Published in final edited form as:
Clin Gastroenterol Hepatol. 2015 December ; 13(13): 2323–2332.e9. doi:10.1016/j.cgh.2015.06.023.

Development and validation of a prediction model for admission following Endoscopic Retrograde Cholangiopancreatography

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Abstract

Background & Aims—In outpatients undergoing endoscopic retrograde cholangiopancreatography (ERCP) with anesthesia, rates of and risk factors for admission are unclear. We aimed to develop a model that would allow physicians to predict outcomes of patients during post-anesthesia recovery.

Methods—We conducted a retrospective study of data from ERCPs performed on outpatients from May 2012 through October 2013 at the Indiana University School of Medicine. Medical records were abstracted for pre-, intra-, and early (within the first hr) post-anesthesia characteristics potentially associated with admission. Significant factors associated with admission were incorporated into a logistic regression model to identify subgroups with low, moderate, or high probabilities for admission. The population was divided into training (first 12 months) and validation (last 6 months) sets to develop and test the model.

Results—We identified 3424 ERCPs during the study period; 10.7% of patients were admitted to the hospital and 3.7% developed post-ERCP pancreatitis. Post-anesthesia recovery times were significantly longer for patients requiring admission (362.6±213.0 min vs 218.4±71.8 min for patients not admitted; P<.0001). A higher proportion of admitted patients had high-risk indications. Admitted patients also had more severe comorbidities, higher baseline levels of pain, longer procedure times, performance of sphincter of Oddi manometry, higher pain during the first hour after anesthesia, and greater use of opiates or anxiolytics. A multivariate regression model

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Declaration: An earlier version of these data was presented at Digestive Diseases Week, May, 2014, Chicago, IL.

Contributions: Study design (Coté, Xu, Vassell, Hui); Data collection (Coté, Lynch, Keen, Vassell); Statistical Analysis (Xu, Hui); Manuscript drafting (Coté); Critical Editing (Xu, Hui, Easler, Sherman)

Conflict of interest: None relevant to this manuscript

identified patients that were admitted with a high level of accuracy in the training set (area under the curve [AUC]=0.83) and fair accuracy in the validation set (AUC=0.78). Based on this model, nearly 50% of patients could be classified as low risk for admission.

Conclusion—We developed a model, using factors that can be assessed through the first hour after ERCP, which accurately predicts which patients are likely to be admitted to the hospital. Rates of admission following outpatient ERCP are low, so the policy of prolonged observation might be unnecessary.

Keywords

pancreas; complication; sedation; risk factors

Introduction

Since its emergence in the 1970s, endoscopic retrograde cholangiopancreatography (ERCP) has transitioned from a diagnostic to a predominantly therapeutic procedure that is usually performed in an ambulatory setting, with same-day discharge in the majority of patients. However, ERCP is increasingly performed on patients having greater medical co-morbidities and with higher-risk interventions such as pancreatic sphincterotomy.[1] While numerous studies have measured patient- and procedure-specific risk factors for post-ERCP complications,[2–4] there are limited data to determine the optimal duration for post-procedure observation.[5–7]

In an ideal, value-based health care system,[8] ambulatory patients undergoing ERCP should have a final disposition (admission to the hospital or discharge) as soon as possible. On the one hand, prolonged observation periods of 4–6 hours may identify a greater number of post-procedure complications, thereby reducing the need for delayed admissions.[7, 9] Contrarily, a universal protocol that obligates prolonged observation periods unnecessarily increases health care costs.[10] Historically, moderate sedation regimens resulted in prolonged recovery times for patients to reach an alert state. The widespread use of anesthesiologist-administered sedation for ERCP in the U.S. may have impacted this paradigm, as patients are often awake within minutes of completing the procedure; this may allow clinicians to identify post-procedure complications more rapidly. In an effort to identify patient populations who could be safely managed with short observation periods and those ideally managed with prolonged observation or early admission to the hospital, we performed a cohort study having two primary aims: first, to define post-anesthesia care unit (PACU) times as well as admission and complication rates in an ambulatory population undergoing ERCP at a tertiary referral center. Second, we developed a post-ERCP Admission Probability tool (PEAP) using patient (pre-procedure), technical (intra-procedure), and early post-procedure characteristics associated with unplanned hospitalization.

