

A Prospective Study of Complications of Endoscopic Retrograde Cholangiopancreatography and Endoscopic Ultrasound in an Ambulatory Endoscopy Center

DAUS MAHNKE,* YANG K. CHEN,* MAINOR R. ANTILLON,* WILLIAM R. BROWN,*
ROGER MATTISON,† and RAJ J. SHAH*

*Division of Gastroenterology and Hepatology, Department of Medicine, and the †Department of Anesthesiology, University of Colorado at Denver and Health Sciences Center, Denver, Colorado

Background & Aims: Our aim was to assess the safety of endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS) in an ambulatory endoscopy center (AEC). **Methods:** Complications occurring in consecutive patients undergoing ERCP or EUS from March 2003 to February 2004 at our AEC were recorded prospectively. Comprehensive complications were defined as consensus criteria plus other adverse events: use of reversal agents, unplanned hospital admission, hospitalization beyond planned 23-hour observation, unplanned emergency department or primary care provider visit, and 30-day mortality. **Results:** A total of 497 patients (median age, 57 y; 82% American Society of Anesthesiologists class II or III) underwent 685 procedures. Monitored or general anesthesia was used in 25% of EUS and 50% of ERCP procedures. ERCP interventions were as follows: biliary or pancreatic stenting (N = 168), stone extraction (N = 70), sphincterotomy (N = 62), sphincter of Oddi manometry (N = 53), other (N = 66). EUS indications were as follows: known or suspected pancreatic mass (N = 103), upper-gastrointestinal mass/submucosal lesion (N = 71), luminal malignancy staging (N = 40), other (N = 96); 52% had EUS fine-needle aspiration. There was follow-up evaluation in 94% of the patients. There were 43 comprehensive ERCP complications (12.9%), 18 (5.4%) of these fit consensus criteria: pancreatitis (N = 14), cholangitis (N = 2), and perforation (N = 2). There were 9 comprehensive EUS complications (2.9%), 2 (.7%) of these fit consensus criteria: pancreatitis (N = 1) and bleeding (N = 1). Other adverse events for ERCP and EUS were as follows: prolongation of 23-hour observation (N = 14), emergency room visits (N = 3), primary care physician visits (N = 6), use of reversal agents (N = 3), unplanned admissions (N = 2), infection (N = 3), and death (N = 1). **Conclusions:** ERCP and EUS can be performed in an AEC, provided mechanisms for admission and anesthesia support are in place. The assessment of comprehensive complications is more reflective of adverse events related to ERCP and EUS than consensus criteria alone.

Gastroenterologists now commonly perform routine endoscopic procedures in ambulatory endoscopy centers (AECs). AECs provide greater autonomy, enhanced scheduling efficiency, and significant financial incentives. Furthermore, upper endoscopy and colonoscopy are performed safely in AECs, given the low rates of complications.^{1,2}

When compared with these routine procedures, however, endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS) have higher equipment costs, longer sedation and recovery times, and higher rates of complications that may require 23-hour postprocedural observation or unplanned hospital admission. Given these factors, and the limited availability of ambulatory anesthesia and/or other ancillary services, the performance of these more complex procedures has been limited to in-hospital endoscopy or radiology suites. It is our hypothesis that ERCP and EUS can be performed safely in an AEC, provided that ambulatory anesthesiology services, prompt and reliable emergency transport for hospital admission, and the necessary equipment and personnel for advanced endoscopy are available. The aim of this study was to assess the complications associated with performing ERCP and EUS in an AEC. To reflect the overall frequency of complications most accurately, we have included complications that met previously published consensus criteria (bleeding, perforation, infection, and pancreatitis) and other adverse events.³

Abbreviations used in this paper: AEC, ambulatory endoscopy center; ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; FNA, fine-needle aspiration; PACU, postanesthesia care unit.

