Improving Endoscopic Retrograde Cholangiopancreatography (ERCP) Performance and Complication Rates: A Single Operator Retrospective Review from 2004-2011

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Dedication

This thesis is dedicated to patients suffering from Hepatobiliary Disease. It is my hope that this work will improve the care that you receive. I also dedicate this work to my parents who have always been supportive of my academic pursuits.

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Abstract

Objective: To determine if a one year advanced ERCP fellowship program leads to better outcomes in a community gastroenterologist who has 5 years of experience performing ERCPs in the community without this additional training.

Design: Retrospective review of 400 patients before and after 1-year advanced ERCP fellowship (2009). During the pre-training period (2004-2008) 173 patients underwent an ERCP procedure. During the post-training period (2010-2011) 213 patients underwent an ERCP procedure. The outcome measurements from these two cohorts were compared (utilizing Chi-Square test) with each other to determine if there was a statistically significant difference in outcomes between the two groups.

Setting: Single Urban Medical Center

Main Outcome Measurements: Rate of common bile duct cannulation; Rate of Post-procedure pancreatitis; Rate of usage of Common bile duct stents, pancreatic duct stents; Rate of Biliary and Pancreatic duct sphincterotomy.

Results: Key ERCP outcome measures were statistically different in the two cohorts: Rate of Common Bile Duct cannulation, a marker of technical ERCP competency, increased from 83% to 93% ($p = 0.0026$). The primary complication related to ERCP, post-ERCP pancreatitis decreased from 6.9% to 1.9%

($p = 0.025$).

Limitations: Single operator study.

Conclusions: Further guided experience in the form of a 1-year Advanced ERCP fellowship was shown to improve technical competency and decrease complications related to undergoing an ERCP procedure.

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Introduction

Endoscopic Retrograde Cholangiopancreatography (ERCP) is a relatively common procedure with approximately 500,000-600,000 performed annually in the United States.[1] The indications for ERCP can be seen in Table 1.

These indications for ERCP were defined at a consensus meeting on ERCP in 2002.[12] There has been interest in improving the performance and safety of this technically difficult procedure since its introduction in 1968 by Dr. McCune as a minimally-invasive method for investigating the hepatobiliary system, specifically that common bile duct and the pancreatic duct.[16] Essentially, ERCP is able to provide direct visualization of the bile ducts and the pancreatic ducts through the Ampulla of Vater, as shown in Figure 1. A side-viewing endoscope and instrumentation can be introduced for tissue sampling, cannulation of ducts, and insertion of stents or retrieval of gallstones, as shown in Figure 2. With the introduction of computed tomography (CT), magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasound (EUS) the role of ERCP has changed to become a procedure largely used for therapeutic interventions.

Table 1: Indications for ERCP[12]

Indications for ERCP	Diagnosis	Treatment
1. Gallstone diseases (Common Bile Duct Stones)	Endoscopic Ultrasound CT Cholangiography	ERCP to remove stones
2. Pancreatic and Biliary Malignancies	Contrast-enhanced CT Tissue diagnosis with EUS, CT, Ultrasound guided biopsy with ERCP	ERCP for palliative interventions (insertion of stents)
3. Pancreatitis	CT MRCP	ERCP for drainage of pancreatic pseudocysts, removal of stones, placement of stents
4. Sphincter of Oddi dysfunction	CT, MRCP, EUS to rule out structural lesions Sphincter Manometry	ERCP

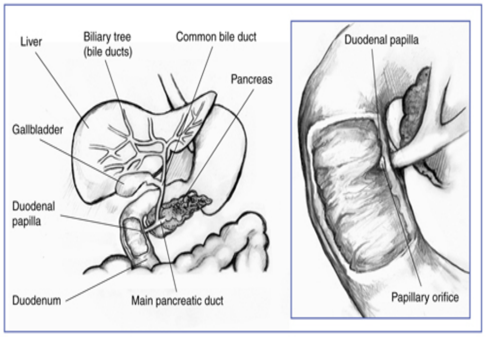

Figure 1: Biliary Anatomy showing the biliary tree and pancreatic duct.

