30 cases to the network.

Definitions of Variables

ERCP difficulty (or complexity) was graded from 1 (lowest difficulty=standard ERCP) to 3 (highest difficulty=tertiary ERCP), according to prior publication.[26] American Society of Anesthesiology (ASA) grade was an estimate of comorbidities, ranging from I (healthy), II (mild systemic disease), and to III-V (severe systemic disease). Trainee involvement was defined as fellow involvement by using percentage of time trainees handled the duodenoscope (0%, 1%-50%, 51%-99%, or 100%). Sedation type included moderate and "monitored anesthesia care" (MAC/propofol-induced deep sedation) or general anesthesia.

Endoscopist-specific data were gathered at a baseline survey at registration of that physician into the Quality Network. Number of cases performed in training for each physician was organized into 6 categories: 0, 1-100, 101-150, 151-200, 201-250, >250 procedures. Years of ERCP experience for each physician were defined as the numbers of years in performing ERCP at the baseline questionnaire. Lifetime volume was similarly defined as the estimated cumulative lifetime number of procedures performed. Annual volume was defined as the estimated numbers of ERCPs performed in the preceding year, surveyed at baseline registration. Additional endoscopist-specific variables were created to be surrogates of efficiency of each physician in straightforward cases: procedure time in grade 1 cases was defined as the median time from inserting scope to removing scope in grade 1 difficulty cases performed by each physician. Fluoroscopy time in grade 1 cases was similarly defined as the median duration fluoroscopy used in grade 1 difficulty cases for each physician.

Fourteen parameters evaluated were stratified by case-specific and endoscopist levels. Case-specific variables were as follows: trainee involvement, ERCP difficulty, ASA grade, sedation type (moderate or propofol/general anesthesia), admission status (inpatient or outpatient), and indications (including suspected or known stone, clarification of biliary image findings, chronic pain, obstructive jaundice, active pancreatitis, chronic pancreatitis, abnormal liver enzymes, tumor ablation, and biliary post-surgical problems). Endoscopist-level variables were as follows: country setting (US, UK, others), institution setting (academic or community), number of years in ERCP,

lifetime volume, annual volume, number of cases in training, procedure time in grade 1, and fluoroscopy time in grade 1.

Methodology

The primary outcome of interest was conventional deep biliary cannulation success (without precut); that is, requiring a precut was deemed a "failure". The secondary outcome of interest was overall deep biliary cannulation success (allowing the use of precut). Deep biliary cannulation success was defined as the tip of the catheter passing beyond the native papilla into the biliary duct.

For most numerical variables (years of ERCP, lifetime volume, annual volume, procedure time, and fluoroscopy time in grade 1), distributions were positively skewed, so they were split into two or four categories by using median or quartile. To account for the inherent clustering within these data (i.e., the same endoscopist performing multiple procedures over time), a multilevel model with random intercepts including individual endoscopist was constructed. First, univariate multilevel logistic regression analyses were performed. For each outcome, adjusted cannulation success rates and their corresponding p values were calculated. Correlations between variables were evaluated using Spearman' rank correlation coefficients. Second, variables with an adjusted p-value < 0.2 in the univariate analysis were selected for entry into a multivariate multilevel logistic regression. A backward stepwise approach was used to fit models to these variables. Adjusted odds ratios (OR) and their corresponding 95% confidence intervals were reported. No interaction terms were considered in the multivariate analysis. All analyses were performed using SAS version 9.2 (SAS Institute Inc, Cary, North Carolina). All tests were 2-sided, and p values <0.05 were considered statistically significant.

With such a large sample of subjects undergoing this procedure (n=13,018), we had an extremely high degree of power to detect very small differences (e.g. 96% power to detect a 2% difference in rates) in conventional biliary cannulation success pertaining to case-specific variables. Since the number of endoscopists was much lower than the overall number of procedures, our power to detect differences pertaining to endoscopist-level factors was lower. For example, with 42 doctors in each of 2 groups (e.g. low annual volume vs. high annual volume), we were only powered to detect differences in conventional biliary cannulation success rates of 11% or greater (e.g. 85% vs. 96%) with sufficient power, assuming that an endoscopist's success during one procedure is moderately correlated (i.e. an intra-class correlation coefficient of 0.4) with other procedures he/she performs.

