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Safety, risk stratification, and cost of ERCP in patients with cirrhosis: a prospective controlled study

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Abstract

Introduction Given that ERCP has major procedure-related complications in non-cirrhotic patients, the complications and the cost of therapeutic ERCP were not studied in cirrhotic patients.

Aim We aimed to study the complications and cost of ERCP compared to patients without cirrhosis.

Patients and methods Outcome and complications of therapeutic ERCP were prospectively studied in patients with cirrhosis and compared to patients without cirrhosis undergoing ERCP. Patients with cirrhosis were evaluated using the Child-Pugh classification, MELD, MELD Na, and APRI scores. Safety was assessed up to 30 days following the procedure.

Results Pancreatitis, perforation, bleeding, and cardiopulmonary complications were not different in both groups (8% vs. 9.3, 0% vs. 2%, 3.3% vs. 4%, and 4% vs. 2% respectively), while cholangitis occurred more frequently in cirrhosis (13.3% vs. 1.3% respectively). Hospital stay was longer, and mortality and costs were significantly higher among patients with cirrhosis. Patients with Child C cirrhosis developed more complications and had higher mortality. A MELD score cut-off of ≥ 11.5 separated all mortalities. Similarly, MELD-Na and APRI separated patients with cirrhosis who had more frequent complications and mortalities.

Conclusions Patients with cirrhosis experienced more complications and costs, and cirrhotic patients who developed moderate to severe complications were more likely to die.

Keywords ERCP, Liver cirrhosis, Cholangitis, Obstructive jaundice, Cost

Introduction

Since its introduction in the sixties of the last century, ERCP has come to be the preferred therapeutic modality for many biliary and pancreatic diseases [1]. However, due to its major and sometimes catastrophic complications, and with the advances in imaging technology and endoscopic ultrasound, non-invasive imaging techniques are preferred as diagnostic tools, except in cases where intra-ductal biopsy, intra-ductal ultrasound, and or cholangioscopy are indicated. Liver cirrhosis is associated with a disturbed coagulation profile and thrombocytopenia, which can contribute to bleeding with invasive procedures. The impaired immune function of patients with cirrhosis and the CBD manipulation during ERCP increase the risk factors for bacterial cholangitis, peritonitis, hepato-renal syndrome, and hepatic encephalopathy [2, 3].

Because of disease-related complications of cirrhosis, varieties of scores have been derived to estimate the prognosis of patients with cirrhosis to identify patients who are at risk of morbidity and mortality. The practical

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advantages of these scores include their noninvasiveness, widespread availability, and reproducibility.

Child score was introduced as an index of liver disease severity and prognosis. Elements of the Child score include bilirubin, albumin, ascites, and encephalopathy; although it is simple in the evaluations of the liver condition, it has been affected by its fallibility to subjective assessment (ascites and encephalopathy), and the ceiling effects are affected by extraneous factors (e.g., diuretics) [4].

Many years ago, the model of end-stage liver disease (MELD) score was proposed as an objective predictor of short-term mortality among patients with cirrhosis undergoing transjugular intrahepatic portosystemic shunt placement [5]. Its simplicity and availability make it widely accepted for the assessment of liver disease including medical urgency and organ allocation.

Several prognostic scores are used to predict prognosis prior to operative intervention in patients with cirrhosis, such as the Child-Turcotte-Pugh classification and the MELD and MELD Na scores. Different scores were used in a few studies with few numbers of patients to predict complications in patients with cirrhosis undergoing ERCP, and large prospective controlled studies are lacking. The cost analysis of ERCP was not studied previously in patients with cirrhosis.

Aim of the study

We aimed to assess the safety, costs, and feasibility of the ERCP procedure in patients with cirrhosis versus patients without cirrhosis additionally, to evaluate different function and fibrosis scores to predict post-procedure-related complications in patients with cirrhosis.

Patients and methods

Study design

Patients

Patients with liver cirrhosis undergoing ERCP for obstructive jaundice were prospectively included. Matched case-control patients without cirrhosis undergoing ERCP for the same indication were included in the same period. From December 2019 to June 2021, 150 patients with cirrhosis underwent ERCP, and a similar number without cirrhosis were included.