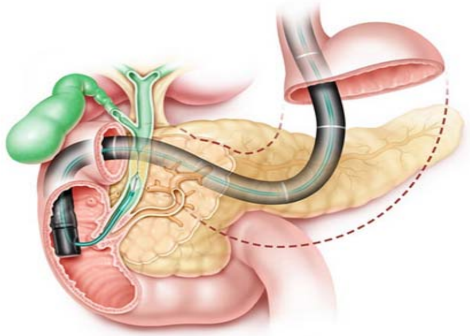

Figure 2: ERCP side-viewing scope with cannulation of the common bile duct.

ERCP is a procedure that requires substantial training to become effective with the procedure. Verma et al. showed that an endoscopist's ERCP performance improves while undergoing a 4th year ERCP fellowship immediately following his gastroenterology fellowship in a single operator experience.[2] Studies have shown and the American Society for Gastrointestinal Endoscopy (ASGE) recommends that the endoscopist have at least 180-200 ERCP attempts before competence can be presumed.[3,4] In most training programs it has been noted that this threshold is not met by most gastroenterology fellows. A median of 140 ERCPs were performed by fellows over a 3 year period. Only 36% of fellows exceeded the 200 ERCP procedures that would normally be required to indicate that the endoscopist could be expected to reach procedural competence. Moreover, this threshold of greater than 200 ERCPs to achieve procedural competence may be too low for endoscopist to *consistently* achieve deep biliary cannulation.[3] Yet, 91% of fellows are expected to perform unsupervised ERCP in post-fellowship practice.[5] It is currently unknown how many ERCPs are being performed by those who received additional training in ERCP versus those who have completed a gastroenterology fellowship. In addition to training, several studies have shown that ERCP performance improves in practitioners who perform more than 50 ERCPs per year and if they are practicing in medical centers that perform more than 200 ERCPs per year.[17] One way of improving ERCP outcomes is by improving the ability of the operator during an ERCP procedure. Thus, we sought to assess whether a community gastroenterologist performing ERCPs for many years in the community would benefit from the guided training received during a 1-year advanced ERCP fellowship.

Methods

Data Source

Institutional Review Board (IRB) clearance was obtained from Maricopa Integrated Health Systems (MIHS) to access patient records of patients who underwent ERCP with the endoscopist (A.N.).

All ERCP procedures performed by endoscopist (A.N.) before training (2004-2008) and after training (2010-2011) were retrieved from the electronic medical record, catalogued according to date and entered into a database. These entries were cross-referenced with billing statements from the medical center to ensure that all procedures were recorded and included.

Operator Characteristics

Prior to the study period starting in 2004, the endoscopist (A.N.) had completed a gastroenterology fellowship at a large tertiary-care referral center from 1995-1997. Subsequently, he underwent advanced training in hepatology and worked as an attending gastroenterologist and hepatologist. Starting in 1999-2001, A.N. performed approximately 150 ERCPs but this experience consisted of getting the 2nd or 3rd chance at deep biliary cannulation after a fellow or gastroenterologist had failed to achieve cannulation. From 2002-2003, A.N. moved to a different hospital system and also had limited exposure to ERCP consisting of observation and occasional attempts at ERCP. By 2004, he began to perform ERCP at Maricopa Medical Center where the study data first began to be collected. After 4 years of performing about 40 ERCPs per year at Maricopa, A.N. decided to undergo advanced ERCP training to improve his ERCP procedural skills at the University of Arizona medical center (Tucson, AZ). During this year, A.N. was able to perform approximately 350 ERCPs with guidance from senior endoscopists and gradually performed ERCPs independently. A.N. then returned to Maricopa Medical Center where he again performed ERCPs at a much higher volume (approximately 150 ERCPs per year) on a similar patient population. He continues to perform ERCPs currently at Maricopa Medical Center in 2013.

Study Variables

The database contained many variables related to an ERCP procedure. The primary study variables were the outcome measurements: the common bile duct (CBD) cannulation rates, pancreatic duct (PD) cannulation rates, CBD sphincterotomy rates, PD sphincterotomy rates, and needle-knife intervention rates, procedure time. The CBD cannulation rate has been shown to be an indication of relative competency of the endoscopist and was used for this purpose in this study.[6] Also, complication rates of post-procedure pancreatitis, hemorrhage, and perforation were recorded. In addition to these important outcome measures, other variables were also included: baseline characteristics of the patients (age, weight, height, race, smoking status, alcohol use status, indication for ERCP), inpatient vs. outpatient procedure, admission and discharge date, laboratory values (liver enzymes, bilirubin, amylase and lipase). The demographic characteristics of these cohorts can be seen in Table 3.

