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Outcomes of Endoscopic Retrograde Cholangiopancreatography in Patients with Sickle Cell Disease

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ABSTRACT

Limited data exist on the safety of endoscopic retrograde cholangiopancreatography (ERCP) in patients with sickle cell disease (SCD). The objective of this study is to assess ERCP outcomes in SCD. Patients older than 18 with SCD or its variants undergoing ERCP 2008-2014 were identified from the National Inpatient Sample. Case-control matching based on age, sex and race was performed. Complications of ERCP were assessed against controls; specific SCD-related outcomes were assessed in comparison with SCD patients who did not undergo ERCP. 334 patients with SCD underwent ERCP, representing a weighted population of 1669. Complications related to ERCP were infrequent, though the rate of post-ERCP bleeding was higher in SCD patients compared to controls (2.2% vs. 0.6%; p<0.001). When adjusted for independent factors for post-ERCP hemorrhage including age, sex, hospital size, hospital teaching status and indication for ERCP, the adjusted OR for post-ERCP hemorrhage was still higher in the SCD cohort (aOR 5.59; 95% CI, 3.63 – 8.61). Rates of post-ERCP pancreatitis were similar (5.4% vs. 4.9%; p=0.42). Complications after ERCP specific to SCD were higher when compared to other SCD patients. The incidence of painful crisis (8.0%), infection (4.0%), pneumonia (4.3%) and acute chest syndrome (5.3%) were higher in SCD patients undergoing ERCP. Sickle cell disease is an independent risk factor for post-ERCP hemorrhage in patients undergoing ERCP. Additionally, the rates of SCD-related complications are higher in patients undergoing ERCP. Therefore, proper precautions must be taken prior to ERCP to minimize the risks associated with this procedure in SCD patients.

Keywords: Endoscopic retrograde cholangiopancreatography, Hepatobiliary, Sickle cell disease

1. Introduction

Sickle cell disease is an autosomal recessive disorder caused by a mutation encoding the beta-globin component of hemoglobin[1]. The resultant dysmorphic hemoglobin S polymerizes into long chains under low oxygen states, leading to the characteristic ”sickle” shape of these cells. The abnormal shape and polymerization of the hemoglobin creates microvascular occlusion in capillary beds. This occlusion manifests clinically as ischemia and potentially necrosis of end organs.

Patients with sickle cell disease (SCD) suffer from both severe chronic hemolytic anemia and acute episodes of vaso-occlusive disease due to trapping of red blood cells (RBC) in the microvasculature. Vaso-occlusive crises are the hallmark of the disease and contribute to morbidity and mortality. The disease most commonly affects individuals from Africa and is also seen in persons of Mediterranean, Arab and Indian descent in concert with other hemoglobinopathies, such as hemoglobin C (HbC), hemoglobin D (HbD), hemoglobin E (HbE) and hemoglobin S-b-thalassemia[2,3]. Approximately 100,000 people have sickle cell anemia in the United States[4]. This estimation is expected to increase as newborn screening, primary stroke prevention, infection prophylaxis and medical management improve[5]. Complications of SCD can affect any part of the body, posing both diagnostic and therapeutic dilemmas to physicians. Notably, the biliary system is one of the most common sites affected.

Due to the abnormal structure of hemoglobin, red blood cells in SCD patients have a shorter life span. Chronic hemolysis leads to continuous heightened production of bilirubin, which subsequently leads to the development of pigmented gallstones. Overall, 70% of patients with sickle cell disease develop cholelithiasis during their lifetime[6,7]. With improving life expectancy in the disease, this number is likely to rise.

