

Quality indicators, including complications, of ERCP in a community setting: a prospective study

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Background: There are no large studies documenting quality outcomes and complication rates of ERCP in community practice. The American Society for Gastrointestinal Endoscopy (ASGE)/American College of Gastroenterology Task Force on Quality proposed 5 questions regarding ERCP in community practice. The ASGE Committee on Outcomes Research recommended 8 ERCP-specific quality indicators be used to provide a better accounting of quality in ERCP.

Objective: To determine ERCP quality outcomes, including complications, in a community practice.

Design: Prospective study.

Setting: Eight community hospitals in the Minneapolis-St. Paul, Minnesota, area.

Patients: Every patient undergoing ERCP by Minnesota Gastroenterology PA from December 1, 2005, through July 31, 2006.

Main Outcome Measurements: ASGE-recommended quality indicators, especially 30-day complication rates.

Results: A total of 805 ERCP procedures were performed in 696 patients. Therapeutic ERCP accounted for 78.4%. The complication rate was 5.0% (5.7% of therapeutic and 2.3% of diagnostic procedures). Pancreatitis occurred in 3.2% of procedures (3.6% of therapeutic and 1.7% of diagnostic procedures). Infection (0.75%), hemorrhage (0.62%), and perforation (0.12%) only occurred after therapeutic ERCP. Cardiopulmonary complications occurred in 2 patients (0.25%). Precut sphincterotomy was performed in 26 cases (3.2%), and sphincter of Oddi manometry in 23 cases (2.9%). Success rates were 94.0% for biliary cannulation, 87.0% for stone extraction, and 90.2% for relieving biliary obstruction. A total of 530 patient satisfaction surveys were completed and revealed that the response to the question, "Would you have the procedure done again by this physician?" was the most sensitive indicator of patient satisfaction.

Conclusions: In this community practice, complication rates compare very favorably with those of academic centers. The technical success rates achieved or exceeded rates recommended by the ASGE/American College of Gastroenterology Task Force. (Gastrointest Endosc 2009;70:457-67.)

Numerous large studies have documented the high complication rates in patients who undergo ERCP,¹⁻⁹ yet such studies have all originated from academic gastroen-

Abbreviations: ACG, American College of Gastroenterology; ASA, American Society of Anesthesiologists; ASGE, American Society for Gastrointestinal Endoscopy; GHAA, Group Health Association of America; MINGI, Minnesota Gastroenterology; NP/PA, nurse practitioner or physician assistant; NPRA, nurse peer review advisor; PRC, Peer Review Committee; SOM, sphincter of Oddi manometry.

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terology departments. The rates of complications in community gastroenterology practices have not been well studied.^{10,11} The 2006 American Society for Gastrointestinal Endoscopy (ASGE)/American College of Gastroenterology (ACG) Task Force on Quality in Endoscopy proposed 11 research questions, with 5 of the questions specifically directed at ERCP in the community (Table 1).¹¹ In 2002, the ASGE Committee on Outcomes Research published 8 ERCP-specific quality indicators designed to provide a more complete description of quality in ERCP (Table 2).¹² The aim of this prospective study was to determine ERCP outcomes in a community practice by using 7 of the 8 ASGE quality indicators, with particular attention to the 30-day complication rate.

TABLE 1. Proposed research questions specific to the community setting¹¹

How often is purely diagnostic ERCP performed in general clinical practice?

What are the complication rates of ERCP in general practice?

What is the overall technical success rate of ERCP in the community setting?

What is the utilization rate of precut sphincterotomy in the community setting?

What is the incidence of pancreatitis, bleeding, and perforation in community practice?

TABLE 2. Eight American Society for Gastrointestinal Endoscopy quality indicators¹²

Demographics and patient comorbidity: age, sex, ASA classification

Endoscopists' procedure volume

Procedure indication and intent

Procedure difficulty developed by Schutz and Abbott¹³

Unplanned events (complications)

Technical procedure success

Patient satisfaction: modification of the GHAA-9 Patient Satisfaction Survey

Clinical procedural success

ASA, American Society of Anesthesiologists; GHAA, Group Health Association of America.

Capsule Summary**What is already known on this topic**

- Large ERCP studies from academic centers have documented complication rates of 5.0% to 15.9%, but rates in community practice are unknown.

What this study adds to our knowledge

- A prospective quality outcomes study of 805 ERCP procedures performed in a community practice revealed a complication rate of 5.0%. Pancreatitis was the most common complication, occurring in 3.2% of all procedures.

