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Original Article

Characteristics and Outcomes of ERCP at a Canadian Tertiary Centre: Initial Results from a Prospective High-Fidelity Biliary Endoscopy Registry

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ABSTRACT

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is an essential procedure in the management of pancreatic and biliary disease. While its role is firmly established, further well-designed prospective ERCP research is required, as a large portion of previous work has employed retrospective or administrative methodologies, both prone to potential biases. The aim of the Calgary Registry for Advanced and Therapeutic Endoscopy (CReATE) is to be a high-fidelity prospective multicentre registry.

Methods: The study population consisted of consecutive adult ERCP patients from September 2018 to September 2019. Informed consent was acquired for each patient. All relevant preprocedural, procedural, peri-procedural and postprocedural data were captured in real time by a full-time third-party research assistant directly observing procedures. Outcomes were ascertained by comprehensive medical record review and patient phone interview 30 days after the index procedure.

Results: Five endoscopists performed 895 ERCP procedures, 90.1% of which were deemed successful. Suspected choledocholithiasis was the most common indication for ERCP, followed by suspected or confirmed stricture(s), at 61.0% and 29.5%, respectively. 61.0% of procedures were performed on ERCP-naive patients. Post-ERCP pancreatitis occurred following 4.9% of procedures, with clinically significant bleeding or perforation occurring following 1.8% and 0.1% of procedures, respectively.

Discussion: Through 12 months, CReATE captured 895 procedures prospectively, with each entry containing over 300 data fields. Active expansion to additional tertiary centres is underway, and this will enhance the existing data pool. CReATE has the potential to improve multiple facets of ERCP, including training, optimal procedural techniques, mitigation of adverse events and personalized patient care.

Keywords: *ERCP; Endoscopy; Health services; Registries*

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BACKGROUND

Endoscopic retrograde cholangiopancreatography (ERCP) is well recognized as an important therapeutic modality for biliary and pancreatic pathology. ERCP is the first-line modality for management of choledocholithiasis (1), decompression of pancreatic or biliary strictures (2) and for evaluation and/or treatment of proximal biliary neoplasia (3). It is also an important modality in the treatment of several benign pancreaticobiliary disorders, including Sphincter of Oddi dysfunction and pancreas divisum (4). In conjunction with other endoscopic, surgical and radiographic techniques, ERCP is therefore a cornerstone in the management of pancreatico-biliary disease. It is estimated that over 450,000 ERCPs are performed annually in the United States (5).

While ERCP is effective, there are several well-established adverse events associated with its performance, including post-ERCP pancreatitis (PEP), bleeding, perforation, cholecystitis, cholangitis and cardiopulmonary events (6). PEP in particular has been well-studied, with reported rates of approximately 10% in a systematic review of over 100 randomized trials (7). Those performing ERCP must therefore carefully consider these potential risks, balanced against the many benefits of the procedure and available alternatives. Thus, endoscopists performing ERCP must possess high baseline procedural skill, but also require high quality evidence guiding optimal case selection, technique and methods for mitigating adverse events, in addition to data informing training and credentialing.

Several studies have described ERCP outcomes and their predictors using large cohorts, but most have been retrospective (8), and several have made use of administrative databases (9,10). Given their designs, these studies are susceptible to several potential sources of bias that are often beyond the control of study investigators (11,12). There are relatively few well-designed prospective ERCP registries (13–17). Though these assess ERCP outcomes and adverse events in a prospective setting, they are still prone to some potential biases primarily due to endoscopist or trainee self-reporting of peri-procedural parameters. None of these studies employed real-time data collection by a third party, such as a research assistant or automated outcome capture, in order to eliminate self-reporting bias. Furthermore, the granularity of data collection is generally low among these studies, with several important potentially predictive variables not recorded due to logistics or resource requirements.

The Calgary Registry for Advanced and Therapeutic Endoscopy (CReATE) was created with the goal of capturing all potentially relevant pre-, intra-, peri- and postprocedural variables for consecutive patients undergoing ERCP in real-time by a third-party observer. By capturing all relevant patient-, endoscopist-, trainee- and procedure-related data, CReATE is the first truly prospective high-fidelity ERCP registry of its kind.

METHODS

Study Design and Setting

CReATE is a prospective ERCP registry that captures procedural data in real-time via entry by a full-time research assistant (RA) dedicated to the registry's maintenance, improvement and data acquisition. The registry was launched in Calgary, Alberta, Canada in September 2018. At our tertiary centre, over 1500 ERCPs are performed annually, with a referral catchment population of approximately 1.5 to 2 million. ERCPs in Calgary are currently performed by a group of five endoscopists with variable practice experience and annual procedure volumes. Between one and two advanced therapeutic endoscopy trainees (postdoctoral fellows) train under direct supervision of the consultant endoscopists in any given year.