Methods

Baseline data obtained included history, clinical examination, liver tests, renal tests, blood count, INR, and abdominal ultrasonography. MRCP or abdominal CT was ordered when indicated.

All patients with cirrhosis were additionally evaluated by using the Child-Turcotte-Pugh classification, model of end-stage liver disease (MELD), and MELD Na scores and aspartate aminotransferase to platelet ratio index (APRI) [4–7]. Cirrhosis was diagnosed if any of the following showed confirmed its presence at any time before the procedure: liver biopsy result showing > F3 fibrosis on the Metavir score, radiological or endoscopic evidence of portal hypertension, or non-invasive liver fibrosis test (transient elastography > 12.5 kPa or FIB-4 > 3.25) [8].

Endoscopic procedures

Pre-procedure medications All patients were well hydrated and received prophylactic broad-spectrum intravenous antibiotics (cefoperazone 1 g every 12 h) before the procedure. Antibiotic administration started 1 day before the procedure and continued for 72 h after the procedure.

Four units of fresh frozen plasma were given if the INR was more than 1.8.

Platelet transfusion was done if the platelet count was less than 30,000 per microliter (mcL).

ERCP ERCP was done under propofol anesthesia for all patients. Olympus side-viewing duodenoscope (TJF190VR, Olympus, Tokyo, Japan) was used for all procedures. Zebra J-tip or straight tip guide wire (0.35/400 cm) was advanced through triple lumen papillotome (both Boston Scientific Corp, Massachusetts, USA), and the guide wire was advanced through malignant stenosis if present.

After attaining selective bile duct cannulation using guide wires, a cholangiogram was done under fluoroscopic guidance. Therapeutic interventions were done according to the findings during the procedure. These included sphincterotomy, precut sphincterotomy, sphincteroplasty, stone extraction (with balloons or baskets), stricture dilatation, insertion of pancreatic and/or biliary plastic stents, biliary metal stents, and insertion of nasobiliary tubes.

Outcome measures

We evaluated the following outcome measures: successful cannulation, successful drainage, stone extraction, stent placement, and ERCP-related complications.

Intervention was considered effective with drop of serum bilirubin to less than 3 g/dl within 30 days' stent occlusion, or primary non-functioning was defined as the persistence of jaundice or bilirubin level of more than 5 mg/dL, alkaline phosphatase, GGT, and transaminases 3 times the normal values and/or dilated bile ducts by

ultrasound and/or CT follow-up indicating re-endoscopy [9–11].

Procedure-related morbidity and mortality were defined as complications or deaths directly related to the ERCP procedure within 1 month. Cholangitis, a month post-ERCP, was considered procedure-related.

Follow-up

Patients were evaluated clinically and by laboratory investigations at day 1, day 3, day, 7, and day 30 after the procedure.

Determination of costs

A. Direct cost was estimated by determination of direct hospitalization costs for every patient (fees of specialist and consultant, imaging cost, laboratory investigations (liver profile, renal profile, and INR), procedure cost, and repeated procedure to treat complications, and cost for hospital admissions)
B. Indirect cost was estimated by determination of time lost away from productivity and activity and the times spent for procedures, hospitalization, visits for consolations, and investigations multiplied by 100 Egyptian pounds for every day

Statistical analysis of the data

Data were fed to the computer and analyzed using the IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using numbers and percentages. Quantitative data were described using range (minimum and maximum), mean, standard deviation, and, median. The significance of the obtained results was judged at the 5% level.

The used tests were as follows:

1. Chi-square test: for categorical variables, between different groups
2. Fisher's exact: correction for chi-square when more than 20% of the cells have an expected count of less than 5
3. Student *t*-test: for normally distributed quantitative variables, to compare two studied groups
4. Mann-Whitney test: for abnormally distributed quantitative variables, to compare two studied groups
5. Receiver operating characteristic curve (ROC): it is generated by plotting sensitivity (TP) on the *Y*-axis versus 1-specificity (FP) on the *X*-axis at different cut-off values. The area under the ROC curve denotes the diagnostic performance of the test. An area of more than 50% gives acceptable performance, and an area of about 100% is the best performance for the test. The ROC curve allows also a comparison of performance between two tests

