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A prospective evaluation of radiation-free direct solitary cholangioscopy for the management of choledocholithiasis

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Abstract

Background and Aims—Endoscopy has replaced many radiological studies for the GI tract. However, ERCP remains a hybrid endoscopic-fluoroscopic procedure, which limits its portable delivery, creates delays due to fluoroscopy room unavailability and exposes patients/providers to radiation. We evaluated fluoroscopy/radiation-free management of patients with non-complex choledocholithiasis using direct solitary cholangioscopy (DSC).

Methods—Patients underwent fluoroscopy-free biliary cannulation, sphincterotomy then cholangioscopy to establish location, number/size of stones and document distance from ampulla to bifurcation to guide balloon advancement. Stones were extracted using a marked balloon catheter advanced to the bifurcation and inflated to the bile duct diameter, documented on prior imaging. Repeat cholangioscopy was performed to confirm stone clearance.

Results—Fluoroscopy-free biliary cannulation was successful in all 40 patients (100%). Advanced cannulation techniques were required in 5 patients. Papillary balloon dilation was performed in 8 patients and electro-hydraulic lithotripsy in 3 patients. Discrete stones were visualized in 31 patients and stone debris/sludge in 8 patients. Fluoroscopy-free stone/debris/sludge extraction was successful in all these patients. Brief fluoroscopy was used in 2 patients (5%) to confirm stone clearance. No stone/debris/sludge was noted in 1 patient. Mild pancreatitis was noted in 2 patients (5%) and bleeding in 1 (2.5%).

Conclusions—This study establishes the feasibility of fluoroscopy/radiation-free, cholangioscopic management of non-complex choledocholithiasis, with, success and adverse event rates similar to standard ERCP. DSC represents a significant procedural advance in the

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management of biliary disorders, which need not be confined to the fluoroscopy suite, and can be reimagined as bedside procedures in emergency department or intensive care unit settings.

Keywords

Cholangioscopy; ERCP; Radiation; Fluoroscopy; Choledocholithiasis

Introduction

Endoscopy has evolved to become the predominant imaging and therapeutic modality for the GI lumen, largely replacing radiological contrast studies. The final GI luminal frontiers, where endoscopy is not yet the primary modality for diagnosis and therapy, are the bile and pancreatic ducts. Endoscopic retrograde cholangiopancreatography (ERCP), a hybrid endoscopic/radiological procedure, remains the predominant pancreaticobiliary diagnostic and therapeutic modality.

From the standpoint of endoscopy unit efficiency and safety, a hybrid endoscopic/radiological procedure creates several issues: a separate fluoroscopy room is necessary within the endoscopy unit to perform ERCP, which incurs substantial cost. A full schedule in the fluoroscopy room will result in delays for additional patients needing ERCP, even if other endoscopy rooms have availability, thereby impacting endoscopy unit efficiency and the timely delivery of patient care. Furthermore, fluoroscopy use during ERCP exposes patients and endoscopy room personnel to ionizing radiation, which can have deleterious health consequences.

Although cholangioscopy has been available for decades, technological and logistical issues limited its early adoption.³ A digital version of the cholangioscope (SpyGlassDS™) is now available,⁶ which allows excellent visualization of the bile duct. Cholangioscopy improves ERCP outcomes in the diagnosis of bile duct malignancy by allowing direct visualization and targeted biopsy,^{9, 10} and in the management of large bile duct stones by facilitating lithotripsy.^{3, 11}

Although predominantly used as a complementary technique to ERCP, digital cholangioscopy has now evolved sufficiently that it may finally offer a viable, robust, and purely endoscopic alternative to ERCP, allowing liberation from the fluoroscopy room and from the associated radiation exposure.

Radiation-free-ERCP using cholangioscopy or EUS-based approaches have previously been described by our group and others, for pregnant patients.^{12–14} However, fluoroscopy-based ERCP remains the current standard of care in patients with biliary obstruction due to gallstone disease. Here we present a prospective study evaluating the ability of cholangioscopy to facilitate fluoroscopy-free ERCP in selected patients. We propose that therapy of non-complex bile duct stones should be achievable with direct solitary cholangioscopy (DSC) alone, without the need for fluoroscopy.

Methods

Screening

Patients referred to our tertiary care therapeutic endoscopy service over an 18-month period were screened for inclusion into this study. Those with high suspicion for non-complex bile duct stone disease based on clinical presentation, laboratory studies and noninvasive imaging were selected for enrollment. Pregnant patients, minors, patients with cholangitis, or coagulopathy were excluded from the study. Comprehensive inclusion/exclusion criteria are listed in Supplementary Table 1. The Stanford Institutional Review Board approved this study (Protocol #32194) and the study was registered at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study?term=NCT03074201) (NCT03074201).