Statistical Analysis

We first utilized descriptive statistics to find the mean values and percentages for the baseline characteristics. Baseline characteristics were compared utilizing the t-test and Chi-Square test depending on the data type to ensure that the two cohorts had similar patient characteristics and indications for undergoing ERCP. Chi-Square Test was utilized to compare the pre-ERCP and the post-ERCP training cohorts to see if there were meaningful statistical differences for the dichotomous variables (cannulation rates, stent placement rates, pancreatitis rates) being analyzed. Possible confounding factors include the possible variation in the level of difficulty in the ERCP cases before and after training. The methodology was essentially to characterize the two cohorts (including baseline characteristics and outcome measurements) before and after ERCP fellowship training. This methodology can be visualized in Figure 3 below.

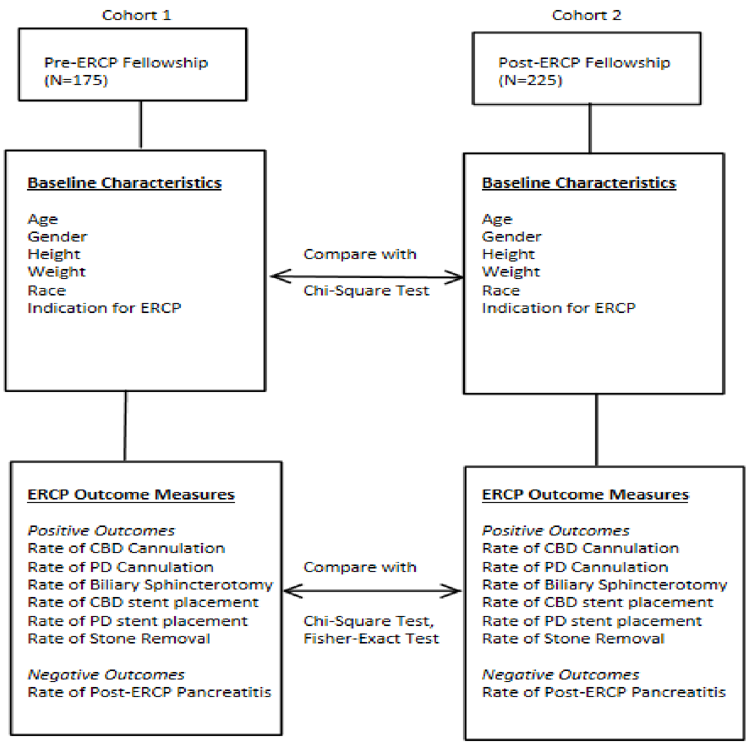

Figure 3: Methodology Schematic

The Chi-Square test utilizes a contingency table to calculate whether the outcome variables (categorical variables) showed differences that were statistically significant between the two cohorts. An example of the Chi-Square contingency table is seen in Table 2.

	Outcome Variable	Outcome Variable	
Patients undergoing ERCP **prior** to additional ERCP training	A	B	(a+b) = n1 = 175
Patients undergoing ERCP **after** additional ERCP training	C	D	(c+d) = n2= 225
	(a+c)	(b+d)	N= 400

Table 2: Chi-Square Contingency table example

A power analysis was done to assess the sample size(s) that would be necessary to reach statistically significant results.

The power analysis equation for the Chi-Square test is given by:

$\mathrm{N} = \frac{2*W*p(1-p)}{\Delta^2}$, where p is equal to the difference in percent from cohort 1 to cohort 2

The variable W is determined by a preset value based on α, the level of statistical significance desired. A power of 80%, with β=0.2 was chosen for our power analysis; this determines the probability of making a type 2 error (false negative). This was determined by utilizing the chart in Figure 4.