Study Population

Inpatients and outpatients referred to our centre's endoscopy unit for consideration of an ERCP are booked for a procedure by a consultant advanced/therapeutic endoscopist if appropriate. An attempt is made to approach consecutive patients aged 18 or over referred for an ERCP, regardless of indication or disposition, for inclusion in the CReATE registry. Those willing to participate and capable of providing informed consent are enrolled after which data acquisition begins.

Eligibility Criteria

Patients are required to meet all of the following criteria to be included in the registry:

- any standard indication for ERCP, in the absence of standard contraindications;
- age ≥ 18 years;
- ability and willingness to give informed consent to be included in the registry and/or to involvement in one (or more) prospective sub-studies, or accompaniment by a surrogate who is willing and able to provide consent.

Study Outcomes

The primary outcome for this study was the post-ERCP pancreatitis rate among all comers. Secondary outcomes included intraprocedural or immediate adverse events, clinically significant bleeding (as defined by requirement for transfusion, admission or reintervention), perforation, cholangitis or sepsis.

A steering committee has also been assembled to begin formulating additional targeted research questions. Broadly, the next aims of CReATE are to:

- enhance understanding of:
  - the risk factors for benign and malignant conditions of the pancreatic and biliary systems,
  - the clinical effectiveness and outcomes relating to ERCP,

  - the ideal circumstances under which ERCP and related techniques should be performed,
  - the risk factors for and timelines surrounding ERCP adverse events, and
  - the educational aspects of ERCP as they relate to proficiency and outcomes;
- provide a high-fidelity electronic data scaffold that facilitates patient recruitment for randomized and observational prospective studies in pancreatico-biliary endoscopy;
- eventually establish a collaborative network of academic therapeutic endoscopists across North America.

Data Management and Acquisition

CReATE is supported by the Clinical Research Unit (CRU), a core research support centre affiliated with the University of Calgary's Cumming School of Medicine. The CRU administers a secure web application specializing in healthcare registry implementation and maintenance (REDCap, Vanderbilt University, Nashville, TN) (18). This web portal allows for facile access to secure data, and also permits data pooling with other academic centres. The portal allows for prospective data collection and data sorting and extraction.

All data fields in the registry were initially created by the principal investigator, and have since undergone several revisions after feedback from the co-investigators, consultants, trainees, RA and nursing staff following a pilot test. Data fields are organized into six data collection modules: (1) patient information, (2) preprocedure data, (3) procedural data, (4) peri-procedural data, (5) postprocedural data and (6) 30-day follow-up. The specific fields comprising each form are listed in Supplementary Material 1. Furthermore, patient consent can be taken electronically, in lieu of or in addition to a physical paper version. A patient withdrawal form is also available electronically. Upon enrolment, each patient is assigned a unique study identification number, and can be searched by virtually any data field.

Over 300 data fields are collected in real-time on a portable tablet and/or one of the computers located in the ERCP suite. Patient data are collected through a combination of preprocedural patient interview and electronic and/or physical medical record review, and include demographics, medical and surgical history, relevant medications (including opioids and antithrombotic/antiplatelet drugs), disposition and social history. Preprocedural, procedural and peri-procedural data are collected through a combination of direct observation and in-room consultation with the procedural trainees(s), consultant(s) and/or nurse(s), and include procedural indication, history and timing of prior ERCPs, intraprocedural details, devices used, and extent of trainee involvement, among several other fields. Prior to discharge, subjective postprocedure patient-reported data are collected.

Study Ethics, Integrity and Quality

The registry was approved and is regulated by the Conjoint Health Research Ethics Board (CHREB) at the University of Calgary (REB18-0410). A Consent to Approach form is obtained by the patient's nurse, and a patient is approached about our registry only if this initial consent is given. An informed consent discussion is then undertaken, and any questions answered prior to giving consent. Any involved endoscopists or trainees have or will also sign consent permitting deidentified use of personal data. All patients are managed according to established best practice as per international research and consensus on ERCP. Treatment does not differ according to whether or not the patient chooses to participate in the study. Patient data are deidentified any time removal from the web portal is planned for subsequent analysis.

In accordance with the Declaration of Helsinki and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), participants are free to withdraw from participation in the registry at any time, for any reason, without prejudice to their future medical care by physicians or our institution. Investigators may also withdraw participants in the interest of patient safety.