Procedure

Study patients underwent cholangioscopy performed by a single endoscopist (S.B.) with the patients under general anesthesia. All ERCPs with cholangioscopy at our institution are performed with the patient under general anesthesia and with antibiotic prophylaxis. Rectal indomethacin (100 mg) was administered to each patient with a native ampulla for post-ERCP pancreatitis prophylaxis.

Our fluoroscopy-free ERCP protocol, depicted in Figure 2, consisted of deep biliary cannulation using a sphincterotome, confirmed by free advancement of a guidewire and by visualization of a bilious aspirate. Advanced cannulation techniques were occasionally used. If the pancreatic duct (PD) was inadvertently cannulated at the first attempt, based on a clear aspirate, either a Goff septotomy was performed, or the guidewire was left in place to define the position for PD entry, thereby facilitating correct orientation for successful bile duct cannulation using the double-wire technique. Needle-knife pre-cut sphincterotomy was limited to visibly impacted stones at the ampulla.

After confirmed biliary cannulation, biliary sphincterotomy was performed, followed by cholangioscopy. Suction was applied after cholangioscope insertion to clear views, followed by minimal gentle biliary insufflation with 0.9% saline solution. The number and location of stones relative to the ampulla were documented and the distance from the ampulla to the bifurcation of the common hepatic duct was measured, to guide subsequent balloon sweeps. The approximate diameter of the bile duct was known from prior non-invasive imaging. The cholangioscope was then withdrawn over a long (450 cm) guidewire and a stone extraction balloon size-matched to the diameter of the bile duct was advanced into the bile duct. This balloon was marked in 1-cm increments and advanced to just below the documented level of the common hepatic duct bifurcation where it was inflated and balloon sweeps were then performed for stone extraction until 2 consecutive sweeps were negative. The number of stones extracted were matched to the number of stones visualized cholangioscopically. Balloon sphincteroplasty was occasionally performed to facilitate extraction of larger stones. For stones that were unexpectedly complex based on size relative to the distal bile duct, electrohydraulic lithotripsy (EHL) was performed. The cholangioscope was then re-advanced into the bile duct to confirm clearance of all stones/fragments from the bile duct.

Postprocedure Follow-up

Patients were called (or evaluated in person if inpatients) the day after the procedure, 1 week, 1 month, and 6 months after the procedure. Any adverse events and need for subsequent biliary interventions were documented.

Analysis

We evaluated patient demographics, biliary cannulation and procedural characteristics including adverse events. Medians and ranges are reported for demographics and procedure parameters.

Results

Over the 18-month period of study enrollment, 1012 ERCPs were performed at our institution. Eighty-five patients with suspected biliary stone disease were screened, 44 patients were excluded as indicated in our study flow diagram (Figure 1) and 41 patients were enrolled. One study patient was subsequently excluded due to severe duodenal bulb stenosis. Of the study group, 70% were female and 65% were inpatients (Table 1). Four patients (10%) were admitted with gallstone pancreatitis.

Procedure Parameters

Thirty-five patients (87.5%) had a native ampulla and 5 patients had undergone prior sphincterotomy. A peri-ampullary diverticulum was present in 3 patients (7.5%) and 5 patients (12.5%) had previously failed biliary cannulation (n=2) or stone extraction (n=3) at an outside institution.

Fluoroscopy-free biliary cannulation was successful in all 40 (100%) study patients. Median cannulation time for all patients was 64 seconds (range 2 seconds – 15.4 minutes) (Table 2). Advanced biliary cannulation techniques including Goff transpancreatic septotomy, double-wire and needle-knife precut sphincterotomy were used in 5 patients (12.5%), with a median cannulation time of 73 seconds (63 seconds – 15.4 minutes) (Table 2). The needle-knife was used in a single patient with an impacted stone at the ampulla. Sphincterotomy was performed in all patients with a native ampulla and additional papillary balloon dilation was performed in 8 patients (20%). EHL was performed in 3 patients (7.5%).

Discrete stones were visualized in 31 patients and stone debris/sludge in 8 patients. Fluoroscopy-free stone/debris/sludge extraction was successful in all of these patients, but limited fluoroscopy (12–24 seconds) was used in 2 patients (5%) after stone extraction to confirm clearance of unexpectedly complex stones, necessitating EHL in 1 patient. No residual stones were evident in either patient. The median number of stones extracted was 2 (0–15 stones). No stones or sludge/debris were visualized in 1 patient.

Procedure Duration

Overall median procedure duration (“scope in” to “scope out”) was 34.1 minutes (Table 2). Median procedure duration for patients undergoing stone extraction using standard techniques was 28.6 minutes (6.5 – 55 minutes), whereas median procedure duration for

patients undergoing EHL or papillary balloon dilation was 52.6 minutes (34.5 minutes – 1 hour 52 minutes) (Table 2). The mean duration of procedures performed on inpatients was 29.1 minutes (6.5 – 67.4 minutes), whereas the mean duration of procedures performed on outpatients was 36.2 minutes (18.4 – 112 minutes).