As the ASGE/ACG Task Force on Quality recommended, ERCP success rates were calculated in cases in which the physician obtained the appropriate position in relation to the papilla. If cannulation of the papilla was attempted, the procedure was considered an ERCP and was included in the study.¹¹ Diagnostic and therapeutic procedures in both inpatients and outpatients were included. An acute ERCP was defined as any procedure occurring within 24 hours of admission. A diagnostic ERCP was defined by injection of contrast dye into either the pancreatic duct or bile duct without performing a therapeutic maneuver. A therapeutic ERCP was defined as any procedure that included a sphincterotomy, stent placement, dilation, or retrieval of a stone.

Technical success was broken down into 3 categories: cannulation, stone removal, and drainage. Each category was then stratified into successful, partially successful, or failed as defined by the ASGE.^{11,12} Cannulation was considered successful when the tip of the catheter was passed beyond the papilla into the desired duct. Partially successful was defined as superficial cannulation when only contrast passed beyond the papilla. Stone removal was considered successful when all stones were removed. Partial success occurred when all stones were not removed but adequate biliary or pancreatic drainage was provided. Failed stone removal was defined as an inability to remove all stones or provide adequate drainage. Successful drainage occurred when all biliary ducts were drained. Partial success occurred when the major ducts but not all ducts opacified were drained. Failed drainage was defined as an inability to drain any of the ducts.

Before each ERCP, the physician completed a preprocedure form that included patient information and physician intent. Immediately after the procedure, the physician completed a postprocedure form detailing the findings, grade of difficulty by using the modified Schutz score,^{12,13} and technical aspects of the procedure. The data from the preprocedure and postprocedure forms were entered into an Excel spreadsheet for subsequent analyses. On discharge from the hospital, the patient was given a modified

PATIENTS AND METHODS

An uncontrolled, prospective study was conducted examining 7 ASGE quality indicators for ERCP in all patients undergoing the procedure at Minnesota Gastroenterology, PA (MNGI), a community practice comprising 50 gastroenterologists. The study was performed from December 1, 2005, through July 31, 2006. Thirteen physicians at MNGI are credentialed to perform ERCP at 8 community hospitals in Minneapolis, St. Paul, and surrounding suburbs. The 8 hospitals are managed by 3 different health care systems: HealthEast Care System, Allina Hospitals and Clinics, and Fairview Health Services. The protocol and consent for use of patients' medical records for publication were approved by the institutional review boards of all 3 health care systems, and all patients signed an informed consent form. MNGI billing records during the study period were reviewed to ensure that all ERCP cases were included.

Group Health Association of America (GHAA)-9 Patient Satisfaction Survey^{14,15} and a medical questionnaire to complete and mail to the MNGI central office. The questionnaire included questions that addressed both patient satisfaction and potential complications. After 30 days, every patient was contacted by a trained nurse practitioner or physician assistant (NP/PA) to complete a detailed telephone questionnaire that included questions to identify complications and hospitalizations. If the GHAA-9 had not been received by mail, the NP/PA completed the survey with the patient over the telephone. If the mail or telephone questionnaire suggested a complication or the patient had sought medical attention, the NP/PA requested the medical records from the institution where the patient was treated and from referring offices. After 3 attempts to reach a patient by telephone had failed, a letter was mailed asking the patient to contact MNGI. If no contact was made after the mailing, the medical records from the institution where the patient was treated and from referring offices were requested and reviewed for complications.

All medical records of suspected complications were then reviewed using MNGI's Peer Review Committee (PRC) protocol. The PRC is composed of several MNGI physicians and a nurse peer review advisor (NPRA). Only physicians who are credentialed to perform ERCP review ERCP cases, and physicians never review their own cases. Members of the PRC, including the NPRA, reviewed and abided by the definitions of complications and severity grading proposed by Cotton et al.¹⁶ The initial review was performed by the NPRA, who has 20 years of GI nursing experience and 4 years of experience as the NPRA. If, after her review, a complication was suggested, a physician member of the PRC reviewed the case in more detail to determine whether a complication had occurred. If a complication occurred, it was defined and graded as described above.

Statistical analysis

The data were analyzed by using the SAS software package 9.1 (SAS Institute Inc, Cary, NC). Univariate tests were performed to examine the association of having a complication with sex, age, procedure type, class, anesthesia use, antibiotic use, and grade of difficulty. Categorical variables were analyzed by using a χ^2 test, whereas continuous variables were analyzed with a 2-sample *t* test. Multivariate logistic regression was performed, including in the model all variables found to be significant on univariate analyses to evaluate the independent effects of factors while controlling for the contribution of the other variables in the model. Additionally, logistic regression analyses were performed to examine the association of physician experience with complications and technical success. For all analyses, a *P* value < .05 was considered statistically significant. All *P* values are presented uncorrected for multiple testing of data; however, it is recognized that Bonferroni's

TABLE 3. Status of the papilla in 805 procedures

Status	Total (%) no. procedures
Virgin	597 (74.1)
Previous sphincterotomy or stent	185 (23.0)
Previous cannulation	11 (1.4)
Previous failed cannulation	11 (1.4)
Percutaneous transhepatic cholangiography assisted	1 (0.1)
Total	805

method of correction for multiple testing of outcome data would remove all findings of statistical significance, except for *P* values of .001. Therefore, in all other instances in which nominal significance is indicated, the findings should be taken as tentative and for descriptive purposes only. Additional analyses were also performed to examine the association of complications with patient satisfaction. Methods used for these analyses include the χ^2 test, Fisher's exact test, and analysis of variance models.