TABLE 2.1 W Values for $\alpha = 0.05$

		W	
POWER	**β**	**One-Tailed**	**Two-Tailed**
70%	0.30	4.7	6.2
75%	0.25	5.4	6.9
80%	0.20	6.2	7.85
85%	0.15	7.2	9.0
90%	0.10	8.6	10.5
95%	0.05	10.8	13.0

Figure 4: W value chart for Chi-Square Test

To detect a difference of 10% (i.e., the complication rate difference of 5% from 2 to 7%, the sample size for the dataset should be equal to N = 153 for each cohort group. If the difference in percentages between groups is smaller, then a larger sample size would be needed to detect this difference.

Results

A total of 172 ERCPs were performed between 2004 -2008, during the pre-training time period. 223 ERCPs were performed between 2010-2011 in the post-training period. In terms of the baseline characteristics – the age, gender, race, weight, height, and indications for undergoing an ERCP were statistically similar between the two cohorts. The baseline characteristics for the two cohorts are tabulated in Table 3.

Baseline Characteristics of Cohorts			
Pre-ERCP Training (2004-2008)		**Post-ERCP Training (2010-2011)**	
Number of ERCPs	N = 172	Number of ERCPs	N = 213
Age	Mean 43.8 +/- SD 18.58	Age	Mean 42.4 +/- 17.40
Gender	65% Female, 35% Male	Gender	68% Female, 32% Male
Race	60% Hispanic 25% Caucasian 10% Native American 4% African American 2% Asian	Race	56% Hispanic 21% Native American 17% Caucasian 6% African American
Height	Mean - Women: 5’4’’ Mean - Men: 5’8’’	Height	Mean - Women: 5’3’’ Mean - Men: 5’6’’
Weight	Mean - Women: 165 lbs Mean - Men: 194 lbs	Weight	Mean - Women: 184 lbs Mean - Men: 179 lbs
Body Mass Index (BMI):	31.3 +/- SD 8.05	Body Mass Index (BMI):	32.7 +/- SD 8.67
Indications for ERCP			
Gallstones (Choledocholithiasis) (Gallstone Pancreatitis)	119 (70%)	Gallstone (Choledocholithiasis) (Gallstone Pancreatitis)	142 (68%)
Mass Related (Cancer, Cystic disease)	18 (11%)	Mass Related (Cancer, Cystic disease)	27 (13%)
Pancreatitis	16 (9%)	Pancreatitis	21 (10%)
Bile leak	15 (9%)	Bile leak	19 (9%)

Table 3: Baseline Characteristics of Cohorts

From this data it can be seen that the rate of CBD Cannulation increased from a rate of 83% to a 93% (Chi-Square = 9.062, p-value: 0.0026). This implies that the endoscopist competency level was also improved after undergoing an ERCP fellowship. Additionally, the rate of post-procedure pancreatitis decreased from a rate of 6.9% to 1.9% (Chi-Square = 4.997, p-value: 0.025). Common interventions during ERCP were evaluated: Pancreatic Sphincterotomy, Common Bile Duct Sphincterotomy, CBD Stent placement, PD Stent Placement. Changes in these core interventions would suggest that the endoscopist altered his technique. There were differences in the rate of pancreatic cannulation, biliary duct sphincterotomy, pancreatic duct placement, and pancreatic duct sphincterotomy. The endoscopist utilized CBD sphincterotomy more frequently, from 71% of cases to 82% of cases (Chi-Square = 5.61, p-value = 0.0179). Additionally, whereas prior to training the endoscopist did not utilize pancreatic duct stent placement, its utilization was significantly increased from 0% to 25%. Pancreatic duct sphincterotomy was also increasingly utilized after training from 0% to 8% (Chi-Square = 12.53, p-value = 0.0004). The pancreatic duct was also cannulated more frequently from 35% pre-training to 47% post-training. In addition the length of time to complete the procedure was significantly increased from 33 minutes to 44 minutes in the after-training cohort. A summary of these differences in the pre-training and post-training period can be seen in Table 4.

