



Digestive Endoscopy

Endoscopic retrograde cholangiopancreatography complications in the era of cholangioscopy: Is there an increased risk?

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ABSTRACT

Background: Single-operator cholangioscopy allows direct visualization of the biliary tree and is being used in the diagnosis and treatment of various biliary conditions. To date, there are few data examining complications of single-operator cholangioscopy.

Methods: We evaluated all endoscopic retrograde cholangiopancreatography procedures over a two-year period and compared its complication rate to single-operator cholangioscopy in a tertiary care centre with extensive experience in single-operator cholangioscopy.

A total of 2087 patients (55% men, mean age 57.4 ± 16.4) had a therapeutic endoscopic retrograde cholangiopancreatography, out of which 169 also had single-operator cholangioscopy performed on them.

Results: 169 single-operator cholangioscopy procedures were performed (53% men) with a mean patient age of 60.7 ± 15.2 years. Out of the 2087 patients, 160 complications occurred (7.7%), and included pancreatitis ($n = 47$, 2.2%), infection ($n = 24$, 1.1%), bleeding ($n = 44$, 2.1%), perforation ($n = 16$, 0.8%) and other ($n = 29$, 1.4%). Univariate analysis on overall complications identified seven variables with a p value < 0.2 , which were included in the multivariate analysis. Biliary sphincterotomy, pancreatic duct stent placement, and ampullectomy were associated with increased complications. Single-operator cholangioscopy was not associated with increased complications on multivariate analysis.

Conclusion: Single-operator cholangioscopy is not associated with an increased rate of complications when compared to endoscopic retrograde cholangiopancreatography. The types and frequencies of overall endoscopic retrograde cholangiopancreatography complications are similar to previously reported series.

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1. Introduction

The diagnosis and treatment of biliary disorders can be challenging. Biliary strictures may arise from a variety of benign and malignant conditions that can mimic one another both clinically and radiographically [1,2]. In difficult or indeterminate cases, direct visualization of the biliary tract with cholangioscopy may augment conventional endoscopic retrograde cholangiopancreatography (ERCP) by providing the capability to visually direct biopsies and to evaluate epithelial abnormalities [3]. In addition to its diagnostic role, cholangioscopy has been used to extract of large or difficult calculi, to guide ablation of malignant intraductal

obstructions, and to assist in locating and crossing difficult strictures and the cystic duct [4–6].

Cholangioscopy uses a flexible fibre optic cholangioscope that is passed through the working channel of a standard side-viewing duodenoscope directly into the biliary system. The technique was first introduced in the 1970s; however, the routine use of “mother-baby-scope” system is limited by its high cost and technological shortcomings, including the need for two endoscopists. A recently developed and more affordable single-operator cholangioscopy (SOC) system (SpyGlass Direct Visualization System, Boston Scientific Corporation, Natick, MA), with tip maneuverability and lens irrigation has been added to our arsenal. Though not far since its inception, initial reports with SOC are promising [7–9].

Complications arising from ERCP include pancreatitis, perforation, bleeding and infection, and have been previously well described [10–14]. To date, only two studies have evaluated complications related to ERCP with cholangioscopy. The first study from Sethi et al., demonstrated significantly more overall

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complications and episodes of cholangitis in the group undergoing cholangioscopy [15]; however, a majority (>90%) of cases in this study were performed with the mother–baby system. A recent study from Draganov et al. using exclusively the SOC system did not confirm these findings [9]. Herein, we review our experience with therapeutic ERCP and SOC over a two-year period to determine the nature and frequency of complications, and to identify procedural and clinical correlates that may predict their occurrence.

2. Patients and methods

2.1. Study design

All consecutive patients undergoing therapeutic ERCP between August 2007 and September 2009 were evaluated in this study. The study population was derived from a previously established electronic database of ERCP procedures performed at our institution. ERCPs were considered therapeutic when more than a diagnostic cholangiogram/pancreatogram was performed. The database is prospectively maintained by our endoscopy department. Immediate procedural complications are recorded at the time of occurrence based on physician reporting. Delayed complications were added via physician reporting and confirmed after extensive retrospective chart review of all procedures. For the retrospective chart review, each ERCP case was reviewed via medical records to detect previously unidentified complications within 30 days of the procedure (SH, MC, AP, IS). The chart review included identification of emergency room visits, hospitalizations, or clinic visits within 30 days that could be procedure-related. The subsequent clinic visit (>30 days) was also reviewed for any mention of medical care locally that may not have been captured in the medical records at our institution. Where appropriate, labs (haematocrit and amylase) were reviewed for evaluation of bleeding and post-ERCP pancreatitis. Any possible complication was logged. Thereafter, further review of every possible complication was performed by two more experienced clinician (CH, BS) for final determination of a complication based on the definitions below while the main operator was blinded (MK). Institutional review board approval was obtained.