Adverse Events

Two patients (5%) were noted to have mild pancreatitis after cholangioscopy. Biliary cannulation was achieved in 62 seconds and 170 seconds in these 2 patients, neither of whom required advanced cannulation techniques. The latter patient was believed to have pre-existing gallstone pancreatitis, as a bile duct stone noted on outpatient pre-procedure imaging was not visualized during cholangioscopy, suggesting spontaneous passage. The patient was experiencing abdominal pain before the procedure, which persisted after the procedure and an MRCP scan confirmed absence of the biliary stone and was consistent with mild pancreatitis, with features suggesting evolution over a few days. One patient developed upper gastrointestinal bleeding (2.5%) 18 days after the procedure. An upper endoscopy was performed at an outside institution and a duodenal ulcer was reported to be the source of her bleeding. The total volume of sterile saline solution used for insufflation during cholangioscopy did not correlate with adverse events. None of the patients developed cholangitis or other infectious sequelae.

Postprocedure Follow-up

Median follow-up duration was 10.5 months (2 weeks – 18 months). Upon follow-up assessment, 77% of patients had undergone a subsequent cholecystectomy. One patient with gallstones whose cholecystectomy was delayed developed recurrent symptomatic choledocholithiasis requiring repeat ERCP. Notably, this was one of the two patients in whom fluoroscopy was used after EHL, and biliary stone clearance after DSC had been confirmed.

Discussion

The U.S. per capita annual effective radiation dose from radiological procedures has increased six-fold over the last 3 decades and it is estimated that up to 2% of all cancers in the United States today may be attributable to medical radiation.¹ As the health impact of ionizing radiation have become more apparent, radiation sparing alternatives to ERCP have been explored. This study establishes the feasibility of direct solitary cholangioscopy (DSC) as a fluoroscopy and radiation-free alternative, with success and adverse event rates similar to standard ERCP for the therapy of non-complex bile duct stone disease.

Ultrasound-facilitated approaches for achieving fluoroscopy-free ERCP have been reported by our group and others.^{12–15} In a recent case series, EUS-assisted ERCP was attempted in 31 patients with choledocholithiasis, successfully in 84%.¹⁸ With EUS-based approaches, confirmation of stone clearance from the bile duct without fluoroscopy remains a challenge, but can potentially be performed by repeating EUS again, after the ERCP. However, this would require three sequential procedures (EUS-ERCP-EUS) resulting in a longer overall procedure duration.¹⁸ A potential hazard with the EUS approach is that guidewire

advancement and subsequent balloon sweeps are performed blindly. Although biliary cannulation is confirmed by aspiration of bile, it is conceivable that the guidewire may occasionally advance into a cystic duct and blind balloon inflation may potentially result in ductal rupture and a bile leak. Additional issues with an EUS-based approach include the fact that not all advanced endoscopists performing ERCP are trained in EUS and many hospitals performing ERCP do not have EUS capability.

A cholangioscopy-based approach to fluoroscopy-free ERCP has many advantages. Cholangioscopy does not require additional training in EUS and is within the standard skill set of many therapeutic endoscopists. The platform is small, portable and rapidly deployable in non-fluoroscopy rooms, which are typically smaller. Cholangioscopy allows visual confirmation of guidewire localization in the bile duct rather than in the cystic duct and measurement of distance from the bifurcation to the ampulla, to allow subsequent safe, complete and effective balloon sweeps. Cholangioscopy can also facilitate guide wire advancement into the left or right main hepatic ducts to accomplish extraction of more proximal stones. If unexpectedly complex stone disease is encountered due to stone size or location, EHL can be readily performed. Finally, cholangioscopy is more accurate than cholangiography for identification of persistent choledocholithiasis after presumed stone clearance at ERCP.²⁰

Adverse event rates noted with DSC were not dissimilar to those reported for standard ERCP. This may relate to our selected patient cohort with stone disease only. Our prior work indicated that ERCP along with cholangioscopy was associated with cholangitis/infection in 9.7% of patients.²¹ In contrast, none of the patients in this study developed cholangitis. This may be, in part, because most enrolled patients had native ampullas, with a lower likelihood of bacterial colonization of the bile duct; additionally, prophylactic antibiotics were administered to all patients. Measures to minimize elevation of intrabiliary pressures during cholangioscopy, including the lack of contrast injection, application of suction and limited insufflation with sterile saline solution, may have also contributed.