Table 1 Descriptive data of the studied groups according to gender, associated diseases, and etiology of liver disease

	Cirrhosis ($n = 150$)		Non-cirrhotic ($n = 150$)		Test of sig.	*P*
	No.	%	No.	%		
Gender						
Male	90	60.0	50	33.3	$\chi^2 = 21.429$*	< 0.001*
Female	60	40.0	100	66.7		
Age (years)						
Min.–max.	25.0–87.0		19.0–87.0		$t = 3.928$*	< 0.001*
Mean ± SD.	60.01 ± 12.37		52.37 ± 20.33			
Median	60.0		52.0			
Co-morbidity						
No	86	57.3	95	63.3	1.128	0.288
DM	15	10.0	24	16.0	2.387	0.122
HTN	17	11.3	38	25.3	9.818*	0.002*
IHD	6	4.0	21	14.0	9.158*	0.002*
Thyrotoxicosis	2	1.3	4	2.7	0.680	$^{FE}p = 0.684$
Hypothyroidism	2	1.3	0	0.0	2.013	$^{FE}p = 0.498$
Asthmatic	2	1.3	2	1.3	0.000	$^{FE}p = 1.000$
Thalassemia	0	0.0	1	0.7	1.003	1.000
Cause of cirrhosis						
Non-viral	28	18.7				
HCV	94	62.7				
HBV	28	18.7				

* significante

Table 2 Comparison between the two studied groups according to laboratory data and costs

	Cirrhotic ($n = 150$)	Non-cirrhotic ($n = 150$)	Test of sig.	*P*
Hb (g/dl)				
Min.–max.	7.20–15.20	8.40–17.50	$t = 2.753$*	0.006*
Mean ± SD.	11.59 ± 1.84	12.19 ± 1.91		
Median	11.80	12.10		
WBCs (× 10^3/μl)				
Min.–max.	3.10–33.0	3.50–99.0	$U = 10939.50$	0.679
Mean ± SD.	10.54 ± 5.49	11.37 ± 11.57		
Median	8.90	9.25		
Platelets (× 10^3/μl)				
Min.–max.	59.0–769.0	1.17–599.0	$U = 7486.00$*	< 0.001*
Mean ± SD.	221.71 ± 121.87	271.53 ± 94.96		
Median	197.0	266.50		
Serum creatinine			8750.50*	0.001*
Min.–max.	0.30–7.60	0.40–6.05		
Mean ± SD.	1.20 ± 1.05	0.97 ± 0.86		
Median	0.90	0.70		
ALK			9945.00	0.082
Min.–max.	82.0–2118.0	24.0–1668.0		
Mean ± SD.	452.43 ± 365.32	377.39 ± 282.28		
Median	336.0	304.50		
GGT			9840.00	0.061
Min.–max.	19.0–1184.0	12.0–2345.0		
Mean ± SD.	333.77 ± 294.09	396.84 ± 370.62		
Median	248.50	280.50		
AST (U/L)			$U = 10723.50$	0.483
Min.–max.	15.0–761.0	11.0–1146.0		
Mean ± SD.	150.24 ± 128.27	156.19 ± 167.61		
Median	100.50	100.0		
ALT (U/L)			$U = 9067.0$*	0.004*
Min.–max.	11.0–692.0	11.0–1132.0		
Mean ± SD.	109.73 ± 103.44	194.07 ± 220.34		
Median	80.0	105.0		
Total bilirubin (mg/dl)			6.610*	< 0.001*
Min.–max.	0.50–35.0	0.20–27.0		
Mean ± SD.	12.45 ± 8.62	6.72 ± 6.22		
Median	10.10	4.60		
Direct bilirubin (mg/dl)			$t = 8.325$	< 0.001
Min.–max.	0.30–33.20	2.10–5.60		
Mean ± SD	9.64 ± 7.22	3.73 ± 0.68		
Median	8.20	3.70		
INR			4927.0*	< 0.001*
Min.–max.	0.90–3.50	0.90–2.50		
Mean ± SD.	1.39 ± 0.34	1.17 ± 0.21		
Median	1.30	1.14		
Costs			$U =$	
Direct cost				
Min.–max.	4170–19800	1050–19300	7430.500	< .000
Mean ± SD.	7581 ± 3081	6085 ± 2355		
Median	6550	5950	8285.500	