2.2. Definition of complications

An ERCP complication was defined as any event that occurred during the 30-day period following the procedure that negatively affected the health status of the patient for any length of time. Consensus criterion was used for defining complications [16] including pancreatitis, bleeding, and infection. Pancreatitis was defined by the presence of abdominal pain within 24–48 h of the procedure and a 3-fold or higher increase in the serum lipase. Bleeding was defined by clinical evidence of blood loss (not solely endoscopic evidence), a decrease in haemoglobin greater than 2 g/dL, need for blood transfusion, and/or need for angiographic, endoscopic or surgical intervention. Infection was defined by a fever of greater than 38 °C at 24–48 h with or without a concomitant leukocytosis. All other complications were recorded in our database if they required a visit to the emergency room, inpatient hospital admission or resulted in the prolongation of a current admission.

2.3. Procedures

All therapeutic ERCP procedures were performed by dedicated pancreaticobiliary specialists at our institution with the assistance of an endoscopy nurse and a gastroenterology fellow who usually performed part of the case. All procedures used Olympus duodenoscopes (TJF160F, TJF 160VF, Olympus, America, Center Valley, PA) and had patients in the supine position under general endotracheal anaesthesia. If not previously performed, a biliary sphincterotomy

was affected prior to SOC. All SOC were performed using the Spy-Glass system (Boston Scientific, Natick, MA) by a single endoscopist (MK). All ERCPs were performed using short wires, however this was exchanged for a long wire if a SOC was done. Antibiotics were not given routinely before SOC. Indications for SOC included evaluating indeterminate biliary lesions, guiding photodynamic therapy (PDT), and aiding in removal of large or difficult stones (with or without holmium laser lithotripsy).

2.4. Statistical analysis

Patient characteristics and complications between the two groups (ERCP versus ERCP+SOC) were compared using the Student's *t*-test for continuous variables, a chi-square test for categorical variables, and a Fisher's exact test for categorical variables with infrequent occurrences. Clinically relevant risk factors for complications were analyzed in a univariate model to identify independent predictors for the development of overall ERCP complications. Based on univariate analysis, factors with a *p* value < 0.20 were included in a multivariate analysis. Odds ratios and 95% confidence intervals were calculated. All *p* values were two-sided, and a *p* value of 0.05 or less was considered statistically significant. Statistical analysis was conducted using SAS version 9.2 (SAS Institute, Inc, Cary, NC, USA).

3. Results

A total of 2087 consecutive patients (55% men) had a therapeutic ERCP at our institution from August 2007 until September 2009. The mean age was 57.4 ± 16.4 years and 509 patients (24%) were aged 70 or older. Ninety-one percent of patients had their procedures performed as an outpatient, and most were ASA class II or III (91%). Nine-hundred and nineteen patients (44%) had a previous ERCP. A total of 169 SOC procedures were performed (53% men) with a mean patient age of 60.7 ± 15.2 years. Baseline clinical and procedural characteristics are shown in Table 1. Those undergoing SOC were more likely to be >70 year old, outpatients, and to have had a prior ERCP procedure (Table 1).

One hundred sixty total complications occurred (7.7%) and included pancreatitis (*n* = 47, 2.2%), bleeding (*n* = 44, 2.1%), infection (*n* = 24, 1.1%), and perforation (*n* = 16, 0.8%). In 4 patients, infection was mild, requiring admission, the other 20 presented with fever managed in the ambulatory setting with PO antibiotics.

There were 29 (1.4%) additional complications including abdominal pain with normal lipase (*n* = 14), cardiopulmonary complications (*n* = 8), gallbladder wire perforation (*n* = 1), cystic duct leak (*n* = 1), intrahepatic duct leak (*n* = 1) and death within 30 days (*n* = 4). The cystic duct and intrahepatic duct leaks were both treated with biliary stenting and resolved. The cardiopulmonary complications included severe hypertension (*n* = 2), inability to extubate immediately following the procedure (*n* = 3), PEA arrest within 1 week (*n* = 2) and air embolism (*n* = 1). The four deaths were secondary to peritonitis (10 days after procedure), PEA arrest, intracranial bleed, and sepsis. None of these were thought to be directly related to the procedure.

When complications between ERCP versus ERCP+SOC were compared, there were significantly more bleeding complications in the ERCP alone group. No statistically significant difference was found in pancreatitis, infection, perforation, or other complications between the two groups (Table 2).

Pancreatic duct (PD) stenting was separated into prophylactic PD stenting (5 French) and therapeutic PD stenting (7 or 10 French PD stents placed for pancreatic strictures, stones, or leaks). Two hundred fourteen therapeutic PD stents were placed and 30 complications were encountered including abdominal pain (with normal

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