	Pre-Training ERCPs	Post-Training ERCPs	p-value
Common Bile Duct (CBD) Cannulation Rate	143/172 (83%)	197/213 (93%)	P = 0.0045 Chi-Square 8.06
Pancreatic Duct (PD) Cannulation Rate	61/172 (35%)	100/213 (47%)	P = 0.023 Chi-Square 5.16
Rate of Post-Procedure Pancreatitis	12/172 (6.9%)	4/213 (1.9%)	P = 0.025 Chi-Square 4.997
Rate of Biliary Duct Sphincterotomy	122/172 (71%)	174/213 (82%)	P = 0.0179 Chi-Square 5.61
Rate of Pancreatic Duct Sphincterotomy	0/172 (0%)	17/213 (8%)	P = 0.0004 Chi-Square 12.53
Rate of Common Bile Duct (CBD) stent placement	30/172 (17.4%)	53/213 (25%)	P = 0.101 Chi-Square 2.69
Rate of Pancreatic Duct (PD) stent placement	0/172 (0%)	53/213 (25%)	
Rate of Needle Knife Sphincterotomy	2/172 (1%)	20/172 (11.6%)	P = 0.001 Chi-Square 10.46
Duration of the ERCP	33.4 +/- 22.2 minutes	43.8 +/- 26.4 minutes	P = 0.001 Two-tailed t-test
Length of Stay after ERCP	6.8 +/- 8.97 days	3.85 +/- 3.9 days	P= 0.0001 Two-tailed t-test

Table 4: ERCP Outcome Measures compared between two cohorts with Chi-Square/T-test Calculations

Post-procedure pancreatitis was characterized according to the revised Atlanta classification, which defines pancreatitis as having at least two of three of the following features:

(1) Abdominal pain consistent with acute pancreatitis (acute onset of persistent, severe, epigastric pain that often radiates to the back).

(2) Serum lipase activity (or amylase activity) at least 3x the upper limit of normal.

(3) Characteristic findings of acute pancreatitis on contrast-enhanced CT and less commonly MRI transabdominal ultrasound.[7, 8]

In Table 5A and 5B, the patients who had elevations to at least three times the upper limit of normal were included to further assess whether they also experienced abdominal pain.

Patients	Date of Procedure	Lipase Before ERCP	Lipase After ERCP	Change in Lipase Levels	Presence of Abdominal Pain	Categorized as Pancreatitis
1	7/23/2004	70	810	**740**	Yes	Yes
2	8/4/2004	435	1203	**742**	Yes	Yes
3	12/1/2004	NA	1163	**1163**	Yes	Yes
4	10/28/2005	461	2143	**1682**	Yes	Yes
5	9/11/2006	19	10310	**10291**	Yes	Yes
6	11/8/2006	116	5383	**5267**	Yes	Yes
7	1/5/2007	3413	7140	**3727**	Yes	Yes
8	5/22/2007	512	2713	**2201**	Yes	Yes
9	3/23/2008	385	22017	**21632**	Yes	Yes
10	8/14/2008	62	7032	**6970**	Yes	Yes
11	9/17/2008	220	3826	**3606**	Yes	Yes
12	11/25/2008	NA	1423	**1423**	Yes	Yes

Table 5A: Characteristic of Pre-Training ERCP patients who develop pancreatitis

Patients	Date of Procedure	Lipase Before ERCP	Lipase After ERCP	Change in Lipase levels	Presence of Abdominal Pain	Categorized as Pancreatitis
1	10/22/2010	42	2768	2726	Yes	Yes
2	2/28/2011	186	2869	2683	Yes	Yes
3	4/8/2011	228	1964	1736	Yes	Yes
4	7/1/2011	44	1092	1048	Yes	Yes
5	9/19/2011	288	945	657	No	No

Table 5B: Characteristics of Post-Training ERCP patients who develop pancreatitis

If the patient had both elevations in lipase levels three times the upper limit of normal and experienced post-procedure abdominal pain, they were said to have experienced post-procedure pancreatitis. Contrast-enhanced CT findings were not assessed in this study due to a lack of consistent CT imaging studies amongst the cohort populations. In the pre-training cohort, all patients who had elevations in lipase to three times the upper limit of normal also experienced either mild to severe abdominal pain after 1-2 days following their ERCP procedure. In the post-training cohort, all but one patient who had elevations of lipase to 3x the upper limit of normal also experienced mild to severe abdominal pain. Some patients had lipase levels collected before the ERCP and after the ERCP; this is the ideal scenario because it will give a baseline lipase to compare the post-procedure lipase level to see if there was a significant increase. However, some patients did not have lipase levels drawn at all during their hospital stay. Some patients had lipase levels before the ERCP but not afterwards. Some patients had lipase levels after the ERCP but not before the ERCP. It was assumed that if the lipase levels were drawn following an ERCP, there may have been a clinical suspicion for post-procedure pancreatitis. Laboratory reporting for both cohorts can be seen in Table 6. It can be seen that about half of patients from both cohorts received lipase levels before and after the ERCP procedure, while about a quarter of patients from both cohorts had lipase levels drawn before the ERCP or did not have lipase levels drawn at all during the clinical encounter.