Methods

Study cohort

We conducted a retrospective cohort study including all patients undergoing ERCP at Indiana University Health University Hospital, Indianapolis, Indiana between May, 2012 and October, 2013 (18-month period). This represents a tertiary care referral center for ERCP, with the majority of procedures being performed for therapeutic indications.[1] Patients were identified using an electronic endoscopy reporting software (Provation® MD, Minneapolis, MN). We abstracted relevant pre- and post-procedure variables including admission data from the linked electronic medical record (Cerner, Kansas City, MO). Patients were excluded if the ERCP was performed in non-ambulatory settings (inpatient or outside hospital transfer) or for missing PACU data. Our institutional review board approved the study before commencing procurement of data.

Definitions

We defined an admission as a hospitalization that obligated an overnight stay at our facility on the same or next day (i.e., admitted within 24 hours of discharge from PACU) following ERCP; we excluded outpatient and emergency room encounters resulting in discharge. All admissions were manually reviewed by two investigators (S.L. and G.C.) to confirm their veracity and to assign a reason for admission: 1) known or suspected complication of the index ERCP, such as post-ERCP pancreatitis (PEP); 2) flare of the underlying disease for which ERCP was performed (e.g., abdominal pain in the setting of obstructive chronic pancreatitis); 3) routine care of the underlying disease for which ERCP was performed (e.g., admission for next-day cholecystectomy); 4) unrelated to the ERCP or related disease (e.g., observation for obstructive sleep apnea following the administration of general anesthesia). In order to develop PEAP and define subgroups having a low or high probability of admission, we limited our analysis to evaluate risk factors associated with admission for reasons 1) and 2); patients having admission for reasons 3) and 4) were excluded. In the process of manually reviewing all admissions, we also evaluated for the incidence of PEP using a standardized definition.[11] Our standard practice is to discharge all patients unless there is a suspected complication or need to expedite further care (e.g., next-day cholecystectomy).

Postoperative care unit

Following ERCP with anesthesia-administered sedation, we present length of time in PACU (time to discharge home or decision to hospitalize) and detail pain characteristics and other relevant clinical factors during the first hour post-ERCP. We describe time in PACU using the empirical distribution, indicating the proportion of patients in PACU over time. For continuous variables, we used mean and standard deviation for normally distributed and median and interquartile range (IQR) for non-normally distributed variables. Due to the clustered nature of the data (i.e., one patient might undergo multiple ERCPs during the study period), we used the adjusted Wilcoxon rank sum tests for clustered data, as implemented by the SAS macro %CLUSWILCOX, to compare continuous variables between admission and no admission groups.[12, 13] Comparisons of categorical variables between admission and no admission groups were performed using the Rao and Scott chi-square test.[14]

Risk factors

For the development of a clinically useful instrument, potential risk factors for unplanned admission following ERCP were classified as pre-procedure, intra-procedure, and early (within one hour of procedure completion) post-procedure. Refer to supplementary methods for additional details.

Post-ERCP Admission Probability Tool (PEAP)

In an effort to develop and then test the performance of PEAP based on independent risk factors for admission, we separated the cohort chronologically into training (first 12 months) and validation cohorts (last 6 months). We developed the Post-ERCP Admission Probability tool (PEAP) by selecting covariates that were significantly associated with admission using logistic regression models for each phase of care followed by a comprehensive model incorporating all phases (pre-procedure, intra-procedure, 1-hour post-procedure). Refer to supplementary methods for additional details.

Results

Admission and post-ERCP pancreatitis rates

We identified 3709 ERCPs on 2,499 individuals, including 2509 (68%) in the training and 1,200 (32%) in the validation cohort. A total of 229 (6.1%) ERCPs were excluded due to missing data (figure 1). Same- or next-day admission rates for known or suspected complications of ERCP, after excluding immediate admissions for unrelated indications, was 367/3424=10.7%. Of these, 252 (68.7%) were ERCPs performed for pancreatic indications, 38 (10.4%) for biliary indications, and 77 (21.0%) for indeterminate indications. PEP was observed in 127/3,480 cases (3.6%), 112 (88.2%) of who were admitted within 24 hours of the ERCP. Of those who were not admitted within 24 hours of the ERCP (n=3,087), 30 (1.0%) required admission within 30 days for a procedure-related complication. The median length of stay for subjects admitted following ERCP or within 24 hours was 2 days (IQR, 3).