RESULTS AND DISCUSSION

Results

During the registry period, a total of 13,018 ERCP procedures in native papilla were performed by 85 endoscopists. Conventional deep biliary cannulation success rate was 89.8% (ranging from 63.9% to 100% for different endoscopists). Precut sphincterotomy was performed in 876 (876 / 13018, 6.7%) ERCPs, and deep biliary cannulation was achieved in 745 (85.1%) of those procedures. Overall deep biliary cannulation success rate (including some precut-assisted cases) was 95.6% (ranging from 80.2% to 100% for different endoscopists). A conventional cannulation success rate of >80% was achieved by 73 (85.9%) endoscopists, and >90% achieved by 42 (49.4%) endoscopists. Overall cannulation success rate (including precuts) of >80% was achieved by all endoscopists, and >90% by 71 (83.5%).

Case-specific characteristics

These were presented in Table 1. Of all the procedures, 6235 (47.9%) were grade 1 difficulty, 3037 (23.3%) were grade 2, and 3746 (28.8%) were grade 3. Preprocedure anesthesia risk stratification showed that 2480 (19.1%) patients were classified as ASA I, 6573 (50.5%) were classified as ASA II, and 3965(30.5%) were classified as ASA III-V. For sedation type, 5820 (44.7%) ERCPs were performed under moderate anesthesia, and 7198 (55.3%) were under MAC/propofol or general anesthesia. 6286 (48.3%) ERCP procedures were performed on inpatients and 6732 (51.7%) were on outpatients (including those that may have stayed overnight or longer as an inpatient after

procedures). With respect to trainee involvement, trainees were involved in 4113 (31.6%) procedures. The most common indications for ERCP were suspected or known stone, which together accounted for 36.8% of all procedures.

Table 1. The Case-specific Characteristics.

Variables	n (%)
Trainee involvement	
0%	8905 (68.4)
1-50%	1794 (13.8)
51-99%	1389(10.7)
100%	930 (7.1)
ERCP difficulty	
1	6235 (47.9)
2	3037(23.3)
3	3746 (28.8)
ASA grade	
I	2480 (19.1)
II	6573 (50.5)
III-V	3965 (30.5)
Adminssion staus	
Inpatient	6286 (48.3)
Outpatient	6732 (51.7)
Sedation level	
Moderate	5820 (44.7)
Propfol/general	7198 (55.3)
Indications	
Suspected or known stone	4791 (36.8)
Obstructive Jaundice	2381 (18.3)
Chronic pain	1984 (15.2)
Abnormal liver tests	1165 (9.0)
Chronic pancreatitis	1109 (8.5)
Biliary post-surgical problem (leak, stricture)	609 (4.7)
Clarification of biliary image findings	426 (3.3)
Pancreatitis (acute, active)	434 (3.3)
Tumor ablation	119 (0.9)

Endoscopist-specific characteristics

These were summarized in Table 2. Of all the endoscopists, 60 (70.6%) were from the United States, and 16 (18.8%) were from the United Kingdom; Canada, Australia, Brazil, Norway, and Venezuela were other countries represented in the "other"

category. 3922 (37%) procedures were completed by 34 (44.7%) academic endoscopists, and 6679 (63%) procedures were conducted by 42 (55.3%) community endoscopists.

Forty (47.1%) endoscopists did not receive formal ERCP training, 6 (7.1%) in 1-100 ERCPs, 8 (9.4%) in 101-150 ERCPs, 5 (5.9%) in 151-200 ERCPs, 7 (8.2%) in 201-250 ERCPs, and 19 (22.4%) in more than 250 ERCPs . ERCP experience in terms of duration of practice for each endoscopist also varied, from 0 to 36 years (median, 12; interquartile range [IQR], 6-20), and from 175 to 15,000 lifetime ERCP procedures performed (median 1200; IQR, 587-2500). Annual volume varied from 10 to 940 ERCP procedures performed in the year preceding registration into the Network (median, 150; IQR, 90-239). Median procedure time in grade 1 difficulty cases was 25 minutes (IQR, 20-30), ranging from 10 to 48 minutes for individual endoscopists. Median fluoroscopy time in grade 1 difficulty cases was 3 minutes (IQR, 1.9-4.6), ranging from 0.3 to 10.1 minutes for individual endoscopist.

