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WJGE mainly publishes articles reporting research results and findings obtained in the field of gastrointestinal endoscopy and covering a wide range of topics including capsule endoscopy, colonoscopy, double-balloon enteroscopy, duodenoscopy, endoscopic retrograde cholangiopancreatography, endosonography, esophagoscopy, gastrointestinal endoscopy, gastroscopy, laparoscopy, natural orifice endoscopic surgery, proctoscopy, and sigmoidoscopy.

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Retrospective Cohort Study

Endoscopic retrograde cholangiopancreatography for bile duct stones in patients with a performance status score of 3 or 4

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Abstract

BACKGROUND

As the aging population grows worldwide, the rates of endoscopic retrograde cholangiopancreatography (ERCP) for common bile duct stones (CBDS) in older patients with a poor performance status (PS) have been increasing. However, the data on the safety and efficacy of ERCP for CBDS in patients with a PS score of 3 or 4 are lacking, with only a few studies having investigated this issue among patients with poor PS.

AIM

To examine the safety and efficacy of ERCP for CBDS in patients with a PS score of 3 or 4.

METHODS

This study utilized a retrospective multi-centered design of three institutions in Japan for 8 years to identify a total of 1343 patients with CBDS having native

papillae who underwent therapeutic ERCP. As a result, 1113 patients with a PS 0-2 and 230 patients with a PS 3-4 were included. One-to-one propensity-score matching was performed to compare the safety and efficacy of ERCP for CBDS between patients with a PS 0-2 and those with a PS 3-4.

RESULTS

The overall ERCP-related complication rates in all patients and propensity score-matched patients with a PS 0-2 and 3-4 were 9.0% (100/1113) and 7.0% (16/230; $P = 0.37$), and 4.6% (9/196) and 6.6% (13/196; $P = 0.51$), respectively. In the propensity score-matched patients, complications were significantly more severe in the group with a PS 3-4 than in the group with a PS 0-2 group ($P = 0.042$). Risk factors for complications were indications of ERCP and absence of antibiotics in the multivariate analysis. Therapeutic success rates, including complete CBDS removal and permanent biliary stent placement, in propensity score-matched patients with a PS 0-2 and 3-4 were 97.4% (191/196) and 97.4% (191/196), respectively ($P = 1.0$).

CONCLUSION

ERCP for CBDS can be effectively performed in patients with a PS 3 or 4. Nevertheless, the indication for ERCP in such patients should be carefully considered with prophylactic antibiotics.

Key Words: Endoscopic retrograde Cholangiopancreatography; Complication; Performance status; Risk factor

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Core Tip: In 196 propensity-matched patients, the overall complications and technical success in patients with a performance status (PS) 3 or 4 were comparable to those of patients with a PS 0-2. However, complications were more severe in patients with a PS 3 or 4. In the multivariate analysis, indications of endoscopic retrograde cholangiopancreatography (ERCP) and the absence of antibiotics were significant risk factors for complications. Although ERCP for common bile duct stones can be effectively performed in patients with a PS 3 or 4, the indication for ERCP should be carefully considered, and prophylactic antibiotics should be administered to patients with a PS 3 or 4.

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INTRODUCTION

As the aging population grows worldwide, the rates of endoscopic retrograde cholangiopancreatography (ERCP) among the elderly are increasing. In particular, common bile duct stones (CBDS) are the most common indication for ERCP, and endoscopists often perform ERCP for CBDS in the elderly with poor Eastern Cooperative Oncology Group performance status (ECOG-PS) score[1], which is an objective index of activity in daily life, in clinical practice. Although several studies have reported that the safety and efficacy of ERCP for elderly patients aged ≥ 80 -90 years were comparable to those in younger patients, the performance status (PS) score varied in the previous studies[2-10].

PS is an important tool utilized for the clinical determination of the indications and strategies of ERCP for CBDS in elderly patients. Evidence available from studies evaluating the safety and efficacy of ERCP for biliopancreatic diseases in patients with a poor PS score is limited[11,12]. Furthermore, few studies have investigated the safety and efficacy of ERCP for CBDS in patients with a poor PS score. In the present study, we assessed the safety and efficacy of ERCP for CBDS in patients with a PS score of 3 or 4 in comparison with those having a PS score of 0-2.