Pre-, intra-, and post-procedure characteristics

Patients requiring admission in both the training and validation cohorts were more likely to have one or more major medical comorbidities and have a higher pre-procedure pain score (table 1). Consistent with our previous analysis of indications for ERCP performed at an endoscopic referral center, a substantial number of patients underwent ERCP for more complex indications such as chronic pancreatitis and sphincter of Oddi dysfunction (SOD) (supplementary table 2).[1] Since these data were abstracted before the dissemination of the EPISOD trial, which revealed no benefit of endoscopic sphincterotomy for patients with suspected SOD type III,[15] the influence of that trial on our endoscopic practice would not be evident. Additionally, the majority (> 95%) of ERCPs were associated with at least one therapeutic maneuver (supplementary table 2). We also summarize ERCP indications and maneuvers by the indication class (biliary, pancreatic, and indeterminate; supplementary tables 2A–C).

The duration of ERCP was significantly longer among patients requiring admission in both the training and validation cohorts ($p<0.0001$ for each comparison), with absolute differences of 12.7±24.1 and 10.9±49.1 minutes for each cohort, respectively (table 1). Additionally, PACU times (362.6±213.0 vs. 218.4±71.8, $p<0.0001$) were significantly longer for patients requiring admission in the training cohort. These differences persisted in the validation cohort (243.2±129.0 vs. 191.2±68.4, p=0.001). Overall time to discharge or admission was > 120 minutes in both cohorts (supplementary figure 1).

We explored several different pain-specific parameters while in PACU, including first reported pain score, highest score, change from pre-procedure baseline, average, median, last reported score, and the AUP (table 2). Each measure of pain was significantly higher among patients requiring admission as compared to those discharged home; exceptions were highest reported pain score and change from the pre-procedure pain score to the first reported pain score in PACU. Among these pain measures, the AUP had the best correlation with admission (data not shown) and was considered for each of the models described below.

Pre-procedure administration of opiates, antiemetics, and anxiolytics was infrequent (3% or less) in all groups (table 2). In the training cohort, antiemetic administration before ERCP occurred more frequently in those requiring admission (2.7% vs. 0.8%, p=0.0131); we did not observe any other differences in pre-procedure medication administration. Intra-procedure administration of opioids, antiemetics, and anxiolytics were similar between those subsequently admitted or discharged; similar to pre-procedure data, the majority of individuals did not receive any analgesia during their procedure. Administration of anxiolytics during ERCP was more frequent in those requiring hospitalization in the training cohort (13% vs. 8%, p=0.0069).

Consistent with higher pain scores in PACU, the proportion of subjects receiving opiates, antiemetics, and anxiolytics during the first hour in PACU was significantly higher among those requiring admission (p<0.0001 for all comparisons, table 2). Among those receiving at least one dose of an opiate in PACU, the morphine equivalent dose was significantly higher for patients admitted within 24 hours of the procedure. These differences were consistent in the training and validation cohorts.

Multivariate models for predictors of admission during each stage of care

We incorporated pre-procedure, intra-procedure, and early post-procedure variables into separate logistic regression models for each stage of care (supplementary table 3). Pre-procedure factors significantly associated with a higher probability of post-ERCP admission included ERCPs performed for pancreatic indications; biliary obstruction was associated with lower odds of admission. Younger age, female sex, and greater medical co-morbidity were also associated with a higher probability of admission. Factors identified during ERCP or the first hour in PACU that were significantly associated with admission included procedure duration, performance of sphincter of Oddi manometry, stent placement, greater pain in PACU, increased use of opiate, and use of an antiemetic agent. All continuous variables, including procedure duration, major and non-major comorbidities, younger age, area under the pain curve, and amount of opiate used were found to have a linear relationship with the logarithm of the odds of admission by binning the continuous variables into intervals with equal length and plotting log-odds of admission against the intervals. Logistic regression models developed for each stage of care had fair accuracy (> 0.70) in correctly distinguishing patients who were discharged home from those who required admission within 24 hours of the procedure. A similar model restricted to ERCPs performed for pancreatic indications reflected similar relationships (supplementary table 4A). Pancreatic stent placement (OR 3.26, 95% CI 1.80, 5.93) and use of anxiolytics in recovery (OR 4.02, [1.62, 10.01]) were noteworthy intra- and post-procedure factors in this subgroup. In a subgroup analysis of ERCPs performed for biliary indications, the only independent risk factor for unplanned admission was ERCP time (OR 1.03 for each additional minute, [1.01, 1.06]).