	Pre-ERCP only (+)	Both Pre and Post ERCP (+)	Post-ERCP only (+)	Neither Pre or Post ERCP
Pre-Training	41 (23.8%)	85 (49.4%)	14 (8.1%)	33 (19.1%)
Post-Training	55 (25.8%)	93 (43.7%)	11 (5.1%)	53 (24.8%)

Table 6: Laboratory Testing (Lipase Measurements) performed before and after ERCP

Discussion

In regards to ERCP performance, cannulation of the common bile duct and complications related to the ERCP are the primary endpoint variables that can be quantified to assess an endoscopist's skill level. The biliary cannulation rate varies between studies but is in the range of 84-99%.[14, 15] Difficult cannulation increases the likelihood that the ERCP procedure will be unsuccessful but it also increases the risk for ERCP-induced pancreatitis. Various techniques have been tried to aid the endoscopist in obtaining access to the bile duct, including needle-knife sphincterotomy, papillary roof exicision, guide-wire assisted and the rendezvous technique. These techniques may aid in increasing the likelihood of cannulating the biliary ducts but has been associated with higher incidence of complications, especially pancreatitis. Increasingly, many therapeutic endoscopists are undertaking more challenging cases that were not possible a few years ago. If deep biliary cannulation is not obtained, more invasive procedures are utilized to access the biliary ducts (i.e. rendezvous technique). Due to the complications and consequences of failed biliary cannulation, improving cannulation rates would improve outcomes for patients who meet the indications for undergoing an ERCP procedure.

The complications of ERCP can result in prolonged hospitalization and depending on the series reviewed can result in mortality from 1 of 500 to 1 of 1000 cases.[9] The main complication associated with ERCP is pancreatitis. The incidence of pancreatitis after ERCP has been reported to be between 1.6-15.1%, with most studies in the 4-5% range. Most cases of post-procedure pancreatitis are in the mild to moderate in severity category.[13] Other possible complications include hemorrhage, perforation, cholangitis, cholecystitis, and stent-related complications. Available data shows that adverse events appear to be related to the features of the patient, the procedure, the endoscopist, and the institutions. In addition to the risks of complications related to ERCP, failed biliary or pancreatic cannulation lead to more invasive procedures to accomplish therapeutic goals and can be a source of significant stress for the patient and physician. With the availability of non-invasive procedures such as endoscopic ultrasound and Magnetic resonance cholangiopancreatography (MRCP), ERCP has become primarily a therapeutic procedure.[10]

The changes in ERCP technique that occurred as a result of a 1-year dedicated ERCP fellowship were gathered through endoscopist's (A.N.) personal recollection of changes that he noted through training. This was corroborated with the data collected and shows that prophylactic pancreatic stent placement, pancreatic sphincterotomy, common bile duct sphinterotomy and utilization of needle knife sphincterotomy were increasing utilized/new maneuvers that helped improve the cannulation rate. In addition to these tools, the endoscopist became more comfortable with manipulating the biliary and pancreatic ductal anatomy. It is thought that utilization of these tools and improved comfort in the manipulation of the anatomic structures led the endoscopist to improve his cannulation and complication rates.

Efforts at Improving ERCP Quality

An ideal ERCP procedure consists of correcting abnormalities in the biliary and pancreatic ductal system by removing stones that may be obstructing the passage of bile or pancreatic fluid, opening up ducts blocked by strictures or masses resulting from cancerous or cystic growth, placing stents and the ability to sample tissue suspicious for cancer. Additionally, these objectives should be accomplished without damaging the normal surrounding ductal structures and tissues or introducing bacteria that could eventually lead to pancreatitis or cholangitis.

