

# Outcomes and risk factors for ERCP-related complications in a predominantly black urban population

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## ABSTRACT

**Objective** There is a lack of literature on postendoscopic retrograde cholangiopancreatography (ERCP) complications in predominantly black urban populations of low socioeconomic status. The aim of this study was to determine the incidence and predictors of post-ERCP complications in this patient population.

**Design** Retrospective review of ERCP cases performed at two hospitals from 2007 to 2017 was performed. The categories of complications evaluated were overall complications, severe or fatal complications, pancreatitis, bleeding, infection, perforation and cardiopulmonary events. Predictors of complications were determined by univariate analysis.

**Results** A total of 1079 ERCP procedures were reviewed. There were 106 complications (9.8%). Twenty-one were severe (1.9%) and 20 were fatal (1.9%). Both post-ERCP pancreatitis (PEP) and post-ERCP bleeding occurred in 18 patients (1.7%) each. Risk factors for overall complications were male sex (OR 1.54), ASA grade IV or V (OR 2.19), prior history of PEP (OR 6.98) and pancreatic duct stent placement (OR 2.75). Those who were ASA grade III or lower (OR 0.4) or who underwent biliary stone extraction (OR 0.62) had fewer complications. PEP was more likely in those with a prior history of PEP (OR 37.6). Those with a suspected or known biliary duct stone had less frequent pancreatitis (OR 0.32). Post-ERCP bleeding was more likely in the presence of cholangitis (OR 8.72).

**Conclusion** Outcomes of ERCP in a predominantly black urban population demonstrate a lower incidence of PEP and all-cause mortality compared with historical data reported in the general population. Potential risk factors for post-ERCP complications were identified but require larger studies for validation.

## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure with numerous indications for use, mainly related to pancreaticobiliary disorders.<sup>1</sup> ERCP was first introduced in 1968 and has evolved in its utility.<sup>2</sup> Advances in diagnostic and therapeutic modalities, such as MR cholangiopancreatography, laparoscopic procedures with intraoperative cholangiography and endoscopic ultrasound (EUS), have allowed ERCP

## Summary box

### What is already known about this subject?

▶ Endoscopic retrograde cholangiopancreatography (ERCP) has mainly become a therapeutic modality for a variety of pancreaticobiliary diseases. The main complications arising from this procedure are well recognised, though the reported incidences vary widely. Many studies have also identified patient and procedure-related risk factors in the general population.

### What are the new findings?

▶ This study is one of the first to determine the incidence, severity, risk factors and mortality related to post-ERCP complications in a predominantly black urban patient population of low socioeconomic status.

### How might it impact on clinical practice in the foreseeable future?

▶ Endoscopists can have a more complete understanding of potential adverse events associated with ERCP in this patient population, allowing them to potentially identify manoeuvres that may reduce the risk of adverse events.

to become a mainly therapeutic procedure.<sup>3</sup> ERCP is technically challenging and carries a high risk of complications compared with other endoscopic procedures.

The overall ERCP-related complication rate reported in multiple large-scale studies and reviews has been highly variable. One systematic survey of prospective studies involving 16855 patients noted the total complication rate to be 6.9%.<sup>4</sup> Other large studies reported complication rates between 4% and 12%.<sup>5–8</sup> The most common complication is post-ERCP pancreatitis (PEP). Other complications include post-ERCP bleeding, infection, perforation and cardiopulmonary events.<sup>9</sup> These complications are associated with increased morbidity, mortality and healthcare costs.<sup>10 11</sup> Providing safe, effective therapy with ERCP requires an understanding of



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the possible complications, careful selection of patients for appropriate indications, and the implementation of appropriate periprocedural measures.

As providers affiliated with two urban, academic medical centres in central Brooklyn, New York, the majority of our patient population is of Afro-Caribbean and African American ethnicity, underinsured and low socioeconomic status. And while racial disparities in postoperative morbidity and mortality have been demonstrated in black patients, there is a paucity of literature focused on describing post-ERCP complications in this same group.<sup>12</sup> Obtaining data from this cohort will provide better understanding of this population's characteristics that may influence ERCP outcomes. Additionally, as the Arthur Ashe Institute for Urban Health is located within our main research institution (SUNY Downstate Medical Centre), we have a strong interest in healthcare disparities affecting our population's health.