Table 2 (continued)

	Cirrhotic ($n = 150$)	Non-cirrhotic ($n = 150$)	Test of sig.	*P*
Sum:	1355308	979400		
Indirect cost				
Min.–max.	121–2783	24–2783		< .000
Mean ± SD.	584 ± 467	415 ± 428		
Median	467	363		
Sum	87604	38962	7302.500	
Total cost				
Min.–max.	4291–22583	2139–22083		< .000
Mean ± SD.	8165 ± 3517	6497 ± 2719		
Median	7034	6313		
Sum	1442912	1018362		

Abbreviations: *n* Number, *SD* Standard deviation, *Hb* Hemoglobin

* significante

Results

The study included 150 patients with cirrhosis and obstructive jaundice (60% males, mean age 60 ± 12.4 years); 35 patients were Child A, 67 patients were Child B, and 48 patients were Child C, and 150 matched patients were with obstructive jaundice without cirrhosis (56% males, mean age 52.4 ± 20.3 years). Tables 1 and 2 show the patients' baseline characteristics and laboratory data. Patients with cirrhosis were older and had less hypertension and ischemic heart disease than patients without cirrhosis. They also had lower hemoglobin and platelets and higher bilirubin and INR.

Table 3 shows the indications for ERCP and the therapeutic interventions performed. Patients without cirrhosis more often had ERCP for stone obstruction of the CBD, and patients with cirrhosis had more malignant obstruction of the CBD or CHD. Biliary cannulation was successful in 98% and 98.3% of patients with and without cirrhosis, and consequently, patients with cirrhosis had more stents placed and patients without cirrhosis had more stones extracted.

Table 4 shows the adverse events and complications in the study groups. Clinical pancreatitis, perforation, bleeding, and cardiopulmonary complications were not different in patients with and without cirrhosis, while cholangitis occurred more frequently in patients with cirrhosis (13.3% vs. 1.3% respectively). Hospital stay was longer, and mortality was significantly higher among

Table 3 Indications and therapeutic interventions

	Cirrhotic ($n = 150$)		Non-cirrhotic ($n = 150$)		χ^2	*P*
	No.	%	No.	%		
Cause of obstruction:						
Calcular	80	53.3	109	72.7	12.026*	0.001*
CBD malignant stricture	56	37.3	34	22.6	6.144*	0.01/3*
CHD malignant stricture	20	13.4	5	3.4	7.714*	0.005*
Primary sclerosing cholangitis	2	1.3	0	0.0	2.013	$^{FE}p = 0.498$
Igg4 syndrome	0	0.0	2	1.3	2.013	$^{FE}p = 0.-498$
Mirizzi syndrome	1	0.7	0	0.0	1.003	$^{FE}p = 1.000$
Intervention						
Failed cannulation	3	2.0	2	1.3	0.226	$^{FE}p = 0.681$
Papillotomy	44	29.3	81	54.0	18.775*	< 0.001*
Papilloplasty	0	0.0	9	6.0	9.278*	$^{FE}p = 0.003$
Plastic stent	117	78.0	90	60.0	11.360*	0.001*
Metal stent	13	8.7	5	3.3	3.783	0.052
Stone extraction	16	10.7	57	38.0	30.433*	< 0.001*
Precut	4	2.7	6	4.0	0.414	0.520

CBD Common bile duct, *CHD* Common hepatic duct

* significante

Table 4 Comparison between the two studied groups according to all complications (pancreatitis in 31 and 38 patients, bleeding in 5 and 6 cases, perforation in 0 and 3 cases, cholangitis in 20 and 2 cases, and cardiopulmonary complications in 6 and 3 cases and mortality in 25 and 2 cases) in cirrhotic and non-cirrhotic patients respectively