MATERIALS AND METHODS

Patients and study design

The data of patients with native major duodenal papilla who had undergone therapeutic ERCP for CBDS between April 2012 and February 2020 at Kumamoto Chuo Hospital, Saiseikai Kumamoto Hospital, and Kumamoto City Hospital in Japan were retrospectively reviewed. The exclusion criteria were (1) failure to detect CBDS during ERCP; (2) history of therapeutic ERCP; and (3) a gastrointestinal tract that has already been surgically altered such as by employing Billroth II or Roux-en-Y reconstruction. The institutional review boards of the participating institutions approved this study and opt-out consent was applied. One-to-one propensity score matching analysis was performed to adjust for confounding factors between patients with a PS score of 0–2 and patients with a PS score of 3 or 4, and the safety and efficacy of ERCP for CBDS were compared between these two groups.

Outcomes and definitions

The primary outcome was the rates of post-ERCP complications and the rate of technical success such as complete stone removal and permanent biliary stent placement.

Post-ERCP complications included post-ERCP pancreatitis (PEP), bleeding, cholangitis, perforation, and aspiration pneumonia. These complications and their severity were diagnosed based on a lexicon for endoscopic complications[13]. When several complications were noted in the same patient, the most severe complication was selected for analysis.

Successful cases of complete stone removal or permanent biliary stent placement were considered a therapeutic success in this study.

Procedure

ERCP was performed in the prone or semi-prone position using side-viewing duodenoscopes (Olympus JF-260, TJF-260V; Olympus Medical Systems, Tokyo, Japan). Midazolam with pethidine hydrochloride was used for the purpose of sedation by the endoscopist. We determined the doses of midazolam and pethidine hydrochloride based on our sedation protocol using the data pertaining to the age and weight of patients. In patients aged 75–89 years and weighing < 70 kg, the dose of pethidine hydrochloride and midazolam was 17.5 mg–35 mg and 1 mg, respectively. In patients aged 75–89 years and weighing ≥ 70 kg, the dose of pethidine hydrochloride and midazolam was 17.5 mg–35 mg and 2 mg, respectively. In patients aged ≥ 90 years, the dose of pethidine hydrochloride and midazolam was 17.5 mg and/or 1 mg, respectively, regardless of the weight of the patients.

When a trainee with experience of < 200 ERCP procedures performed ERCP, an experienced endoscopist supervised them. After biliary cannulation using a standard ERCP catheter and a 0.025-inch guidewire, biliary stent placement or stone removal after endoscopic sphincterotomy (EST), endoscopic papillary balloon dilation (EPBD), or endoscopic papillary large balloon dilation (EPLBD) was performed. The treatment strategy for complete stone removal or permanent biliary stent placement was decided upon by the endoscopist.

Statistical analysis

Chi-squared test or Fisher's exact test was used for categorical variables, and Welch's *t*-test was used for continuous variables. A multivariate logistic regression model employed variables with *P* values < 0.20 in the univariate analyses to identify the predictive factors for post-ERCP complications.

One-to-one propensity score matching with a caliper of 0.2 was performed to adjust for confounding factors associated with post-ERCP complications between patients with a PS score of 0–2 and patients with a PS score of 3 or 4. Factors presented in Table 1 were used to construct propensity scores using the logistics regression model.

All statistical analyses were performed using EZR version 1.53 (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R software (The R Foundation for Statistical Computing, Vienna, Austria, version 4.1.0)[14]. Two-sided *P* values < 0.05 were considered statistically significant.

RESULTS

Patient characteristics

A total of 1343 patients met the inclusion criteria for this study. Altogether, 1113 and 230 patients were included in the groups with a PS score of 0–2 and 3–4, respectively. Details of patients' characteristics are presented in Table 1. Significant differences were noted in age, sex, indications of ERCP for CBDS, a history of cerebrovascular diseases, a history of multiple underlying diseases, antithrombotic treatment, non-dilated common bile duct (CBD), antibiotics, trainee involvement, difficult cannulation, EST, EPBD, EPLBD, use of balloon catheter, large stones, protease inhibitor, and rectal non-steroidal anti-inflammatory drugs. No significant differences were noted in patients' characteristics between the two groups.

