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Original Article

Outcomes of endoscopic retrograde cholangiopancreatography-guided gallbladder drainage compared to percutaneous cholecystostomy in acute cholecystitis

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Backgrounds/Aims: Endoscopic retrograde cholangiopancreatography-guided gallbladder drainage (ERGD) is an alternative to percutaneous cholecystostomy (PTC) for hospitalized acute cholecystitis (AC) patients.
Methods: We retrospectively analyzed propensity score matched (PSM) AC hospitalizations using the National Inpatient Sample database between 2016 and 2019 to compare the outcomes of ERGD and PTC.
Results: After PSM, there were 3,360 AC hospitalizations, with 48.8% undergoing PTC and 51.2% undergoing ERGD. There was no difference in median length of stay between the PTC and ERGD cohorts ($p = 0.110$). There was a higher median hospitalization cost in the ERGD cohort, $62,562 (interquartile range [IQR] $40,707–97,978) compared to PTC, $40,413 (IQR $25,244–65,608; $p < 0.001$). The 30-day inpatient mortality was significantly lower in hospitalizations with ERGD compared to PTC (adjusted hazard ratio 0.16, 95% confidence interval [CI]: 0.1–0.41; $p < 0.001$). There was no difference in association with blood transfusions, acute renal failure, ileus, small bowel obstruction, and open cholecystectomy conversion ($p > 0.05$) between hospitalizations with ERGD and PTC. There was lower association of acute hypoxic respiratory failure (adjusted ratio [AOR] 0.46, 95% CI: 0.29–0.72; $p = 0.001$), hypovolemia (AOR 0.66, 95% CI: 0.49–0.82; $p = 0.009$) and higher association of lower gastrointestinal bleed (AOR 1.94, 95% CI: 1.48–2.54; $p < 0.001$) with ERGD compared to PTC.
Conclusions: ERGD is a safer alternative to PTC in patients with AC. The risk complications are lower in ERGD compared to PTC but no difference exists based on mortality or conversion to open cholecystectomy.

Key Words: Cholecystostomy; Cholangiopancreatography, endoscopic retrograde; Inpatients; Cholecystitis, acute; Health care costs

INTRODUCTION

Acute cholecystitis (AC), inflammation of the gall bladder, is a common healthcare problem with rising incidence over the last 16 years [1]. This has resulted in a growing healthcare cost burden, reportedly up to $6 to $9 billion annually [1,2]. The main treatment method for AC is laparoscopic cholecystectomy (LC), provided the risk of concurrent comorbidities and the likelihood of open surgical conversion is low [3,4]. However, operational risks may still be high in elderly patients or patients with significant comorbidity, making urgent LC inappropriate [5]. Therefore, for high-risk patients or those with symptoms

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for over 72 hours, surgeons often opt for delayed LC after four weeks to allow the inflammation to subside. After recovering from AC, patients should be considered for cholecystectomy. On the other hand, in cases that are ineligible for LC, percutaneous cholecystostomy (PTC) and endoscopic retrograde cholangiopancreatography (ERCP)-guided gallbladder drainage (ERGD) are considered alternatives [6,7]. However, so far, there are only a few studies comparing the success rates and adverse events between endoscopic and percutaneous biliary drainage for AC [8]. The usefulness of PTC as a drainage method for high-risk patients is endorsed by multiple case-series studies [9,10]. However, preliminary data using ERCP-guided drainage is encouraging [4,11]. In recent years, endoluminal drainage techniques are becoming popular due to earlier recovery times and a reduced need for repeat interventions. ERGD utilizes endoscopic techniques to access the gallbladder via a natural orifice and could be the first-line alternative to PTC in the future [4]. Notably, data on the direct comparison of PTC and ERGD is limited to a few small-scale studies. We intended to evaluate the outcomes between PTC and ERGD using a large sample size from the National Inpatient Sample (NIS) database for the US population. NIS has been previously utilized to report procedural outcomes for gallbladder disorders [12,13].