RESULTS

Procedures, indications, and findings

A total of 805 ERCP procedures were performed in 696 patients. The study included 472 (58.6%) procedures in women and 333 (41.4%) procedures in men (mean age 61.1 years, range 3-96 years) during an 8-month period from December 1, 2005, through July 31, 2006. Preprocedure risk stratification noted that 87.7% of the patients were American Society of Anesthesiologists (ASA) classification I or II, 12.3% were classification III, and none were classification IV. Acute procedures accounted for 35.1% and elective procedures for 64.9%. Using the modified Schutz score, we found that 80.0% of the procedures were grade 1 difficulty, 11.0% were grade 2, and 9.0% were grade 3.¹³ The status of the papilla was virgin in 597 (74.1%) patients, whereas 185 (23.0%) had undergone a previous stent placement or sphincterotomy (Table 3).

The most common indications for ERCP were choledocholithiasis and suspected stones, which together accounted for 55.8% of all procedures (Table 4). The most common finding was biliary stones in 334 (41.5%) procedures, with only 109 (13.5%) resulting in a normal finding (Table 5).

Therapeutic procedures were performed in 631 patients (78.4%) and diagnostic procedures in 174 (21.6%). Of the therapeutic procedures, sphincterotomy was performed in 529 (83.8%) patients, precut sphincterotomy was performed in 26 (4.1%), plastic bile duct stents were placed in 139 (22.0%), plastic pancreatic stents were

TABLE 4. ERCP indications

Indication	No.	Percentage of 805 procedures*
Choledocholithiasis	251	31.2
Clinical and biochemical or imaging data suggestive of pancreatic or biliary tract disease	203	25.2
Suspected stone	198	24.6
Jaundice thought secondary to biliary obstruction	132	16.4
Stent placement across strictures, fistulae, postoperative bile leak, or large common bile duct stones	58	7.2
Ampullary cancer in poor surgical candidates	32	4.0
Other	25	3.1
Pancreatitis of unknown etiology, gallstone pancreatitis	24	3.0
Sphincter of Oddi manometry	23	2.9
Bile leak	21	2.6
Signs/symptoms suggesting pancreatic malignancy when direct imaging is equivocal or normal	15	1.9
Pancreatic therapeutics	12	1.5
Balloon dilation of ductal strictures	8	0.99
Stent removal	8	0.99
Primary sclerosing cholangitis	7	0.87
Tissue sampling from pancreatic or bile duct	7	0.87
Preoperative evaluation of chronic pancreatitis or pancreatic pseudocyst	2	0.25

*Percentages add up to more than 100 because a given procedure could have more than 1 indication.

TABLE 5. ERCP findings

Finding	No.	Percentage of 805 procedures*
Biliary stones	334	41.5
Dilated duct	280	34.8
Normal	124	15.4
Biliary strictures	80	9.9
Suspected cancer	58	7.2
Bile leak	34	4.2
Pancreatitis	25	3.1
Sphincter of Oddi dysfunction	18	2.2
Primary sclerosing cholangitis	13	1.6
Other	9	1.1
Biliary sludge	7	0.87
Occluded stent	7	0.87
Ampullary abnormal	3	0.37
Stent removal	2	0.25
Cholangitis	1	0.12

*Percentages add up to more than 100 because a given procedure could have more than 1 finding.

placed in 35 (5.5%), and metallic stents were placed in 34 (5.4%). Biliary sphincter of Oddi manometry (SOM) was performed in 23 (2.9%) patients.

Procedure intent and success

Physician reporting of intent and subsequent success or failure was not always completed accurately. A procedure could have had more than one intent, and, in some cases, the success outcomes did not correspond to the reported intent(s). However, of the 805 procedures, the physician reported at least one intent and subsequent success correctly in 796 (98.9%) instances (Table 6). Of the 764 cases

in which bile duct cannulation was listed as the intent, 94.0% of the procedures were successful, 2.0% were partially successful, and 4.1% failed. The success rate of biliary cannulation in a virgin papilla was 92.9%. In the 93 cases in which pancreatic duct cannulation was listed as the intent, 87.1% of the procedures were successful, 5.4% were partially successful, and 7.5% failed. In the 92 cases in which stone extraction was listed as the intent, 87.0% of the procedures were successful, 3.3% were partially successful, and 9.8% failed. In the 61 cases in which “drain all ducts” was listed as the intent, 90.2% of the procedures were successful and 9.8% failed.