Development and application of a comprehensive model including all phases of care

Pre-procedure, intra-procedure, and early post-procedure variables significantly associated with admission selected using stage-specific logistic regression models were incorporated into a comprehensive regression model (table 3). Factors independently associated with admission included ERCP time, performance of sphincter of Oddi manometry, pain characteristics in the PACU, anxiolytic use in PACU, medical comorbidities, female sex, and undergoing stent placement. Biliary obstruction remained the only factor associated with lower odds of admission. There was substantial overlap in risk factors for admission when the population was restricted to patients undergoing ERCP for pancreatic indications (supplementary table 4B), with female sex, stent placement, comorbidities, ERCP time, post-procedure pain and anxiolytic use remaining important predictors.

Patients were divided into three risk categories based on the distribution of predicted probability of 24-hour admission in the training cohort (table 4). The majority of patients (58% in the training and 53% in the validation cohort) were classified as low or high risk for 24-hour admission. In the training cohort, the observed rate of admission ranged from 2.5% in the low risk group, 11.5% in the moderate risk group, and 45.6% in the high risk group. In the validation cohort, the 24-hour admission rate ranged from 3.0% in the low risk category, 8.0% in the moderate risk group, and 30.4% in the high risk group. This final model had good accuracy (AUC = 0.82) in identifying patients requiring 24-hour admission in the training cohort, and fair accuracy (AUC = 0.77) in the validation cohort. The inclusion of two-hour PACU data resulted in similar AUCs in the training and validation cohorts (figure 2).

Discussion

Safety of ambulatory ERCP in an era of therapeutic intervention

In many parts of the world, the majority of patients undergoing ERCP are routinely admitted to the hospital for observation. These data confirm prior observations that the majority of patients (> 85%) can be safely discharged with a low frequency of delayed admission for complications.[6, 9, 10, 16] Our study population represents a particularly high-risk group, given the frequency of SOD, chronic pancreatitis, and other pancreatic pathology as the indication for the procedure. Not surprisingly, pre-procedure factors associated with unplanned admission are in concert with known risk factors for PEP.[2, 4] We did not use the ERCP complexity score suggested by an American Society for Gastrointestinal Endoscopy working party[17] since we aimed to use a large dataset to develop robust models for predicting post-procedure hospitalization and such a scoring system would have required manual record review; future studies should measure the value of the ERCP complexity score in predicting post-ERCP hospitalization.

Since the inception of this study, the EPISOD trial has impacted the use of ERCP for patients with suspected SOD type III; however, these data remain useful when applied to patients with SOD types I–II and other indications highlighted in supplementary table 3. From the standpoint of practice management, it is reasonable to advise nearly all patients to expect discharge following their ERCP; those having one or more high risk indications or demographics (specifically young women) could be advised that while the majority are successfully discharged, there is a higher chance of unplanned admission. Even when considering intra-procedure factors such as performance of sphincter of Oddi manometry and prolonged procedure time, the observed admission rate was never high enough to warrant universal admission. This is in contrast to a policy of admitting all high risk patients following outpatient ERCP.[9]

In our cohort, only a minority of patients received analgesics prior to or during ERCP. Pain appears to be a critical factor associated with unplanned admission, with the majority requiring at least one dose of opiates in PACU. In the moderate sedation era, nearly all patients received a substantial dose of opiates during the procedure; this presumably translated into lower pain in the early stages of recovery. To improve patient satisfaction and perhaps prevent transient pain experienced immediately after ERCP, the incremental benefit of intra-procedure administration of analgesics during anesthesia-administered sedation should be explored. Similarly, administration of antiemetics and anxiolytics in the late intra-procedure or immediate post-procedure period may also benefit high-risk patients by preventing nausea provoked by opiate utilization or the ERCP itself.

