Annals of Hepatology 27 (2022) 100689

Contents lists available at ScienceDirect

Annals of Hepatology

journal homepage: www.elsevier.es/annalsofhepatology

Original article

Safety and efficacy of common endoscopic treatments in patients with decompensated liver cirrhosis

Hang Yang[1], Yi Mou[1], Bing Hu*

Department of Gastroenterology, West China Hospital, Sichuan University, No. 37, Guo Xue Xiang, Wu Hou District, Chengdu 610041, China

ARTICLE INFO

Article History:
Received 12 January 2022
Accepted 11 February 2022
Available online 19 February 2022

Keywords:
Decompensated liver cirrhosis
Endoscopic treatment
Endoscopic resection
Endoscopic retrograde cholangiopancreatography
Adverse event

ABSTRACT

Introduction: The safety and efficacy have always been a concern, when patients with decompensated liver cirrhosis (DLC) receive endoscopic treatments.
Methods: To evaluate the safety and efficacy of common endoscopic treatments including endoscopic resection (ER) and endoscopic retrograde cholangiopancreatography (ERCP) applying to patients with DLC, we performed a retrospective study finally including 81 patients receiving ER (43 endoscopic mucosal resection (EMR) and 38 endoscopic submucosal dissection (ESD)) and 131 patients treated by ERCP.
Results: There were no significant differences in the rate of degeneration and invariability of Child-Pugh (CP) class and the overall rate of adverse events between two groups (93.8%/8.6% ER vs. 96.2%/15.3% ERCP). Both the degeneration rate of CP class (35.4%) and the rate of adverse events (27.1%) in subgroup CP class C of ERCP group were significantly higher (P=0). The rate of poor outcomes was higher in ERCP group (12.2%) than that in ER group (2.5%) (P=0.02). And subgroup CP class C of ERCP group had a higher poor outcome rate (27.1%) (P=0).
Conclusion: ER and ERCP could remove focal lesions or relieve symptoms induced by targeted diseases without significant changes of CP class. Significant benefits and risks coexisted in CP class C patients with DLC when receiving ERCP.

1. Introduction

Common endoscopic treatments include esophageal varices related endoscopic treatment, ER (EMR and ESD), and ERCP treatment. Esophageal varices related endoscopic treatment plays a critical role and is usually the first option to prevent or treat portal hypertension–related bleeding which can be catastrophic and fatal [1, 2]. EMR and ESD have been recommended in the curative treatment of dysplasia, epithelial neoplasm, polyps/adenoma, and early esophageal/gastric/colorectal cancers [3–5]. The main adverse events are bleeding, perforation, and stricture during or after EMR and ESD [6, 7]. Bleeding is the most common adverse event of EMR [7]. Pancreatitis, bleeding, and cholangitis are the three most common adverse events after ERCP [8]. For patients with liver cirrhosis (LC), surgery poses high risks of adverse events such as DLC and bleeding and death [9]. Furthermore, patients with DLC are susceptible to acute-on-chronic liver failure (ACLF) after extrahepatic insults [10]. Therefore, it is vital to conclude related clinical practices to provide experience on endoscopic treatments on patients with LC or DLC. Regarding ER, one study reported that the overall curative rate of ER was 84.0% in 126 patients undergoing 164 procedures in gastrointestinal tract without the occurrence of liver decompensation [11]. And ER is safe and effective in patients with CP A/B cirrhosis and should be proposed as the first option for the treatment of superficial neoplasia [11]. Regarding on ERCP, one study including 31,294 patients with LC (69.8% receiving therapeutic ERCP and 30.2% receiving diagnostic ERCP) reported the higher hemorrhages rate (2.5% vs. 1.2%), the lower rate of perforation (0.1% vs. 0.2%), and post-ERCP pancreatitis (8.6% vs. 7%) compared with non-cirrhosis group, especially in therapeutic group (post-ERCP pancreatitis:7.9% vs. 5.1% and hemorrhage: 2.7% vs. 2.1%, compared with diagnostic group) [12]. However, in present clinical studies, whether patients have LC or not and whether LC is at compensated stage or not are grouping indicators to evaluate the safety and efficacy. There is still a paucity of literature available regarding the safety and efficacy of different common endoscopic treatments on patients with DLC. Therefore, we carried out a single center retrospective clinical trial focusing on different common