Unplanned events

The NP/PAs successfully contacted 573 of the 696 patients (82%). Because patients may have had multiple procedures, this contact accounted for 673 (84%) of the 805 procedures. Of these contacts, 351 (44%) triggered full chart reviews for complications. The 123 patients who could not be contacted accounted for 127 procedures; all these procedures underwent full chart review. The chart reviews triggered by the NP/PA contact, combined with the cases in which patient contact could not be established, led to a total of 478 (59%) cases being reviewed for complications. Of 805 procedures, complications occurred in 38 (4.7%) patients (Table 7). There were 2 patients who

TABLE 6. Outcomes for procedures in which intent and subsequent success were reported correctly (broken down by status of the papilla)

Intent*	Status of papilla	Failed	Partial	Successful
		No. (%)†	No. (%)†	No. (%)†
Bile duct cannulation (n = 764)	Total	31 (4.1)	15 (2.0)	718 (94.0)
	Virgin	28 (4.8)	13 (2.2)	538 (92.9)
	Previous cannulation	0 (0.0)	0 (0.0)	6 (100)
	Previous failed cannulation	1 (9.1)	1 (9.1)	9 (81.8)
	Previous sphincterotomy or stent	2 (1.2)	1 (0.6)	164 (98.2)
	PTC assisted	0 (0.0)	0 (0.0)	1 (100)
	Pancreatic duct cannulation (n = 93)	Total	7 (7.5)	5 (5.4)
Virgin	6 (8.1)	4 (5.4)	64 (86.5)	
Previous cannulation	0 (0.0)	0 (0.0)	2 (100)	
Previous failed cannulation	0 (0.0)	1 (100)	0 (0.0)	
Previous sphincterotomy or stent	1 (6.3)	0 (0.0)	15 (93.8)	
PTC assisted	0 (0.0)	0 (0.0)	0 (0.0)	
Stone extraction (n = 92)	Total	9 (9.8)	3 (3.3)	80 (87.0)
	Virgin	6 (8.2)	3 (4.1)	64 (87.7)
	Previous cannulation	0 (0.0)	0 (0.0)	1 (100)
	Previous failed cannulation	0 (0.0)	0 (0.0)	0 (0.0)
	Previous sphincterotomy or stent	3 (16.7)	0 (0.0)	15 (83.3)
	PTC assisted	0 (0.0)	0 (0.0)	0 (0.0)
	Drain all ducts (n = 61)	Total	6 (9.8)	0 (0.0)
Virgin		5 (11.9)	0 (0.0)	37 (88.1)
Previous cannulation		0 (0.0)	0 (0.0)	1 (100)
Previous failed cannulation		0 (0.0)	0 (0.0)	0 (0.0)
Previous sphincterotomy or stent		1 (5.6)	0 (0.0)	17 (94.4)
PTC assisted		0 (0.0)	0 (0.0)	0 (0.0)

PTC, Percutaneous transhepatic cholangiography.

*Intents add up to more than 805 because a single procedure could have more than 1 intent.

†Percentages reported are based on rounded output from SAS and may add up to more than 100% in a given row.

each developed 2 complications, producing a complication total of 40 (5.0%) for all procedures. Therapeutic procedures accounted for 36 complications (producing a therapeutic complication rate of 5.7%) and diagnostic procedures for 4 complications (producing a diagnostic complication rate of 2.3%). Pancreatitis was the most common complication, occurring in 26 (3.2%) of all patients; pancreatitis developed in 23 (3.6%) of the therapeutic cases and in 3 (1.7%) of the diagnostic cases. In the 2 patients in whom 2 complications developed, one patient had pancreatitis and pulmonary embolism, and the other had infection and pancreatitis. Aside from the typical complications of pancreatitis, hemorrhage, perforation, and in-

fection, there were 2 other complications: one case of pulmonary embolism and one case of a respiratory arrest requiring 3 days of ventilation. Using the Cotton et al¹⁶ scale for grading complications, we found that 17 (2.1%) of the 805 patients had complications that were graded as mild, 17 (2.1%) were graded as moderate, and 4 (0.5%) were graded as severe.