RESULTS

After 12 months, CReATE prospectively captured data from 895 procedures, performed by 5 endoscopists with or without the participation of advanced endoscopy fellows. The baseline patient and procedural characteristics of these procedures are shown in Table 1. Most cases were performed for indications of suspected choledocholithiasis (61.0%), followed by suspected or confirmed strictures (29.5%) and cholangitis (4.6%). 61.0% of procedures were performed on ERCP-naive patients with native papillae. Technical success of the ERCP procedure was achieved in 90.1% of cases. Procedural characteristics are provided in Table 2. Post-ERCP pancreatitis occurred in 4.9% of all procedures performed, including those with cholangioscopy or pancreatoscopy. 2.8% of procedures resulted in clinically significant bleeding. One patient (0.1%) experienced a small perforation observed immediately following sphincterotomy; this was clipped endoscopically and a biliary stent placed. The patient then underwent a normal computed tomography scan and was discharged from hospital after 1 day of asymptomatic observation. All relevant postprocedural outcomes within 30 days are shown in Table 3.

DISCUSSION

ERCP is a commonly performed procedure that, while effective, has the potential to result in unplanned healthcare resource utilization, serious adverse events or death (6,19).

Table 1. Demographics and procedural parameters for 895 ERCP procedures

Characteristics	Number of procedures (%)
Sex	
Female	461 (51.5)
Male	434 (48.5)
Age—mean (SD)	58.5 (18.4)
Disposition	
Outpatient	410 (45.8)
Inpatient	483 (54.1)
Antiplatelet or anticoagulant use	
Yes	268 (29.9)
No	627 (70.1)
Primary indication for ERCP	
Suspected or confirmed CBD stone(s)	546 (61.0)
Suspected or confirmed CBD stricture(s)	264 (29.5)
Cholangitis	41 (4.6)
Other (specific indications recorded)	44 (4.9)
Prior ERCP	
Yes	348 (38.9)
No	546 (61.0)
Trainee involved	
Yes	514 (57.4)
No	378 (42.2)
Rectal NSAID given for mitigation of pancreatitis	
Yes	329 (36.8)
No	541 (60.4)

CBD Common bile duct; ERCP Endoscopic retrograde cholangiopancreatography; NSAID Nonsteroidal anti-inflammatory drug; SD Standard deviation.

Table 2. Procedural characteristics and outcomes for 895 ERCP procedures

Characteristics	Number of procedures (%)
Targeted duct	
CBD	813 (90.8)
PD	63 (7.0)
Both	10 (1.1)
Total cannulation attempts*	
1 or 2	238 (43.6)
3–5	103 (18.9)
6–10	52 (9.5)
Greater than 10	86 (15.8)
Cannulation time, minutes—mean (SD)*	5.12 (8.21)
Pancreatic duct cannulation or double wire usage†	153 (29.9)
Maneuvers performed*	
Standard sphincterotomy	484 (88.6)
Balloon sphincteroplasty	99 (18.1)
Precut sphincterotomy (any kind)	100 (18.3)
Needle-knife papillotomy	61 (11.2)
Cholangioscopy performed	24 (2.7)
Pancreatoscopy performed	2 (0.2)
Procedure time, minutes—mean (SD)	25.0 (16.5)
General anaesthesia used	
Yes	107 (12.0)
No	788 (88.0)
Mean doses of sedating medications used‡	
Midazolam, mg IV—mean (SD)	5.53 (7.39)
Fentanyl, μg IV—mean (SD)	94.25 (38.76)
Diphenhydramine, mg IV—mean (SD)	46.87 (9.61)
Procedural success	806 (90.1)
Reasons for procedural failure	
Sedation-related issues	4 (0.4)
Inability to locate papilla of interest	5 (0.6)
Inability to cannulate duct of interest	46 (5.1)
Inability to clear duct of interest or relieve obstruction	37 (4.1)
Stent(s) placed in CBD	85 (9.5)

CBD Common bile duct; IV Intravenous; PD Pancreatic duct; SD Standard deviation.

*Calculated only from 546 procedures with native papillae; †calculated only from procedures with native papillae where the CBD was the target, $n = 512$; ‡calculated only from procedures where conscious sedation was used, $n = 788$.

Though numerous patient-, endoscopist- and procedure-related risk factors for the development of adverse events have been elucidated (20–22), there is the potential to uncover many more. Furthermore, there remain several unanswered questions regarding trainee involvement as well as optimal and novel procedural techniques. Self-reporting bias, retrospective study designs, lack of granularity and pitfalls associated with administrative databases are among the limitations of existing data.