Abbreviation: ACLF, Acute-on-chronic liver failure; CP, Child-Pugh; DLC, Decompensated liver cirrhosis; EMR, Endoscopic mucosal resection; ER, Endoscopic resection; ERCP, Endoscopic Retrograde Cholangiopancreatography; ESD, Endoscopic submucosal dissection; INR, International normalized ratio; LC, Liver cirrhosis; OR, Odds ratio; PEP, Post-ERCP pancreatitis; TIPS, Transjugular intrahepatic portosystemic shunts

* Corresponding author at: Department of Gastroenterology, West China Hospital, Sichuan University, No. 37, Guo Xue Xiang, Wu Hou District, Chengdu 610041, China.
E-mail address: hubingnj@163.com (B. Hu).
[1] The first two authors contributed equally to this paper.

https://doi.org/10.1016/j.aohep.2022.100689

endoscopic treatments. The primary purpose of this study was to examine whether liver function could be affected by common endoscopic treatments and whether symptoms induced by targeted diseases could be relieved. The second purpose was to find which kind of endoscopic treatment in which CP class would be riskier and what the associated risk factors would be.

2. Patients and methods

2.1. Patients

This study was approved by the Ethics Committee on Biomedical Research, West China Hospital of Sichuan University (Date of registration: November 19, 2020). Initially, 269 patients (126 ER (61 EMR + 65 ESD) and 143 ERCP) were diagnosed as DLC and received endoscopic treatments from January 1, 2010 to October 1, 2020. Patients were excluded if they did not have an established diagnosis of cirrhosis, had ACLF, received more than one kind of endoscopic treatment, under 18 years old, were pregnant or with HIV infection, and were without complete clinical information. Data including age, gender, the diagnosis of DLC, LC cause, the presence of varices and related interventions (ligation and transjugular intrahepatic portosystemic shunts (TIPS)), CP class, targeted diseases and symptoms, endoscopic treatment, adverse events, and outcomes were collected and entered after each case. Finally, a total of 212 patients with DLC were collected in this retrospective research. Each of them only received one kind of endoscopic treatment (EMR/ESD/ERCP) with complete clinical data.

2.2. Definitions

(1) The diagnosis of DLC was based on the information of cause, physical examinations, serum biomarkers, and imaging findings, which could be responsible to LC and portal hypertension (e.g., the presence of varices, ascites, and hypersplenotrophy). (2) The liver function was assessed according to the CP classification. We calculated each patient's CP class before and after endoscopic treatments and counted the total number of patients whose CP class degenerated (e.g., CP class C to B or A, CP class B to A), were invariable (e.g., CP class A to A, CP class B to B, and CP class C to C), and increased (e.g., CP class A to B or C, CP class B to C) in each subgroup/group. In CP class C, increased score (e.g., from 10 to 11), decreased score (e.g., from 11 to 10), and invariable score (e.g., from 10 to 10) were counted. CP classification data were collected in about 5 days after treatments. (3) Patients were given vitamin K and/or fresh plasma if the international normalized ratio (INR) was >1.5. Similarly, patients with thrombocytopenia were infused with platelets before endoscopic treatments if the platelet count was <50,000/mm^3 [13, 14]. Coagulopathy was rectified to possible normalcy before endoscopic treatments. All patients included in the study had received intravenous prophylactic antibiotics. (4) Adverse events found during procedures or in 3 days after procedures were collected mainly including bleeding, perforation, and stricture of ER and pancreatitis, bleeding, and cholangitis of ERCP. Poor outcomes included endoscopy-related mortality and cirrhosis-related mortality in 1 month. Those patients who died after suffering from post-endoscopy adverse events were considered as endoscopy-related mortality and those who died of adverse events of LC such as acute variceal bleed, hepatic encephalopathy, and sepsis were considered as cirrhosis-related mortality. (5) All the patients receiving ER or ERCP were according to corresponding guidelines. Endoscopic treatments were performed by experienced endoscopists using a standard endoscopy. Patients in ERCP group were administrated with either conscious sedation or anesthesia. Patients in ER group were administrated with anesthesia.