MATERIALS AND METHODS

Data source and study population

The NIS database is a publicly available inpatient database that allows weighted sample data representing all nonfederal hospitals in the US [14]. The NIS was analyzed to extract data from January 1st, 2016 to December 31st, 2019. More details on the sample and design of the NIS can be found at https://www.hcup-us.ahrq.gov. Using the International Classification of Diseases, tenth Revision, Clinical Modification (ICD-10-CM), all patients (≥18 years of age) with a diagnosis of AC (ICD-10-CM codes given in the Supplementary Table 1) were considered for the study. Patients were divided into two cohorts based on whether they underwent percutaneous transhepatic drainage (ICD-10-PCS in the Supplementary Table 1) or ERGD (ICD-10-PCS in the Supplementary Table 1) within the first 72 hours before undergoing cholecystectomy. Exclusion criteria included; (1) cholecystectomy was not performed or performed within the first 72 hours of hospitalization; (2) patient had gallbladder perforation, hepatic abscess, or pregnancy; these are high-risk conditions and could influence the choice of drainage procedure and timing of subsequent cholecystectomy [4]; (3) patients who were admitted electively or transferred; and (4) patient who underwent ERCP but no stenting for gallbladder drainage was performed. Failure of EGRD was defined as patients having to undergo PTC after the procedure or open cholecystectomy during the index hospitalization. The outcomes of this study were reported according to The Strengthening the Reporting of observational studies in epidemiology (STROBE) guidelines [15].

Outcomes of interest

The primary outcomes were the length of stay (LOS), mean inpatient cost, and mortality comparison between the two groups. Secondary outcomes included the open cholecystectomy risk and complication rate, including variables such as blood transfusion, acute hypoxic respiratory failure (AHRF), acute renal failure (ARF), hypovolemia, hypovolemic shock, bile duct perforation, choleperitonitis, ileus, small bowel obstruction (SBO), and melena/lower gastrointestinal bleed (LGIB). Other covariates of interest included bio-demographical characteristics. The Elixhauser list of 31 comorbidities that utilizes ICD diagnosis codes was to report the Elixhauser Comorbidity Index score (ECI) [16].

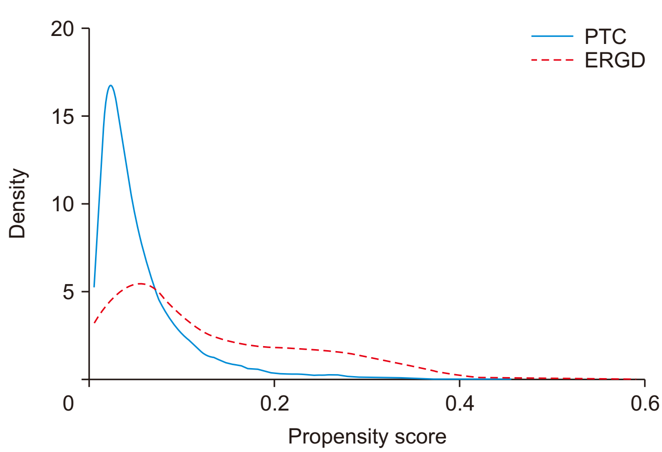

Fig. 1. Covariance graph before propensity matching the cohorts. ERGD, endoscopic retrograde cholangiopancreatography-guided gallbladder drainage; PTC, percutaneous cholecystostomy.