The aim of this study was to determine the incidence, severity, risk factors and mortality related to post-ERCP complications in a predominantly black urban patient population of low socioeconomic status.

## PATIENTS AND METHODS

The ERCP procedures were performed by a total of seven endoscopists at two urban academic medical centres. All cases were performed with a trainee performing at least part of the procedure. All cases were also performed under general anaesthesia.

All patients 18 years of age or older that underwent ERCP at the University Hospital of Brooklyn (UHB) at SUNY Downstate Medical Center and Kings County Hospital Center (KCHC) from 1 January 2007 to 14 July 2017, were included. Procedural findings and technical details were collected from the endoscopy documentation software at each institution starting from the time of their inception: MD-Reports (Infinite Software Solutions, Staten Island, New York, USA) at UHB (2010) and EndoWorks (Olympus, Tokyo, Japan) at KCHC (2007). Additionally, a database kept for the clinical care of those patients undergoing ERCP at both institutions was reviewed for data regarding demographics, clinical history, blood test results, diagnoses and complications.

## Variables

The variables documented for each case included the characteristics of the patients and the specifics of each procedure (table 1). The primary outcomes of interest in this study were overall post-ERCP complications, complications graded as severe or fatal, pancreatitis, haemorrhage, infection, perforation, cardiac and pulmonary events, and all-cause mortality within 30 days of the procedure. Complications and their severity were defined by established consensus criteria.<sup>13</sup> The severity of all other complications besides pancreatitis, haemorrhage, perforation and cholangitis was graded based on the need for hospitalisation and/or surgical treatment.

**Table 1** Characteristics of patients who underwent ERCP

Variable	N (%)
<b>Age</b>	
<40 years	172 (20.6)
40–70 years	464 (55.6)
>70 years	199 (23.8)
<b>Sex</b>	
Female	533 (63.8)
Male	302 (36.2)
<b>Ethnicity</b>	
Afro-Caribbean	358 (42.9)
African American	305 (36.5)
Hispanic	79 (9.5)
White	38 (4.6)
Asian	27 (3.2)
African	12 (1.4)
Middle Eastern	10 (1.2)
Unknown	6 (0.7)
<b>Comorbidities</b>	
Diabetes mellitus	306 (36.7)
Chronic kidney disease	38 (4.6)
<b>Context</b>	
Biliary obstruction	878 (81.4)
Suspected or known stone	821 (76.1)
Prior ERCP	237 (22)
Cholangitis	123 (11.4)
Active pancreatitis	106 (9.8)
Prior ERCP complication	51 (4.7)
Pancreatic duct abnormality	42 (3.9)
Postoperative bile leak	33 (3.1)
Ampullary abnormality	9 (0.8)
Pancreatic pseudocyst	5 (0.46)
<b>Procedural</b>	
Biliary sphincterotomy	653 (60.5)
Biliary stone extraction	543 (50.3)
Antibiotics before the procedure	461 (42.7)
Biliary stent insertion	191 (17.7)
Small pancreatic-duct stent placed	111 (10.3)
Pancreatogram	38 (3.5)
Precut sphincterotomy	36 (3.3)
Pancreas divisum	1 (0.09)
<b>ASGE complexity score</b>	
1	168 (17.8)
2	564 (59.7)
3	173 (18.3)
4	40 (4.2)
<b>HOUSE complexity score</b>	

Continued

**Table 1** Continued

Variable	N (%)
1	777 (75.6)
2	171 (16.6)
3	79 (7.7)

ASGE, American Society for Gastrointestinal Endoscopy; ERCP, endoscopic retrograde cholangiopancreatography.

Mild was associated with an unplanned hospital stay of two to three nights, moderate was associated with an unplanned hospital stay of four to 10 nights, and severe was associated with an unplanned stay >10 nights or transfer to an intensive care setting or if surgical intervention was required. Procedural complexity was scored by both an established grading scale published by an American Society for Gastrointestinal Endoscopy (ASGE) working party and a novel grading scale (The HOUSE classification) proposed by Olsson *et al.*<sup>14 15</sup> Perforation was classified into four categories according to severity as previously described.<sup>16</sup>

### Analysis

Categorical variables were analysed with a  $\chi^2$  test. Clinically relevant risk factors were examined by univariate analysis and calculated with ORs with 95% CIs. A  $p < 0.05$  was regarded as statistically significant. Statistical analysis was performed using IBM SPSS Statistics V.25.