An important complication of cholelithiasis is choledocholithiasis[8]. In the general population with known cholelithiasis, the incidence of choledocholithiasis is 10-15% (9). In SCD patients, the incidence ranges from 18-30%[9,10]. As a result, the need for intervention is much higher in this population. Endoscopic retrograde cholangiopancreatography (ERCP) is a valuable tool for therapeutic removal of obstructing stones both in pre- and post-cholecystectomy patients[11]. To date, the literature for overall safety of ERCP in patients with SCD is scarce[12]. Given the limited data of ERCP outcomes in patients with sickle cell disease, our study aim was to examine both ERCP-related complications and SCD-related complications in a large national cohort. This analysis was conducted to provide gastroenterologists with stronger evidence to perform ERCP in this group of patients and to provide them with anticipatory guidance about the specific risks associated with the procedure in these patients.

2. Methods

2.1. Data source

The Nationwide Inpatient Sample (NIS) database was used to collect data from the years 2008 to 2014. The NIS is the largest all-payer inpatient database, comprising approximately 20% of all inpatient admissions to nonfederal hospitals in the United States. Patient records include information extracted from inpatient discharge data using billing codes. It is publicly available as part of the Healthcare Cost and Utilization Project (HCUP).

The NIS database includes unique identifiers, demographics, primary and secondary diagnosis codes (up to 30), primary and secondary procedure codes (up to 15), hospital characteristics and a variety of other variables related to the patient, hospital and nature of the admission.

Quality control of this database provides reliable and accurate information pertaining to each hospital discharge. Therefore, results extracted from this database can be used to represent the population of the United States as a whole.

Cost of hospitalization was calculated using charge ratios provided by HCUP and each individual cost was adjusted for inflation referencing September 2018 data.

2.2. Study population

The study population consisted of all patients aged 18 years or older within the NIS database who were hospitalized and underwent inpatient ERCP. Procedural coding using the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9 CM) were used to select patients who underwent ERCP, as outlined in **(Table 1)**. All patients with a diagnosis of SCD along with its variants were included, as outlined in **(Table 2)**.

Table 1: ERCP ICD-9 CM Procedure Codes.

Procedure Code	Procedure Description
Diagnostic ERCP Codes	
51.1	Endoscopic retrograde cholangiopancreatography (ERCP)
51.11	Endoscopic retrograde cholangiography (ERC)
51.14	Other closed (endoscopic) biopsy of biliary duct or sphincter of Oddi
52.13	Endoscopic retrograde pancreatography (ERP)
52.14	Closed (endoscopic) biopsy of pancreatic duct
Therapeutic ERCP Codes	
51.84	Endoscopic dilation of ampulla and biliary duct
51.85	Endoscopic sphincterotomy and papillotomy
51.86	Endoscopic insertion of nasobiliary drainage tube
51.87	Endoscopic insertion of stent (tube) into bile duct
51.88	Endoscopic removal of stone(s) from biliary duct
52.93	Endoscopic insertion of stent (tube) into pancreatic duct
52.94	Endoscopic removal of stone(s) from pancreatic duct
52.97	Endoscopic insertion of nasopancreatic drainage tube
52.98	Endoscopic dilation of pancreatic duct

Table 2: Sickle Cell Disease and Variant ICD-9 CM Codes.

Diagnosis Code	Diagnosis Description
Sickle Cell Disease	
282.6	Sickle-cell disease, unspecified
282.61	Hb-SS disease without crisis
282.62	Hb-SS disease with crisis
Sickle Cell Variants	
282.41	Hemoglobin S – Beta thalassemia without crisis
282.42	Hemoglobin S – Beta thalassemia with crisis
282.63	Hemoglobin SC disease without crisis
282.64	Hemoglobin SC disease with crisis
282.68	Hemoglobin S-D and Hemoglobin S-E disease

The control population consisted of non-sickle cell disease patients who underwent ERCP during the same time period. Selection was performed using case-control matching. Patients were selected randomly using SPSS version 25 (IBM Corp. Armonk, NY). Three non-sickle patient controls were selected randomly for each sickle patient who underwent ERCP. Cases and controls were matched on race, sex and age range to minimize confounding.