2.3. Statistical analysis

Continuous variables were expressed as means and standard deviations or as median ranges. Categorical variables were expressed as frequencies and percentages. The differences of parametric variables between two groups were compared using Student's t test. Chi-squared test or Fisher's exact test was used for the comparison of differences in categorical variables as appropriate. A P value <0.05 was considered statistically significant. All analyses were performed using SPSS v. 22.0 statistical software (IBM Corp., USA).

3. Results

3.1. Patients' characteristics

A total of 212 patients with DLC receiving ER (EMR or ESD) or ERCP were included in the analysis. There were no significant differences of age and gender between two/three groups (age: ER 60.1 (9.5) vs. ERCP 57.6 (12.6), P=0.126; EMR 59.5 (9.98) vs. ESD 60.8 (9.1) vs. ERCP 57.6 (12.6), P=0.273). Etiologies of cirrhosis were shown in Table 1. Two main etiologies in two/three groups were viral B hepatitis and alcohol abuse. There was a significant difference of alcohol abuse percentage in two/three groups (ER 23.5% vs. ERCP 7.6%, **P=0.002**; EMR 16.3% vs. ESD 31.6% vs. ERCP 7.6%, **P=0.01**). (Table 1)

3.2. Safety

3.2.1. The rate of degeneration and invariability of CP class

We calculated each patient's CP class before and after endoscopic treatments and counted the total number of patients whose CP class degenerated or were invariable in each subgroup/group. There was no significant difference of CP class in two/three groups before and after one kind of endoscopic treatment (the overall rate of degeneration and invariability of CP class: EMR 97.7% vs. ESD 89.5% vs. ERCP 96.2% P=0.196). (1) In the level of CP class A, the rate of EMR, ESD, and ERCP was 95.7%, 96%, and 89.5%, respectively (P=0.627). (2) In the level of CP class B, the rate of ESD was 75% significantly lower than 100% of EMR and 95.3% of ERCP (**P=0.04**). In the level of CP class C, the degeneration rate in ERCP group was as remarkably high as 35.4% (17/48), and this rate calculation only included cases with degeneration. (Table 1)

3.2.2. The rate of adverse events

There was no significant difference of the overall adverse event rate in two/three groups before and after one kind of endoscopic treatment (ER 8.6% vs. ERCP 15.3%, P=0.205; EMR 7.0% vs. ESD 10.5% vs. ERCP 15.3%, P=0.343). In three levels of CP class, the rate of adverse events was not significantly different showed in Table 1.

3.3. Efficacy

3.3.1. The rate of poor outcomes

There were significant differences in the rate of poor outcomes between ER (2.5%) and ERCP (12.2%) (**P=0.02**). In the level of CP class C subgroup of ERCP group, the rate (29.17%, 14/131) was highest compared with other 8 subgroups. As the Table 1 showed, the rate was zero or very low in other 8 subgroups. Endoscopy related poor outcomes were only two cases in CP class C subgroup after ERCP (2/14). One case with choledocholithiasis before ERCP was because of post-ERCP bleeding and coagulation dysfunction, and the other case with unexplained bile duct stricture before ERCP was because of post-ERCP cholangitis and sepsis. (Table 1)

Table 1
Patients' characteristics, adverse events, and poor outcomes.