## RESULTS

### Procedures

A total of 1079 ERCP procedures were performed and documented over 10 years. The demographics, indications and frequency of special interventions are outlined in [table 1](#).

### Overall complications

There was a total of 106 complications (9.8%). The incidence of all complications and their severity grades is listed in [table 2](#). The multivariate analysis results for overall complications, pancreatitis, bleeding, fatal outcomes, cholangitis and perforation are shown in [tables 3–8](#), respectively. Six factors were found to be independently associated with overall complications. Subjects who were of male gender (OR 1.54, 95% CI 1.03 to 2.31), American Society of Anesthesiologists (ASA) grade IV and V (OR 2.19, 95% CI 1.37 to 3.51), had a prior history of PEP (OR 6.98, 95% CI 2.18 to 22.4) and had pancreatic duct stent placement (OR 2.75, 95% CI 1.65 to 4.59) were at increased risk. Those who were ASA grade III or lower (OR 0.4, 95% CI 0.25 to 0.64) or who underwent biliary stone extraction (OR 0.62, 95% CI 0.41 to 0.94) were predicted to have significantly fewer complications. Of note, the overall complication rate did not reduce with time when comparing the first 5 years of data with the most recent 5 years (11.2% vs 8.7%,  $p = 0.17$ ).

**Table 2** Incidence of post-ERCP complications

Complications	No	%
Overall	106	9.8
Pancreatitis	18	1.7
Mild	10	0.9
Moderate	5	0.5
Severe	2	0.2
Death	1	0.1
Bleeding	18	1.7
Mild	9	0.8
Moderate	7	0.6
Severe	2	0.2
Death	0	0
Infection	40	3.7
Cholangitis	21	1.9
Cholecystitis	6	0.6
Retroperitoneal abscess	2	0.2
Other	2	0.2
Death	9	0.8
Cardiopulmonary events	23	2.1
Cardiac	4	0.4
Pulmonary	9	0.8
Death	10	0.9
Perforation	7	0.6
Bowel perforation	5	0.5
Sphincter perforation	2	0.2
Death	0	0

ERCP, endoscopic retrograde cholangiopancreatography.

### Pancreatitis

ERCP caused acute pancreatitis in 18 patients (1.7%). This was graded as mild in 10 patients, moderate in five patients and severe in two patients. There was one fatality ([table 2](#)). Initial univariate analysis revealed 17 potential predictors of pancreatitis. The only variable that remained an independently significant predictor of pancreatitis was having a prior history of PEP (OR 37.6, 95% CI 10.1 to 139.5). Having a suspected or known biliary duct stone predicted less frequent pancreatitis (OR 0.32, 95% CI 0.12 to 0.82).

### Bleeding

ERCP caused bleeding in 18 patients (1.7%). This was graded as mild in nine patients, moderate in seven patients and severe in two patients. There were no fatalities ([table 2](#)). The only variable that was an independently significant predictor of bleeding was the presence of cholangitis (OR 8.72, 95% CI 1.84 to 41.31). Neither undergoing biliary sphincterotomy nor anticoagulant use up to 7 days prior to ERCP were significant predictors of bleeding.