As expected, lifetime volume was moderately correlated with annual volume ($r = 0.44$, $p = 0.0001$), and years performing ERCP ($r = 0.60$, $p < 0.0001$), respectively. In contrast, there was very little correlation between years of experience and annual volume ($r = -0.13$; $p = 0.29$). The endoscopist's median average fluoroscopy and procedure times in grade 1 difficulty cases were, not surprisingly, associated with one another ($r = 0.69$, $p < 0.0001$).

Table 2. The Endoscopic-specific Characteristics

Variables	Endoscopist
Country setting-no. (%)	
US	60 (70.6)
UK	16 (18.8)
Others	9 (10.6)
Hospital setting-no. (%)	
Academic	34 (44.7)
Community	42 (55.3)
Training experience-no. (%)	
0	40 (47.1)
1-100	6 (7.1)
101-150	8 (9.4)
151-200	5 (5.9)
201-250	7 (8.2)
>250	19 (22.4)
Years of ERCP (yr)	
Median (range)	12 (0-36)
IQR	6-20
Lifetime Volume	
Median (range)	1200 (175-15000)
IQR	587-2500
Annual volume	
Median (range)	150 (10-940)
IQR	90-239
Procedure time for grade 1 (minute)	
Median (range)	25 (10-48)
IQR	20-30
Fluoroscopy time for grade 1 (minute)	
Median (range)	3 (0.3-10.1)
IQR	1.9-4.6

Univariate multilevel logistic regression analysis

The adjusted conventional deep biliary cannulation success rates were presented in Table 3. Five case-specific factors were significantly associated with conventional cannulation success: trainee involvement, ERCP difficulty, ASA grade, outpatient, and indications. Of the endoscopist-specific factors, only country setting was significantly associated with conventional deep biliary cannulation success (Table 3).

Table 3. Univariate multilevel analysis of predicting factors for conventional deep biliary cannulation success rate, with and without adjustment for clustering by endoscopists.

Variables	Conventional cannulation success rate		
	Not-adjusted	Adjusted*	Adjusted p value
Case-specific			
Trainee involvement			<0.0001
0%	90.0	89.2	
1-50%	82.4	81.3	
51-99%	92.4	93.1	
100%	98.7	99.0	
ERCP difficulty			<0.0001
1	89.6	90.2	
2	90.0	89.5	
3	90.1	86.2	
ASA grade			<0.0001
I	91.4	92.1	
II	90.1	89.4	
III-V	88.4	87.7	
Adminssion staus			0.002
Inpatient	88.4	88.6	
Outpatient	91.2	90.5	
Sedation level			0.139
Moderate	88.9	88.8	
propofol /general	90.6	90.2	
Indications			<0.0001
Suspected or known stone	91.8	92.1	
Obstructive Jaundice	84.0	84.5	
Chronic pain	92.9	91.4	
Abnormal liver tests	91.0	90.3	
Chronic pancreatitis	90.1	88.9	