	ERCP ERCP	ER EMR	ESD	*P value* (ER vs ERCP)	*P value* (ERCP vs EMR vs ESD)
Total number	131	43	38		
Age, years, mean (SD)	57.6(12.6)	59.5(9.98)	60.8(9.1)	0.126	0.273
Sex, male, n (%)	71(54.2%)	28(65.1%)	27(71.1%)	0.061	0.127
Cause					
HBV	84	29	24	0.883	0.917
Alcohol	10(7.6%)	7(16.3%)	**12(31.6%)**	**0.002**	**0.01**
Schistosoma	1	2	1		
AIH	4	1	1		
HCV	2	1			
PBC	9	2			
Others	5	1			
SBC	16				
D and I rate of CP	126(96.2%)	42(97.7%)	34(89.5%)	0.319	0.196
CP A, n (%) (Invariability)	17(89.5%)	22(95.7%)	24(96%)	0.317	0.627
CP B, n (%)	61(95.3%)	17(100%)	9(75%)	0.371	**0.04**
CP C, n (%) (Degeneration)	**17(35.4%)**	0(0%)	0(0%)		
Adverse events	20(15.3%)	3(7.0%)	4(10.5%)	0.205	0.343
CP A, n (%)	1(5.3%)	1(4.30%)	0(0.00%)	0.49	0.525
CP B, n (%)	6(9.4%)	1(5.9%)	3(25%)	0.497	0.213
CP C, n (%)	**13(27.1%)**	1(33.3%)	1(100%)	0.569	0.433
Poor outcomes	**16(12.2%)**	1(2.3%)	1(2.6%)	**0.02**	
CP A, n (%)	0(0.0%)	0(0.0%)	1(4.0%)		
CP B, n (%)	2(3.13%)	0(0.0%)	0(0.0%)		
CP C, n (%)	**14(29.17%)**	1(33.33%)	0(0.0%)		

Abbreviation: AIH autoimmune hepatitis, CP Child–Pugh, D and I rate of CP degeneration and invariability of CP class, EMR endoscopic mucosal resection, ER endoscopic resection, ERCP endoscopic retrograde cholangiopancreatography, ESD endoscopic submucosal resection, HBV hepatitis B virus, HCV hepatitis C virus, PBC primary biliary cholangitis, SBC secondary Biliary Cirrhosis, SD standard deviation.

3.4. Safety and efficacy in ERCP group

3.4.1. The degeneration and invariability rate of CP class in ERCP group

There were significant differences in the degeneration and invariability rate of CP class between class A and B subgroups (89.5% (17/19) vs. 95.3% (61/64), P=0.322). The degeneration rate of CP class C subgroup was 35.4% (17/48) and significantly higher than that of CP class B subgroup (10.9%, 7/64) (**P=0.002**). In the level of CP class C, this rate calculation only included degeneration cases. We also compared the changes of CP classification scores in ERCP group, uninceased score rate in CP class A, B, and C three levels was 89.5% (17/19), 89.1% (57/64), and 89.6% (43/48), respectively (P=1). (Table 2)

3.4.2. The rate of adverse events in ERCP group

Significant difference in the rate of adverse events were showed in three CP class levels (A 5.3% (1/19) vs. B 9.4% (6/64) vs. C 27.1% (13/48), **P=0.02**). There was no significant difference between CP class A and B subgroup (P=1). The rate of CP class C subgroup was significantly higher than that of CP class B subgroup (**P=0.021**). (Table 2)

3.4.3. The rate of poor outcomes in ERCP group

The rate of poor outcomes in three CP class subgroups has significant difference (A 0% (0/19) vs. B 3.1% (2/64) vs. C 29.2% (14/48), **P=0**). There was no statistical difference between CP class A and B subgroups (P=1). The rate of CP class C subgroup was significantly higher than that of CP class B subgroup (**P=0**). (Table 2)

3.4.4. CP class C accounts more proportion in ERCP group

A total of 131 patients was collected in subgroups CP class A (19/131 14.5%), B (64/131 48.9%), and C (48/131 36.6%) based on the CP classification. There was a significant difference between ERCP group and ER group (A 48/81 59.3%, B 29/81 35.8%, and C 4/81 4.9%) (**P_A=0**, P_B=.066, and **Pc=0**). (Table 3)

Table 2
The degeneration and invariability rate of CP class, adverse events, and poor outcomes in ERCP group.

	CP A	CP B	CP C	*P value* (A vs B)	*P value* (B vs C)	*P value* (A vs B vs C)
Before ERCP	19	64	48			
After ERCP						
Degeneration	0	7(10.9%)	**17(35.4%)**		**0.002**	
Invariability	17	54	31			
Increase	2	3	0			
D and I rate of CP	17(89.5%)	61(95.3%)		0.322		
Adverse events	1(5.3%)	6(9.4%)	13(27.1%)	1	**0.021**	**0.02**
Bleeding		1(Papillary muscle tear)	2			
Perforation						
Stricture						
Sepsis	1	2	2			
PEP		3	3			
ACLF			6			
Poor outcomes	0(0%)	2(3.1%)	**14(29.17%)**	1	**0**	**0**

Abbreviation: ACLF acute-on-chronic liver failure, CP Child–Pugh, D and I rate of CP degeneration and invariability of CP class, ERCP endoscopic retrograde cholangiopancreatography, PEP post-ERCP pancreatitis.