**Table 3** Predictors of overall post-ERCP complications

Variable	Complications (n=106)	No complications (n=973)	OR	95% CI	P value
<b>Clinical</b>					
Age					
<40 years	19	201	0.84	0.5 to 1.41	0.51
40–70 years	54	543	0.82	0.55 to 1.23	0.34
>70 years	33	229	1.47	0.95 to 2.27	0.08
Sex					
Male	49	348	1.54	1.03 to 2.31	0.04
Female	57	625	Reference group	Reference group	
Ethnicity					
Afro-Caribbean	49	422	1.12	0.75 to 1.68	0.57
African American	31	351	0.73	0.47 to 1.14	0.16
White	6	37	1.52	0.63 to 3.68	0.36
Other	20	163	1.16	0.69 to 1.93	0.58
ASA grade					
I	0	19	0.21	0.01 to 3.54	0.28
II	30	320	0.71	0.46 to 1.11	0.14
III	37	425	0.6	0.39 to 0.91	0.02
IV and V	28	127	2.19	1.37 to 3.51	0.001
Obesity	33	316	0.94	0.61 to 1.45	0.78
Prior PEP	5	7	6.98	2.18 to 22.4	0.001
Suspected or known duct stone	88	782	1.19	0.7 to 2.03	0.51
<b>Procedural</b>					
ASGE complexity grade					
1	15	154	0.86	0.48 to 1.54	0.62
2	62	503	1.36	0.87 to 2.12	0.18
3	15	159	0.83	0.47 to 1.48	0.53
4	2	39	0.45	0.11 to 1.92	0.28
HOUSE complexity score					
1	70	708	0.76	0.48 to 1.21	0.25
2	20	154	1.28	0.76 to 2.15	0.35
3	9	70	1.23	0.6 to 2.55	0.57
Biliary stone extraction	41	489	0.62	0.41 to 0.94	0.02
Pancreatogram	7	36	1.84	0.8 to 4.25	0.15
Pancreatic duct stent	23	89	2.75	1.65 to 4.59	0.0001
Biliary sphincterotomy	68	588	1.17	0.77 to 1.78	0.46
Biliary precut	7	29	2.3	0.98 to 5.39	0.05

ERCP, endoscopic retrograde cholangiopancreatography; PEP, post-ERCP pancreatitis.

### Cholangitis

Twenty-one (1.9%) patients developed cholangitis after ERCP. Those who underwent ERCP for a suspected or known malignant biliary stricture (OR 5.32, 95% CI 2.0 to 14.1), had incomplete biliary drainage (OR 3.48, 95% CI 1.14 to 10.6) and had a HOUSE procedure complexity score of 2 (OR 2.96, 95% CI 1.15 to 7.64) were at increased risk for developing cholangitis. Patients with a HOUSE procedure complexity score of 1 (OR 0.28, 95% CI 0.11

to 0.71) were predicted to have less frequent cholangitis. None of the patients with failed biliary access developed cholangitis. No combined percutaneous-endoscopic procedures were performed either.

### Perforation

Perforation was observed in seven (0.6%) patients. Three (0.3%) of these cases were duodenal perforations and all required surgery. One case of type II perforation

**Table 4** Predictors of post-ERCP pancreatitis

Variable	PEP (n=18)	No PEP (n=1061)	OR	95% CI	P value
<b>Clinical</b>					
Age					
<40 years	6	213	1.99	0.74 to 5.37	0.17
40–70 years	9	588	0.8	0.32 to 2.05	0.65
>70 years	3	260	0.62	0.18 to 2.15	0.45
Sex					
Male	6	391	0.86	0.32 to 2.30	0.76
Female	12	670	Reference group	Reference group	
Ethnicity					
Afro-Caribbean	7	464	0.82	0.32 to 2.13	0.69
African American	5	377	0.7	0.25 to 1.97	0.5
White	2	40	3.19	0.71 to 14.35	0.13
Other	4	180	Reference group	Reference group	
ASA grade					
I	0	19	Reference group	Reference group	
II	5	320	0.64	0.24 to 1.75	0.39
III	10	477	1.53	0.60 to 3.91	0.37
IV and V	0	156	0.16	0.01 to 2.61	0.2
Obesity	5	353	0.77	2.73 to 2.18	0.62
Prior PEP	4	8	37.6	10.1 to 139.5	<0.0001
Suspected or known duct stone	10	846	0.32	0.12 to 0.82	0.02
Rectal indomethacin use	1	31	1.96	0.25 to 15.17	0.52
<b>Procedural</b>					
ASGE complexity grade					
1	4	164	1.56	0.51 to 4.81	0.44
2	12	553	1.84	0.68 to 4.93	0.22
3	1	173	0.3	0.04 to 2.28	0.25
4	1	40	1.5	0.20 to 11.56	0.7
HOUSE complexity score					
1	13	765	1.01	0.36 to 2.85	0.99
2	3	170	1.05	0.3 to 3.66	0.94
3	2	77	1.6	0.36 to 7.08	0.54
Antibiotics before procedure	5	456	0.51	0.18 to 1.44	0.2
Biliary stone extraction	6	524	0.51	0.19 to 1.38	0.18
Biliary stent insertion	3	100	1.92	0.55 to 6.75	0.31
Pancreatogram	3	41	3.11	0.69 to 14	0.14
Pancreatic duct stent	4	108	2.52	0.82 to 7.8	0.11
Biliary sphincterotomy	14	642	2.28	0.75 to 6.99	0.15
Biliary precut	0	36	0.76	0.05 to 12.85	0.85