Table 3--continued

Indications	Conventional cannulation success rate		
	Not-adjusted	Adjusted*	Adjusted p value
Biliary post-surgical problem	86.2	85.5	
Clarify biliary image findings	89.9	89.5	
Pancreatitis (acute, active)	86.4	86.6	
Tumor ablation	94.1	94.1	
Endoscopist-specific			
Country setting			0.048
US	90.9	90.5	
UK	86.5	86.4	
Other	85.3	87.8	
Hospital setting			0.514
Academic	90.6	90.2	
Community	89.7	89.2	
Training experience			0.306
0	90.1	89.3	
1-100	93.1	93.3	
101-150	89.2	89.1	
151-200	87.5	89.2	
201-250	82.7	84.9	
>250	90.1	90.4	
Years of ERCP			0.790
≤6	90.0	90.1	
7-12	87.5	89.2	
13-20	91.1	89.5	
>20	88.4	88.0	
Lifetime volume			0.812
≤587	89.5	89.3	
588-1200	88.9	89.8	
1201-2500	87.7	88.2	
>2500	91.7	89.8	
Annual volume			0.534
≤90	85.7	87.9	
91-150	88.8	88.4	
151-239	89.9	90.1	
>239	91.0	90.6	
Procedure time for grade 1			0.859
≤25	90.0	89.6	
>25	89.5	89.4	
Fluoroscopy time for grade 1			
≤3	90.0	90.0	0.427
>3	89.6	88.9	

*: Adjusted success rates were obtained from multilevel logistic regression models that

accounted for clustering of cases within endoscopists.

The adjusted overall deep biliary cannulation success rates were presented in Table 4. Five case-specific factors were significantly associated with success rate: trainee involvement, ERCP difficulty, ASA grade, sedation level, and indications. Four endoscopist-specific factors were significantly associated with success rate: country setting, annual volume, and the endoscopist's median procedure time and fluoroscopy time in grade 1 difficulty cases (Table 4).

Table 4. **Univariate multilevel analysis of predicting factors for overall deep biliary cannulation success rate, with and without adjustment for clustering by endoscopists.**

Variables	Overall cannulation success rate		
	Not-adjusted	Adjusted[*]	Adjusted p value
Case-specific			
Trainee involvement			<0.0001
0%	96.3	95.1	
1-50%	89.9	90.1	
51-99%	95.8	96.8	
100%	99.3	99.5	
ERCP difficulty			0.016
1	94.3	95.0	
2	95.9	95.7	
3	97.4	93.5	
ASA grade			<0.0001
I	96.4	96.7	
II	95.8	95.3	
III-V	94.6	93.0	
Admission status			0.119
Inpatient	94.5	94.7	
Outpatient	96.6	95.4	
Sedation level			0.013
Moderate	93.8	94.2	
propofol /general	97.0	95.8	
Indications			<0.0001
Suspected or known stone	96.5	96.8	
Obstructive Jaundice	91.8	91.9	
Chronic pain	98.4	96.3	
Abnormal liver tests	96.4	95.1	
Chronic pancreatitis	95.9	93.7	
Biliary post-surgical problem	94.1	94.3	
Clarify biliary image findings	94.8	94.4	

Table 4--continued

Indications	Overall cannulation success rate		
	Not-adjusted	Adjusted*	Adjusted p value
Pancreatitis (acute, active)	92.6	91.7	
Tumor ablation	97.5	96.5	
Endoscopist-specific			
Country setting			0.026
US	96.6	95.5	
UK	91.1	91.9	
Other	94.7	96.3	
Hospital setting			0.858
Academic	95.0	94.9	
Community	95.5	94.7	
Training experience			0.783
0	96.4	95.3	
1-100	96.0	96.1	
101-150	92.9	94.3	
151-200	93.2	94.7	
201-250	88.6	92.2	
>250	94.5	95.1	
Years of ERCP			0.735
≤6	94.6	95.0	
7-12	95.4	95.6	
13-20	96.8	95.2	
>20	93.8	93.9	
Lifetime volume			0.097
≤587	93.5	93.7	
588-1200	92.5	93.8	
1201-2500	94.6	94.7	
>2500	97.9	96.8	
Annual Volume			0.007
≤90	89.9	92.2	
91-150	93.3	94.0	
151-239	94.9	95.3	
>239	98.1	97.1	
Procedure time for grade 1			0.041
≤25	96.5	95.8	
>25	93.3	93.7	
Fluoroscopy time for grade 1			0.024
≤3	96.5	95.9	
>3	93.8	93.7	

* Adjusted success rates were obtained from multilevel logistic regression models that

accounted for clustering of cases within endoscopists.

Multivariate multilevel logistic regression analysis

Due to multicollinearity among the variables based on initial correlation analyses, lifetime volume (correlated with annual volume and experience) and procedure time (correlated with fluoroscopy time) were not included in the multivariate models.