2.3. Variables studied

The goal of the study was to evaluate the safety of ERCP in SCD patients. The primary outcomes of the study were (1) complications related to ERCP directly, which included hemorrhage, post-ERCP pancreatitis, perforation and cholecystitis and (2) unique complications related to sickle cell disease, which included acute chest syndrome, pain crisis, stroke, fever, infection, bacteremia, pneumonia, thrombosis and mortality.

Secondary outcomes evaluated included cost of hospitalization, length of stay and procedure failure rates. Failure was defined as the need to perform percutaneous transhepatic cholangiography (PTC) (ICD-9 code 87.51) or open bile duct exploration (ICD-9 code 51.13) after ERCP.

Post-ERCP pancreatitis was defined using previously defined criteria (13, 14). Bleeding after ERCP was identified by specific ICD-9 codes defining post-ERCP hemorrhage (998.11, 909.3). Patients with a diagnosis of bleeding on admission (primary diagnosis) were excluded to capture diagnoses related to procedures done during the hospitalization. Cholecystitis after ERCP was identified using ICD-9 codes 575.0 and 575.1, excluding those listed as primary or secondary diagnosis codes. Perforation after ERCP was defined by ICD-9 code 569.83.

In order to define severity of comorbidities, the Elixhauser comorbidity index was used. This is a well-established measure of predicting in-patient mortality and has been validated in prior studies (15-17). Comorbidity software created by HCUP was used to create these variables based on known diagnosis codes.

2.4. Statistical analysis

Data analysis was performed using SPSS version 25. Individual discharge weights provided by HCUP were used to reflect national data. Analysis for categorical data was completed using chi-square tests and for continuous data using the student t test. A p value of less than 0.05 was considered statistically significant. Both univariate and bivariate analyses were performed to assess the indications as well as complications associated with ERCP in patients with sickle cell disease. Finally, logistic regression was employed to determine odds ratios of complications related to ERCP.

The study was exempt from institutional review board committee review owing to the de-identified nature of the data.

3. Results

3.1. Patient demographics and hospital characteristics

A total of 334 patients with SCD or a disease variant were identified who underwent ERCP during the study period from 2008 to 2014. When applying discharge weights, this represented a national estimate of 1669 patients. Using case-control matching in SPSS, 4884 non-sickle cell individuals were randomly selected. These individuals were matched with the SCD cohort based on age categories, race and sex in order to minimize confounding. Demographic information of these cohorts is presented in **(Table 3)**.

Table 3: Patient Demographics and Hospital Characteristics.

Variable	All	Sickle Cell Disease (n=1669)	Control (n=4884)	P-value
Patient Age (Years)				0.18
Mean (SD)	35.23 (16.1)	34.3 (14.3)	35.6 (16.6)	
Sex				0.904
Female	54.50%	54.20%	54.60%	
Male	45.50%	45.80%	45.40%	
Race				0.159
White	3.30%	3.30%	3.30%	
Black	87.70%	87.70%	87.60%	
Hispanic	6.30%	5.40%	6.60%	
Asian or Pacific Islander	0.90%	0.60%	1.00%	
Native American	0.80%	0.00%	1.00%	
Other	1.10%	3.00%	0.40%	
Primary Payer				<0.001
Medicare	16.90%	26.90%	13.60%	
Medicaid	31.90%	32.60%	31.70%	
Private and HMO	32.70%	29.60%	33.80%	
Self-pay	12.30%	8.40%	13.70%	
No charge	1.40%	0.90%	1.50%	
Other	4.70%	1.50%	5.80%	
Hospital Bed Size				0.446
Small	7.30%	6.00%	7.70%	
Medium	22.10%	21.90%	22.20%	