Table 1 Baseline characteristics of the patients

	All patients			Propensity score-matched patients		
	Patients with a PS 0-2 (n = 1113)	Patients with a PS 3 or 4 (n = 230)	P value	Patients with a PS 0-2 (n = 196)	Patients with a PS 3 or 4 (n = 196)	P value
Age [mean (SD)]	72.9 (14.0)	84.4 (9.1)	< 0.001	83.6 (8.2)	83.4 (9.2)	0.79
Female (%)	498 (44.7)	146 (63.5)	< 0.001	113 (57.7)	117 (59.7)	0.76
Indications of ERCP for CBDS						
Acute cholangitis (%)	607 (54.5)	194 (84.3)	< 0.001	160 (81.6)	160 (81.6)	1.0
Biliary pancreatitis (%)	59 (5.3)	5 (2.2)	0.041	5 (2.6)	5 (2.6)	1.0
Obstructive jaundice without cholangitis (%)	263 (23.6)	20 (8.7)	< 0.001	21 (10.7)	20 (10.2)	1.0
Asymptomatic CBDS (%)	184 (16.5)	11 (4.8)	< 0.001	10 (5.1)	11 (5.6)	1.0
Underlying diseases						
Diabetes Mellitus (%)	78 (7.0)	12 (5.2)	0.39	14 (7.1)	12 (6.1)	0.84
Cardiovascular diseases (%)	152 (13.7)	42 (18.3)	0.080	40 (20.4)	39 (19.9)	1.0
Cerebrovascular diseases (%)	55 (4.9)	53 (23.0)	< 0.001	31 (15.8)	31 (15.8)	1.0
Dialysis (%)	35 (3.1)	8 (3.5)	0.84	7 (3.6)	8 (4.1)	1.0
Liver cirrhosis (%)	15 (1.3)	0 (0.0)	0.089	0 (0)	0 (0)	1.0
Multiple underlying diseases (%)	99 (8.9)	37 (16.1)	0.002	33 (16.8)	30 (15.3)	0.78
Antithrombotic treatment	280 (25.2)	94 (40.9)	< 0.001	80 (40.8)	73 (37.2)	0.54
Billroth-1 reconstruction (%)	28 (2.5)	6 (2.6)	1.0	8 (4.1)	6 (3.1)	0.79
Post-cholecystectomy (%)	124 (11.1)	19 (8.3)	0.24	19 (9.7)	18 (9.2)	1.0
Presence of gallstones (%)	715 (64.2)	147 (63.9)	0.94	123 (62.8)	121 (61.7)	0.92
Normal serum bilirubin (%)	540 (48.5)	104 (45.2)	0.39	94 (48.0)	87 (44.4)	0.54
Platelet counts [mean (SD)] ($\times 10^6/L$)	19.1 (7.1)	19.5 (9.9)	0.44	18.7 (7.7)	18.6 (7.9)	0.93
PT-INR [mean (SD)]	1.2 (0.91)	1.2 (0.42)	0.29	1.3 (1.8)	1.2 (0.42)	0.47
Non-dilated CBD (< 10 mm) (%)	454 (40.8)	70 (30.4)	0.004	53 (27.0)	60 (30.6)	0.50
Periampullary diverticulum (%)	341 (30.6)	60 (26.1)	0.18	62 (31.6)	56 (28.6)	0.58
Antibiotics (%)	881 (79.2)	216 (93.9)	< 0.001	178 (90.8)	182 (92.9)	0.58
Trainees (%)	199 (17.9)	27 (11.7)	0.026	25 (12.8)	24 (12.2)	1.0
Successful biliary cannulation (%)	1099 (98.7)	225 (97.8)	0.35	192 (98.0)	192 (98.0)	1.0
Difficult biliary cannulation (%)	309 (27.8)	48 (20.9)	0.033	46 (23.5)	42 (21.4)	0.72
Contrast-assisted cannulation (%)	772 (69.4)	168 (73.0)	0.30	135 (68.9)	143 (73.0)	0.44
Wire-guided cannulation (%)	120 (10.8)	23 (10.0)	0.82	21 (10.7)	20 (10.2)	1.0
PGW-assisted cannulation (%)	156 (14.0)	30 (13.0)	0.75	28 (14.3)	26 (13.3)	0.88
Precut sphincterotomy (%)	63 (5.7)	9 (3.9)	0.34	12 (6.1)	7 (3.6)	0.35
Pancreatic injection (%)	513 (46.1)	93 (40.4)	0.13	87 (44.4)	81 (41.3)	0.61
EST (%)	973 (87.4)	186 (80.9)	0.011	154 (78.6)	160 (81.6)	0.53
EPBD (%)	125 (11.2)	38 (16.5)	0.034	38 (19.4)	31 (15.8)	0.43
EPLBD (%)	158 (14.2)	60 (26.1)	< 0.001	53 (27.0)	50 (25.5)	0.82