ERCP, endoscopic retrograde cholangiopancreatography; PEP, post-ERCP pancreatitis.

was managed endoscopically with an over-the-scope clip though laparoscopy was performed after to confirm closure of the defect.<sup>15</sup> A second case of type II perforation was managed endoscopically with placement of three standard endoclips. The remaining two perforations were type IV and were managed medically.<sup>15</sup> No

patients died due to complications from a perforation. The only risk factor associated with an increased risk of perforation was ASA grade IV and V (OR 7.11, 95%CI 1.58 to 32.1). In the setting of standard sphincterotomy, there were two type II perforations and two type IV perforations (non-significant). No cases of perforation



**Table 5** Predictors of post-ERCP bleeding

Variable	Bleeding (n=18)	No bleeding (n=1061)	OR	95% CI	P value
<b>Clinical</b>					
Age					
<40 years	3	216	0.78	0.22 to 2.73	0.7
40–70 years	11	586	1.27	0.49 to 3.31	0.62
>70 years	4	259	0.88	0.29 to 2.71	0.83
Sex					
Male	9	388	1.73	0.68 to 4.41	0.25
Female	9	673	Reference group	Reference group	
Ethnicity					
Afro-Caribbean	7	464	0.82	0.32 to 2.13	0.68
African American	5	376	0.71	0.25 to 1.98	0.5
White	0	42	0.65	0.04 to 10.94	0.76
Other	6	179	2.46	0.91 to 6.65	0.08
Anticoagulant use	2	166	0.68	0.15 to 2.98	0.61
Presence of cholangitis	2	15	8.72	1.84 to 41.31	0.006
<b>Procedural</b>					
Biliary sphincterotomy	14	642	2.28	0.75 to 6.99	0.15
Biliary precut	1	34	1.78	0.23 to 13.74	0.58

ERCP, endoscopic retrograde cholangiopancreatography.

occurred in the setting of precut sphincterotomy or in the single patient with Billroth II anatomy. No patients with suspected sphincter of Oddi dysfunction (SOD) underwent ERCP.

### Severe and fatal outcomes

There were 21 severe and 20 fatal outcomes in this series. Severe complications were due to the following: cardiopulmonary events (n=9), bowel perforation (n=4), cholangitis (n=3), immediate bleeding (n=2), pancreatitis (n=2) and sphincterotomy perforation (n=1). The 20 fatal outcomes were due to the following: cardiopulmonary events (n=10), sepsis (n=9) and pancreatitis (n=1). Overall, two factors independently predicted severe or fatal complications: poor health status (ASA IV and V; OR 3.13, 95% CI 1.59 to 6.17) and Afro-Caribbean ethnicity (OR 2.57, 95% CI 1.33 to 4.96).

### DISCUSSION

ERCP has mainly become a therapeutic modality for a variety of pancreaticobiliary diseases. The main complications arising from this procedure are well-recognised, though the reported incidences vary widely.<sup>1</sup> Many studies have also identified patient and procedure-related risk factors in the general population though few have investigated the incidence, severity, risk factors and mortality of post-ERCP complications in black urban populations.<sup>8,9</sup>

In this study, where 79.4% of patients were Afro-Caribbean and African Americans of low socioeconomic status, the prevalence of overall complications was 9.8%, which falls within the range of previously reported

rates between 4% and 12% in the overall population.<sup>5–8</sup> However, our reported rate may be lower than the actual number of delayed complications. Though we were able to capture 99.1% of our procedures, we did not have a standard method for collecting data on delayed complications that occurred in patients who presented to other medical institutions or outside providers.