Complications	Cirrhotic ($n = 150$)		Non-cirrhotic ($n = 150$)		χ^2	P
	No.	%	No.	%		
Pre–ERCP pancreatitis						
No **(293)**	147	98	146	97.3	0.667	$^{FE}p = 0.684$
Yes **(7)**	3	2	4	2.7		
Post-ERCP pancreatitis						
No **(231)**	119	79.3	112	74.7	0.922	0.337
Yes **(69)**	31	20.7	38	25.3		
Chemical **(43)**	19	12.7	24	16.0	0.679	0.410
Clinical **(26)**	12	8.0	14	9.3	0.168	0.681
Bleeding						
No **(289)**	145	96.7	144	96.0	0.094	0.759
Yes **(11)**	5	3.3	6	4.0		
From papilla **(6)**	4	2.7	2	1.3	0.680	$^{FE}p = 0.684$
During endoscopy from papilla **(1)**	1	0.7	0	0.00	1.003	$^{FE}p = 1.000$
Mass in antrum **(1)**	0	0.0	1	0.7	1.003	$^{FE}p = 1.000$
From mass in duodenum **(1)**	0	0.0	1	0.7	1.003	$^{FE}p = 1.000$
Ulcer in stomach **(2)**	0	0.0	2	1.3	2.013	$^{FE}p = 0.498$
Perforation						
No **(150)**	150	100.0	147	98.0	3.030	$^{FE}p = 0.247$
Yes **(3)**	0	0.0	3	2.0		
Anesthesia						
No **(291)**	144	96.0	147	98.0	1.031	$^{FE}p = 0.501$
Yes **(9)**	6	4.0	3	2.0		
Desaturation **(5)**	3	2.0	2	1.3	0.203	$^{FE}p = 1.000$
Hypotension **(4)**	3	2.0	1	0.7	1.014	$^{FE}p = 0.622$
Cholangitis						
No **(278)**	130	86.7	148	98.7	18.775*	$< 0.001^{*}$
Procedure related **(22)**	20	13.3	2	1.3		
Outcome						
Improved **(272)**	125	83.3	147	98.0	19.065*	< 0.001*
Died **(28)**	25	16.7	3	2.0		
Days of admission						
Min.–max	0.25–23.0		0.25–23.0		-	< 0.001
Mean ± SD.	4.81 ± 3.88		3.61 ± 3.88			
Median	4.0		3.0			

* significante

Table 5 Causes of mortality in the studied patients

Cardiopulmonary complications	3
Pancreatitis	6
Bleeding	2
Cholangitis and infections	11
Combined causes:	
Renal impairment +metabolic acidosis:	2
Bleeding+ renal impairment +metabolic acidosis:	1

patients with cirrhosis. Patients with Child C cirrhosis developed more complications and had higher mortality. The causes of death are listed in Table 5.

Table 6 shows the correlation between rates of complications and severity of liver cirrhosis. CTP class A patients experienced fewer overall complications and mortality than class B and C patients (3.3% morbidity and 0.0% mortality vs. 15.7% and 28% for class B and 26.7% and 72% for CTP C).

Table 6 Correlation between rates of complications and severity of liver cirrhosis

		Child-Turcotte-Pugh class($n = 58$)						**MELD score ($n = 58$)**				**MELD Na ($n = 58$)**				**APRI ($n = 58$)**			
		A		**B**		**C**		**≤ 11.5**		**> 11.5**		**≤ 21.13**		**> 21.13**		**≤ 1.49**		**> 1.49**	
		No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Clinical pancreatitis ($n = 12$)	Mild	1	8.3	4	33.3	2	16.7	0	0.0	7	58.3	2	16.7	5	41.7	5	41.7	2	16.7
	Moderate	1	8.3	2	16.7	1	8.3	2	16.7	2	16.7	2	16.7	2	16.7	2	16.7	2	16.7
	Severe	0	0.0	0	0.0	1	8.3	0	0.0	1	8.3	0	0.0	1	8.3	1	8.3	0	0.0
Bleeding ($n = 5$)	Mild	1	20.0	0	0.0	2	40.0	1	20.0	2	40.0	1	20.0	2	40.0	1	20.0	2	40.0
	Moderate	0	0.0	0	0.0	2	40.0	1	20.0	1	20.0	1	20.0	1	20.0	1	20.0	1	20.0
	Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
ERCP-related cholangitis **($n = 20$)**		2	10.0	8	40.0	10	50.0	2	10.0	18	90.0	6	30.0	14	70.0	7	20.0	13	80.0
Death ($n = 25$)		0	0.0	7	28.0	18	72.0	0	0.0	25	100.0	5	20.0	20	80.0	8	32.0	17	68.0
Cardiopulmonary (anesthesia related) ($n = 6$)		0	0.0	2	33.3	4	66.7	0	0.0	6	100.0	2	33.3	4	66.7	4	66.7	2	33.3
Whole group ($n = 150$)		5	3.3	23	15.3	40	26.7	6	4	62	41.3	19	12.7	49	32.7	29	19.3	39	26