The results of multivariate analysis on conventional success were summarized in Table 5. Outpatients (OR 1.21 [95%CI, 1.05-1.38] vs inpatients) independently predicted conventional (no precut) success, whereas high (grade 3) ERCP difficulty level (OR 0.59 [95%CI, 0.48-0.72] vs grade 1), high comorbidities as measured by ASA grade (II: OR 0.81 [95%CI, 0.67-0.97]; III-V: OR 0.77 [95%CI, 0.63-0.94], all versus ASA I), and some indications (obstructive jaundice: OR 0.51 [95%CI, 0.44-0.60], biliary post-surgical problem (e.g. leaks, post-operative strictures): OR 0.51 [95%CI, 0.39-0.67], and acute or active pancreatitis: OR 0.67 [95%CI, 0.49-0.92] , all versus cases with a known or suspected stone) were independent predictors for lower success rates. High level of trainee involvement (versus no trainee) (51%-99% involvement: OR 1.58 [95%CI, 1.21-2.06] and 100% involvement: OR 11.96 [95%CI, 6.59-21.71]) were independently predictive of higher success rates, whereas low level of trainee involvement (1-50% involvement: OR 0.53 [95%CI, 0.44-0.65] versus no trainee), implying that perhaps less experienced trainees that are only able to participate in a small part of the case, hurt success rates. Of note, none of the endoscopist-specific factors was significantly related with conventional cannulation success.

Table 5. Multivariate multilevel logistic regression analysis of predicting factors for conventional (no precut allowed) deep biliary cannulation success rate.

Variables	Conventional cannulation success	
	OR (95%CI)	p value
Case-specific		
Trainee involvement		<0.0001
0%	Reference	
1-50%	0.53 (0.44-0.65)	
51-99%	1.58 (1.21-2.06)	
100%	11.96 (6.59-21.71)	
ERCP difficulty		<0.0001
1	Reference	
2	1.03 (0.88-1.20)	
3	0.59 (0.48-0.72)	
ASA grade		0.033
I	Reference	
II	0.81 (0.67-0.97)	
III-V	0.77 (0.63-0.94)	
Sedation level		0.108
Propofol/general	Reference	
Moderate	0.84 (0.68-1.04)	
Adminssion staus		0.008
Inpatient	Reference	
Outpatient	1.21 (1.05-1.38)	
Indications		<0.0001
Suspected or known stone	Reference	
Obstructive Jaundice	0.51 (0.44-0.60)	
Chronic pain	1.16 (0.89-1.50)	
Abnormal liver tests	0.80 (0.63-1.02)	
Chronic pancreatitis	0.93 (0.72-1.22)	
Biliary post-surgical problem	0.51 (0.39-0.67)	
Clarify biliary image findings	0.77 (0.55-1.10)	
Pancreatitis (acute, active)	0.67 (0.49-0.92)	
Tumor ablation	2.15 (0.96-4.81)	
Endoscopist-specific		
Country setting		0.217
US	Reference	
Other	0.77 (0.46-1.30)	
UK	0.73 (0.49-1.09)	

The results of multivariate analysis on overall conventional success were summarized in Table 6. For overall cannulation success, allowing the use of precut to achieve success, similar factors were found to be independently associated with overall deep biliary cannulation success: moderate to high trainee involvement (51%-99%: OR 1.55 [95%CI, 1.05-2.27]; 100%: OR 9.16 [95%CI, 4.18-20.05], versus no trainee) predicted higher success rates, whereas high ERCP difficulty (grade 3: OR 0.70 [95%CI, 0.51-0.97], versus grade 1), low trainee involvement (1-50%: OR 0.50 [95%CI, 0.38-0.66], versus no trainee), high ASA grade (III-V: OR 0.52 [95%CI, 0.38-0.70], versus ASA I), and certain indications (obstructive jaundice: OR 0.45 [95%CI, 0.35-0.57], chronic pancreatitis: OR 0.63 [95%CI, 0.41-0.98], biliary post-surgical problem: OR 0.53 [95%CI, 0.35-0.79], acute or active pancreatitis: OR 0.46 [95%CI, 0.29-0.71], and clarification of biliary image findings: OR 0.58 [95%CI, 0.35-0.96], all versus cases with a known or suspected stone) were independent predictors of lower success rates. In addition, moderate sedation (OR 0.67 [95%CI, 0.49-0.92], versus deep/general anesthesia) predicted lower success, and outpatient status was not significantly predictive. Two endoscopist-specific factors were significant for this outcome, however: endoscopist annual volume (>239: OR 2.79 [95%CI, 1.46-5.31]), and endoscopist's median fluoroscopy time used in grade 1 difficulty cases (≤3: OR 1.72 [95%CI, 1.10-2.69]).