The most prominent patient-related risk factor for overall complications was a history of PEP, which is consistent with previous studies.<sup>17–19</sup> Sicker patients (classified as ASA IV and V) at the time of procedure were also at increased risk of complications, consistent with the findings of a previous large retrospective study.<sup>8</sup> However, patients classified as ASA III were actually less likely to experience a complication. Also, unlike previous studies, male patients were found to have a significant increase in risk.<sup>17–19</sup> These differences may be explained by the relatively low number of patients included in the present study. Other potential reasons for this observation are that male patients in our cohort tended to be sicker (ASA IV and V) and underwent more complicated ERCP procedures (ASGE complexity level  $\geq 3$  and/or HOUSE class  $\geq 2$ ) which may have put them at an increased risk of developing complications.

Regarding procedure-related factors, precut sphincterotomy was a significant risk factor for overall complications, which has been previously demonstrated.<sup>17,19–21</sup> Of note, in this study, placement of a small pancreatic duct stent was a risk factor for overall complications. This is surprising not only because pancreatic duct stents have been shown to decrease the risk of PEP, but also because

**Table 6** Predictors of post-ERCP severe or fatal complications

Variable	Severe or fatal (n=41)	Not severe or fatal (n=1038)	OR	95% CI	P value
<b>Clinical</b>					
Age					
<40 years	4	215	0.41	0.15 to 1.17	0.1
40–70 years	23	574	1.03	0.55 to 1.94	0.92
>70 years	14	249	1.64	0.85 to 3.18	0.14
Sex					
Male	18	379	1.36	0.73 to 2.55	0.34
Female	23	659	Reference group	Reference group	
Ethnicity					
Afro-Caribbean	27	445	2.57	1.33 to 4.96	0.005
African American	9	373	0.5	0.24 to 1.06	0.07
White	2	41	1.25	0.29 to 5.34	0.77
Other	4	172	0.54	0.19 to 1.55	0.25
ASA grade					
I	0	19	Reference group	Reference group	
II	8	322	0.5	0.23 to 1.11	0.09
III	17	465	0.81	0.43 to 1.54	0.51
IV and V	14	144	3.13	1.59 to 6.17	0.001
Obesity	17	349	1.4	0.74 to 2.64	0.3
Suspected or known duct stone	37	811	2.59	0.91 to 7.34	0.07
<b>Procedural</b>					
ASGE complexity grade					
1	6	162	1.03	0.42 to 2.54	0.94
2	22	543	1.37	0.66 to 2.86	0.4
3	4	170	0.6	0.21 to 1.74	0.35
4	1	40	0.68	0.09 to 5.13	0.71
HOUSE complexity score					
1	27	751	0.79	0.39 to 1.62	0.52
2	9	165	1.56	0.72 to 3.35	0.26
3	2	77	0.66	0.16 to 2.79	0.57
Biliary stone extraction	15	527	0.56	0.29 to 1.07	0.08
Antibiotics preprocedure	23	440	1.74	0.93 to 3.26	0.09

ERCP, endoscopic retrograde cholangiopancreatography.

placing the stent was not found to be a specific risk factor for PEP, post-ERCP bleeding or death.<sup>9</sup> Furthermore, placement of a pancreatic duct stent was not found to be related to performance of pancreatography, which has been shown to be a risk factor for overall complications and pancreatitis.<sup>8</sup> While the stents were unlikely to actually cause PEP, this surprising outcome may be confounded by the stents being placed in sicker patients (ASA IV and V) and during more complicated ERCP procedures (ASGE complexity level  $\geq 3$  and/or HOUSE class  $\geq 2$ ), therefore skewing the results in favour of the non-stented cases. Also of note, while most assume that therapeutic procedures are more dangerous and biliary

sphincterotomy has previously been shown to increase the risk of bleeding and overall complications, biliary stone extraction in this study was actually associated with a decreased risk of overall complications.<sup>8</sup> A possible explanation for this difference could be that stone extraction was predominantly performed in healthier patients. Similarly, the more complex and more difficult procedures (ASGE complexity level  $\geq 3$  and/or HOUSE class  $\geq 2$ ) did not carry a higher risk for overall complications.<sup>14 15</sup> And even though the proportion of these procedures was expectedly lower than in larger centres (23.4% vs 56.8%), defining ERCP complexity in a retrospective setting can be difficult.<sup>8</sup>