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Patients and Methods

Patient Selection

Consecutive patients undergoing ERCP and/or EUS at the Anschutz Outpatient Pavilion of University of Colorado Hospital's Centers for Advanced Medicine between March 2003 and February 2004 were studied. All procedures were performed by 1 of 3 attending endoscopists, either alone or with a gastroenterology trainee. All procedure data were collected prospectively using a data collection sheet and entered into a database. Institutional review board approval for the collection of data and follow-up evaluation of patients was obtained.

Endoscopy Unit

The AEC is a part of a multispecialty ambulatory surgical center that is owned and operated by the University of Colorado Hospital. Capital items such as endoscopes and fluoroscopy equipment, and devices and accessories, are purchased by the hospital. A physician practice director has a contractual agreement with the hospital to manage the endoscopy unit's budget, operations, and personnel. Costs of ambulance transfer to the hospital for admission are absorbed by the hospital.

Our ambulatory endoscopy unit's anesthesia services, preanesthesia care unit, and postanesthesia care unit (PACU) are shared with surgical departments (eg, orthopedics, otolaryngology, and general surgery). The anesthesiology services staff are composed of certified registered nurse anesthetists and attending anesthesiologists. Five attending gastroenterologists perform general endoscopic procedures, 3 of whom also perform ERCP and EUS (Y.C., M.A., and R.S.). There are 6 endoscopy rooms, 2 of which are equipped for ERCP, cholangioscopy, biliary manometry, and EUS. All the physicians and nurses in our AEC also staffed the inpatient endoscopy unit during the study period. The inpatient endoscopy unit did not have biliary manometry capabilities.

Sedation and Recovery

The endoscopists determined the patients' American Society of Anesthesiologists physical status classifications before each procedure.⁴ If required, the anesthesiology staff was consulted by the endoscopist based on the patient's comorbidities, sedation requirements, and the anticipated length of the procedure. Non-propofol intravenous sedation was directed by the endoscopist and administered by a registered gastrointestinal nurse. Each of the endoscopists performing ERCP and EUS had 1 day per week allotted for cases requiring monitored sedation or general anesthesia, which was provided by a nurse anesthetist or anesthesia resident under the direction of an attending anesthesiologist. Antibiotic prophylaxis was administered when appropriate.

After their procedures, all patients were observed in a PACU, staffed by dedicated PACU nurses, under the supervision of an anesthesiologist. While in the PACU, patients were assessed for suspected endoscopic complications, but laboratory tests were not obtained routinely. Patients had periodic evaluations, using the postanesthesia discharge scoring system, which is based on vital signs, activity level, pain, bleeding, and nausea.⁵ In general the patients' recovery times ranged from 1 to 4 hours. All patients and

patient escorts received detailed written instructions specific to their procedure concerning possible postprocedure symptoms and complications. The patients were instructed to contact the on-call endoscopy staff or their referring physician, or to return to an emergency facility if abdominal pain, fever, nausea, vomiting, or signs of bleeding developed.

Because of the higher risks for complications associated with ERCP for suspected sphincter of Oddi dysfunction and pancreatic endotherapy (sphincterotomy, lithotripsy, stone extraction, stent placement, and so forth), patients who underwent these procedures were prescheduled for 23-hour postprocedural observation. Prophylactic pancreatic duct stenting for high-risk patients undergoing ERCP was at the discretion of the endoscopist. These high-risk patients and those who had an unplanned hospital admission from the PACU (patients who developed symptoms suggestive of complications during PACU monitoring for 2–3 h) were transported via ambulance to a university-affiliated hospital located 6 miles from the AEC.

Complication Assessment

Per clinical protocol, an endoscopy-unit registered nurse made a telephone call to each patient 24 hours after their procedure to assess for possible symptoms and complications and to answer any questions. Further, for the purposes of this study, all patients were contacted by telephone 30 days or more after their procedure. A standardized telephone interview and a review of the electronic medical record were used to obtain follow-up data. Complications associated with ERCP were defined as follows. First, any patient who met consensus criteria as outlined by Cotton et al.³ Second, we recorded other adverse events that required additional health care use beyond the scheduled postprocedure follow-up care as complications: such as unplanned hospital admissions or hospitalization beyond the planned 23-hour postprocedure observation period, unplanned emergency department or primary care contact, use of reversal agents, noncholangitis infection, and 30-day mortality. We designated these additional adverse events plus the consensus-criteria complications as *comprehensive* complications. For purposes of analysis, we attributed a complication that was associated with a combined ERCP/EUS to the procedure we believed to be the most likely cause of the complication.