Low risk patients: how long should patients be observed in the PACU?

The majority (> 70%) of post-ERCP complications can be identified within the first six hours post-procedure.[9] As reflected in these data, our practice has been to observe almost all of our patients for several hours after their procedure, with selective testing of serum amylase/lipase in the PACU for those at-risk for PEP.[5–7, 10, 18, 19] However, these data were generated in an era of moderate sedation, where patients would receive high doses of opiates for sedation that could have masked the symptoms of post-ERCP complication. With the widespread use of propofol-based anesthesia for ERCP, patients frequently wake up within minutes of endoscope withdrawal and with little or no analgesia on board (table 2). In addition, anesthesia interferes with an assessment of intra-procedure pain, a previously implicated predictor of unplanned admission.[18] We posit that this change in sedation strategy further shortens the time for patients to declare themselves in the PACU. Our current model suggests that many patients can be safely discharged after one hour of post-procedure observation. A computer model will never supplant good clinical judgment; however, incorporating our model into the electronic medical record might empower PACU nurses to update the treating physician after the first hour of data are entered. For example, the nurse could notify the physician to promptly consider discharge for a patient undergoing low-risk ERCP of short duration and having low pain scores during the first hour. In our cohorts, this represents nearly 50% of ambulatory ERCP cases and would dramatically reduce the costs of prolonged periods in the PACU.

High risk patients: when should we pull the trigger and admit for observation?

Perhaps the worst-case scenario for patients undergoing outpatient ERCP is to be discharged from the PACU only to return for admission within 24 hours as a result of a post-procedure complication or symptom flare. In order to provide the highest quality of care for these individuals, post-ERCP recovery should be the minimum amount of time to determine whether a patient can be safely discharged or admitted for observation. This would be in line with a mandate from the Institute of Medicine to include timeliness and efficiency as quality metrics.[20] Based on the results of our study, it appears the necessary clinical information to accurately predict admission is available within the first hour post-procedure for the majority of patients. Our model performed reliably when applied to a separate validation cohort, suggesting the feasibility of identifying a high-risk subgroup who may benefit from an enhanced PACU protocol as applied in some post-procedure settings.[19] This might include the use of a two-tiered observation unit focused on: 1) rapid assessment and discharge of low risk patients; 2) early post-anesthesia pain and nausea interventions among high risk patients, to optimize patient satisfaction with the goal of minimizing post-procedure observation times and readmissions following discharge.[21–23]

Limitations (refer to supplementary discussion)

Summary—There is a critical need to improve the efficiency of post-ERCP observation, minimizing prolonged periods for low-risk individuals and expediting admission for those unlikely to be discharged. Our study tests a model that could be incorporated into the electronic medical record and provide real-time feedback to health care providers. Procedure indication and complexity, along with female sex, baseline comorbidities, and pain characteristics during the first hour in PACU are the most important factors associated with unplanned admission. While it is unlikely that we will completely “automate” the discharge/admit process, a computer-generated assessment of the patient’s probability for admission that includes pre-, intra-, and post-procedure data may expedite care. Furthermore, greater attention to periprocedural pain management, such as with the use of balanced propofol regimens,[24–26] may improve patient satisfaction and impact post-procedure admissions for pain management. Future studies should evaluate the impact of incorporating a real-time model such as PEAP into the electronic medical record on PACU time, admission rates, and patient satisfaction.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

We would like to thank Kimberly Pawlecki, Patricia C. Bowling, Gabrielle Oldham, Gregory N. McCart, Alisa Judy-Malcolm, and Matthew Warner, MD for their assistance with this project.