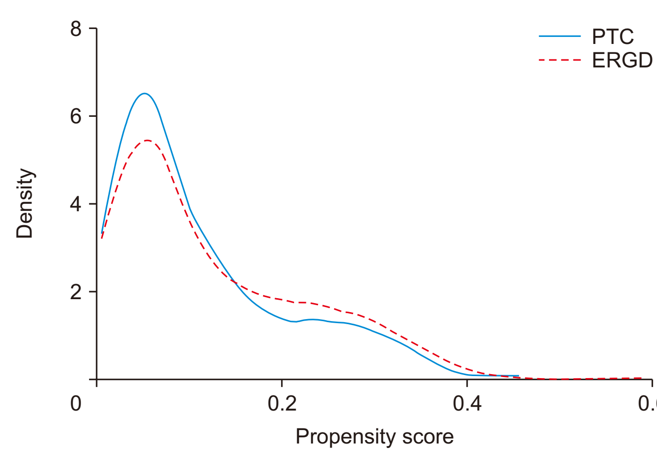

Fig. 2. Covariance graph after propensity matching the cohorts. ERGD, endoscopic retrograde cholangiopancreatography-guided gallbladder drainage; PTC, percutaneous cholecystostomy.

Table 1. Baseline demographical and hospital characteristics of hospitalizations before and after propensity matching

Patient characteristic	ERGD	Percutaneous cholecystostomy (unmatched)	*p*-value	Percutaneous cholecystostomy (matched)	*p*-value
No. of patient (%)	1,720	26,090		1,640	
Sex			< 0.001		
Male	710 (41.3)	14,845 (56.9)		790 (48.2)	< 0.001
Female	1,010 (58.7)	11,240 (43.1)		850 (51.8)	
Median age (yr)	62 (43–75)	73 (62–83)	< 0.001	64 (44–78)	0.002
Median LOS (day)	4 (3–6)	5 (3–7)	< 0.001	4 (3–6)	0.110
Median hospital cost (USD)	62,562 (40,707–97,978)	44,332 (28,103–71,049)	<0.001	40,413 (25,244–65,608)	< 0.001
Age group (yr)			< 0.001		0.017
18–34	300 (17.4)	655 (2.5)		240 (14.6)	
34–49	285 (16.6)	1,900 (7.3)		270 (16.5)	
50–64	350 (20.3)	5,330 (20.4)		325 (19.8)	
65–79	485 (28.2)	9,320 (35.7)		450 (27.4)	
≥ 80	300 (17.4)	8,885 (34.1)		355 (21.6)	
Race/ethnicity			< 0.001		0.014
White	1,110 (64.5)	18,730 (71.8)		1,075 (65.5)	
Black	145 (8.4)	2,690 (10.3)		140 (8.5)	
Hispanic	320 (18.6)	3,070 (11.8)		260 (15.9)	
Asian or Pacific Islander	65 (3.8)	720 (2.8)		65 (4.0)	
Native American	20 (1.2)	130 (0.5)		10 (0.6)	
Other	60 (3.5)	750 (2.9)		90 (5.5)	
Elixhauser Comorbidity Index score			< 0.001		0.006
0	270 (15.7)	1,225 (4.7)		325 (19.8)	
1	355 (20.6)	2,395 (9.2)		350 (21.3)	
2	330 (19.2)	3,755 (14.4)		270 (16.5)	
≥3	765 (44.5)	18,715 (71.7)		695 (42.4)	
Median annual income in patient's zip code (USD)			< 0.001		0.051
$1–24,999	495 (28.7)	6,800 (26.1)		435 (26.5)	
$25,000–34,999	365 (21.4)	6,605 (25.3)		370 (22.5)	
$35,000–44,999	445 (25.8)	6,515 (24.9)		385 (23.7)	
$45,000 or more	415 (24.1)	6,170 (23.6)		450 (27.4)	
Insurance type			< 0.001		< 0.001
Medicare	774 (44.8)	18,132 (69.5)		820 (50.0)	
Medicaid	297 (17.3)	2,348 (9.0)		285 (17.4)	
Private	504 (29.3)	4,800 (18.4)		451 (27.5)	
Uninsured	145 (8.7)	810 (3.1)		84 (5.1)	
Hospital characteristics					
Hospital region			< 0.001		< 0.001
Northeast	360 (20.9)	6,865 (26.3)		425 (25.9)	
Midwest	345 (20.1)	6,035 (23.1)		360 (22.0)	
South	575 (33.4)	8,590 (32.9)		550 (33.5)	
West	440 (25.6)	4,600 (17.6)		305 (18.6)	
Hospital status			0.080		< 0.001
Rural	60 (3.5)	995 (3.8)		45 (2.7)	
Urban non-teaching	405 (23.5)	4,570 (17.5)		260 (15.9)	
Urban teaching	1,255 (73.0)	20,525 (78.7)		1,335 (81.4)	
Died during hospitalization	5 (0.3)	395 (1.5)	< 0.001	30 (1.8)	< 0.001