Table 3
Patients composition of CP class in ER group and ERCP group.

	ERCP	ER	*P value*
CP A	19(14.5%)	48(60.8%)	**0**
CP B	64(64.2%)	29(51.5%)	0.066
CP C	48(31.4%)	4(4.9%)	**0**
	131	81	

3.4.5. The analysis of targeted diseases in CP class C of ERCP group

Targeted diseases included 41.6% (20/48) choledocholithiasis without cholangitis, 27.1% (13/48) choledocholithiasis with cholangitis, 8.3% (4/48) post-liver transplantation with adverse events, 6.25% (3/48) hilar occupation, and 16.7% (8/48) unexplained jaundice and bile duct stricture. We put post-liver transplantation with adverse events and hilar occupation together as the end-stage liver group generally with poor outcomes. There were no significant differences in unincreased CP classification score rate (P=0.282), degeneration rate (P=0.216), adverse event rate (P=0.37), and poor outcome rate (P=0.194). In subgroup of choledocholithiasis with cholangitis and end-stage liver, the rate of poor outcomes was comparatively higher (38.5% and 57.1%) (Table 4). After correcting for confounding factors including age, adverse events, intervention before endoscopic treatment (ligation and TIPS), and specific intervention during endoscopy (stent), logistic regression analysis identified end-stage liver was significantly correlated with poor outcomes (odds ratio (OR) 1.54, 95% confidence interval 1.54−14165.132; P=0.032). (Fig. 1)

4. Discussion

To evaluate the safety and efficacy of common endoscopic treatments on patients with DLC, we finally collected 212 patients with DLC who received ER (EMR/ESD) or ERCP. (1) We found patients were ensured with the similar safety when receiving ER or ERCP after the comparisons of the overall rate of degeneration and invariability of CP class and adverse events between groups. ERCP group was riskier with higher poor outcome rates. (2) CP class C subgroup of ERCP group had both more benefits and risks after comparing the rate of degeneration and invariability of CP class and adverse events between different CP class subgroups in ERCP group. (3) We focused on CP class C subgroup and found it accounted for more proportion in ERCP group and had more cases with cholangitis, post-liver transplantation with adverse events, and hilar occupation, in which 9 cases had poor outcomes (9/14). And end-stage liver might be an independent risk factor of poor outcomes, However, as the sample number was not enough in CP class C subgroup of ERCP and independent variables are all unordered dichotomous or tricomorphous variables, the range of 95% confidence interval was wide.

Liver compensated adaptation and reserve capability of patients with LC is impaired. Symptoms and comorbidities associated with hypohepatia such as coagulopathy and hepatic encephalopathy may appear after endoscopic interventions. Patients with DLC accompanied with esophageal varices have increasing bleeding risks. And receiving TIPS will increase hepatic encephalopathy risk. Endoscopic therapy is challenging and associated with a higher risk of adverse events. Outcomes of patients with targeted diseases are tightly associated with both the targeted diseases' severity and underlying diseases' conditions. Therefore, it is critical to evaluate specific issues unique to patients with DLC to optimize outcomes and avoid adverse events, besides the careful evaluation of the stage and condition of targeted diseases. We aimed to evaluate the safety and efficacy of ER and ERCP on the condition of DLC.