Table 6. Multivariate multilevel logistic regression analysis of predicting factors for overall (allowing precut) deep biliary cannulation success rate.

Variables	Overall cannulation success	
	OR(95%CI)	p value
Case-specific		
Trainee involvement		<0.0001
0%	Reference	
1-50%	0.50 (0.38-0.66)	
51-99%	1.55 (1.05-2.27)	
100%	9.16 (4.18-20.05)	
ERCP difficulty		0.005
1	Reference	
2	1.26 (0.99-1.59)	
3	0.70 (0.51-0.97)	
ASA grade		<0.0001
I	Reference	
II	0.78 (0.59-1.02)	
III-V	0.52 (0.38-0.70)	
Sedation level		0.012
Propofol/general	Reference	
Moderate	0.67 (0.49-0.92)	
Admission status		0.431
Inpatient	Reference	
Outpatient	1.09 (0.88-1.35)	
Indications		<0.0001
Suspected or known stone	Reference	
Obstructive Jaundice	0.45 (0.35-0.57)	
Chronic pain	1.03 (0.63-1.70)	
Abnormal liver tests	0.71 (0.47-1.08)	
Chronic pancreatitis	0.63 (0.41-0.98)	
Biliary post-surgical problem	0.53 (0.35-0.79)	
Clarify biliary image findings	0.58 (0.35-0.96)	
Pancreatitis (acute, active)	0.46 (0.29-0.71)	
Tumor ablation	1.28 (0.38-4.34)	
Doctor level		
Country setting		0.396
US	Reference	
UK	0.71 (0.41-1.22)	
Other	0.78 (0.36-1.66)	

Table 6--continued

Variables	Overall cannulation success	
	OR(95%CI)	p value
Doctor level		
Annual volume		0.013
Table Continued		
≤90	Reference	
91-150	1.28 (0.72-2.29)	
151-239	1.85 (0.95-3.60)	
>239	2.79 (1.46-5.31)	
Fluoroscopy time for grade 1		0.018
>3	Reference	
≤3	1.72 (1.10-2.69)	

Discussion

Deep biliary cannulation success in native papilla is a widely accepted measure of competence in ERCP during training, and quality of an endoscopist in ERCP practice. Identifying predictors for successful biliary cannulation in native papilla, both at a case- and at an endoscopist-/team-level, have important implications in improving the quality of ERCP and patient care. Overall, this cohort of volunteer physicians achieved a group conventional deep biliary cannulation success rate of 89.8%, which met the rate recommended by the ASGE/ACG Task Force.[7] Further multivariate analyses suggest that only case-specific factors are significant predictors for conventional native papilla biliary cannulation success, and that endoscopist- and institution-level factors may not be as important.

Our results supported the notion that procedures anticipated to be more complex (based on pre-procedural data) are associated with a decreased conventional and precut-assisted cannulation success rates, providing some validation for the use of this difficulty scale.[16][17] Verma et al found no correlation between conventional cannulation success and procedure difficulty for trainees.[23] Prior studies have had a heterogeneous group of endoscopists, and most of the previous studies did not adjust other factors affecting cannulation outcome. ERCP indications, which are known ahead of attempting a case, were also viewed as important impact factors in this study.