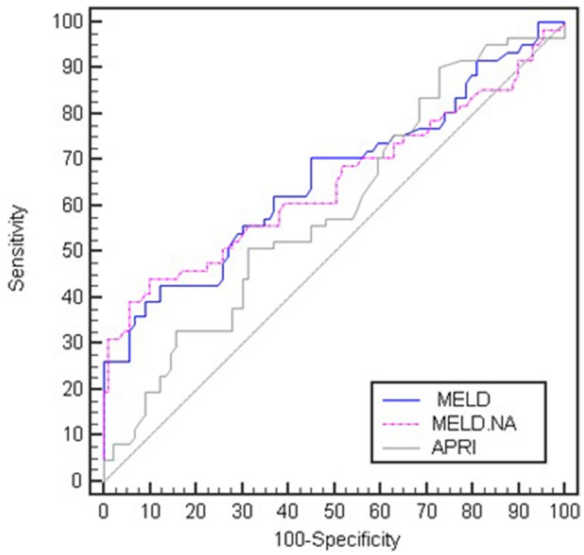

Fig. 1 The utility of the different evaluated scores to predict complications in patients with cirrhosis

At the MELD score cut-off of ≤11.5, 4% of patients developed complications, and no mortalities occurred, while at a score of > 11.5, 41% of patients developed complications, and all mortalities occurred. At MELD-Na scores of ≤21.13, the complications and mortalities were 12.7% and 20%, and at a cut-off of >21.13, the rates were 32.7% and 80%. With the APRI at a level of ≤ 1.49 and > 1.49, the complication and mortalities were 19.3% and 32% and 26% and 68%, respectively. Applying the New Wilson Index, a score of ≤ 5 and > 5 showed 5.3% and 16% and 40% and 84% morbidity and mortality, respectively (Figs. 1, 2, and 3).

Discussion

In this study, we demonstrate that pancreatitis as a complication of therapeutic ERCP was not more frequent in patients with cirrhosis. Several previously published studies reported no association between the presence of cirrhosis and pancreatitis as a complication of ERCP, except when alcohol is the underlying cause of cirrhosis [12]. However, Inamdaret al. found a significant association of post-ERCP pancreatitis with decompensated cirrhosis, which they attributed to the accumulation of administered intravenous fluids in the third space due to portal hypertension [13].

Although cirrhosis is not among the risk factors of ERCP-related pancreatitis, it is strongly linked to post-procedure bleeding. Thrombocytopenia, congestive duodenopathy, and coagulopathies are independent risk factors for bleeding. In this series, bleeding in patients with cirrhosis occurred less frequently than in patients