There are two main controllable strategies to improve ERCP Quality:

(1) Improvements in Instrumentation

(2) Improvements in the Endoscopist's Technique

Improvements in Instrumentation

When ERCP was first introduced, the principle available technique for cannulation was repetitive probing with a catheter. Subsequently, the variety of available equipment, accessories, and endoscopic techniques to gain duct access and to perform therapy has expanded dramatically. A major improvement in the design of the cannula was a sphincterotome. A sphincterotome has an electrosurgical cutting wire at the distal end of the catheter. During a procedure electrical current can be passed within the catheter to the exposed cutting wire which can be used to incise the major or minor papilla. The primary function of the cutting wire is sphincterotomy. Randomized controlled trials have shown that the use of a sphincterotome led to more successful ERCP cannulation rates without a difference in the rate of complications.

Guidewires are often used in conjunction with sphincterotomes to obtain and secure deep cannulation, stent placement, stone extraction and other therapeutic techniques. There have been contradictory studies on whether guidewires improve cannulation rates or decrease complications but they have become a common part of the ERCP technique for many endoscopists. The use of a needle-knife catheter to facilitate access (pre-cut) papillotomy is used when standard methods are unsuccessful. These needle-knife catheters have a retractable electrosurgical cutting wire. The control handle of the catheter contains a mechanism for projecting the wire forward from the distal aspect of the catheter. Pre-cut papillotomy may increase the ability to cannulate the biliary duct but seems to increase the risk for complications, specifically perforations. Prophylactic pancreatic stent placement seems to have a significant protective role against the complication of pancreatitis after pre-cut (access) papillotomy as well as in other high-risk settings. Previously it has been shown that pancreatic-duct stent placement helped to facilitate bile duct cannulation, this was shown in a small retrospective review of 39 patients.[11]

The result of this study demonstrates that improvement in biliary cannulation as well as reduction in post-ERCP pancreatitis is possible even for an endoscopist with many years of experience in ERCP who are receive further guided training in the form of a 1-year advanced ERCP fellowship program. Specifically, biliary cannulation improved by 10% and post ERCP pancreatitis decreased by 4%. Most importantly, the physician before the training year could cannulate the bile duct successfully in about 80% of cases, but showed inconsistent performance during the four years while performing ERCPs in a community hospital. It suggests that training under the guidance of a therapeutic endoscopist changed his techniques, particularly, his understanding of pancreatic anatomy improved and by learning the appropriate utilization of pancreatic stents and needle-knife papillotomy, he could improve biliary cannulation and reduce the risk of post-ERCP pancreatitis. Before the training year, he placed no pancreatic stents. The use of pancreatic stents to aid in cannulation and reduce post-procedure pancreatitis has been shown in a previous study.[11]

It can also be seen that despite the endoscopist's (A.N.) increased length of time necessary to complete the procedure and the increased use of more invasive techniques with statistically significant increases in pancreatic duct sphincterotomy, pancreatic duct cannulation, needle-knife sphincterotomy, and pancreatic duct stent placement the rate of post-ERCP pancreatitis was notably decreased. This study may aid in determining appropriate credentialing requirements for endoscopist wanting to perform ERCPs in the hospital setting.

Limitations of the study

Being a retrospective study and limited to a single operator who had no formal training in ERCP before the training year limits the use of the data to those endoscopists who are self-trained in ERCP and obtained privileges to perform ERCPs. The weaknesses in this study were that this study only included one operator and data collection was not standardized. For instance, the time period of laboratory collection was did not occur at the same times and sometimes laboratory studies were not obtained by the medical team. It was assumed that if the medical team did not receive laboratory investigations for pancreatitis, that they did not warrant this investigation and therefore did not have lipase/amylase levels drawn. Another major weakness of this study is that it was not specified whether the patient had a native papilla in the sphincter of Oddi. If a patient has had previous sphincterotomies, stent placement or needle-knife (pre-cut) sphincterotomy this can give a distorted view of the true ability of the endoscopist. Previous manipulations to the sphincter make it much easier for the endoscopist to cannulate the biliary ducts.[2] It would inflate the cannulation rates and would not be a true assessment of the endoscopist's ability. The strengths of this study were that the endoscopist came back to the same institution after undergoing his ERCP fellowship training. He performed ERCPs on a statistically similar cohort of patients, eliminating this selection bias. To generalize these results, a prospective study using a standardized protocol should be conducted which includes multiple endoscopists who have a similar background as A.N. These gastroenterology fellowship trained endoscopists should have limited exposure (i.e. less than 200 cumulative ERCPs) who are performing ERCPs in the community before undergoing further ERCP fellowship training. If similar findings are demonstrated through this type of study, requiring endoscopists to obtain further training in a structured ERCP training program may lead to better outcomes for patients undergoing this procedure.

