

# New approach to decrease post-ERCP adverse events in patients with primary sclerosing cholangitis



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## ABSTRACT

**Background and study aims** Endoscopic retrograde cholangiopancreatography (ERCP) is often performed in patients with primary sclerosing cholangitis (PSC). Our aim was to validate a treatment approach with the objective of decreasing ERCP related adverse events (AEs).

**Patients and methods** All patients who had undergone ERCP for PSC during the period from 2002–2012 were identified (group I). This group had traditional ERCP (no bile aspiration prior to contrast injection with balloon dilation and stent placement for treatment of dominant strictures). To decrease ERCP-related AEs, we changed the ERCP approach in which bile aspiration was performed prior to contrast injection and balloon dilation alone was performed for treatment of dominant strictures. This was tested prospectively in all patients undergoing ERCP for PSC from 2012–2014 (group II).

**Results** The risk of overall AEs and cholangitis was relatively less in group II compared with group I [(2.1% vs. 10.3%;  $P=.38$ ) and (0% vs. 4.4%;  $P=.68$ )]. On bivariate analysis, change in ERCP approach was associated with decreased risk of post-procedure cholangitis (0% vs. 10.2%,  $P=.03$ ) and overall AE (0% vs. 18.6%,  $P=.03$ ). There were no AEs in 22/46 patients in group II who had bile aspiration with balloon dilation. On multivariate analysis, only biliary stent placement was associated with increased risk of AEs (OR 4.10 (1.32–12.71);  $P=.02$ ) and cholangitis (OR 5.43, 1.38–21.38;  $P=.02$ ) respectively.

**Conclusion** Biliary aspiration and avoidance of stenting approach after dilation of strictures during ERCP in PSC patients appears to be associated with decreased risk of cholangitis and overall AEs. Future prospective randomized controlled trials are needed to validate our observation.

## Introduction

Primary sclerosing cholangitis (PSC) is a chronic inflammatory and cholestatic disorder of the intra- and extra-hepatic bile ducts, closely associated with inflammatory bowel disease (IBD) [1–4]. Dominant strictures develop in 45% to 58% of PSC patients and it is characterized by a stenosis  $\leq 1.5$  mm in the common bile duct or  $\leq 1$  mm in the hepatic ducts. Treatment of a dominant stricture with balloon dilation alone or balloon dilation with stent placement is attempted to provide biliary drainage and to reduce symptoms. In the presence of a dominant stricture, the suspicion for cholangiocarcinoma (CCA) is high and the distinction between CCA and benign in-

flammatory stricture is often difficult. ERCP with brush cytology and/or biopsy in combination with fluorescence in situ hybridization (FISH) provides additional diagnostic yield in such cases. Since patients with PSC undergo repeated ERCP examinations and have stenotic and narrow bile ducts, they may be at risk for development of ERCP-related adverse events (AEs), in particular bacterial cholangitis. Rates of post-ERCP AEs vary widely between studies ranging from 2.5% to 14% [5–9]. Some studies have shown that ERCP is associated with increased risk of AEs in patients with PSC when compared to non-PSC patients [6–10].

In our earlier study, although the overall risk of post-ERCP AEs was low at 4.3%, cholangitis was the most common AE [9].

With the increased frequency of ERCP performed in PSC patients for surveillance, factors that could potentially reduce the procedure related AEs need to be determined. We hypothesized that biliary aspiration prior to contrast indication during ERCP may reduce the pressure in the biliary system and thus decrease the overall AE rate, particularly the risk of cholangitis in patients with PSC. We also hypothesized that avoiding biliary stent placement after dilation of dominant bile duct strictures in PSC may lead to a decrease in cholangitis risk mainly due to elimination of stent dysfunction risk.

Based on these observations, we changed our ERCP approach in which bile aspiration was performed prior to contrast injection in all patients undergoing ERCP for PSC. Also, dominant strictures were treated with balloon dilation alone without stent placement. Our aim was to validate this approach to ERCP interventions in PSC patients with the objective of decreasing AEs.

## Patients and methods

All consecutive patients with PSC who underwent ERCP from 2002 to 2012 at Cleveland Clinic were retrospectively analyzed using the electronic medical records database. A total of 156 patients were included in this group. For the purpose of discussion, we will consider this as group I.