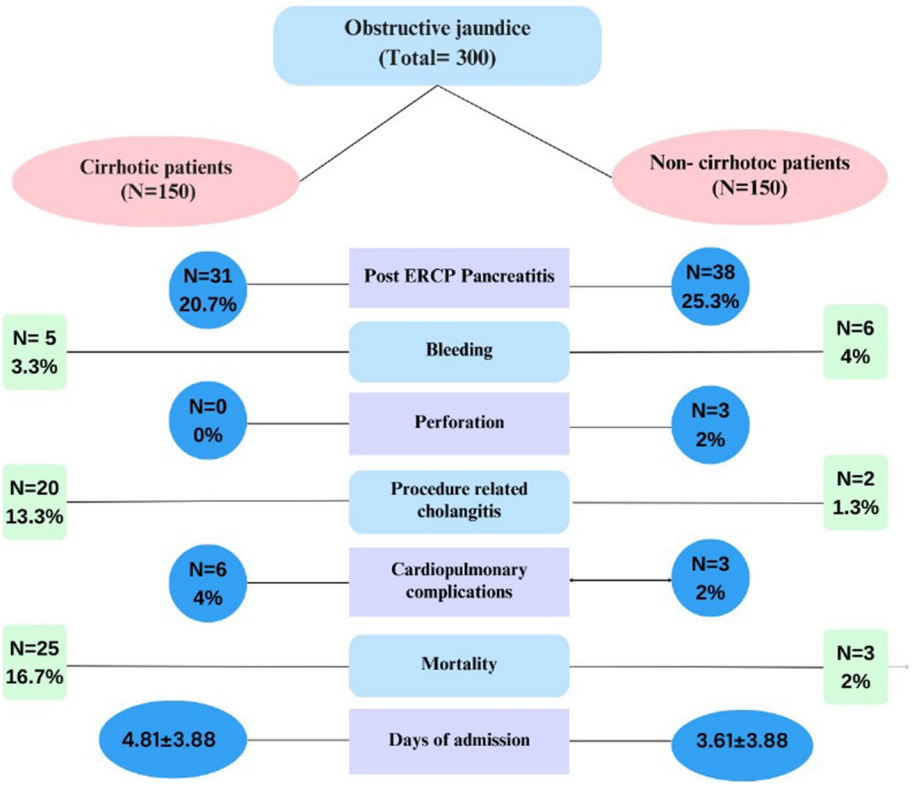

Fig. 2 The flow chart of complications occurred in studied patients

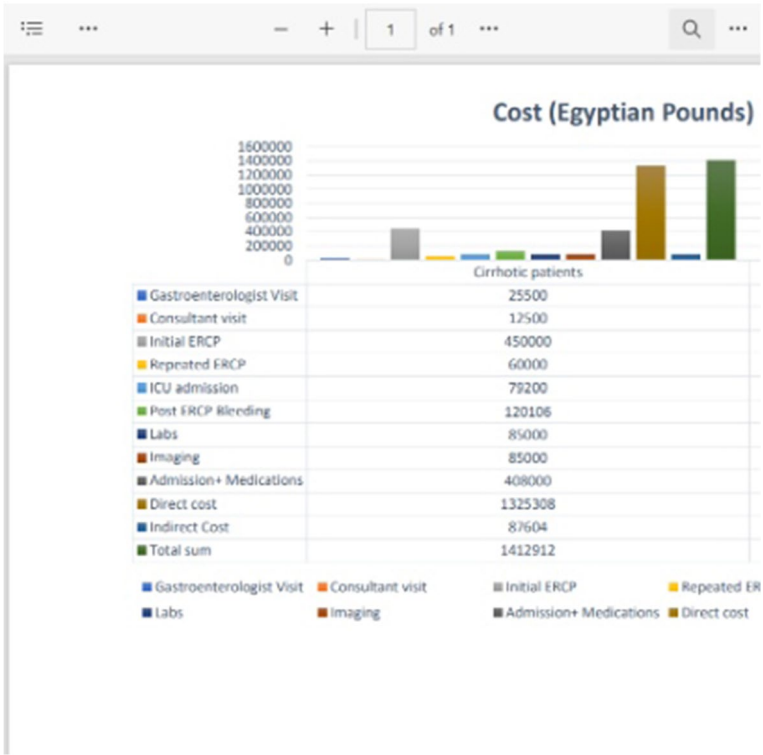

Fig. 3 The cost analysis (direct and indirect) of studied patients

without cirrhosis. However, procedure-related bleeding from the papilla after papillotomy occurred more in patients with cirrhosis. Variable rates of post-ERCP bleeding were previously reported [3, 12–15], with increased bleeding rates with increased severity of cirrhosis (from 2.1 to 25%) [3, 5, 6]. On the other hand, other studies reported no significant association found between post-sphincterotomy complications and severity of liver cirrhosis [15–18].