Values are presented as number (%) or median (interquartile range).
ERGD, endoscopic retrograde cholangiopancreatography-guided gallbladder drainage; LOS, length of stay.

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Statistical analysis

Due to intrinsic differences in baseline patient and hospital characteristics between patients undergoing PTC and ERGD, we settled for propensity score matched (PSM) analyses to adjust the differences before regression analysis [17]. Propensity scores were computed by modeling a logistic regression with the dependent variable as the odds of undergoing an ERGD and the independent variables were age, sex, race, baseline ECI, primary payer, hospital characteristics including location, region and academic status, and day of the procedure. Later, the balance between the matched groups was examined (Fig. 1, 2). Due to the non-parametric nature of the database, the Mann–Whitney test and the chi-squared test were utilized, respectively. Medians with interquartile ranges (IQR) were generated for continuous variables and frequencies with proportions for categorical variables. Cox regression models were used to predict the power of ERGD compared to PTC regarding the timing for 30-day all-cause mortality. Outcomes were reported in adjusted hazard ratios (HRadj) with a 95% confidence interval (CI). Logistic regression was used to report the association of therapy with adverse outcomes reported in adjusted ratios (AOR) with a 95% CI as in prior studies [18,19]. Outcomes of linear regression were reported as adjusted standard mean differences with p-values, and standard errors were as ±standard error. Analyses were performed using Stata: Statistical software for data science version 16.0. The threshold for statistical significance was 0.05, with two-sided p-values. NIS contains deidentified patient data. The present study was not applicable for institutional review board oversight, because the NIS database is accessible to the public and the patients in the database are de-identified. Due to the public availability of this database, patient consent was also waived.

RESULTS

A total of 27,810 hospitalizations satisfied the selection criteria before matching. Before matching, 1,720 (6.18%) underwent ERGD, and 26,090 (93.82%) underwent PTC. Using nearest neighbor matching, we matched 1,640 hospitalizations with PTC (controls) to the selected hospitalizations with ERGD (cases). A propensity score was generated from hospital-level variables (Table 1) and comorbidities (Table 2). The cohorts were matched using demographical, hospital factors, and comorbidities mentioned in Table 1. The covariate balance was assessed using a two-way plot shown in Fig. 1 (before match) and Fig. 2 (after match). The matched cohort showed no statistical difference between major comorbidities, including congestive heart failure, cardiac arrhythmias, valvular disease, pulmonary circulation, peripheral vascular disease, hypertension, diabetes, chronic pulmonary disease, hypothyroidism, renal failure, liver disease, peptic ulcer disease, excluding bleeding, metastatic cancer, solid tumor without metastasis, coagulopathy, and psychoses ($p > 0.05$) (Table 2). There was a female (58.7% vs. 51.8%) and Hispanic race (18.6% vs. 15.9%) prevalence in hospitalizations with ERGD compared to PTC ($p < 0.05$). The median age was lower in hospitalizations with ERGD (62 years, IQR 43–75 years) than PTC (64 years, IQR 44–78 years; $p = 0.002$). There was no difference in median LOS among both cohorts. The median hospitalization cost was higher in hospitalizations with ERGD $62,562 (IQR $40,707–97,978) than PTC $40,413 (IQR $25,244–65,608) ($p < 0.001$). Mortality was higher in hospitalizations with PTC compared to ERGD (1.8% vs. 0.3%, $p < 0.001$). Additional demographics are described in Table 1. In matched cohorts, there was no difference in blood transfusions, ARF, ileus, and SBO ($p > 0.05$). There was a high prevalence of AHRF (3.7% vs. 1.7%) and hypovolemia (6.4% vs. 4.4%) in PTC compared to the ERGD group ($p < 0.001$). LGIB