Precut sphincterotomy was performed in 26 procedures, and complications developed in 3 patients: specifically, one occurrence each of mild pancreatitis, moderate pancreatitis, and moderate infection. Although patients who underwent precut sphincterotomy had a higher rate of complications than patients without precut

TABLE 7. Complications in 805 procedures: comparison of diagnostic and therapeutic ERCP

Complication	Diagnostic (n = 174)	Therapeutic (n = 631)	Combined (n = 805)
	No. (%)	No. (%)	No. (%)
Overall	4 (2.3)	36 (5.7)	40* (5.0)
Hemorrhage	0 (0.0)	5 (0.79)	5 (0.62)
Infection	0 (0.0)	6 (0.95)	6 (0.75)
Pancreatitis	3 (1.7)	23 (3.6)	26 (3.2)
Perforation	0 (0.0)	1 (0.16)	1 (0.12)
Other (cardiorespiratory, pulmonary embolism)	1 (0.57)	1 (0.16)	2 (0.25)

*The 40 complications occurred in 38 (4.7%) of the 805 procedures.

sphincterotomy (11.5% vs 4.5%, respectively), this difference was not statistically significant (Fisher's exact test, $P = .12$). The rate of pancreatitis with precut sphincterotomy was also higher (7.7% vs 3.1%, respectively), but again it was not statistically significant (Fisher's exact test, $P = .20$). Biliary SOM was performed in 23 procedures, and complications developed in 2 patients; in both patients, moderate pancreatitis occurred. Procedures with SOM had a higher rate of complications than procedures without (8.7% vs 4.6%, respectively), but this difference was not statistically significant (Fisher's exact test, $P = .30$). When specifically examining the pancreatitis rate with SOM, the rate was higher (8.7% vs 3.1%, respectively), but it was not statistically significant (Fisher's exact test, $P = .17$).

In this study, there were significantly more complications in therapeutic procedures compared with diagnostic procedures (5.7% vs 2.3%, respectively; χ^2 test, $P = .04$). The only other significant risk factor for complications was the length of time of the procedure (reported for 754 procedures). The mean procedure time for ERCPs in which complications developed ($n = 37$) was 32.7 minutes, whereas ERCPs in which no complications developed ($n = 717$) had a mean procedure time of 26.0 minutes (2-sample t test, $P = .03$). Several variables examined were not significantly associated with an increased risk of complications, including age, sex, ASA risk classification, grade of difficulty, and fluoroscopy time.

Deaths

Death from all causes within 30 days occurred in 11 patients (1.4%; 6 women and 5 men; Table 8). The mean age of the 11 patients who died was 82.1 years (range 70-92 years). Six patients died in hospice or a nursing home. Although the specifics of death are unknown, 5 were presumed to be related to advanced malignancy; the sixth

patient was an 88-year-old man with a bile leak. Five additional patients died in the hospital, and the individual causes of death were ovarian cancer, bladder cancer, acute renal failure, myocardial infarction, and sepsis. The PRC reviewed all the cases and did not attribute any of these deaths to ERCP. All cases of death within 30 days of ERCP were then reviewed by 2 independent outside reviewers (Martin Freeman, MD, Hennepin County Medical Center, Minneapolis, MN, and Bret Petersen, MD, Mayo Clinic, Rochester, MN), who both concurred with the PRC assessments.

Physician procedure experience

The 13 physicians have been performing ERCP between 6 and 28 years (mean 16.6; median 17 years). No relationship between the years of experience and the risk of a complication was discovered (logistic regression, $P = .30$). Physician procedure volume was highly variable (range 23-208; median 50). Logistic regression analysis found no relationship between the number of procedures performed and the risk of a complication ($P = .53$). When compared with all other physicians, one physician had a significantly higher rate of complications (4.2% vs 12.8%, respectively; Fisher's exact test, $P = .02$). That physician performed 47 procedures in which there were 6 (12.8%) complications. The physician's patient mix was not significantly different from that of the other physicians; 4 procedures were grade 2 difficulty and the rest were grade 1. However, one complication assigned to this physician was of questionable significance. In that patient, ERCP with sphincterotomy and stone removal was successfully performed, but because of a fever and 2 extra hospital days, the patient was categorized as having a mild infection complication. If this case is subtracted, the physician had a rate of complication rate of 10.6%, and the P value is no longer significant (Fisher's exact test, $P = .06$).

No relationship was found when examining the association between physician procedure volume and technical success (logistic regression P values: biliary cannulation, $P = .58$; pancreatic cannulation, $P = .47$; stone extraction, $P = .95$). Examining the association between years of ERCP experience and technical success also revealed no significant relationships (logistic regression P values: biliary cannulation, $P = .07$; pancreatic cannulation, $P = .13$; stone extraction, $P = .67$). Note that with a P value of .07, biliary cannulation was marginally significant with an estimated odds ratio of 1.04 (95% CI, 0.998-1.085). This means that for each year increase in experience, success is 1.04 times more likely.