Although INR is the most commonly used test to assess the possibility of bleeding prior to operative procedure, we found no significant association between a higher INR and the development of bleeding post-ERCP, similar to several previous reports [2, 10, 18–21]. This might be explained by the precarious rebalanced hemostatic state caused by decreased synthetic power of the cirrhotic liver to produce both anticoagulant and pro-coagulant proteins [22–24]. However, Adler et al. avoid ERCP if the INR is > 1.7 [15]. The use of fresh frozen plasma has been shown not to reduce the risk of bleeding even with the use of standard rates of transfusions [18, 25]. The discrepancy in bleeding rates between different studies has been attributed to the differences in the characteristics of studied patients and the type of procedures.

Cardiopulmonary complications are among the major hazards post-ERCP. In our study, patients with cirrhosis developed more cardio-pulmonary complications than patients without cirrhosis, but this was not significant. With the progress of liver disease, concomitant progress of cardiac dysfunction occurs [26–28], with reduced ejection fraction [26–28] and the possibility of the associated hepato-pulmonary syndrome, portopulmonary hypertension, and hepatic hydrothorax as added risk factors [29].

In our study, cholangitis developed in 13.3% of patients with cirrhosis versus 1.3% of patients without cirrhosis. Other studies reported variable rates of cholangitis [2, 15]. Possible explanation of increased post-ERCP cholangitis is bacterial translocation caused by bile duct manipulation especially when the biliary drainage is incomplete [30, 31]. Poor immune function and portal bacteremia are possible added factors. The lower rates of cholangitis in other studies may be attributed to their retrospective nature, variability of diagnostic code, and that these studies captured only the data base of hospitalized patients.

In this report, there was a higher rate and severity of morbidity and higher mortality rate in patients with cirrhosis. Infection and cholangitis represented the major cause of mortality among patients with cirrhosis. The increased rates of morbidity and

mortality in patients with cirrhosis reflected on the length of hospital stay.

We evaluated the risk stratification of procedure-related complications in patients with cirrhosis using Child-Turcotte-Pugh classification, the MELD and MELD-Na scores, APRI, and the New Wilson index.

CTP class A patients experienced less overall complications and mortality than class B and C patients. Similarly, a MELD score ≤ 11.5 categorized patients with 4% morbidity and no mortalities. Similar results were previously reported [12–14]. The MELD-Na score and APRI also segregated patients with low vs. high risk of morbidity and mortality.

The overall percentage of mortality in patients with cirrhosis was 16.7. Causes of mortality were pancreatitis, cardiopulmonary, bleeding, cholangitis, and hepato-renal syndrome, all occurring in the setting of moderate to severe complications. Lower rates of mortality in patients with cirrhosis were reported in other studies [21, 23]; however, these studies were retrospective analyses, and the cause of death was obtained by telephone. Our study was prospective, and patients were followed up for 1 month following the procedure.

The increased bilirubin in patients with cirrhosis with obstructive jaundice is not linearly related to the severity of liver cirrhosis and is partly caused by biliary obstruction. This is a limitation of our study and other studies that use the Child-Turcotte-Pugh classification and the MELD and MELD Na scores, where bilirubin is one of the measurable variables in these scores.

The strengths of our study include its prospective nature the inclusion of patients without cirrhosis as a comparator group, and the several scores we used for risk stratification plus the direct and indirect costs were calculated in both groups.

In conclusion, ERCP is safe in patients with cirrhosis; however, these patients experienced more complications and costs than patients without cirrhosis. Patients with more advanced liver disease were more likely to develop complications, and patients who developed moderate to severe complications were more likely to die. Hospital stay and costs were more in patients with cirrhosis.

Abbreviations

ERCP	Endoscopic retrograde cholangiopancreatography
DM	Diabetes mellitus
IHD	Ischemic heart disease
HTN	Hypertension
ALT	Alanine transaminase
AST	Aspartate transaminase
ALK	Alkaline phosphatase
GGT	Gamma-glutamyl transpeptidase
HCV	Hepatitis C virus
HBV	Hepatitis B virus
INR	International normalization ratio

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Availability of data and materials
Please contact the author for data requests.

Declarations

Ethics approval and consent to participate
This study was approved by the ethics committee of the National Liver Institute (IRB number: IRB00003413). All patients undergoing ERCP gave written informed consent for the study and for the procedure.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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