Grant Support: NIH/NIDDK 5K23DK095148

Abbreviations

ERCP	Endoscopic retrograde cholangiopancreatography
PEAP	Post-ERCP Admission Probability
PEP	Post-ERCP pancreatitis
PACU	Post-anesthesia care unit
IQR	Interquartile range
ICD-9	International Classification of Diseases version 9
MS-DRG	Medicare Severity Disease Related Groups
CPT	Current Procedural Terminology
AUP	Area under the Pain Curve
95%CI	95% confidence interval
SOD	Sphincter of Oddi dysfunction

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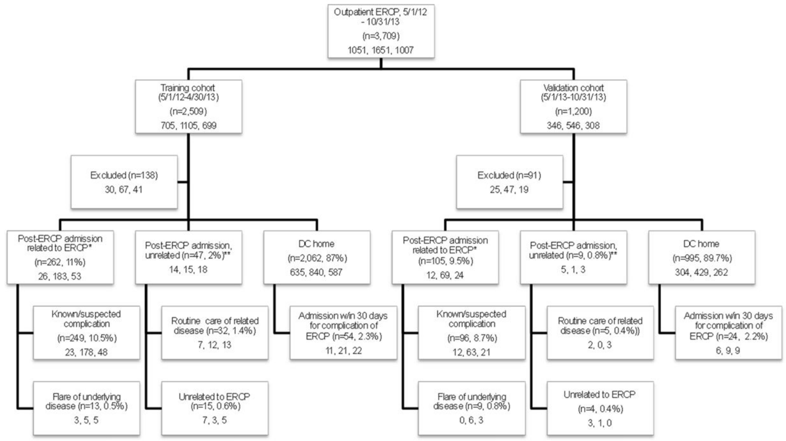

Figure 1. Disposition of ambulatory ERCP cases, 5/2012 – 10/2013

* Admitted within 24 hours of discharge

** Dropped from model development

The three numbers at the bottom of each box indicates the actual number (n) of patients by ERCP Indication class: Biliary, Pancreatic, or Indeterminate. Please see methods section for definitions.

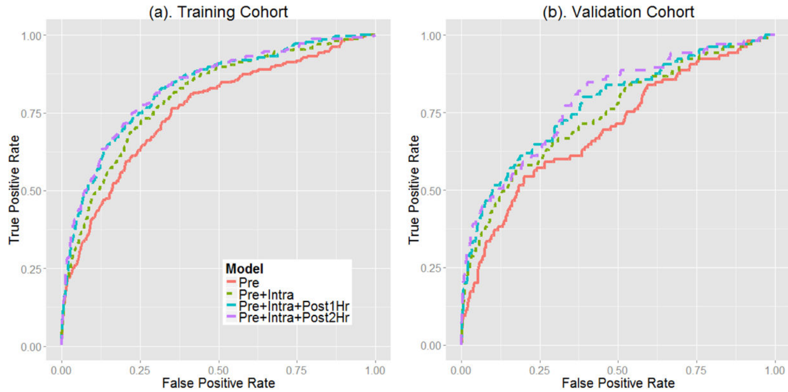

Figure 2. Receiver Operating Curves for cumulative stages of care

Receiver operating curves are shown for the training (a) and validation (b) cohorts. We developed four models using significant factors during pre-procedure → pre-procedure + intra-procedure → pre-procedure + intra-procedure + first hour in PACU → all three prior stages + second hour in PACU. Each model was rated fair to good based on the AUC; training cohort: 0.76 (pre), 0.80 (pre, intra), 0.83 (pre, intra, post one hour), 0.83 (pre, intra, post 2 hours); validation cohort: 0.70 (pre), 0.74 (pre, intra), 0.78 (pre, intra, post one hour), 0.79 (pre, intra, post 2 hours).