Table 2. Complication rate in hospitalizations undergoing ERGD compared to percutaneous drainage for acute cholecystitis before and after propensity matching

Variable	ERGD	Percutaneous cholecystostomy (unmatched)	*p*-value	Percutaneous cholecystostomy (matched)	*p*-value
Blood transfusion	20 (1.2)	685 (2.6)	< 0.001	25 (1.5)	0.360
Acute hypoxic respiratory failure	30 (1.7)	1,280 (4.9)	< 0.001	60 (3.7)	< 0.001
Acute renal failure	200 (11.6)	5,920 (22.7)	< 0.001	220 (13.4)	0.120
Hypovolemia	75 (4.4)	2,755 (10.6)	< 0.001	105 (6.4)	0.009
Shock	0 (0.0)	50 (0.2)	0.069	0 (0.0)	-
Bile duct perforation	0 (0)	0 (0)	-	0 (0.0)	-
Choleperitonitis	5 (0.3)	15 (0.1)	< 0.001	0 (0.0)	0.029
Ileus	50 (2.9)	920 (3.5)	0.180	50 (3.0)	0.810
Small bowel obstruction	5 (0.3)	75 (0.3)	0.980	10 (0.6)	0.170
Melena/Lower gastrointestinal bleed	165 (9.6)	1,725 (6.6)	< 0.001	85 (5.2)	< 0.001

Values are presented as number (%).
ERGD, endoscopic retrograde cholangiopancreatography-guided gallbladder drainage.

was higher in hospitalizations with ERGD than PTC (9.6% vs. 5.2%), $p < 0.001$.

In matched cohort on logistic regression, there was no difference in association with blood transfusions (AOR 0.76, 95% CI: 0.42–1.37; $p = 0.360$), ARF (AOR 0.84, 95% CI: 0.69–1.04; $p = 0.120$), ileus (AOR 0.95, 95% CI: 0.63–1.41; $p = 0.810$), SBO (AOR 0.47, 95% CI: 0.16–1.38; $p = 0.170$), and risk of conversion to open cholecystectomy (AOR 0.95, 95% CI: 0.27–3.29; $p = 0.360$) between hospitalizations with ERGD and PTC. There was lower association of AHRF (AOR 0.46, 95% CI: 0.29–0.72; $p = 0.001$), hypovolemia (AOR 0.66, 95% CI: 0.49–0.82; $p = 0.009$) and higher association of LGIB (AOR 1.94, 95% CI: 1.48–2.54; $p < 0.001$) with ERGD compared to PTC for AC hospitalizations.

The 30-day inpatient mortality was significantly lower in hospitalizations with ERGD compared to PTC (HRadj 0.16, 95% CI: 0.1–0.41; $p < 0.001$).

DISCUSSION

The present study reports inpatient outcomes between PTC compared to ERGD in hospitalizations with AC. There were 3,360 PSM weighted hospitalizations for the study period that met inclusion criteria, with 48.8% undergoing PTC and 51.2% undergoing ERGD. There was no difference in median LOS between both cohort. The median hospitalization cost was significantly higher in hospitalizations with ERGD than in PTC. The mortality was higher in hospitalizations with PTC than in ERGD (1.8% vs. 0.3%). There was no difference in association with blood transfusions, ARF, ileus, SBO, and open chole-

Table 3. Elixhauser comorbidities comparison before and after propensity matching