Large	70.60%	72.20%	70.10%	
Hospital Region				<0.001
Northeast	16.80%	24.90%	14.10%	
Midwest	14.20%	15.90%	13.70%	
South	45.40%	50.30%	43.90%	
West	23.50%	9.00%	28.30%	
Hospital Teaching Status				0.001
Teaching	65.20%	75.10%	61.80%	
Nonteaching	34.80%	24.90%	38.20%	
Weekend Admission	22.60%	23.40%	22.30%	0.694
Elixhauser Comorbidity Index				0.87
0	30.40%	33.20%	29.40%	
1	25.00%	25.70%	24.70%	
2	17.30%	15.90%	17.80%	
3+	27.30%	25.20%	28.10%	

The median age of all patients included in the study was 31 years. Due to case-control matching based on race and age, there were no statistically significant difference between groups. The majority of patients were black as would be expected due to the higher prevalence of SCD in this population. Patients with SCD were more likely to have Medicare or Medicaid compared to non-sickle cell patients (p<0.001). Also, patients with SCD were more commonly cared for in the Northeast and in teaching hospitals compared to non-sickle cell patients (p<0.001).

There was no difference between groups with regards to Elixhauser comorbidity index (p=0.870), as can be seen in (Table 3). The mean length of stay was 8.7 days in the SCD group versus 7.4 days in the control group (p=0.009). There was no significant difference (p=0.124) in the mean cost of hospitalization between sickle cell patients ($22,813.37) and the control group ($20,583.02). However, the cost of hospitalization was higher (p<0.001) in teaching hospitals ($23,456.11) compared to nonteaching hospitals ($16,860.75).

3.2. Indications for ERCP

The various indications for ERCP both in the sickle cell disease group and in controls are shown in **(Table 4)**. SCD patients had ERCP significantly more often than non-sickle cell patients for choledocholithiasis (33.8% vs. 18.0%, p<0.001), cholangitis (18.0% vs. 10.5%, p<0.001) and jaundice (13.2% vs. 4.1%, p<0.001). SCD patients were less likely to have ERCP for acute pancreatitis (17.7% vs. 30.7% p<0.001), biliary strictures (8.1% vs. 13.2%, p<0.001) and abnormal liver tests (1.4% vs. 2.8%, p=0.001) when compared to non-sickle cell patients.

Table 4: Indications for ERCP.

Variable	All (n=6553)	Sickle Cell Disease (n=1669)	Control (n=4884)	P-value
Choledocholithiasis with or without gallstones	22.00%	33.80%	18.20%	<0.001
Cholangitis	12.30%	17.90%	10.50%	<0.001
Acute Pancreatitis	27.30%	17.80%	30.70%	<0.001
Biliary Stricture	11.90%	8.10%	13.20%	<0.001
Jaundice	6.40%	13.30%	4.10%	<0.001
Abnormal liver tests	2.40%	1.40%	2.80%	0.001

3.3. ERCP related outcomes

Various ERCP-related complications were evaluated in the study including cholecystitis, perforation, post-ERCP bleeding or hemorrhage and post-ERCP pancreatitis **(Table 5)**. Overall, the rates of these complications were low in both groups. There were no perforations in either group. According to the data user agreement, any individual count of less than 10 cannot be reported and therefore cholecystitis was not reported. The rates of post-ERCP pancreatitis were not significantly different between groups (5.4% in SCD vs. 4.9% in controls, p=0.42).

Table 5: Complications of ERCP.

Variable	All (n=6553)	Sickle Cell Disease (n=1669)	Control (n=4884)	P-value
Cholecystitis	IS	IS	IS	0.246
Perforation	0%	0%	0%	-
Post-ERCP Hemorrhage	1.00%	2.20%	0.60%	<0.001
Post-ERCP Pancreatitis	5.00%	5.40%	4.90%	0.42

The rate of post-ERCP hemorrhage was significantly higher in the SCD group (2.2%) compared to the control group (0.6%) with p value of <0.001. There was no statistical difference in post-ERCP hemorrhage between teaching and non-teaching hospitals.