Table 1

Sample Characteristics

Variable	Training Cohort				Validation Cohort			
	Total (n=2324)	Admission (n=262)	No Admission (n=2062)	P value	Total (n=1100)	Admission (n=105)	No Admission (n=995)	P value
Age (mean ± SD)	53.4 ± 16.4	47.0 ± 15.2	54.2 ± 16.4	<0.0001	53.0 ± 16.6	48.6 ± 16.7	53.5 ± 16.5	0.0028
Sex (% female)	1408 (60.6%)	202 (77.1%)	1206 (58.5%)	<0.001	655 (59.6%)	68 (64.8%)	587 (59.0%)	0.2624
Number of comorbidities, median ± IQR (mean ± SD)*								
• Major	1 ± 1 (0.77 ± 0.89)	1 ± 1 1.05 ± 1.25	1 ± 1 0.73 ± 0.83	0.0002	0 ± 1 (0.4 ± 0.58)	1 ± 1 (0.70 ± 0.81)	0 ± 1 0.36 ± 0.54	<0.0001
• Non-major	0 ± 1 (0.34 ± 0.53)	0 ± 1 0.52 ± 0.73	0 ± 1 0.32 ± 0.49	0.0020	1 ± 1 (0.9 ± 0.95)	1 ± 2 (1.17 ± 1.11)	1 ± 1 0.87 ± 0.93	0.0848
Pre-procedure pain score (median ± IQR)	0 ± 4	1 ± 5	0 ± 4	0.0031	0 ± 4	2 ± 6	0 ± 4	0.0036
Pre-procedure time, minutes (mean ± SD)¥	127.4 ± 54.1	131.0 ± 53.0	127.0 ± 54.3	0.1204	129.3 ± 148.3	125.5 ± 63.1	129.7 ± 154.6	0.6124
Intra-procedure time, minutes (mean ± SD)	72.7 ± 24.4	84.0 ± 30.1	71.3 ± 23.2	<0.0001	73.6 ± 49.2	83.4 ± 27.0	72.5 ± 50.9	<0.0001
PACU time, minutes (mean ± SD)	234.7 ± 108.4	362.6 ± 213.0	218.4 ± 71.8	<0.0001	196.1 ± 77.7	243.2 ± 129.0	191.2 ± 68.4	<0.0001
ERCP indication class				<0.0001				<0.0001
• Biliary	661 (28.4%)	26 (9.9%)	635 (30.8%)		316 (28.7%)	12 (11.4%)	304 (30.6%)	
• Pancreatic	1023 (44%)	183 (69.9%)	840 (40.7%)		498 (45.3%)	69 (65.7%)	429 (43.1%)	
• Indeterminate	640 (27.5%)	53 (20.2%)	587 (28.5%)		286 (26%)	24 (22.9%)	262 (26.3%)	

SD = standard deviation; IQR = interquartile range

* As defined by Medicare Severity Disease Related Groups (MS-DRG); distributions are nonparametric so we report median ± IQR and mean ± SD to illustrate differences.

¥ Pre-procedure time is defined as time from registration to entry into the procedure room.

Table 2

Pain characteristics and utilization of medication

Variable	Training Cohort				Validation Cohort			
	Total (n=2324)	Admission (n=262)	No Admission (n=2062)	P value	Total (n=1100)	Admission (n=105)	No Admission (n=995)	P value
Change between first PACU pain score and pre-procedure pain score (median ± IQR)	0 ± 2	1 ± 6	0 ± 1	0.0001	0 ± 2	1 ± 5	0 ± 2	0.0137
Pain scores during the first hour in PACU (median ± IQR)								
• Area under the pain curve	58 ± 257.3	273.9 ± 352.5	37 ± 232.5	<0.0001	101.3 ± 291	273.5 ± 296	76.8 ± 265.3	<0.0001
• First reported pain score	0 ± 5	5 ± 8	0 ± 5	<0.0001	0 ± 6	5 ± 8	0 ± 5	<0.0001
• Last reported pain score	0 ± 4	4 ± 6.5	0 ± 4	<0.0001	1 ± 4	4 ± 5	0 ± 4	<0.0001
• Median pain score	0 ± 5	5 ± 7	0 ± 5	<0.0001	1 ± 5	5 ± 7	0 ± 5	<0.0001
• Highest pain score	3 ± 7	7 ± 7.5	2 ± 6	<0.0001	3 ± 7	6 ± 4	3 ± 7	<0.0001
Pre-procedure Medication Use								
Opiate administration, n (%)	45 (1.9%)	8 (3.1%)	37 (1.8%)	0.1593	19 (1.7%)	1 (1%)	18 (1.8%)	0.4876
Use of antiemetics	23 (1%)	7 (2.7%)	16 (0.8%)	0.0131	12 (1.1%)	2 (1.9%)	10 (1%)	0.4398
Use of anxiolytic	17 (0.7%)	4 (1.5%)	13 (0.6%)	0.1299	7 (0.6%)	1 (1%)	6 (0.6%)	0.6347
Intra-procedure Medication Use								
Use of opiate	784 (33.7%)	83 (31.7%)	701 (34.0%)	0.4384	219 (21.8%)	25 (23.8%)	194 (19.5%)	0.2952
Morphine equiv. dose of opiates (median ± IQR)	20 ± 10	20 ± 10	20 ± 10	0.5024	20 ± 10	20 ± 35	20 ± 10	0.4117
Use of antiemetics	1864 (80.2%)	210 (80.2%)	1654 (80.2%)	0.9816	1014 (92.2%)	93 (88.6%)	921 (92.6%)	0.1428
Use of anxiolytic	199 (8.6%)	34 (13%)	165 (8%)	0.0069	67 (6.1%)	9 (8.6%)	58 (5.8%)	0.2568
Post-procedure Medication Use (First hour in PACU)								
Use of opioids	1109 (47.7%)	189 (72.1%)	920 (44.6%)	<0.0001	533 (48.5%)	77 (73.3%)	456 (45.8%)	<0.0001
Morphine equiv. dose of opiates (median ± IQR)	6.7 ± 8	10.7 ± 8.3	6.7 ± 6.7	<0.0001	6.7 ± 9.3	9.3 ± 8	6.7 ± 8.3	0.0039
Use of antiemetics	837 (36%)	152 (58%)	685 (33.2%)	<0.0001	412 (37.5%)	60 (57.1%)	352 (35.4%)	<0.0001
Use of anxiolytic	91 (3.9%)	30 (11.5%)	61 (3%)	<0.0001	64 (5.8%)	20 (19.1%)	44 (4.4%)	<0.0001