**Table 7** Predictors of post-ERCP cholangitis

Variable	Cholangitis (n=21)	No cholangitis (n=1058)	OR	95% CI	P value
<b>Clinical</b>					
Age					
<40 years	2	216	0.41	0.09 to 1.78	0.23
40–70 years	14	580	1.65	0.66 to 4.12	0.28
>70 years	5	262	0.95	0.35 to 2.62	0.92
Sex					
Male	6	392	0.49	0.19 to 1.21	0.12
Female	15	666	Reference group	Reference group	
ASA grade					
I	0	19	1.24	0.07 to 21.2	0.88
II	6	321	0.92	0.35 to 2.39	0.86
III	10	472	1.13	0.48 to 2.68	0.78
IV and V	5	152	1.86	0.67 to 5.16	0.23
Ethnicity					
Afro-Caribbean	12	466	1.69	0.71 to 4.05	0.24
African American	5	379	0.56	0.20 to 1.54	0.26
White	0	45	0.52	0.03 to 8.69	0.65
Other	4	168	1.25	0.41 to 3.75	0.7
Suspected or known malignant stricture					
Primary sclerosing cholangitis	0	5	4.45	0.24 to 83.1	0.32
<b>Procedural</b>					
ASGE complexity grade					
1	3	165	0.92	0.26 to 3.22	0.9
2	9	552	0.68	0.27 to 1.72	0.41
3	6	168	2.25	0.84 to 6.09	0.11
4	0	40	0.59	0.04 to 9.98	0.72
HOUSE complexity score					
1	9	767	0.28	0.11 to 0.71	0.01
2	7	166	2.96	1.15 to 7.64	0.03
3	3	76	2.3	0.66 to 8.08	0.19
Antibiotics before procedure	12	448	2.23	0.71 to 6.98	0.17
Incomplete biliary drainage	4	67	3.48	1.14 to 10.6	0.03
Biliary stent placement	3	161	0.93	0.27 to 3.19	0.91

ERCP, endoscopic retrograde cholangiopancreatography.

Pancreatitis is the most common complication after ERCP with an overall estimated incidence of 4.8%–11.9% in two recent systematic reviews.<sup>22 23</sup> The pancreatitis rate in this study was 1.7% using the widely accepted consensus definition for pancreatitis.<sup>13</sup> Several studies have shown that the incidence and severity of PEP can be reduced with either prophylactic placement of a pancreatic duct stent or rectal administration of nonsteroidal anti-inflammatory drugs.<sup>22–31</sup> In this study, however, neither prophylactic stent placement nor rectal administration of indomethacin decreased the risk of PEP. This is likely

due to the low number of patients who received these interventions. Interestingly, what was actually found to decrease the risk of PEP in this study was if patients had a suspected or known biliary duct stone prior to ERCP. As mentioned previously, a prior history of PEP was a risk factor for overall complications in this study. This was also seen to be true for the development of PEP, which is consistent with prior studies.<sup>18 19</sup>

Post-ERCP bleeding in this study was observed in 1.7% of patients, consistent with previously reported values of 0.3%–2% in the general population.<sup>9 23</sup> The number