ERCP is seldom indicated in acute and active pancreatitis, with negative randomized trials in mild to moderate acute gallstone pancreatitis,[26] and predicts lower

conventional and precut-assisted success rates, likely because of duodenal and periampullary edema and distortion; lower success provides another reason to avoid or delay ERCP in this situation. Obstructive jaundice (mostly representing cancer cases, or more uncommonly an unrecognized impacted stone) predicts a lower chance of success than in suspected stone cases; a recent randomized trial promoted avoiding ERCP in obstructive jaundice in surgically resectable tumors.[27] Post-surgical biliary issues (mostly leaks and strictures) also predicts lower success, and this has not been previously reported; although a minority have surgically altered upper GI anatomy, most do not, and it is not clear why this is the case, but some anatomic distortion, edema, or need for atypical positioning because of recent surgery (supine instead of prone), may contribute. Therefore, pre-procedure evaluations based on procedure complexity and indications are important especially for less experienced endoscopists, to choose cases in which one is anticipated to have a reasonable success rate, and to weigh lower anticipated success into decision-making and consent.

Trainee involvement has been shown to be a significant risk factor for post-ERCP pancreatitis.[28] The BSG study reported a cannulation success rate of 54% in the procedures with trainee involvement and considered that much trainee involvement was likely to affect ERCP quality due to inadequate experience,[10] but the audit did not survey the details of trainee involvement in ERCP procedures. In the current study, conventional and precut-assisted cannulation success rates were decreased only in the procedures with low trainee involvement. In contrast, the odds of success rates were slightly increased 1.6-fold for the trainees able to complete 51-99% of the procedures without assistance,

and 11-fold when trainees completed the procedures alone, respectively. This may be due to the fact that 62.6% of the procedures were straightforward (grade 1) when the trainees handled the duodenoscope more than 50% of the time, although it appears to predict success/failure independent of procedure difficulty. Another explanation is that the trainees able to perform most of the case unassisted are less harmful than the trainees capable of a low degree of involvement who may cause ampullary edema with their brief attempts at cannulation, and lower the overall success rate of the procedure. Lastly, it could be confounded by more skilled attending endoscopists allowing more trainee involvement than those less skilled; this seems less likely.

In the present study, high ASA score was surprisingly another factor predicting low conventional and precut-assisted cannulation success. Again, perhaps difficulties with levels of sedation or positioning of the patient may influence cannulation in some way. In addition, perhaps for similar reasons, our results suggest that outpatient ERCP may have a higher conventional cannulation success rate. Prior studies suggested outpatient ERCP as safe as inpatient ERCP,[29][30] but a grade 1 outpatient and a grade 1 inpatient may have subtly different complexities to their planned procedure. Previous reports have found higher technical success rates achieved under deep sedation and general anesthesia than moderate ("conscious") sedation because of better patient tolerance and compliance.[31][32] Our results showed that deep sedation / general anesthesia was not associated with conventional cannulation success, but did predict success overall if precut was allowed; this may suggest that when the procedure becomes difficult or prolonged, one's ability to move to a more advanced technique like precut is hindered by

moderate sedation. Additionally, a striking fact is that the use of deep sedation /general anesthesia in ERCP was more common in US than in UK. Country was significant as a predictor of success in univariate analysis, but when corrected for differences in sedation use, and other practice differences, it was not predictive as expected.

Training and maintenance of competence remain ever important topics in ERCP. Current ASGE recommendations based on learning curve state that most fellows require at least 180-200 cases to achieve competency, with at least half of these cases being therapeutic.[7] A recent study, however, found that at least 350 to 400 supervised procedures were needed for a trainee to achieve an overall 80% biliary cannulation success rate in patients with native papilla.[23] In the present study, 63.5% endoscopists received <200 procedures during their training, and 47% less than 100; this is similar to a recent survey reporting 60.4% of all responders who completed <180 cases in fellowship.[33] Previous training volume did not appear to have a significant impact on current conventional cannulation success, although endoscopist-specific factor analysis has lower power than that of the case-specific factors. It is noted that endoscopists with less training (<200 cases) had much more years performing ERCP (data was not shown), and their learning curve may have continued to rise and plateau while out in practice. Overall, due to ERCP complexity and risks, adequate training during fellowship is still essential for those intending to perform ERCP.