Limitations include the absence of a comparison group of patients undergoing standard ERCP in this initial feasibility study, and the lack of generalizability to lower volume practices, where outcomes may not be comparable. DSC requires pre-procedural imaging to estimate bile duct diameter and facilitate safe and effective balloon sweeps by matching the extraction balloon size to the bile duct diameter. However, some form of pre-procedural imaging is the standard of care before performing ERCP. Another potential drawback is that unnecessary sphincterotomy may be performed if spontaneous stone passage has occurred before DSC. Standard ERCP with contrast injection might prevent this possibility. However, sphincterotomy and a balloon sweep is commonly performed by many endoscopists for patients at high risk of choledocholithiasis, despite a normal cholangiogram, as cholangiography only has an estimated 90–95% sensitivity for detecting stones.^{20, 22} EUS is performed by some to confirm bile duct stones, to avoid unnecessary ERCP and sphincterotomy. However, EUS has only an estimated 93% sensitivity for detection of choledocholithiasis¹⁹ and bile duct stones could potentially remain unaddressed, using this approach. The risk of an unnecessary sphincterotomy during DSC can be minimized by reducing the interval between presentation of symptomatic patients and performing the

procedure. The cost of DSC is also a potential limitation. However, the portability of DSC may in the future allow it to be performed at bedside in the emergency department for patients with choledocholithiasis. This may accelerate the delivery of endoscopic care and result in fewer hospital admissions, thereby offsetting the cost of cholangioscopy.

Prior studies evaluating ultrasound-based approaches to radiation-free ERCP have had restrictive inclusion criteria, with study populations curated to exclude patients with >3 stones, and those with potentially difficult cannulations. In our study, we attempted to keep enrollment criteria broad and as “real world” as possible. We therefore included patients with peri-ampullary diverticula, patients referred after failed ERCP at other institutions, and unexpectedly complex patients requiring advanced cannulation or stone extraction techniques. Outcomes in these complex patients were still favorable.

The psychological hurdles of modifying conventional procedure routines and the initial anxiety associated with performing stone extraction without the security and additional dimension provided by fluoroscopy, will need to be overcome for the widespread adoption of DSC. Similar challenges arose during the transition from barium contrast studies to direct luminal visualization with endoscopes, when strong concerns regarding the safety and accuracy of endoscopy were raised.^{23–25} Further evolution of DSC as a viable alternative to standard ERCP will be facilitated by additional cholangioscope-compatible accessory devices, already in production, and by further development of cholangioscopes. This shift toward radiation-free interventions for certain biliary disorders may mark the dawn of a new age in which biliary procedures are performed at bedside for patients ranging from those who are hemodynamically unstable in the intensive care unit to those who present to the emergency department with choledocholithiasis.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Acronyms

ERCP	Endoscopic Retrograde Cholangio-pancreatography
DSC	Direct Solitary Cholangioscopy
ICU	Intensive Care Unit
GI	Gastrointestinal
U.S	United States
PD	Pancreatic Duct

MD	Medical Doctor
EHL	Electrohydraulic lithotripsy
MRCP	Magnetic Resonance Cholangiopancreatography
EUS	Endoscopic Ultrasound

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Figure 1.
Flow diagram for patients presenting with choledocholithiasis over the 18-month period of study enrollment.

Figure 2.
Depiction and description of key procedural steps in the performance of direct solitary cholangioscopy.

Table 1

Demographics

Patient characteristics	
Age	Median: 51.5 years (24–87 years)
Gender	12 male (30%), 28 female (70%)
Hospitalization status	14 outpatients (35%), 26 inpatients (65%)
Follow-up duration	Median: 10.5 months (2 weeks – 18 months)

Table 2

Procedure Parameters

Procedure Parameter	N(%)	Median	Range
Cannulation time			
All patients	40	64 seconds	2 seconds – 15.4 minutes
Standard cannulation techniques	35 (87.5%)	61 seconds	2 seconds – 11.8 minutes
Advanced cannulation techniques	5(12.5%)	73 seconds	63 seconds – 15.4 minutes
Procedure duration			
All patients	40	34.1 minutes	6.5 minutes – 1 hour 52 minutes
Standard stone extraction techniques	33 (82.5%)	28.6 minutes	6.5 minutes – 55 minutes
Advanced stone extraction techniques	8 (20%)	52.6 minutes	34.5 minutes – 1 hour 52 minutes
Cholangioscopy duration	40	9.5 minutes	3.05 – 58.3 minutes
Number of stones extracted	40	2 stones	0 – 15 stones
Saline volume insufflated during cholangioscopy	40	90 mL	70 – 800 mL

Table 3

Adverse Events

Adverse Event	# Patients (%)
Mild Pancreatitis	2 (5%)
Moderate/Severe Pancreatitis	0 (0%)
Bleeding	1 (2.5%)
Cholangitis	0 (0%)
Perforation	0 (0%)
Death	0 (0%)