Statistical Method

The 95% confidence intervals were calculated using the normal approximation of the binomial distribution (modified Wald method).⁶ All continuous variables were reported as medians and ranges. Categorical variables were reported as proportions.

Results

Study Population

From March 2003 to February 2004, 497 consecutive patients underwent 685 procedures (336 EUS and 349 ERCP) in our AEC. During this period, more than 2500 general endoscopic procedures also were performed

in the center. By comparison, at University Hospital 123 patients underwent 119 ERCP and 31 EUS procedures (82% inpatients, 72% using conscious sedation); most of the outpatient procedures were performed in patients awaiting liver transplantation, posttransplantation, or in the rare instances when the staffing at the AEC was below par.

The study population's age and preprocedure American Society of Anesthesiologists classifications are listed in Table 1. Sedation or anesthesia use are listed in Table 2. Fifty-one patients had a planned or prescheduled 23-hour postprocedural observation (47 for ERCP, 4 EUS-guided pseudocyst drainages). Thirty-day telephone follow-up evaluation was obtained in 644 of the 685 procedures (94.0%) and these patients comprise the group analyzed for complication assessment.

Indications and Interventions

Of the 497 patients, 50 (10%) underwent combined ERCP and EUS. Indications, types of interventions, and frequency and severity of complications were reported on a per-procedure basis.

Endoscopic retrograde cholangiopancreatography.

Benign biliary stricture (N = 64, 19.2%), known or suspected sphincter of Oddi dysfunction (N = 63, 18.9%), and chronic pancreatitis (N = 60, 18.0%) were the most common indications for ERCP (Table 3). ERCP was completed successfully in 97% of total cases. The most common interventions at ERCP were stenting of a benign biliary stricture (N = 112), biliary or pancreatic stone extraction (N = 70), and sphincterotomy (N = 62) (Table 4).

Endoscopic ultrasound. A known or suspected pancreatic mass (N = 103, 33.2%) and upper gastrointestinal submucosal or mucosal lesion (N = 71, 23.0%) were the most common indications for EUS

Table 1. Patient Characteristics

Characteristics	No.
Sex	Patients
Male	241 (48%)
Female	256 (52%)
Median age, y (range)	57 (10–91)
Total	497
ASA class	Procedures
I	120 (17.5%)
II	444 (64.8%)
III	120 (17.5%)
IV	1 (<.1%)
V	0 (.0%)
Total	685

ASA, American Society of Anesthesiologists.

Table 2. Sedation Methods

	EUS	ERCP
Number of procedures	336	349
Monitored or general anesthesia ^a	85 (25.3%)	173 (49.6%)
Intravenous sedation ^b	251 (74.7%)	176 (50.4%)
Median fentanyl, μg (range)	162.5 (0–750)	150 (0–500)
Median midazolam, mg (range)	6 (0–16)	6 (0–14)
Median meperidine, mg (range)	100 (0–200)	100 (0–200)
Median diphenhydramine, mg (range)	50 (0–100)	50 (0–100)

NOTE. A total of 685 procedures are included.

^aManaged by anesthesiologist, 165 ERCPs and 80 EUSs with endotracheal intubation.

^bManaged by endoscopist.

(Table 3). EUS was completed successfully in 309 of 310 cases (99.7%). One procedure failed because of an inability to achieve adequate sedation using conscious sedation; the procedure later was performed successfully under general anesthesia. Fine-needle aspiration (FNA) was performed in 160 of 310 (51.6%) EUS cases (Table 4).