Variable	ERGD	Percutaneous cholecystostomy (unmatched)	*p*-value	Percutaneous cholecystostomy (matched)	*p*-value
Congestive heart failure	200 (11.6)	6,905 (26.5)	< 0.001	200 (12.2)	0.610
Cardiac arrhythmias	280 (16.3)	8,910 (34.2)	< 0.001	295 (18.0)	0.190
Valvular disease	95 (5.5)	2,615 (10.0)	< 0.001	80 (4.9)	0.400
Pulmonary circulation	45 (2.6)	1,450 (5.6)	< 0.001	60 (3.7)	0.083
Peripheral vascular disease	75 (4.4)	3,010 (11.5)	< 0.001	75 (4.6)	0.771
Uncomplicated HTN	665 (38.7)	11,250 (43.1)	< 0.001	595 (36.3)	0.157
Paralysis	0 (0.0)	230 (0.9)	< 0.001	10 (0.6)	0.001
Other neurological disorders	70 (4.1)	2,295 (8.8)	< 0.001	65 (4.0)	0.881
Chronic pulmonary diseases	225 (13.1)	5,625 (21.6)	< 0.001	180 (11.0)	0.061
Uncomplicated diabetes	225 (13.1)	4,200 (16.1)	< 0.001	180 (11.0)	0.061
Complicated diabetes	165 (9.6)	5,140 (19.7)	< 0.001	145 (8.8)	0.457
Hypothyroidism	230 (13.4)	4,065 (15.6)	0.014	210 (12.8)	0.630
Renal failure	200 (11.6)	6,165 (23.6)	< 0.001	150 (9.1)	0.019
Liver disease	205 (11.9)	2,560 (9.8)	0.005	165 (10.1)	0.086
Peptic ulcer disease excluding bleeding	50 (2.9)	300 (1.1)	< 0.001	50 (3.0)	0.818
AIDS/HIV	0 (0.0)	55 (0.2)	0.057	0 (0)	-
Metastatic cancer	35 (2.0)	1,335 (5.1)	< 0.001	35 (2.1)	0.846
Solid tumor without metastasis	55 (3.2)	2,280 (8.7)	< 0.001	60 (3.7)	0.466
Rheumatoid arthritis/collagen vascular disorder	50 (2.9)	820 (3.1)	0.593	30 (1.8)	0.041
Coagulopathy	95 (5.5)	2,365 (9.1)	< 0.001	105 (6.4)	0.280
Obesity	390 (22.7)	5,110 (19.6)	0.002	315 (19.2)	0.014
Weight loss	45 (2.6)	2,215 (8.5)	< 0.001	70 (4.3)	0.008
Fluid and electrolyte disorder	455 (26.5)	9,790 (37.5)	< 0.001	380 (23.2)	0.028
Blood loss anemia	10 (0.6)	160 (0.6)	0.877	0 (0.0)	0.002
Deficiency anemia	50 (2.9)	1,080 (4.1)	0.012	50 (3.0)	0.817
Alcohol abuse	45 (2.6)	1,030 (3.9)	0.006	60 (3.7)	0.083
Drug abuse	40 (2.3)	505 (1.9)	0.266	65 (4.0)	0.006
Psychoses	5 (0.3)	210 (0.8)	0.018	5 (0.3)	0.948
Depression	165 (9.6)	2,930 (11.2)	0.036	125 (7.6)	0.042
Complicated HTN	255 (14.8)	8,175 (31.3)	< 0.001	250 (15.2)	0.730

Values are presented as number (%).
ERGD, endoscopic retrograde cholangiopancreatography-guided gallbladder drainage; HTN, hypertension.

cystectomy conversion between hospitalizations with ERGD compared against hospitalizations with PTC. There was a lower association between AHRF and hypovolemia and a higher association of lower GI bleeding with ERGD compared to PTC for AC hospitalizations.