Use of balloon catheter (%)	896 (80.5)	167 (72.6)	0.010	139 (70.9)	144 (73.5)	0.65
Use of basket catheter (%)	504 (45.3)	105 (45.7)	0.94	102 (52.0)	94 (48.0)	0.48
Mechanical lithotripsy (%)	189 (17.0)	33 (14.3)	0.38	35 (17.9)	32 (16.3)	0.79
Biliary stent placement (%)	945 (84.9)	192 (83.5)	0.62	157 (80.1)	164 (83.7)	0.43
Number of CBD stones [mean (SD)]	2.2 (2.7)	2.5 (2.8)	0.052	2.6 (3.4)	2.6 (3.0)	0.87
Large stones (> 10 mm) (%)	195 (17.5)	61 (26.5)	0.002	57 (29.1)	52 (26.5)	0.65
Prophylactic pancreatic stent placement (%)	169 (15.2)	32 (13.9)	0.69	34 (17.3)	30 (15.3)	0.68
Protease inhibitor (%)	453 (40.7)	65 (28.3)	< 0.001	57 (29.1)	60 (30.6)	0.83
Rectal NSAIDs (%)	117 (10.5)	10 (4.3)	0.003	11 (5.6)	9 (4.6)	0.82

CBD: Common bile duct; CBDS: Common bile duct stones; ERCP: Endoscopic retrograde cholangiopancreatography; EST: Endoscopic sphincterotomy; EPBD: Endoscopic papillary balloon dilation; EPLBD: Endoscopic papillary large balloon dilation; PS: Performance status; PGW: Pancreatic guidewire.

after propensity score matching.

Endoscopic retrograde cholangiopancreatography-related complications

ERCP-related complications in all patients and propensity score-matched patients are presented in [Table 2](#). The overall ERCP-related complication rates in all patients and propensity score-matched patients in the groups with a PS score of 0-2 and 3-4 were 9.0% (100/1113) and 7.0% (16/230; $P = 0.37$) and 4.6% (9/196) and 6.6% (13/196; $P = 0.51$), respectively. In all patients, complications were more severe in the group with a PS score of 3-4 than in the group with a PS score of 0-2 ($P = 0.063$), although this finding was not statistically significant. In the propensity score-matched patients, complications were significantly more severe in the group with a PS score of 3 or 4 than in the group with a PS score of 0-2 ($P = 0.042$). The incidence rate of each complication, including PEP, bleeding, cholangitis, perforation, and aspiration pneumonia, was not significantly different between the two groups in all patients and propensity score-matched patients. Among all patients, the severity of PEP was significantly higher in patients with a PS score of 3 or 4 than in those with a PS score of 0-2 ($P = 0.034$), and the severity of other complications was not significantly different between the two groups. Among the propensity score-matched patients, the severity of each complication was not significantly different between the two groups.

Therapeutic success rates of ERCP and mean procedure time

Therapeutic success rates of ERCP and mean procedure time are presented in [Table 3](#). Therapeutic success rates, including successful complete stone removal and permanent biliary stent placement, in all patients and propensity score-matched patients were 98.5% (1096/1113) and 97.4% (224/230; $P = 0.26$) and 97.4% (191/196) and 97.4% (191/196; $P = 1.0$), respectively. The rates of successful complete stone removal in all patients and propensity score-matched patients between patients with a PS score of 0-2 and 3 or 4 were 1064/1113 (95.6%) and 200/230 (87.0%; $P < 0.001$) and 92.3% (181/196) and 87.8% (172/196; $P = 0.18$), respectively. The rates of successful permanent biliary stent placement in all patients and propensity score-matched patients between the group with a PS score of 0-2 and 3 or 4 were 2.9% (32/1113) and 10.4% (24/230; $P < 0.001$) and 5.1% (10/196) and 9.7% (19/196; $P = 0.12$), respectively. Mean procedure times were not significantly different in all patients and propensity score-matched patients between the two groups ($P = 0.42$ and $P = 0.77$, respectively).