Complications

Comprehensive ERCP complications occurred in 43 of 334 cases (12.9%; 95% CI, 9.7%–17.0%; Table 5). Of these, 18 complications fit consensus criteria (5.4%; 95% CI, 3.4%–8.4%) and 25 complications were other adverse events (7.5%; 95% CI,

Table 3. Indications for Procedures in Which Follow-up Data Were Obtained

Procedure	No. (%)
ERCP (N = 334)	
Benign biliary stricture	64 (19.2)
Known or suspected SOD	63 (18.9)
Chronic pancreatitis	60 (18.0)
Malignant stricture	47 (14.1)
Cholelithiasis	38 (11.4)
Primary sclerosing cholangitis	32 (9.6)
Ampullary neoplasm	9 (2.6)
Other	21 (6.2)
Total	334 (100)
EUS (N = 310)	
Pancreatic mass	103 (33.2)
UGI submucosal/mucosal lesion	71 (23.0)
Luminal malignancy staging	40 (12.9)
Biliary stricture	20 (6.5)
Abdominal pain	19 (6.1)
LGI submucosal/mucosal lesion	15 (4.8)
Pancreatic cyst evaluation	15 (4.8)
Pseudocyst drainage	13 (4.2)
Other	14 (4.5)
Total	310 (100)

NOTE. A total of 644 procedures are included.

SOD, sphincter of Oddi dysfunction; UGI, upper-gastrointestinal; LGI, lower gastrointestinal.

Table 4. Interventions During Procedures in Which Follow-up Data Were Obtained (N = 644 procedures)

Procedure	No.
ERCP (N = 334 procedures)	
Stent benign stricture	112
Stone extraction ^a	70
Sphincterotomy	62
Stent malignant stricture	56
Manometry	53
Cholangiopancreatography	36
Diagnostic ERCP alone	30
Failed	10
EUS (N = 310 procedures)	
Fine-needle aspiration	160
Diagnostic procedure alone	125
Pancreatic cyst aspiration	10
Pseudocyst drainage	9
Other	7
Failed	1

NOTE. A total of 644 procedures are included, some patients had more than 1 intervention per procedure.

^aStone extraction included biliary (N = 62) and pancreatic (N = 8).

5.1%–11.0%). Comprehensive complications occurred in 9 of 310 EUS cases (2.9%; 95% CI, 1.5%–5.5%; Table 5). Of these, 2 complications fit consensus criteria (.65%; 95% CI, .02%–2.4%) and 7 were other adverse events (2.3%; 95% CI, 1.0%–4.7%). In patients who underwent combined ERCP and EUS procedures (N = 50), 4 complications occurred: abdominal pain secondary to EUS FNA of a pancreatic lesion (contact with the primary physician required) (N = 1), hospitalization beyond planned 23-hour observation because of nonpancreatitis abdominal pain presumed to be secondary to ERCP and pancreatic stenting (N = 1), and moderate pancreatitis secondary to ERCP (N = 2).

Twenty of the 644 procedures (3.1%; 95% CI, 2.0%–4.8%) resulted in unanticipated admissions. Of these, 5 patients were admitted from PACU, 6 were released from the PACU and later admitted to the university hospital, and 9 were released from the PACU and later admitted to an outside hospital. Of the procedures (N = 573) that did not require planned 23-hour postprocedural observation or unplanned hospital admission, only 11 patients (1.9%; 95% CI, 1.0%–3.5%) returned for an unplanned visit with a primary care provider or to the emergency department for evaluation of postprocedure symptoms or complaints.

There were 2 deaths after ERCP. One patient died from unrelated causes within 30 days of ERCP. Another patient, who had a planned admission after sphincter of Oddi manometry, died from complications of pancreatitis (adult respiratory distress syndrome).