**Table 8** Predictors of post-ERCP perforation

Variable	Perforation (n=7)	No perforation (n=1072)	OR	95% CI	P value
<b>Clinical</b>					
Age					
<40 years	0	219	0.26	0.02 to 4.56	0.36
40–70 years	3	594	0.6	0.13 to 2.71	0.51
>70 years	4	259	4.19	0.93 to 18.82	0.06
Sex					
Male	3	394	1.29	0.29 to 5.80	0.74
Female	4	678	Reference group	Reference group	
ASA grade					
I	0	19	3.29	0.18 to 59.73	0.42
II	1	330	0.33	0.04 to 2.75	0.3
III	2	478	0.42	0.08 to 2.18	0.3
IV and V	4	155	7.11	1.58 to 32.1	0.01
Ethnicity					
Afro-Caribbean	4	467	1.73	0.39 to 7.76	0.48
African American	1	379	0.31	0.04 to 2.54	0.27
White	1	42	4.09	0.48 to 34.72	0.2
Other	1	184	0.8	0.10 to 6.72	0.84
<b>Procedural</b>					
ASGE complexity grade					
1	0	168	0.51	0.03 to 9.56	0.65
2	3	564	2.02	0.21 to 19.51	0.54
3	0	172	0.5	0.03 to 9.29	0.64
4	1	40	7.53	0.77 to 74.04	0.08
HOUSE complexity score					
1	5	775	1.61	0.19 to 13.87	0.66
2	0	172	0.38	0.02 to 6.79	0.51
3	1	78	2.43	0.28 to 21.04	0.42
Sphincterotomy	4	652	3.01	0.86 to 10.52	0.09
Precut sphincterotomy	0	36	1.89	0.11 to 33.78	0.66

ERCP, endoscopic retrograde cholangiopancreatography.

of patients who developed bleeding as a direct result of an ERCP, though, is likely less than the overall reported number as one patient had a bleeding gastric ulcer, one developed bleeding after percutaneous biliary drainage, one had a bleeding Dieulafoy's lesion, and one had bleeding from metastatic liver disease. Of previously identified independent risk factors for postprocedure bleeding (eg, sphincterotomy, coagulopathy, anticoagulant use, etc), only one, the presence of active cholangitis before the procedure, was associated with an increased risk for bleeding in this study, most likely due to the small sample size.<sup>9 31</sup>

Regarding the complications graded as severe or fatal, these were more likely to occur in patients of Afro-Caribbean ethnicity and ASA class IV and V. These findings make intuitive sense as patients of Afro-Caribbean

ethnicity made up the largest proportion of the study population while patients with extremely poor health status would be expected to have poorer outcomes.<sup>8</sup> The overall 30-day post-ERCP mortality rate has previously been reported to be between 2.2% and 5% with an ERCP-related 30-day mortality rate between 0.1% and 1.4%.<sup>5–7</sup> In this study, the overall 30-day mortality rate was 1.9% with a procedure-related mortality rate of 0.1% (n=1). This single death was due to cardiopulmonary arrest that occurred during stent insertion for malignant biliary obstruction.

Predictors of complications found in other large ERCP data analyses (eg, younger age, recurrent attacks of pancreatitis as an indication for the procedure, absence of chronic pancreatitis, etc) were not found to be significant in this study, while no patients underwent ERCP

for evaluation of possible SOD in this study. Additionally, only one patient who underwent ERCP in this study had surgically altered anatomy (Billroth II gastrectomy).

One of the main limitations of this study was the relatively small sample size. Additionally, though the focus of this study was on a black urban population, the generalisability of our conclusions is limited. Furthermore, the lack of any standardised follow-up may have resulted in missing some delayed complications. Another limitation was reporting within the endoscopy documentation software and electronic medical records used at both centres as overall procedure time, biliary cannulation time, number of biliary cannulation attempts, number of pancreatic cannulations and injections, and the amount/type of periprocedural IV hydration were not consistently documented or available. Repetitive attempts or prolonged duration before cannulation (>5–10 min), repetitive pancreatic guidewire cannulation, and pancreatic injection have been attributed with higher rates of PEP while the use of periprocedural IV hydration with lactated ringers has been suggested to decrease the risk of PEP.<sup>9</sup> Also, most cardiopulmonary injury has been shown to occur during prolonged procedures (>30 min).<sup>32</sup> And finally, having no patients in this series with suspected SOD and only one with surgically altered anatomy may have limited the overall number of complications as these two factors have been shown to increase the risk of overall complications, PEP and perforation.<sup>8,9</sup>

In conclusion, outcomes of ERCP in a predominantly black minority population demonstrate a lower incidence of PEP and all-cause 30-day mortality compared with historical data reported in the general population. Regarding this specific population, it appears that a prior history of PEP, poor health status, male sex, and prophylactic pancreatic duct stent placement may be risk factors for the development of post-ERCP complications. These observations are an important initial look into a cohort for which there is a paucity of literature on ERCP outcomes and require larger studies for validation.

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