Once competence is achieved, it is intuitive that think that endoscopists with more years of experience, and/or higher lifetime or annual volumes may have better outcomes.

However, there is no consensus on which is the most crucial factor in maintaining ERCP proficiency, or what volume thresholds should be for recredentialing. The British Joint Advisory Group (JAG) recommends that endoscopists should perform at least 75 ERCPs per year.[34] Freeman et al reported that endoscopists performing more than two ERCPs per week (>50/yr) had significantly higher cannulation rates (96.5% vs. 91.5%).[9] Another study from Austria showed that endoscopists performing >50 ERCPs per year achieved higher cannulation success rates.[24] In contrast, a community study of endoscopists performing a median of 50 ERCPs per year demonstrated no associations between cannulation success and physician procedure volume or years of experience.[15] The above mentioned studies did not separate out cannulation success with and without precut, or native vs cut/stented papillae. Our data showed a small but nonsignificant trend toward higher conventional success rate in higher annual volume endoscopists, but other experience factors were not associated with conventional cannulation success. Endoscopist annual volume (>239: OR 2.79) did significantly predict overall cannulation success if precut was allowed; the discrepancy should be interpreted with caution due to the small sample size of endoscopists. However, it may imply that some of the higher overall success of the more active endoscopist might be due to their ability to comfortably use a more advanced rescue technique like precut sphincterotomy. We explored various other cutoffs for annual volume, including 50, as we previously suggested, and 100 and 200, and a higher cutoff (>300). However, none of these were significant, and the highest quartile volume appeared to be the only category with an odds ratio that did not cross 1.0. The prior studies that chose >50 as a cutoff for analysis would have included this high quartile group in their "higher-volume" category; however, in this

analysis a significant independent association is not seen until one gets to the highest quartile, >200/year.

Fluoroscopy time increases a risk of radiation exposure to patients and staff. It can be influenced by several factors like endoscopist experience, trainee involvement, experience of X-ray technician, and the X-ray equipment quality, as well as procedure related factors.[35-37] The interplay between one quality metric predicting another is unclear. However, our results showed that low median fluoroscopy time in grade 1 difficulty cases ($\leq$ 3 min) predicted cannulation success overall (when precut was allowed), although it did not predict conventional cannulation success.

It has been suggested precut sphincterotomy be reserved for cases of difficult biliary cannulation in the hands of experienced endoscopists.[38] [39] Our results showed an overall cannulation success rate (including precut-rescued cases) of 95.6%, which was comparable with previous studies.[40] [41] Although precut sphincterotomy was initially thought to increase post-ERCP pancreatitis rates, a meta-analysis of persistence versus precut trials showed that persistence is more harmful.[18] It is clear that precut rescue increases cannulation success.

There are limitations with our study. First, as stated above, we have low power to detect the effects of some doctor-level factors on biliary cannulation success due to the modest sample size of endoscopists. Second, the self-reported data of endoscopists cannot be audited for accuracy. In addition, the generalizability of our conclusions may

be limited, because the endoscopists were self-selected and may not reflect average ERCP practice worldwide. However, the spectrum of training, volume, years in practice, practice settings, and success rates, does not suggest a homogenously well-trained, highly skilled, high-volume cohort of academic clinicians.

SUMMARY AND CONCLUSIONS

In conclusion, our results based on this unique international dataset indicate that case-specific factors have greater impact on biliary cannulation success with and without precut than endoscopist-specific ones, but that annual volume and sedation practices may influence ultimate success when advanced techniques such as precut are allowed. These should be considered in case selection and in consenting the patients for ERCP. In addition, with regard to experience factors, annual volume appears to be the most critical factor predicting overall biliary cannulation success, and prior experience/training does not appear to make up for that. In addition, the ideal annual volume for an ERCP endoscopist may be considerably higher than the 50 previously published. Further study with an even larger number of endoscopists is needed to explore the minimum annual volume for maintenance of competence with respect to proficiency of deep biliary cannulation.

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