The second group of patients were prospectively recruited from 2012–2014, in which routine bile aspiration (3–5 ml of bile) prior to contrast injection during ERCP was performed. Also, if a dominant stricture was identified, balloon dilation alone was performed without placement of a biliary stent. This constituted the second group (46 patients), which for the purpose of discussion, we will consider as group II. In group II, all patients with inadvertent pancreatic duct cannulations received rectal indomethacin for prophylaxis against post-ERCP pancreatitis (PEP). If patients received multiple ERCPs, the first ERCP at our institution was included in our study.

### Inclusion and exclusion criteria

All patients with PSC >18 years of age, who underwent ERCP were included in the study. Patients who had undergone liver transplantation or hepatico-jejunostomy and those with active cholangitis prior to the procedure were excluded from the study.

### ERCP procedures

In group 1, according to our usual ERCP protocol, wire-guided cannulation of the bile duct was accomplished using a sphincterotome and guidewire or extraction balloon and guidewire. Needle knife sphincterotomy was used if access could not be obtained by standard cannulation equipment. Inadvertent cannulation or injection of the pancreatic duct was followed by placement of a prophylactic pancreatic stent to reduce the risk of pancreatitis. Dominant strictures were dilated with a dilating balloon followed by stenting which was removed after 2 weeks. Patients were sent home with 5 days of antibiotics following the procedure to prevent cholangitis. All patients received prophylactic intravenous antibiotics during the procedure. Brush cy-

tology specimens were collected prior to dilation for cytology and/or FISH if a dominant stricture was encountered. FISH was only used during the last year of the study period (2012). Our traditional approach for cannulation in our institution is dye-free guidewire cannulation. ERCP procedures were performed by experienced interventional endoscopists using standard endoscopic equipment. All the endoscopists performing ERCP in our study had performed a minimum of 1000 ERCPs prior to the study and had an annual ERCP volume of 400 procedures.

In group II, bile aspiration was performed immediately after biliary cannulation and prior to contrast injection. The other change we instituted was that biliary stents were not placed after balloon dilation of dominant biliary strictures. The ERCP technique did not change during the study period. Data were prospectively collected on therapeutic procedures during ERCP such as sphincterotomy (both biliary and pancreatic), presence of dominant stricture, stricture dilation, biliary and pancreatic stent placement, biliary stone extraction.

Our earlier publication discussed the prospectively maintained database of bile obtained during ERCP [11, 12]. The database was established in 2012 and includes bile samples linked to demographic, clinical, and cholangiographic information. The study was approved by the Cleveland Clinic Institutional Review Board registered with the National Institute of Health (NIH) clinical trial registry. (NCT01565460).

### Adverse events

Post-ERCP AEs were defined based on the ASGE workshop [13]. AEs was recorded up to 30 days following the procedure. PEP was defined as onset of new abdominal pain and three fold elevation in serum amylase and/or lipase 24 hours after the procedure up to 2 weeks. Cholangitis was defined as presence of fever, leukocytosis or positive blood cultures requiring intravenous antibiotics within 14 days after ERCP. Bleeding was defined as clinical evidence of hemorrhage with a decrease in hemoglobin greater than 2 g/dL and/or the need for endoscopic or other methods of obtaining hemostasis within 14 days after ERCP. Perforation was defined as extravasation of contrast or presence of peritoneal or retroperitoneal free air on imaging after the procedure. The timing of the AE was recorded.

### Outcome measures

The primary outcome measure was to compare rates of AEs and in particular cholangitis between the groups. Our secondary outcome measure was to investigate the risk factors predicting the 30-day AEs specifically whether incorporation of a change in our approach (bile aspiration and balloon dilation without stent placement) impacted the overall risk of cholangitis and overall AEs.

### Statistical analysis

Descriptive statistics were computed for all factors. These include medians, 25th and 75th percentiles, range or mean and standard deviation for continuous factors and frequencies and percentages for categorical factors. Baseline patient characteristics, procedure outcomes, and AEs were calculated for groups I and II.

► **Table 1** Comparison of demographic, clinical and procedure characteristics between the two groups.