Discussion

The diagnostic and therapeutic applications of ERCP and EUS continue to expand. The potential advantages of performing these procedures at an ambulatory endoscopy or surgery center include efficient scheduling, physician autonomy, and convenience for patients. We undertook this prospective study to help determine if these procedures could be performed safely in a multispecialty AEC. To assess the risk of this approach fairly we believed it was necessary to record not only the events that met consensus criteria but also to create a comprehensive tabulation of adverse events not typically studied for these procedures or in this setting. For example, we included unscheduled visits to a clinic or emergency facility for postprocedure pain because it represents additional use of health care resources beyond routine postprocedure fol-

Table 5. Consensus Complications and Other Adverse Events for EUS and ERCP

	EUS (N = 310)	ERCP (N = 334)
Consensus complications		
Bleeding		
Mild	1	0
Moderate	0	0
Severe	0	0
Perforation		
Mild	0	1
Moderate	0	0
Severe	0	1
Cholangitis		
Mild	0	0
Moderate	0	2
Severe	0	0
Pancreatitis		
Mild	0	5
Moderate	1	6
Severe	0	3
Total	2 (.65%)	18 (5.4%)
Other adverse events		
Prolongation of planned 23-hour observation ^a	0	14
Unplanned medical evaluation		
Primary care evaluation	2	4
Emergency department evaluation	1	2
Use of reversal agent	2	1
Infection	2	1
Mortality (unknown cause)	0	1
Unplanned admission from PACU		
Arrhythmia	0	1
Pain control	0	1
Total other adverse events	7 (2.3%)	25 (7.5%)
Comprehensive complication rate ^b	9 (2.9%)	43 (12.9%)

^aThe 23-hour observation became an inpatient admission without a definable consensus complication.

^bThe consensus complication rate plus the other adverse events.

low-up care. These typically are not reported using consensus criteria for procedure-related complications.

Complications from EUS with FNA have been reported to be between .5% and 2.9%.⁷⁻¹² The complication rate of diagnostic EUS without FNA has not been reported. In our series, 1 of the patients who underwent EUS without FNA had a sedation-related complication that required the use of a reversal agent. In experienced hands, the complication rate for ERCP by consensus criteria remains approximately 5%–8%, with a mortality rate of .5%–2.0%.¹³⁻¹⁶ Our rate of consensus complications was 5.4%.

An early retrospective study comparing inpatient and outpatient ERCP (in conjunction with biliary sphincterotomy) found comparable rates of complications between the 2 groups.¹⁷ In 1996, Elfant et al¹⁸ prospectively studied 97 consecutive patients undergoing outpatient endoscopic treatment of choledocholithiasis and, despite 5.4% of their patients needing admission because of complications, they encountered no long-term adverse clinical outcomes related to this practice. Furthermore, despite the need to readmit many patients, Elfant et al¹⁸ reported a financial advantage to outpatient therapeutic endoscopy because of savings in hospitalization costs. Two larger studies of therapeutic ERCP revealed similar complication rates between inpatient and outpatient procedures.^{16,17} In 1999, the largest prospective series of therapeutic ERCP to date was released by the Multicenter Endoscopic Sphincterotomy Study Group.¹⁹ They published their experience with same-day discharge after endoscopic biliary sphincterotomy in a group of 614 patients and found that 5.7% later were admitted with complications. Our study did not include a comparison group of hospitalized patients undergoing similar procedures because the vast majority of the ERCP and EUS procedures at our center are performed in an ambulatory endoscopy center. As expected, because of the preprocedural selection of high-risk patients for planned 23-hour observation, our rate of unanticipated hospitalization after ERCP and discharge from the PACU was comparable to previous hospital-based studies and was 4.2% (14/334). Furthermore, among the patients who were discharged from the PACU after routine recovery, only 1.9% returned for an unplanned visit with a primary care provider or to the emergency department for evaluation of postprocedure symptoms or complaints.

From its onset, EUS has been performed mostly in the hospital-based outpatient setting, but in our study it was performed in an ambulatory endoscopy center. Harewood and Wiersema¹² reported a .5% complication rate (1 episode of mild pancreatitis) in a prospective study evaluating 185 patients undergoing FNA of solid pancreatic masses. In 2003, Eloubeidi et al²⁰ evaluated the accuracy and safety of

EUS with FNA in patients who had suspected pancreatic cancer. They reported that among 158 patients, 4 (2.5%) had serious complications: pancreatitis (1 patient), over-sedation (1 patient), and an emergency department visit (2 patients, 1 visit resulting in admission); however, the number of reported complications may have been underestimated because the follow-up rate was low (49% at 24–72 hours, and 39% at 30 days).