Patient satisfaction data and comparison analysis

The modified GHAA-9 Patient Satisfaction Surveys^{14,15} were completed by 530 patients, providing a 66% response rate. Although the volume of data is too great to be fully included in this report, some of the pertinent findings are briefly highlighted here. The patients with complications answered "excellent" or "very good" to the following questions regarding the physician less often than patients without complications: personal manner of the physician (Fisher's exact test, $P = .02$), technical skill of the physician (Fisher's exact test, $P = .001$), and likelihood of returning to the same physician (Fisher's exact test, $P = .01$). Women were less likely to return to the same hospital for the procedure than men (Fisher's exact test, $P < .01$); however, >90% of respondents in both groups indicated a willingness to return to the same hospital. Patients who underwent therapeutic procedures rather than diagnostic procedures were more satisfied with their waiting time for the procedure (χ^2 test, $P < .01$) and were more satisfied with their physician (χ^2 test, $P = .02$). Patients who underwent shorter procedures were more satisfied with their overall visit (analysis of variance, $P = .02$) and would be more likely to return to the same physician (2-sample t test, $P = .03$). The answers to question 8 ("Would you have the procedure done again by this physician?") correlated with the answers to all other satisfaction questions (all Fisher's exact tests, P values $< .03$), suggesting that this is the most sensitive indicator of patient satisfaction.

Univariate analysis

All variables listed on the preprocedure and postprocedure forms were examined when analyzing the risk of complications, except procedure intent and success. Reporting compliance of these 2 categories was variable, undermining the validity of the data. The only 2 variables on univariate analysis that were significant were procedure type (χ^2 test, $P = .04$) and procedure time (2-sample t test, $P = .03$). Procedure time is significantly different by type, with therapeutic procedures being significantly longer than diagnostic procedures (27.6 vs 21.3 minutes, re-

spectively; $P < .001$). However, neither variable was found to be significant on a multivariate logistic regression analysis. This could have been because of the joint behavior of the 2 variables in a multivariate model. It should be noted that a correction for multiple testing of data removes nominal significance from these factors because their P values are not $\leq .001$.

DISCUSSION

This was a prospective study to determine the outcomes and complications of ERCP in a community practice when using 7 of the 8 quality indicators outlined by the ASGE.¹² To the best of our knowledge, this is the first study looking at complications and other quality indicators in a purely community practice. By attempting to measure 7 ASGE quality indicators, we were able to address questions proposed by the ASGE/ACG Task Force specifically regarding ERCP in the community setting.¹¹ Eleven research questions were posed by the ASGE/ACG Task Force, with 5 of the questions specific to ERCP in community practice. Our results, as they relate to each of these 5 questions, are discussed below.

ERCP in the community setting

How often is purely diagnostic ERCP performed in general clinical practice? In this study, diagnostic ERCP accounted for 21.6% and therapeutic ERCP for 78.4% of all procedures. With the increasing availability of EUS and quality of MRCP, it is recommended that ERCP be reserved for only therapeutic cases.¹⁷ The use of EUS in our practice has increased dramatically over the past 4 years and correlates with a steady decrease in the yearly number of ERCPs. In 2004, we performed 1370 ERCPs and 309 EUS; in 2007, we performed 1230 ERCPs and 957 EUS. The decrease in ERCP presumably represents a decrease in diagnostic ERCP, as has been suggested in other studies.^{18,19}

What are the complication rates of ERCP in general practice? What is the incidence of pancreatitis, bleeding, and perforation in the community setting? In this study, the overall complication rate was 5.0%, with complications occurring in 5.7% of therapeutic procedures and 2.3% of diagnostic procedures (Table 7). Pancreatitis was the most common complication, occurring in 3.2% of all procedures (3.6% of therapeutic and 1.7% of diagnostic procedures). Infection (0.75%) and hemorrhage (0.62%) were the next most common events and occurred only in therapeutic procedures. There was only one perforation, which occurred in a therapeutic procedure, for a rate of 0.12%. Using the Cotton et al¹⁶ complication grading scale, we found that mild complications developed in 2.1% of all patients, moderate in 2.1%, and severe in 0.5%.

In this study, there were significantly more complications in therapeutic procedures compared with diagnostic