Independent factors associated with post-ERCP hemorrhage included sex, hospital bed size, teaching status of the hospital, acute pancreatitis and jaundice as the indication for ERCP. In addition, therapeutic maneuvers during the procedure including endoscopic sphincterotomy, endoscopic dilation of the ampulla and biliary duct and endoscopic removal of stones from the bile duct were also associated with post-ERCP hemorrhage. When accounting for these factors, the adjusted odds ratio (aOR) for post-ERCP hemorrhage in sickle cell disease vs. non-sickle cell patients was 5.06 (95% CI, 2.92 – 8.78, p<0.001). The risk was significantly higher in patients undergoing a therapeutic ERCP for removal of stones from the bile duct, aOR 4.52 (95% CI, 2.24 – 9.12, p<0.001).

The overall mortality rate was not statistically different between groups (1.2% in sickle cell disease vs. 0.6% in controls; p=0.277). The failure rate of ERCP was only 0.1% for the entire cohort.

3.4. Sickle cell disease related outcomes

Sickle cell disease has inherent complications of the disease process itself and therefore complications in this cohort undergoing ERCP were compared to the national average for SCD patients not undergoing ERCP during the same study period. Common complications, including acute chest syndrome, pain crisis, stroke, post-operative fever, infection, bacteremia, pneumonia and thrombosis, were evaluated. National estimates were based on SCD patients that did not undergo ERCP during the study period. The findings can be seen in **(Table 6)**.

Table 6: Sickle Cell Disease Complications with ERCP.

Variable	Sickle Cell Disease (n=1669)	National Estimates	P-value
Acute Chest Syndrome	5.30%	4.20%	<0.001
Pain Crisis	8.00%	2.90%	<0.001
Stroke	0.00%	0.10%	0.579
Post-op Fever	1.60%	4.30%	0.731
Infection	4.00%	3.10%	<0.001
Bacteremia	3.00%	1.60%	0.053
Pneumonia	4.30%	2.50%	0.021
Thrombosis	1.00%	0.30%	0.071

Overall, the risk of acute chest syndrome (5.3%), pain crisis (8.0%), infection (4%) and pneumonia (4.3%) were all significantly higher in SCD patients that underwent ERCP compared to the national average (all p>0.05). The risk of stroke, post-operative fever, bacteremia and thrombosis were similar between ERCP and non-ERCP groups.

4. Discussion

This was a retrospective study using national data to evaluate the safety and outcomes of ERCP in patients with sickle cell disease. Overall, 1669 patients with sickle cell disease and its variants were included. Known complications of ERCP were compared between SCD patients and controls without this disease. In order to minimize confounding, SCD-specific complications were compared between patients that underwent ERCP and those that did not.

To date, the largest study evaluating outcomes of ERCP in SCD patients had 54 patients[12]. With 1669 patients nationwide, this is currently the largest study evaluating this specific population.

The most common indication for ERCP in SCD patients with was choledocholithiasis (33.8%). Overall, ERCP was safe in patients with sickle cell disease with no difference in mortality and overall complications. The rates of post-ERCP pancreatitis were comparable between groups. There were no cases of perforation and the risk of cholecystitis was negligible. However, the rate of post-ERCP hemorrhage was statistically higher in the sickle cell disease group with an adjusted odds ratio of 5.06 (95% CI, 2.92 – 8.78, p<0.001). When assessing the indication for ERCP, the risk of hemorrhage was significantly higher in patients undergoing therapeutic ERCP for removal of stones from the bile duct, aOR 4.52 (95% CI, 2.24 – 9.12, p<0.001). Interestingly, the risk of hemorrhage was not associated with performing a sphincterotomy or dilation of the ampulla. It would be expected that patients undergoing stone retrieval would be more likely to have sphincterotomy and/or balloon sphincteroplasty, so this discrepancy is perplexing. The reason for this increased risk of hemorrhage is unknown, though perhaps trauma or size of stones removed may have played a role in the risk for bleeding, as well as medication use such as anticoagulants and antiplatelet agents, which are common in sickle cell disease to prevent or treat thrombosis[18]. Sickle Cell cholangiopathy is a rare condition thought to arise from biliary hypoxia leading to strictures[19]. Whether this type of cholangiopathy increases the risk of bleeding is unknown. Pseudoaneurysm formation and vascular injury are other possible mechanisms to account for this increased rate of bleeding[18]. Unfortunately, details regarding medications are not available through the National Inpatient Sample.