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Appendix

Year	Number of ERCPs performed
2004	25
2005	38
2006	53
2007	31
2008	24
Total	172

Year	Number of ERCPs performed
2009	Training Year
2010	95
2011	118
Total	213

Table 7: Number of ERCPs performed by year

Rate of CBD Cannulation (2004-2008)	
2004	23/25 (92%)
2005	31/38 (81.5%)
2006	43/54 (79.6%)
2007	25/31 (80.6%)
2008	21/23 (91.3%)
Cumulative	143/172 (83%)

Rate of CBD Cannulation (2010-2011)	
2010	88/95 (92.6%)
2011	109/117 (93%)
Cumulative	197/213 (93%)

Table 8: Rate of CBD Cannulation by year

Rate of Post-Procedure Pancreatitis (2004-2008)	
2004	2/25 (8%)
2005	1/38 (2.6%)
2006	4/54 (7.4%)
2007	1/31 (3.0%)
2008	5/23 (22.0%)
Cumulative	13/172 (7.5%)

Rate of Post-Procedure Pancreatitis (2010-2011)	
2010	1/95 (1%)
2011	5/117 (4.3%)
Cumulative	6/213 (2.8%)

Table 9: Rate of Post-Procedure Pancreatitis by year

Rate of Biliary Sphincterotomy (2004-2008)	
2004	16/25 (64%)
2005	24/38 (63%)
2006	38/54 (70%)
2007	24/31 (77%)
2008	20/23 (87%)
Cumulative	122/172 (71%)

Rate of Biliary Sphincterotomy (2010-2011)	
2010	76/95 (80%)
2011	98/118 (84%)
Cumulative	174/213 (82%)

Table 10: Rate of Biliary Sphincterotomy by year

Rate of Pancreatic Sphincterotomy (2004-2008)	
2004	0/25 (0%)
2005	0/38 (0%)
2006	0/54 (0%)
2007	0/31 (0%)
2008	0/23 (0%)
Cumulative	0/172 (0%)

Rate of Pancreatic Sphincterotomy (2010-2011)	
2010	9/95 (9.5%)
2011	8/118 (6.8%)
Cumulative	17/213 (8%)

Table 11: Rate of Pancreatic Sphincterotomy by year

Rate of Common Bile Duct Stent Placement (2004-2008)	
2004	6/25 (24%)
2005	5/38 (13%)
2006	6/54 (11%)
2007	6/31 (19%)
2008	6/23 (26%)
Cumulative	30/172 (17.4%)

Rate of Common Bile Duct Stent Placement (2010-2011)	
2010	19/95 (20%)
2011	40/118 (34%)
Cumulative	53/213 (25%)

Table 12: Rate of Common Bile Duct Stent Placement by year

Rate of Pancreatic Duct Stent Placement (2004-2008)	
2004	0/25 (0%)
2005	0/38 (0%)
2006	0/54 (0%)
2007	0/31 (0%)
2008	0/23 (0%)
Cumulative	0/172 (0%)

Rate of Pancreatic Duct Stent Placement (2010-2011)	
2010	22/95 (23%)
2011	36/118 (31%)
Cumulative	53/213 (25%)

Table 13: Rate of Pancreatic Duct Stent Placement by year

Rate of Needle Knife Sphincterotomy (2004-2008)	
2004	0/25 (0%)
2005	0/38 (0%)
2006	0/54 (0%)
2007	0/31 (0%)
2008	2/23 (9%)
Cumulative	2/172 (1%)

Rate of Needle Knife Sphincterotomy (2010-2011)	
2010	7/95 (7%)
2011	17/118 (14%)
Cumulative	24/213 (11%)

Table 14: Rate of Needle Knife Sphincterotomy by year