TABLE 8. Deaths from all causes within 30 days of ERCP

Patient description	ERCP description	Comments	Cause of death
92-year-old woman with polymyalgia rheumatica on long-term steroid treatment who presented with biliary sepsis and acute renal failure	ERCP revealed multiple stones; a bile duct stent was placed.	Despite appropriate therapy, sepsis and renal failure progressed. The patient died within 24 h.	Sepsis
88-year-old man who presented with a bile leak 1 wk after cholecystectomy for a perforated gangrenous gallbladder	At initial ERCP, a plastic stent was placed, but the leak persisted. ERCP was repeated 5 days later and 2 stents were placed.	The patient died in hospice 29 days later.	Unknown
88-year-old woman with gallbladder adenocarcinoma in whom jaundice and cholangitis developed who underwent an ERCP with plastic stent placement at an outside hospital; referred to an MNGI facility 2 mo later to have the stent changed	The stricture was deemed inappropriate for a metal stent, and a plastic stent was again placed during ERCP.	The patient died in a nursing home within the month.	Unknown; presumed related to advanced malignancy
87-year-old man who presented with weight loss, jaundice, and a double duct sign as revealed by CT	A metal stent was placed during ERCP.	The patient died in hospice within the month.	Unknown; presumed related to advanced malignancy
86-year-old man with dementia with progressive jaundice and a bilirubin level of 12.7 mg/dL	ERCP revealed a biliary stricture suggesting malignancy. Unable to obtain deep cannulation, and the biliary system was not drained.	The family chose not to proceed with percutaneous transhepatic drainage, and the patient was discharged to hospice.	Unknown; presumed related to advanced malignancy
84-year-old woman with multiple medical problems, including organic brain syndrome and metastatic transitional cell bladder cancer, who presented with an elevated bilirubin level and a dilated biliary system and distended gallbladder as revealed by CT; a laparoscopic cholecystectomy was performed, but the patient's bilirubin level continued to increase	During ERCP, unable to obtain deep cannulation, and the biliary system was not drained.	The patient continued to decline and died 3 wk later.	Bladder cancer
81-year-old woman who presented with abdominal pain, weight loss, and a pancreatic mass revealed on CT; the patient had no abnormal liver function tests	ERCP with precut sphincterotomy was attempted, but only superficial cannulation was achieved.	The patient was discharged to hospice and died within the month.	Unknown; presumed related to advanced malignancy
78-year-old man with Pick's dementia in whom jaundice from pancreatic cancer developed	ERCP revealed a tight distal bile duct stricture with a large gallstone in the proximal duct; a plastic stent was placed.	The patient's jaundice improved. The patient was sent to hospice and died within 3 wk.	Unknown; presumed related to advanced malignancy
77-year-old man who underwent an ERCP at an outside facility with metal stent placement because of a malignant biliary stricture; the bilirubin level continued to increase, and the patient was transferred to an MNGI facility for a repeat ERCP 3 days after the previous ERCP	ERCP was repeated with a sphincterotomy, a balloon sweep of the metal stent, and placement of a plastic stent through the metal stent.	The patient had a myocardial infarction 3 days later and died.	Myocardial infarction

(continued on next page)

TABLE 8 (continued)

Patient description	ERCP description	Comments	Cause of death
72-year-old woman who presented with painless jaundice subsequent to a diagnosis of an extensive sarcoma of the gallbladder	Unable to cannulate during ERCP. The patient underwent a percutaneous transhepatic cholangiogram with external drainage.	Renal failure occurred, and the patient died within a month.	Acute renal failure
70-year-old woman who presented with painless jaundice, hepatitis (bilirubin 5.6 mg/dL, aspartate aminotransferase 1778 U/L, alanine aminotransferase 976 U/L), and a bile duct of 11 mm as revealed by CT	ERCP revealed normal findings.	The patient died in the hospital within a month of metastatic ovarian cancer and was incidentally discovered to have end-stage liver disease from autoimmune hepatitis.	Ovarian cancer

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procedures (5.7% vs 2.3%, respectively; χ^2 test, $P = .04$). These results are consistent with those of some previous reports.^{2,4,6,20,21} However, other studies found an equal risk of complications in diagnostic and therapeutic ERCP.^{5,22,23} Although this study found a higher percentage of pancreatitis with therapeutic procedures, this difference is not statistically significant (3.6% vs 1.7%, respectively; χ^2 test, $P = .20$). The only other significant risk factor for complications was the length of the procedure. The mean procedure time for ERCPs in which complications developed was 32.7 minutes, whereas ERCPs in which no complications developed had a mean procedure time of 26.0 minutes (2-sample t test, $P = .03$). Several variables examined were not significantly associated with an increased risk of complications, including age, sex, ASA risk classification, grade of difficulty, and fluoroscopy time.

No relationship was discovered between physician procedure volume or years of experience and risk of complications. These findings are supported by 2 previous large studies,^{6,9} but are in contrast to those of 3 others.^{1,4,8} One physician had a significantly higher rate of complications. However, one complication assigned to this physician was of questionable significance. If this case is subtracted, there is no longer a significant difference in complication rates. The higher rate of complications for this physician was addressed accordingly by our PRC.

Death from all causes within 30 days occurred in 11 patients (1.4% of 805 procedures). The patients who died were older, with a mean age of 82.1 years. Both formal internal peer review and independent external review did not attribute any of the deaths to ERCP.

What is the utilization rate of precut sphincterotomy in the community setting? Precut sphincterotomy has been frequently cited as a higher risk procedure.^{1,2,4,9} Precut sphincterotomy was performed in 26 (4.1%) procedures, and complications developed in 3 (11.5%) patients. This was a higher rate of complications, but the difference was not statistically significant.