Predictive factors for ERCP-related complications after ERCP for CBDS

The results of univariate and multivariate analyses for risk factors of ERCP-related complications for CBDS are presented in [Table 4](#). In univariate analysis, there was a significant difference in indications of ERCP for CBDS, absence of antibiotics, prolonged procedure, difficult biliary cannulation, pancreatic injection, contrast-assisted cannulation, prophylactic pancreatic stent placement, normal serum bilirubin level, and pancreatic guidewire-assisted cannulation. In multivariate analysis, indications of ERCP for CBDS and absence of antibiotics were significant risk factors for ERCP-related complications.

DISCUSSION

Several studies reported that ERCP can be performed for biliopancreatic diseases even in elderly patients aged over 80 years[2-10]. However, PS is an important factor in deciding the therapeutic

Table 2 Comparison of endoscopic retrograde cholangiopancreatography-related complications between patients with a performance status score of 0-2 and 3-4

	All patients		<i>P</i> value	Propensity score-matched patients		<i>P</i> value
	Patients with a PS 0-2 (<i>n</i> = 1113)	Patients with a PS 3 or 4 (<i>n</i> = 230)		Patients with a PS 0-2 (<i>n</i> = 196)	Patients with a PS 3 or 4 (<i>n</i> = 196)	
Overall complications, <i>n</i> (%)	100 (9.0)	16 (7.0)	0.37	9 (4.6)	13 (6.6)	0.51
Severity of overall complications			0.063			0.042
Mild (%)	65 (65.0)	6 (37.5)		7 (77.8)	3 (23.1)	
Moderate (%)	29 (29.0)	8 (50.0)		2 (22.2)	8 (61.5)	
Severe (%)	6 (6.0)	2 (12.5)		0 (0.0)	2 (15.4)	
PEP (%)	50 (4.5)	5 (2.2)	0.14	3 (1.5)	2 (1.0)	1.0
Severity of PEP (%)			0.034			0.10
Mild (%)	34 (68.0)	3 (60.0)		3 (100.0)	0 (0.0)	
Moderate (%)	14 (28.0)	0 (0.0)		0 (0.0)	0 (0.0)	
Severe (%)	2 (4.0)	2 (40.0)		0 (0.0)	2 (100.0)	
Bleeding (%)	18 (1.6)	4 (1.7)	0.78	1 (0.5)	4 (2.0)	0.37
Severity of bleeding (%)			0.12			0.40
Mild (%)	12 (66.7)	1 (25.0)		1 (100.0)	1 (25.0)	
Moderate (%)	3 (16.7)	3 (75.0)		0 (0.0)	3 (75.0)	
Severe (%)	3 (16.7)	0 (0.0)		0 (0.0)	0 (0.0)	
Cholangitis (%)	18 (1.6)	4 (1.7)	0.78	3 (1.5)	4 (2.0)	1.0
Severity of cholangitis (%)			0.077			0.49
Mild (%)	14 (77.8)	1 (25.0)		2 (66.7)	1 (25.0)	
Moderate (%)	4 (22.2)	3 (75.0)		1 (33.3)	3 (75.0)	
Perforation (%)	10 (0.9)	0 (0.0)	0.23	1 (0.5)	0 (0.0)	1.0
Severity of perforation (%)			1.0			NA
Mild (%)	4 (40.0)	0 (0.0)		0 (0.0)	0 (0.0)	
Moderate (%)	5 (50.0)	0 (0.0)		1 (100.0)	0 (0.0)	
Severe (%)	1 (10.0)	0 (0.0)		0 (0.0)	0 (0.0)	
Pneumonia (%)	4 (0.4)	3 (1.3)	0.10	1 (0.5)	3 (1.5)	0.62
Severity of aspiration pneumonia (%)			1.0			1.0
Mild (%)	1 (25.0)	1 (33.3)		1 (100.0)	1 (33.3)	
Moderate (%)	3 (75.0)	2 (66.7)		0 (0.0)	2 (66.7)	

PEP: Post-endoscopic retrograde cholangiopancreatography pancreatitis; PS: Performance status; NA: Not available.

strategy in elderly patients with CBDS. Although conservative therapy or therapeutic ERCP can be selected for CBDS in patients with a PS score of 3 or 4, therapeutic ERCP is better because ERCP can resolve CBD obstruction caused by CBDS if ERCP can be performed safely and effectively even in elderly patients with a PS score of 3 or 4.