Even in the case of 'prospective' studies, one can argue that data entry upon completion of the procedure can introduce recall bias as it pertains to important ERCP-related details, such as number of cannulation attempts. Furthermore, there are several other parameters that are next to impossible to record without a third-party observer. CReATE strives to eliminate these sources of bias by recording procedural data in real-time during the procedure via direct third-party observation by a research assistant. This sets us apart from other well-deigned databases. We have recruited close to 900 patients prospectively in the first year of the registry's implementation, with over 300 data fields captured per patient, thus proving the feasibility of acquiring high-fidelity data in biliary endoscopy without

Table 3. Adverse event outcomes for 895 ERCP procedures

Characteristics	Number of procedures (%)
Intraprocedural or immediate adverse events	
Postsphincterotomy bleeding	27 (3.0)
Postsphincteroplasty bleeding	4 (0.4)
Perforation	1 (0.1)
Requirement for reversal of sedation	1 (0.1)
Cardiopulmonary complications	0 (0.0)
Death	0 (0.0)
Pancreatitis	44 (4.9)
Mild*	42 (4.7)
Moderate or severe*	2 (0.2)
Clinically significant bleeding†	16 (1.8)
Cholangitis or sepsis	9 (1.0)

*Per revised Atlanta classification of pancreatitis (26); †requiring transfusion, admission or intervention (endoscopic or radiographic).

impeding the workflow of the unit. Our procedural characteristics and outcomes are representative of the experience of most tertiary ERCP practices.

We are now actively planning the incorporation of data from two major tertiary Canadian ERCP referral centres into this registry. We anticipate that these additional sites will be recruiting patients by early 2020. The CReATE registry aims to enrol consecutive ERCP patients from these three Canadian tertiary care centres for a minimum of 4 years. Expansion to additional sites in Canada or the United States will also be planned if feasible and appropriate. Furthermore, CReATE is successfully being used as a secure electronic data scaffold for several currently recruiting prospective studies, including a randomized controlled trial (23).

The design of this registry is not without limitations. The main factor prohibiting the widespread adoption of our registry is the high resource requirement involved. The dedication of a full-time research assistant committed to maintenance of the registry, ethical considerations, patient interaction and data acquisition comes at a high cost. We contend that the unprecedented level of data granularity we will obtain on a large scale justifies the cost, but we also recognize that this is the primary roadblock preventing widespread implementation of this registry. It can also be argued that nonacademic centres, with lower institutional and individual procedure volumes, and therefore, with potentially the most to gain from this initiative (24), are least likely to be able to adopt the registry as currently designed.

Therefore, it is incumbent upon our study team to begin planning for the next phase of the registry—one that is more portable and less resource-intensive, while still maintaining a high value in terms of collecting important prospective ERCP data. It is possible that several of the over 300 data fields are less crucial when it comes to the identification of important predictors of ERCP outcomes. Thus, future iterations of this registry could benefit from analyses of initial cohorts to determine which variables are essential. Furthermore, a future focus on patients with native papillary anatomy only may be appropriate, given the higher degree of competence required to perform ERCP in this population, in addition to the higher risk associated with the procedure in this setting (25). Finally, it remains unproven to what extent endoscopist or trainee self-reporting can serve as the approach for data acquisition, and whether clinicians can be trained or be provided with tools to more closely perform true prospective data entry. This is an additional research focus of our registry. Ultimately, our goal is to become the pre-eminent ERCP registry in North America by creating a version of CReATE that is easily and widely adopted.

In summary, CReATE is a novel high-fidelity prospective ERCP registry in the midst of active expansion. We look forward to reporting on several novel aspects of ERCP performance in a large cohort of patients for several years to come.

Supplementary Data

Supplementary data are available at *Journal of the Canadian Association of Gastroenterology* online.

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Declarations

Ethics approval and consent to participate: Our study has received full ethics approval from the Conjoint Health Research Ethics Board (CHREB) at the University of Calgary (REB 18–0410). Written informed consent is required from each patient for study participation.

Consent for publication: Not applicable.

Availability of data and materials: Not applicable.

Competing interests: None relevant.

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Authors' contributions: N.F. conceived of and designed the study. N.F. and H.F.K. drafted the article. S.J.H. and R.J.H. contributed to study design. H.F.K., S.B., M.C., N.F., E.G.M., A.K., R.M., and C.T. are responsible for data acquisition. All authors are responsible for interpretation of data and critical revision of the article for intellectual content. All authors have approved this version of the article.

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