Variable	Group I (n=156)	Group II (n=46)	P value
<b>Demographic and patient characteristics</b>			
Gender (%)			0.32
▪ Female	52 (33.3)	19 (41.3)	
▪ Male	104 (66.7)	27 (58.7)	
Race (%)			0.23
▪ White	128 (82.1)	36 (78.3)	
▪ Black	15 (9.6)	7 (15.2)	
▪ Other	3 (1.9)	1 (2.2)	
Age at diagnosis, mean (SD), years	40.65 (14.7)	44.8 (19.8)	0.12
Age at ERCP, mean (SD), years	43.77 (18.9)	54.96 (15.8)	<0.001
BMI, mean (SD)	28.13 (12.9)	25.48 (5.7)	0.18
<b>Disease Characteristics</b>			
Location of PSC at diagnosis (%)			0.001
▪ IHD	37 (23.7)	24 (52.2)	
▪ EHD	7 (4.5)	3 (6.5)	
▪ IHD + EHD	60 (38.5)	7 (15.2)	
Dominant stricture at diagnosis (%)			0.07
▪ No	94 (60.3)	35 (76.1)	
▪ Yes	36 (23.1)	11 (23.9)	
Mayo risk score, mean (SD)	1.15 (1.5)	-0.13 (8.3)	0.07
PSC Severity (%)			0.05
▪ Mild	32 (20.5)	16 (34.8)	
▪ Moderate	81 (51.9)	15 (32.6)	
▪ Severe	43 (27.6)	15 (32.6)	
Bilirubin, mean (SD)	3.97 (5.5)	1.99 (4.2)	0.02
<b>Procedural characteristics</b>			
Primary cannulation (%)			0.06
▪ Success	142 (91.0)	44 (95.7)	
▪ Failed	12 (7.6)	2 (4.3)	
Precut with needle knife (%)			0.59
▪ Not done	143 (91.7)	44 (95.7)	
▪ Done	11 (7.1)	2 (4.4)	
Biliary sphincterotomy (%)			0.60
▪ Not done	75 (48.1)	19 (41.3)	
▪ Done	38 (24.4)	11 (23.9)	
▪ Prior Sphincterotomy	41 (26.3)	16 (34.8)	
Pancreatic sphincterotomy (%)			0.74
▪ Not done	149 (95.5)	44 (95.6)	
▪ Done	4 (2.6)	2 (4.4)	
▪ Prior Sphincterotomy	1 (0.6)	0 (0)	

► **Table 1** (Continuation)

Variable	Group I (n=156)	Group II (n=46)	P value
Accidental passes into pancreatic duct (%)			0.52
▪ No	138 (88.5)	44 (95.6)	
▪ Yes	15 (9.6)	2 (4.4)	
Contrast inject into pancreatic duct (%)			0.41
▪ No	127 (81.4)	41 (89.1)	
▪ Yes	27 (17.3)	5 (10.9)	
Brushings (%)			0.49
▪ No	72 (46.2)	25 (54.3)	
▪ Yes	82 (52.6)	21 (45.7)	
Biliary stent placement (%)			0.001
▪ No	73 (46.8)	22 (100)	
▪ Yes	83 (53.2)	0 (0)	
<b>Adverse events (%)</b>			0.31
▪ No adverse event	140 (89.7)	45 (97.8)	
▪ Post-ERCP pancreatitis	5 (3.2)	1 (2.2)	
▪ Cholangitis	7 (4.5)	0 (0)	
▪ Bleeding	4 (2.6)	0 (0)	
Post-ERCP pancreatitis/cholangitis (%)			0.18
▪ No	144 (92.3)	45 (97.8)	
▪ Yes	12 (7.7)	1 (2.2)	

SD, standard deviation; BMI, body mass index; IHD, intrahepatic distribution; EHD, extrahepatic distribution; PEP, post-ERCP pancreatitis

Logistic regression models were constructed by including variables that had significant univariable associations with post-ERCP AEs, and then performing backward stepwise selection with a removal criterion of  $P > 0.05$ . R 2.10.1 software (The R Foundation for Statistical Computing, Vienna, Austria) was used to perform all analyses.

## Results

### Baseline and procedural characteristics

A total of 202 consecutive patients with PSC underwent ERCP during the study period from 2002–2014. The baseline, procedural characteristics and outcomes of 156 patients in group I (2002–2012) and 46 patients in group II (2012–2014) were analyzed. The demographic, clinical and procedural characteristics between the two groups are shown in ► **Table 1**. The mean age of the patients undergoing ERCP in group II was significantly higher at 54.9 years when compared to 43.7 years in group I ( $P < 0.001$ ). The other basic demographic characteristics were not significantly different between the patient groups. Primary cannulation was achieved in 91% (142/156) and 95.6% (44/46) in groups I and II respectively. Dye-free guidewire cannulation was successfully performed in 138/142

(97.2%) and 43/44 (97.7%) in groups I and II respectively. For those who failed primary cannulation, pre-cut sphincterotomy with needle knife was performed to achieve access. The distribution of PSC was predominantly intrahepatic in group II and extrahepatic in group I at diagnosis. ( $P = 0.001$ ). However, most of the procedural characteristics did not significantly differ between the two groups. There was no difference in the number of patients with native papillae in group I and group II (26.3% vs. 34.8%,  $P = 0.60$ ) respectively. Biliary sphincterotomy was done in 24.3% (38/156) in group I and 23.9% (11/46) in group II. Dominant strictures were found in 23% (36/156) in group I and 23.9% (11/46) in group II. Bile duct brushings for cytology was performed in 52.5% (82/156) and 45.6% (21/46) in groups I and II respectively. Biliary stents were placed in 53.2% (83/156) in group I and none in group II.