The rate of pancreatitis with precut sphincterotomy was also higher, but, again, it was not statistically significant. Another frequently cited high-risk procedure is SOM.^{9,16,24} Biliary SOM was performed in 23 (2.9%) procedures, and complications developed in 2 (8.7%) patients. This was a higher rate of complications, but the difference was not statistically significant. The pancreatitis rate was also higher, but it too was not statistically significant. The study was not designed to specifically evaluate the risks of these 2 procedures, and no conclusions can be drawn about their increased risks.

What is the overall technical success rate of ERCP in the community setting? In this study, based on self-reporting of intent and subsequent success, bile duct cannulation was successful in 94.0% of procedures, was partially successful in 2.0%, and failed in 4.1% (Table 6). Stone extraction was successful in 87.0% of procedures, was partially successful in 3.3%, and failed in 9.8%. Draining all ducts was successful in 90.2% of procedures and failed in 9.8%. Pancreatic duct cannulation was successful in 87.1% of procedures, was partially successful in 5.4%, and failed in 7.5%. No significant relationship was discovered between physician procedure volume or years of experience and technical success.

We were able to measure 7 of the 8 ASGE quality indicators. The eighth indicator, clinical procedural success, has been identified by the Outcomes Committee as the most difficult indicator to measure objectively,¹² and for several reasons, this indicator was beyond the scope of this study.

It is not possible to accurately establish the exact administrative time and financial costs invested in a study of this type. Two research assistants assisted in all aspects of the study and were paid at senior registered nurse rates. Four NP/PAs completed more than 1000 telephone calls to patients. Clerical workers performed the data entry. The statistician charged an hourly rate for her work. A conservative estimate for the overall cost of this study is in the tens of thousands of dollars.

A rigorous effort was made to contact all patients and account for all complications. However, it is possible that some complications could have been missed. In calculating the complication rates, patients who could not be contacted and whose charts did not document a complication were assumed not to have had a complication. To assess the validity of this assumption, the complication rate was calculated among the patients whom we contacted: 673 associated procedures plus the 5 procedures with complications discovered during chart review. Forty complications in 678 procedures generate a complication rate of 5.9%. Although this rate is slightly higher than the rate of 5.0% calculated among all 805 procedures, a χ^2 test comparing 5.0% of 805 procedures with 5.9% of 673 procedures is not statistically significant ($P = .43$).

The greatest hurdle in completing this study was ensuring complete data collection. We were able to account for every ERCP performed by matching scheduling and billing records with reporting forms. All the procedure-specific data were dependent on physician compliance and candor in self-reporting. Physician compliance with many of the reporting categories was nearly 100%. However, the study does have several limitations. For example, for specific techniques, such as precut sphincterotomy and biliary manometry, the higher complication rates were not statistically different and may be attributable to a type II error, with not enough cases to achieve significance. In addition, the technical success rates analysis was dependent on physician self-reporting of intent and success. Because compliance with reporting on procedure intent and technical success was variable, the validity of the technical success analysis was weakened.

To the best of our knowledge, this is the first large study evaluating complications and other quality indicators in a purely community practice; with 805 procedures, it is one of the 10 largest reported series. To the best of our knowledge, this is also the first study to look at ERCP and patient satisfaction. Our complication rates compare very favorably with rates from large studies (>400 procedures) originating in academic centers.¹⁻⁹ Our overall complication rate was 5.0%, whereas rates reported in academic settings have ranged from 5.0% to 15.9%.^{1,2,4-6,8} Our pancreatitis rate was 3.2%, and reported rates from academic centers have ranged from 1.5% to 7.2%.¹⁻⁹ Hemorrhage in our study occurred in only 0.62% of procedures, whereas in academic studies, it ranged from 0.8% to 2.0%.^{1,2,4-6} In addition, the success rates reported here met or exceeded the recommended rates reported by the ASGE/ACG Task Force.¹¹ The Task Force recommended a $\geq 90\%$ success rate for biliary cannulation, and we were successful in 94.0% of cases. For stone extraction, our 87.0% success rate exceeded the >85% rate recommended by the Task Force. Finally, the Task Force recommended that relieving biliary obstruction be >80% to 90% successful, and in this study, we achieved a 90.2% success rate.

These results may not be applicable to all community practices. MNGI is a large practice with the ability to concentrate ERCP to a select group of endoscopists with a mean of 16.6 years of ERCP experience. Although this study did not find any relationship between years of experience and complication rates, several previous studies demonstrated a relationship.^{1,3,4} Furthermore, this study may not be comparable to those of academic centers. It has been suggested that the higher rate of complications in academic centers is owing to a more difficult case mix and decreased numbers of "routine" cases.^{3,4} Our results address issues that have not previously been well studied and, when taken together with data from academic departments, provide a more complete picture of ERCP quality indices.

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