In the aspect of ER, postoperative bleeding was the most common adverse event of both EMR (from 3.03% to 21.9%) [15−18] and ESD (from 4.3% to 18.2%) [19−22]. The significant statistical differences were controversial, when compared with the bleeding rate of control group from 4.2% to 7.2%, although the rate in LC groups was demonstrated higher than that in controls. Lesion size (polyp size and superficial cancer size) and LC, especially CP class B and C were indicated as independent risk factors of bleeding. In our study, the overall bleeding rate in ER was 4.9% (4/81, 3 (1 A + 1 B +1 C) EMR and 1 (1 C) ESD). Other three cases with adverse events were infection after ESD, and two cases of three were CP class B and upgraded to CP class C after ESD, which was the reason why the rate of degeneration and invariability of CP class B in ESD group was significantly lower than other two groups. Regarding efficacy, there was no significant difference of targeted diseases' treatments between LC groups and control group. En bloc resection rate was from 81.8% to 97.7% [19−22]. In an systematic review, both en bloc removal and R0 resection were achieved in nearly 90% of cases [23]. In our study, all targeted polyps and superficial cancers were successively removed.

In the aspect of ERCP, the overall adverse event rate was from 16.1% to 35% [24−28], and 73.1% was shown in one research on DLC [29]. Cholangitis was focused and its rate was from 0.3% to 32.7% [24, 26, 28, 29]. Cholangitis at admission was also an independent risk factor of death [24]. Bleeding rate was from 2.1% to 10.9%, and might be associated with sphincterotomy [24−28],. Post-ERCP pancreatitis (PEP) rate was from 2% to 30.8% [24, 27-29]. The rate of ACLF was 11.4%, and associated with LC and ERCP [26]. MELD >16/18 and CP class C were also considered as independent risk factors of adverse events [24, 27]. A systematic review with 6,505 patients from 15 studies reported 4.58% bleeding rate, 3.68% PEP rate, and 1.93% cholangitis [30]. Another systematic review based on 31 studies showed a high technical success rate of more than 90% [31]. In our study, the overall adverse event rate was 15.3% (including 3.8% (5/131) cholangitis, 4.6% (6/131) PEP and 2.3% (3/131) bleeding), and the rate of ACLF was 4.5% only in ERCP group.

In our study, the proportion of alcohol-induced LC was significantly higher in ER group, especially in ESD group (31.6%), which is one of the risk factors of gastrointestinal cancer. Therefore, we concluded the proportion in other researches demonstrated from 4.67% to 63.3% [15-17, 19]. In terms of the higher proportion of CP class C in our study with 31.4%, more severe than patients in ER, which is similar to other related researches. Both of two results indicated their specific epidemiology.

To the best of our knowledge, the safety and efficacy of common endoscopic treatments on patients with DLC were firstly evaluated

Table 4
Targeted diseases and related changes of CP class, adverse events, and poor outcomes in CP class C subgroup of ERCP group.

	Total number	Choledocholithiasis without cholangitis	Choledocholithiasis with cholangitis	End stage live (Post transplantation + HCC)	Unexplained jaundice and bile duct stricture	***P value***
Total number	48	20	13	4+3	8	
Unincreased CP score	22	7(35%)	5(38.5%)	3+2(71.4%)	5(62.5%)	0.282
Degeneration of CP class	17	5(25%)	5(38.5%)	2+2(57.1%)	3(62.5%)	0.216
Adverse events	13	6(30%)	4(30.8%)	0+0(0%)	3(37.5%)	0.37
Poor outcomes	14	4(20%)	5(38.5%)	2+2(57.1%)	1(12.5%)	0.194

Abbreviation: HCC hepatocellular carcinoma.