### Adverse events

The overall AE rates were 10.3% (16/156) in group I and 2.1% (1/46) in group II. There was no case of cholangitis in group II as opposed to 7 (4.4%) in group I. There were 5 (3.2%) cases of post-ERCP pancreatitis in group I versus 1 (2.1%) in group II. All patients with post-ERCP pancreatitis were managed conservatively; none requiring admission to the intensive care unit.

► **Table 2** Univariate Analysis for development of any post-procedure adverse event.

Characteristic	Adverse event		P Value
	No (n = 185)	Yes (n = 17)	
Gender (%)			0.99
▪ Female	65 (35.1)	6 (35.3)	
▪ Male	120 (64.9)	11 (64.7)	
Age at diagnosis, mean (SD), yrs	41.6 (16.2)	41.5 (14.8)	0.97
Age at ERCP, mean (SD), yrs	46.2 (19.1)	47.5 (15.6)	0.78
BMI, mean (SD)	27.7 (12.0)	25.9 (6.9)	0.54
Smoker (%)			0.87
▪ Never smoker	143 (77.3)	12 (70.6)	
▪ Smoker	7 (3.8)	1 (5.9)	
▪ Former smoker	33 (17.8)	4 (23.5)	
Alcohol (%)			0.89
▪ Never	159 (85.9)	15 (88.2)	
▪ Yes	17 (9.2)	1 (5.9)	
▪ Former drinker	5 (2.7)	1 (5.9)	
Location of PSC at diagnosis (%)			0.51
▪ IHD	57 (30.8)	4 (23.5)	
▪ EHD	10 (5.4)	0 (0)	
▪ IHD + EHD	59 (31.9)	8 (47.1)	
Dominant strictures			0.18
▪ No	121 (65.4)	8 (47.1)	
▪ Yes	40 (21.6)	7 (41.2)	
PSC severity (%)			0.33
▪ Mild	45 (24.3)	3 (17.7)	
▪ Moderate	85 (45.9)	11 (64.7)	
▪ Severe	55 (29.7)	3 (17.7)	
Mayo risk score, mean (SD)	0.9 (4.3)	0.9 (1.3)	0.92
Bilirubin, mean (SD), mg/dl	3.4 (5.1)	5.4 (6.7)	0.13
Precut with needle knife (%)	10 (5.4)	3 (17.7)	0.13
Biliary sphincterotomy (%)			0.02
▪ Done	40 (21.6)	9 (52.9)	
▪ Prior sphincterotomy	56 (30.3)	1 (5.9)	
Pancreatic sphincterotomy (%)	3 (1.6)	3 (17.7)	0.003
Accidental passes into pancreatic duct (%)	13 (7.0)	4 (23.5)	0.001
Contrast injection into pancreatic duct (%)			0.07
▪ No	157 (84.9)	11 (64.7)	
▪ Yes	26 (14.1)	6 (35.3)	

► **Table 2** (Continuation)

Characteristic	Adverse event		P Value
	No (n = 185)	Yes (n = 17)	
Brushings (%)			0.90
▪ No	89 (48.1)	8 (47.1)	
▪ Yes	94 (50.8)	9 (52.9)	
Biliary stent placement (%)			0.0001
▪ No	102 (55.1)	17 (100)	
▪ Yes	83 (44.9)	0 (0)	

Bleeding was reported in 4 (2.5%) patients in group I, compared to none in group II. There were no cases of perforation or procedure-related mortality.

Among the 46 patients in group II, 22 patients had aspiration and dilation of stricture without stent placement, while the remaining 24 patients had aspiration alone. Dominant strictures were seen in 11 patients, while the remaining patients had strictures from PSC. There were no adverse events in the 22 patients who had aspiration with dilation, while 1 of the remaining 24 patients developed post-ERCP pancreatitis.