Table 3

Comprehensive regression model to distinguish patients admitted or discharged following ambulatory ERCP

Variable	Odds Ratio (95% CI)	P value
Pre-procedure factors		
Age	0.979 (0.964, 0.994)	0.006
Female	2.73 (1.65, 4.51)	< 0.0001
Number of non-major comorbidities	2.49 (1.67, 3.72)	< 0.0001
Number of major comorbidities	2.19 (1.70, 2.81)	< 0.0001
ERCP indication: Bile duct obstruction	0.36 (0.21, 0.62)	0.0002
Intra-procedure factors		
ERCP maneuver: Stent placement	2.11 (1.32, 3.37)	0.0017
ERCP time (in minutes)	1.026 (1.017, 1.035)	< 0.0001
ERCP maneuver: Manometry	2.50 (1.45, 4.30)	0.001
Post-procedure factors		
Area under pain curve	1.004 (1.003, 1.006)	< 0.0001
Use of anxiolytic	3.51 (1.55, 7.96)	0.0026

Table 4

Performance of a post-ERCP Admission Probability tool

Risk of admission category n (%)	Observed admission rate				
	Not Admitted	Immediate Admission	0–1 day admission	2–30 day admission	Total
Training Cohort					
Low	989 (95.7)	23 (2.2)	3 (0.3)	18 (1.7)	1033
Moderate	866 (85.0)	103 (10.1)	14 (1.4)	36 (3.5)	1019
High	142 (54.4)	112 (42.9)	7 (2.7)	0 (0)	261
Total	1997	238	24	54	2313
Validation Cohort					
Low	382 (95.3)	12 (3)	0 (0)	7 (1.8)	401
Moderate	472 (89.1)	38 (7.2)	4 (0.8)	16 (3.0)	530
High	116 (69.1)	49 (29.2)	2 (1.2)	1 (0.6)	168
Total	970	99	6	24	1099

Given an actual admission rate of 11% in our sampling frame, we established cut-off thresholds so that 11% of patients would be classified as high-risk for admission within 24 hours of ERCP and that 10% of admitted patients were incorrectly classified as low risk. The majority of patients could be classified as low- or high-risk for admission after one hour of post-ERCP observation. Therefore, the positive predictive value of being classified as high-risk is 45.6% (95% CI 39.6, 51.6) (i.e., the proportion who actually proceed to admission) in the training and 30.4% (23.4, 37.3) in the validation cohort. Similarly, the negative predictive value of being classified as low-risk (i.e., the proportion who are actually discharged) is 97.5% (96.5, 98.4) in the training and 97.0% (95.3, 98.7) in the validation cohort.