The earlier-described studies have established that ERCP and EUS can be performed safely in hospital-based endoscopy or radiology suites, with same-day discharge for most patients. We included a systematic assessment of adverse events beyond those described by consensus criteria, which reflects the frequency of total adverse events that may impact health care use related to advanced endoscopic procedures.

Patients prescheduled for 23-hour observation after ERCP were those who underwent sphincter of Oddi manometry or pancreatic endotherapy. In a preliminary report of patients from our institution undergoing manometry in our AEC, the consensus complication rate (12%) plus other adverse events (ie, comprehensive complications) was 41%.²¹ Large, multicenter studies have shown that patient-related factors such as performing ERCP for suspected sphincter of Oddi dysfunction have the highest rates of postprocedural pancreatitis.^{22,23} Given the high likelihood of adverse outcomes in patients undergoing these procedures, this study provided extended observation of these patients beyond the PACU setting.

Our decision to perform ERCP and EUS procedures in an AEC setting was driven primarily by the inability of the hospital-based endoscopy unit to accommodate our growing outpatient referral practice. Because our AEC was not designed operationally to accommodate 23-hour observation (as is true presently of most AECs today), high-risk patients had to be transported approximately 6 miles by ambulance to our university-affiliated hospital for extended observation. This arrangement presented a number of reimbursement and resource use issues. First, the Centers for Medicare and Medicaid Services makes an important distinction between a 23-hour observation of asymptomatic patients and a true inpatient admission for management of suspected complications.²⁴ The latter requires an indication for admission (eg, perforation or suspected pancreatitis) and inpatient services rendered can be billed accordingly, whereas Centers for Medicare and Medicaid Services considers the former an extension of postprocedure recovery after an outpatient procedure, and thus Centers for Medicare and Medicaid Services and most other third-party payors will not reimburse the

facility separately for extended 23-hour observation. Specifically, the professional and facility fee reimbursement for the endoscopy service is inclusive of sedation, the endoscopy procedure, and postprocedure recovery. On the other hand, if a patient develops a complication during this 23-hour observation period requiring extended hospitalization (>23 hours), the designation changes from "23-hour observation" to "inpatient admission," and billing for an inpatient service is permitted.

Second, the cost of ambulance transport to another facility requires preplanning and reimbursement for this service has been variable. Third, conducting the 23-hour observation in a hospital bed is probably more costly than doing so in an AEC; future AECs may have to incorporate 23-hour postprocedure observation areas into their practice models. Although it would have been useful to collect associated cost and reimbursement data of such a practice model, our study did not address these issues directly. If outpatients deemed to be higher risk for postprocedural complications are discharged without extended observation, there is an implication of additional resource use and potential risks to be taken into account such as unplanned visits to an emergency room, urgent care facility, or clinic. Further, many tertiary referral centers draw patients from long distances and the risks for delayed recognition and treatment of complications in these patients, if discharged without extended observation, is that these patients later may present to their local primary care physician or emergency facility where a provider may not be trained to recognize or manage potential complications. These issues will require further study.

This prospective study consisted of consecutive patients undergoing procedures at a free-standing AEC. The majority were classified as American Society of Anesthesiologists class 2 or 3. We had an excellent rate of follow-up evaluation (94%). As expected, our rate of consensus-criteria complications and unplanned hospital admissions secondary to either ERCP or EUS compares favorably with previously published hospital-based series. However, our inclusion of other adverse events such as emergency department visits or unplanned contact with a primary care provider enhances our ability to inform patients and their referring physicians of risks beyond consensus criteria associated with these procedures. Furthermore, a comprehensive assessment of complications may be used to assess the quality of endoscopy among individuals and institutions, and to provide a possible basis for the Centers for Medicare and Medicaid Services' move toward a pay-for-performance system.