In patients with acute cholangitis, the mean time to occurrence of cholangitis following ERCP was 5.1 days. The mean length of stay for cholangitis was 7.4 days. Among the 7 patients with cholangitis in group I, 6 patients had biliary stent placement following dilation of dominant biliary strictures. Among the 6 patients, only 1 patient required ERCP which was performed 11 days after the initial procedure with stent clogging. The remaining patients were treated with intravenous antibiotics with clinical improvement. Among the 6 patients with PEP, the mean time to develop pancreatitis was 1.6 days following the procedure. The mean length of stay of 6.6 days. Four patients developed procedure related bleeding; only one of whom required admission to the hospital for blood transfusion.

## Post-ERCP AEs

### Univariate analysis

► **Table 2** summarizes factors associated with development of any post-ERCP AE. Age and gender did not influence the rate of AEs in this study. Biliary sphincterotomy, pancreatic sphincterotomy, accidental wire passage into the pancreatic duct, and biliary stent placement were associated with increased risk of AEs. Aspiration alone did not impact the risk of AEs.

### Multivariate analysis

On bivariate analysis, a change in ERCP approach was associated with decreased risk of overall AE (0% vs. 18.6%,  $P = .03$ ).

► **Table 3** summarizes the factors associated with development of any post-ERCP AE. On multivariate analysis, biliary stent placement (OR 4.10 (1.32 – 12.71);  $P = .02$ ) was associated with

► **Table 3** Adjusted odds ratios of each factor on any post-procedure adverse events on multivariate logistic regression analysis.

Variable	Odds ratio (95% CI)	P value
Biliary aspiration	0.18 (0.02 – 1.43)	0.10
Presence of dominant stricture	0.90 (0.16 – 5.04)	0.91
Biliary stent placement	4.10 (1.32 – 12.71)	0.02
PSC Severity		
▪ Mild	1*	
▪ Moderate	1.95 (0.48 – 7.82)	0.35
▪ Severe	1.12 (0.19 – 6.42)	0.89

PSC, primary sclerosing cholangitis

\* Because all patients receiving the treatment approach had no adverse event, its effect could not be evaluated in multivariate logistic regression.

► **Table 4** Adjusted odds ratios of each factor on post-procedure cholangitis on multivariate logistic regression analysis.

Variable	Odds ratio (95% CI)	P value
Biliary Aspiration	0.22 (0.03 – 1.84)	0.16
Presence of dominant stricture	2.32 (0.67 – 8.04)	0.18
Biliary stent placement	5.43 (1.38 – 21.38)	0.02
PSC Severity		
▪ Mild	1*	
▪ Moderate	1.39 (0.33 – 5.91)	0.66
▪ Severe	0.84 (0.12 – 5.83)	0.86

PSC, primary sclerosing cholangitis

\* Because all patients receiving the treatment approach had no adverse event, its effect could not be evaluated in multivariate logistic regression.

increased risk of AEs. Bile aspiration prior to contrast injection did not impact the overall risk. (OR 0.18 (0.02–1.43);  $P=.10$ ).

## Cholangitis

On bivariate analysis, a change in ERCP approach was associated with decreased risk of cholangitis (0% vs. 10.2%,  $P=.02$ ). ► **Table 4** summarizes factors associated with development of post-ERCP cholangitis. On multivariate analysis, only biliary stent placement (OR 5.43, 1.38–21.38;  $P=.02$ ) was associated with increased risk of post procedure bacterial cholangitis. The independent effect of the change in ERCP approach could not be investigated on multivariate analysis for both cholangitis or other AEs as there were no patients with cholangitis or other AE.

## Discussion

PSC is a chronic progressive inflammatory disorder of intrahepatic and extrahepatic bile ducts. The disease course is characterized by the development of clinically significant biliary strictures, cholangitis, and/or CCA necessitating multiple endoscopic biliary interventions. Use of endoscopic interventions may improve survival and postpone the need for liver transplantation [14, 15]. In this study, we changed the ERCP approach in PSC patients by performing biliary aspiration prior to contrast injection and avoiding biliary stent placement and studied its impact on post-ERCP AEs in patients with PSC. We observed that this change in approach during ERCP in PSC patients was associated with a decreased risk of cholangitis and overall AEs. Biliary stent placement increased the risk of AEs.