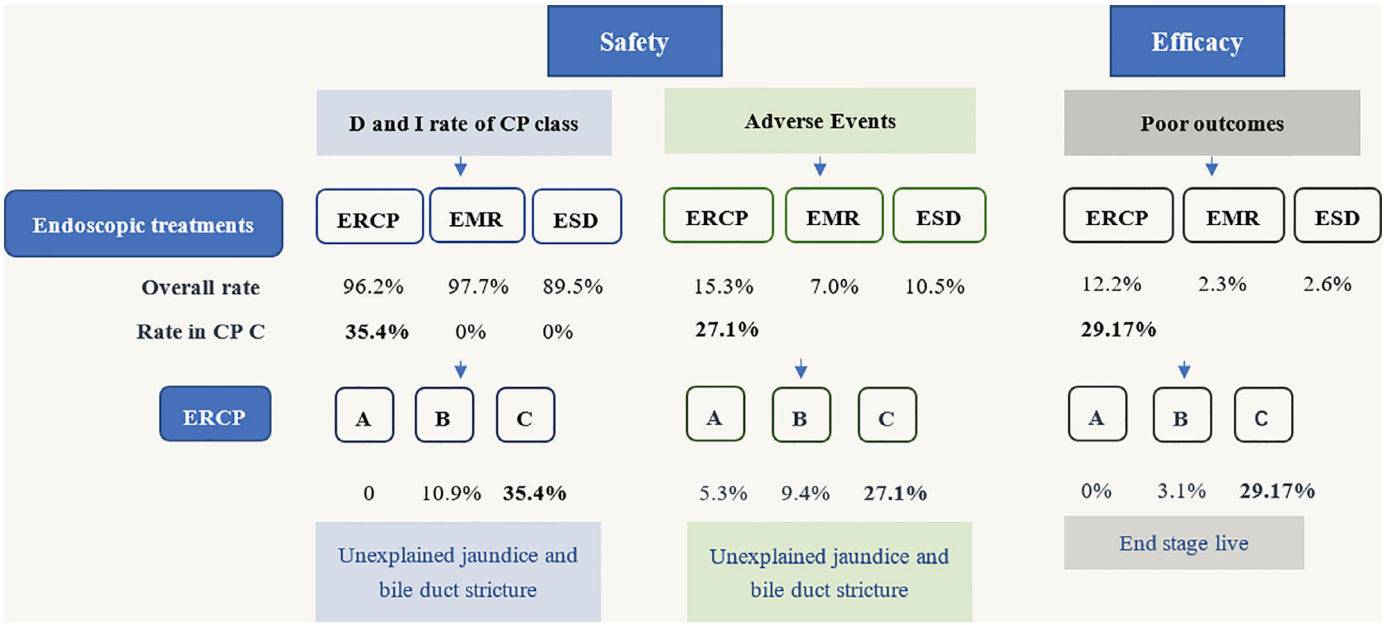

Fig. 1. Graphical abstract
Abbreviation: Child-Pugh (CP), degeneration and invariability of CP class (D and I rate of CP class), endoscopic mucosal resection (EMR), endoscopic retrograde cholangiopancreatography (ERCP), endoscopic submucosal resection (ESD)

and comparisons were firstly made based on different endoscopic therapies and CP classes in patients with DLC which was also rarely involved in present studies. Finally, we found common endoscopic treatments (EMR, ESD, and ERCP) were technically feasible in patients with DLC. And more assessment should be made before ERCP, as it was riskier with a higher poor outcome rate. It could be further focused on CP class C group in ERCP which had both more benefits and risks.

4.1. Limitations

There are some limitations. This study was limited by a single-center design, although it could reduce some bias from endoscopic technique levels and patients' compositions. Other treatments such as peroral endoscopic myotomy, only endoscopic ablation, and gastrointestinal stents were not included. We did not further analyze clinical indicators, long-term outcomes, and the specific location and characteristics of lesions in ER group, as the overall rate of adverse events (7/81, 4 bleeding and 3 infection) and poor outcomes (2/81) were low. Additionally, CP class was used as the grouping indicator to evaluate safety, and the degree of portal hypertension can be considered in future studies.

5. Conclusion

In summary, it was equally safe for CP class A and B patients with DLC to receive common endoscopic treatments including ER and ERCP. Focal lesions or symptoms induced by targeted diseases could be treated without significantly changes of CP class. Significant benefits and risks coexisted when CP class C patients with DLC received ERCP.

Authors' statement

All collaborators in this manuscript meet the definition for authorship based on ICMJE guidelines. All authors participated sufficiently in the work to take responsibility its content, including participation in the concept, design, analysis, writing, or revision of the manuscript.

Authors' contribution

Hang Yang contributed to the design and draft of the manuscript. Hang Yang and Yi Mou collected and statistically analyzed the data. Bing Hu contributed to designing and reviewing the manuscript. The first two authors contributed equally to this paper

Funding

None.

Conflicts of interest

The authors have no conflicts of interest to declare.

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