The number of procedures in our preliminary series is too few to permit us to determine independent risk factors for negative outcomes. Previous larger prospective studies of ERCP have identified several risk factors for pancreatitis: previous occurrence of post-ERCP pancreatitis, suspected sphincter of Oddi dysfunction, difficult cannulation, cirrhosis, and others.^{19,22,23} Both patient characteristics and the type of procedure interventions are important in determining the risk for complications from ERCP. Those factors, along with anesthesia requirements, should be considered when planning ERCP or EUS in an AEC.

An important concern for endoscopists performing procedures in an AEC is sedation-related complications. The majority of our patients (62%) had nonpropofol intravenous sedation directed by an endoscopist. Among our patients who underwent intravenous sedation, 83% were American Society of Anesthesiologists class II or III. We observed a less than 1% rate (3/644) of complications from conscious sedation. These complications were mild and managed with the use of reversal agents alone. One potential limitation to our study was that our series was underpowered to detect rare, severe, life-threatening complications (eg, massive hemorrhage or cardiopulmonary arrest). A large multicenter study would be needed to determine the chance of these rare events occurring.

An early study by Freeman et al¹⁵ suggested that ERCP complication rates correlate with the experience of the endoscopist. Our study was conducted by experienced endoscopists at a tertiary referral center and our findings may not apply to units with less-experienced personnel. In addition, general anesthesia was used in 38% of our patients, and recovery was in an anesthesiologist-supervised PACU in all cases. These features are not routinely part of most AECs, but the longer intravenous sedation times often needed for ERCP and EUS would make anesthesiology support necessary.

Because our AEC is owned by the University Hospital, billing for services are identical in outpatient and inpatient procedures. Billing for accessories and medications are itemized, although many payors reimbursed the facility with a flat fee. The aim of our study was to assess the clinical feasibility and management of immediate and delayed complications that arise from performing ERCP and EUS in the ambulatory endoscopy setting, from a functional rather than a financial angle. Whether performing such advanced endoscopy procedures in a physician-owned AEC is feasible financially depends on whether the increased revenue resulting from improved overall efficiency would adequately offset the lower facility fees typically generated in a traditional AEC model.

Although our study did not assess costs formally, prior studies of hospital-based ERCP procedures have shown a cost benefit based on avoiding unnecessary hospitalizations.^{13,25} However, for AECs the case may be quite different. Whether an AEC is a more cost-effective setting for ERCP or EUS procedures than traditional hospital-based endoscopy suites is unknown. Such cost comparisons will have to take into account multiple variables including the referral base, patient characteristics, capital costs, personnel, anesthesia support, and payer mix. As an example, at our university-based ambulatory center, the direct costs of ERCP are 6.5 times higher than for colonoscopy, yet the reimbursement rate is only 4.5 times higher. For EUS, the direct costs are 3.5 times higher than colonoscopy, yet the reimbursement rate is only 2.5 times higher. It remains to be seen if EUS, as opposed to ERCP, will be more feasible and cost effective at an AEC, especially given its lower rate of complications when compared with ERCP. Another consideration for an AEC is that hospital admission requires ambulance transport at a median reimbursement rate of approximately \$500 (unpublished internal analysis).

In summary, this series assessed the safety of performing ERCP and EUS procedures in a free-standing AEC. In addition, it is a comprehensive prospective assessment of ERCP and EUS complications that consider untoward adverse events beyond consensus criteria alone. Preliminarily, ERCP and EUS performed in an AEC with on-site anesthesiology services appears to be safe. Large multicenter studies and systematic assessment of the cost effectiveness of performing ERCP and EUS in AECs are needed before this approach can be advocated for community-based AECs.

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Address requests for reprints to: Raj J. Shah, MD, Division of Gastroenterology and Hepatology, University of Colorado at Denver and Health Sciences Center, Gastrointestinal Clinic/Mail Stop F735, Anschutz Outpatient Pavilion, 1635 North Ursula Street, Room 2136 A, PO Box 6510, Aurora, Colorado 80045. e-mail: Raj.Shah@UCHSC.edu; fax: (720) 848-2749.

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