ERCP AEs are associated with significant health care expenditure in the United States [16, 17]. Our study was aimed to propose approaches to decrease the overall risk of AEs in patients with PSC. PSC patients are at increased risk for developing cholangitis, particularly after ERCP [8–10]. In a study from Mayo clinic, cholangitis was found to occur at a significantly higher rate in PSC patients undergoing ERCP when compared to non-PSC patients (3.6% vs. 0.2%), with a direct correlation between the length of the procedure and the rate of cholangitis [8]. Other studies also have demonstrated the increased risk of ERCP AEs in PSC patients, particularly cholangitis in the context of complex biliary cannulation [6, 7, 15]. The anatomy of the bile ducts with multiple strictures and poor biliary drainage, the duration and complexity of the procedure are the possible factors that additionally increase the risk of AEs. We hypothesized that biliary aspiration during ERCP would decrease the pressure within the biliary system and reduce the AE rates, especially the risk of bacterial cholangitis in PSC patients. Indeed in this study, the group of patients who underwent bile aspiration prior to contrast injection had lower rates of AEs. Of particular interest, no episode of post-ERCP cholangitis was observed in any of these patients while the rate of post-ERCP cholangitis in the traditional group approached 4.5%.

Although cholangitis is not as common as pancreatitis following ERCP, the fatality rate associated with infections is higher than pancreatitis [5]. Dominant strictures in PSC are associated with increased risk of bile stasis, and warrant repeated endoscopic therapy with endoscopic balloon dilation for im-

proved outcomes. In the presence of dominant strictures, short term stenting (less than 11 days) and endoscopic balloon dilation alone without stenting have been found to be associated with decreased risk of cholangitis [18, 19]. In our study, we observed that incidence of cholangitis was 4.4% in group I. Given the increased risk of cholangitis, we changed our ERCP approach by aspirating bile and avoiding stent placement. With this approach, none of the patients in group II had cholangitis. Institution of the new approach with bile aspiration prior to contrast injection could be the reason for the absence of cholangitis. In fact, recommendations from the American Association of Liver Disease (AASLD) do not endorse stenting, since there is no strong evidence demonstrating additional benefit of stenting over endoscopic dilatation. Stenting should be reserved for strictures that are refractory to dilatation [20].

PEP is a common AE of ERCP. In the largest series of ERCP in PSC patients from Finland, the rate of PEP was 9.0% [7]. In our study PEP rate was 3.2% and 2.1% in group 1 and 2 respectively which is comparatively lower than the other studies. Prophylactic pancreatic stent placement and rectal nonsteroidal anti-inflammatory drugs were routinely used in patients in group II and pancreatic stent was routinely used in group I which could explain the low rates of PEP [21, 22]. Biliary sphincterotomy, inadvertent pancreatic duct injection or guidewire passage, prior history of PEP and difficult cannulation has been proposed as risk factors for PEP [11, 23–29]. In our study, biliary or pancreatic sphincterotomy did not significantly increase the risk of ERCP AEs. Although, these factors were significant on univariate analysis, the factors became insignificant on multivariate analysis because of low number of AEs.

There are several limitations to this study including a heterogeneous patient population undergoing ERCP procedures over a 13-year period. Although statistically not significant, there was a trend towards a higher Mayo PSC risk score in group 1. Also, there were more patients with intrahepatic PSC in group II compared to group I. This heterogeneity could have contributed to the difference in AEs between the 2 groups. Thus, sicker patients may be at higher risk for post-procedure AEs such as cholangitis. In addition, the number of AEs was low, limiting the power of the study. This was particularly the case in group II where there were no cholangitis episodes and only 1 patient had PEP. The improved operator experience in group II could also explain the decreased AE. The other question that remains to be evaluated is whether the avoidance of biliary stents translates to a long-term clinical benefit. We will need long term follow-up of the patient groups to answer the above question. There is one ongoing randomized controlled trial to address this question and until then, we do not know the long-term impact of either technique. (NCT01398917) The strengths of this study are the large sample size, and the use of electronic medical records across the Cleveland Clinic Health System which includes multiple hospitals in the community, thus allowing capture of nearly all AEs even after patient discharge from the main campus hospital and thus making it possible to report the 30-day AEs in this study with high degree of accuracy.

## Conclusions

In summary, changing our approach at ERCP in PSC patients, by aspirating bile prior to contrast injection and avoiding stent placement after dilatation of dominant strictures was associated with a decreased risk of post ERCP AEs particularly the risk of bacterial cholangitis. The role of this approach in reducing the post-ERCP adverse event rates in patients with PSC needs further assessment in randomized studies.

## Competing interests

Dr. Navaneethan is a consultant for AbbVie, Janssen and Takeda. Dr. Parsi is a consultant for Boston Scientific. Dr. Vargo is a consultant for Olympus.

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