Complications related to sickle cell disease itself were compared between patients who underwent ERCP and those who did not. Overall, the risks of acute chest syndrome, pain crisis, infection and pneumonia were significantly higher in the patients with sickle cell disease who underwent ERCP compared to sickle cell patients who did not undergo ERCP during the study period. This is important because these complications of sickle cell disease confer a high morbidity and mortality. A possible mechanism behind the development of acute chest syndrome in this cohort is from hypoventilation from sedation and gastric insufflation leading to left-sided atelectasis[20]. This same mechanism could also explain the increased incidence of pneumonia. Pain crises can be induced by hypoxia, hypothermia, dehydration and other physiologic stressors; it is therefore vital that in the preoperative, operative and post-operative periods, these parameters are optimized[21]. Though it was not possible to elicit whether preoperative antibiotics were given to all patients prior to ERCP in this cohort, the risk of infection was higher amongst those undergoing ERCP, raising the possibility that prophylactic antibiotics may be beneficial for all sickle-cell patients before all ERCPs. A study by Cawich, et al. proposes optimal management of sickle cell disease patients during ERCP and includes pre-procedural administration of antibiotics, management of fluids, close monitoring of vitals including proper oxygenation and chest physiotherapy amongst other interventions during the periods before, during and after ERCP in order to minimize some of the comorbidities seen above[12]. Of note, pre-procedural antibiotics are currently not recommended by the ASGE for routine ERCP with adequate biliary drainage, so further studies specifically in sickle cell disease patients are warranted to clarify if there is indeed benefit[22].

Ultimately, the mortality rate in our cohort was low and not statistically different between the sickle cell and non-sickle cell groups, which is reassuring. The rate of ERCP failure was also negligible between groups ensuring that success rates are high even in this specific population.

The conclusions of this study are limited by the retrospective nature of this study. The data drawn upon were dependent on coders correctly billing interventions and diagnoses encountered during the hospitalization, which introduces inherent bias. To overcome this, matched controls were selected from the same data set to ensure that results are not overestimated. Though rates of post-ERCP hemorrhage were higher in the sickle cell disease group, the severity of hemorrhage could not be adequately discerned. However, it was clear that the rate was significantly higher amongst this cohort when compared to matched controls and that overall mortality in the sickle cell group was not higher. Additionally, other helpful clinical data are not available by

using the NIS database. Factors such as severity of presentation, laboratory values, disease course, medications (such as anticoagulation/ antiplatelet agents), anesthesia and fluids are not available, which raises the possibility of confounding variables. Despite these limitations, the large number of patients included makes this the largest study evaluating the outcomes of ERCP in patients with sickle cell disease.

5. Conclusion

This study confirms that performing ERCP in patients with sickle cell disease carries no greater mortality than the general population, though the risk of post-ERCP hemorrhage is higher, especially when ERCP is performed for stone extraction. Endoscopists performing ERCP should be aware of the possible increased risk of post procedure hemorrhage and take precautions to reduce that risk in patients undergoing stone extraction.

It is also critical to be aware of the increased risk of acute chest syndrome, infection, pain crisis and pneumonia and take appropriate precautions in order to help prevent them. Further studies are warranted to develop standardized protocols to help prevent these complications which will likely include antibiotic prophylaxis in all SCD patients undergoing ERCP.

6. Contributions

All authors contributed equally to the production of this manuscript.

7. Conflicts of interest

All authors declare no relevant conflicts of interest.

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