In the present study, after matching, there was a higher prevalence of males in the PTC cohort (48.2%) and a lower prevalence in the ERGD cohort (41.3%) ($p < 0.001$). There was a higher rate of PTC than ERGD in the age group ≥80 years (21.6% vs. 17.4%; $p < 0.001$). This is consistent with previous reports of higher PTC rates in elderly populations [20]. It could be hypothesized that minimally invasive techniques among the elderly population can result in fewer adverse effects on geriatric physiology, especially when comorbidities are strong predictors in this population [21]. Racial analysis revealed a higher rate of Hispanics undergoing biliary drainage during hospitalization (Table 1), consistent with prior reports concluding that ERCP use is higher in Hispanics, possibly secondary to the increased prevalence of biliary stones in this population [22]. Evidence suggests that patients admitted to hospitals with high volumes of admission for gallbladder disorders in urban settings were more likely to undergo PTC and ERCP-guided drainage than surgical drainage. However, a direct comparison between these two does not exist [23]. In the present study, after PSM, there was a slight increase in the rate of PTC than ERGD based on hospital status (81.4% vs. 73.0%, $p < 0.001$). Perhaps the availability of advanced endoscopists trained in ERCP is sporadic between teaching and non-teaching hospitals, and the availability of interventional radiologists who can manage perioperative complications and experienced medical staff in teaching hospitals leads to higher PTC than ERCP [24]. At this time, a definitive conclusion cannot be made.

The median hospital charged in hospitalizations with PTC was lower than those in the ERGD cohort, while no significant difference existed based on median LOS (Table 1). Previously there has been no direct comparison between PTC and ERGD and their associated LOS and hospitalization charges. The difference in hospital charges is consistent with previous reports and could be secondary to changing insurance policies and models [25]. The study reported higher mortality in PTC than ERGD, with increased risk, on analysis (HRadj 0.16, 95% CI: 0.1–0.41, $p < 0.001$). The mortality prevalence could be explained by the higher prevalence of the elderly population (age ≥ 80 years) in the PTC cohort compared to ERGD. Previous literature reports that the elderly population has similar morbidity and mortality rates for ERCP compared to the younger population [26]. A direct comparison between PTC and ERGD has not previously been reported in terms of mortality for AC hospitalizations. Literature also suggests that occlusion, dislocation, cholangitis, bleeding, pneumothorax, pneumoperitoneum, bile leakage, accidental catheter dislodgement, and sepsis of the biliary tract were the most common complications observed during PTC [27,28]. Pancreatitis, infection, bleeding, and perforation are commonly seen after ERCP drainage [29]. Compared to PTC, we report a lower association between AHRF and hypovolemia in hospitalizations undergoing ERGD (Table 3). This is comparable to a prior study that reported a higher incidence of respiratory complications in patients undergoing PTC to ERGD [4]. There was no significant difference in association of conversion to open cholecystectomy in the ERGD group compared to PTC (AOR 0.95, 95% CI: 0.27–3.29; $p = 0.360$), consistent with previous literature stating no difference [4].

Limitations of this study and the database utilized are (but are not limited to) misclassification of ICD codes to analyze disease symptoms and pharmacotherapy, and the retrospective nature of data extraction. Additionally, due to a lack of randomization and blinding, results could be impacted negatively but this has been minimized with PSM.

In conclusion, ERGD could be an alternative to PTC in hospitalizations that are ineligible for LC and has a lower respiratory complication rate and inpatient mortality. ERGD has a lower association with AHRF, blood transfusions, ARF, and ileus than PTC. There was no difference in blood transfusions, ARF, Ileus, and SBO among both cohorts. Prospective trials in the future would be beneficial.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.14701/ahbps.22-065.

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CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTIONS

Conceptualization: HA. Data curation: SP, PM. Methodology: HA, SP. Visualization: HA, US, SP. Writing - original draft: SS, NLB, SM, US. Writing - review & editing: All authors.

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