Only a few studies are available on the association between poor PS and ERCP-related complications. Previous studies reported that the rate of overall ERCP-related complications was not different between patients with a PS score of 0-2 and 3 or 4 having biliopancreatic diseases[12,15] but the rates of aspiration pneumonia and heart failure were higher in patients with a PS score of 3 or 4 than in patients with a PS score of 0-2[12]. Another retrospective study reported that the risk of pulmonary and severe complications was high, although ERCP could be performed effectively in patients with a PS score of 4

Table 3 Comparison of outcomes of endoscopic retrograde cholangiopancreatography between patients with a performance status score of 0-2 and performance status 3-4

	All patients		<i>P</i> value	Propensity score-matched patients		<i>P</i> value
	Patients with a PS 0-2 (<i>n</i> = 1113)	Patients with a PS 3 or 4 (<i>n</i> = 230)		Patients with a PS 0-2 (<i>n</i> = 196)	Patients with a PS 3 or 4 (<i>n</i> = 196)	
Therapeutic success, <i>n</i> (%)	1096 (98.5)	224 (97.4)	0.26	191 (97.4)	191 (97.4)	1.0
Successful complete stone removal (%)	1064 (95.6)	200 (87.0)	< 0.001	181 (92.3)	172 (87.8)	0.18
Permanent biliary stent placement (%)	32 (2.9)	24 (10.4)	< 0.001	10 (5.1)	19 (9.7)	0.12
Mean procedure time, min (SD)	27.5 (15.7)	26.5 (15.9)	0.42	26.9 (15.7)	27.3 (16.6)	0.77

PS: Performance status.

[11]. These studies included not only patients with CBDS but also patients with various biliopancreatic diseases.

In this study, we examined the outcomes of ERCP in patients with CBDS, which is the most common indication for ERCP. The rates of therapeutic success, including complete stone removal and permanent biliary stent placement, were comparable between patients with a PS score of 0-2 and those with a PS score of 3 or 4. Although the rates of overall and each ERCP-related complication were not different between the two groups, complications were generally observed to be more severe in patients with a PS score of 3 or 4. Therefore, ERCP for CBDS can be performed effectively in patients with a PS score of 3 or 4. However, endoscopists should try their best to reduce the occurrence of ERCP-related complications because these complications can be more severe in patients with a PS score of 3 or 4.

In this study, indications of ERCP for CBDS and absence of antibiotics were significant risk factors for ERCP-related complications in the multivariate analysis. While the patients with acute cholangitis and biliary pancreatitis had a low risk for ERCP-related complications, those with obstructive jaundice without cholangitis and asymptomatic CBDS had a high risk for ERCP-related complications. Therefore, we emphasize that the indication of ERCP for CBDS should be carefully considered in patients with a PS score of 3 or 4. Although patients with acute cholangitis and biliary pancreatitis should be endoscopically treated, conservative treatment or follow-up strategy might be considered as an appropriate alternative in patients without acute cholangitis, especially those with asymptomatic CBDS. Regarding the use of antibiotics, the European Society of Gastrointestinal Endoscopy guidelines suggested the use of antibiotic prophylaxis in selected patients such as immunocompromised patients[16]. Antibiotic prophylaxis before ERCP to prevent ERCP-related cholangitis and aspiration pneumonia may be administered in patients with a PS score of 3 or 4 because such patients can be immunocompromised.

A previous study revealed that long procedure time was a significant risk factor for ERCP-related complications in patients with a PS score of 4[11]. Although not statistically significant, a prolonged ERCP procedure tended to increase ERCP-related complications in this study. Permanent biliary stent placement without CBDS removal is a therapeutic option to shorten the procedure time. However, a randomized control trial demonstrated that long-term biliary complications at a median follow-up duration of 20 mo were significantly higher in the permanent biliary stent placement group (complication rate: 36%) than in the complete CBDS removal group (complication rate: 14%)[17]. Another retrospective study at a median follow-up duration of 623 d showed similar results[18]. Therefore, complete CBDS removal should be considered at first, and permanent biliary stent placement can be an option in patients with a PS score of 3 or 4 for whom a short prognosis is predicted, who have an underlying disease that is severe, and who are expected to receive prolonged ERCP procedures such as for large and multiple CBDS.

Unlike the results of previous reports[11,12], the rates of aspiration pneumonia were not different between the two groups, and there were no cardiovascular complications in this study. Our sedation protocol using the data pertaining to the age and weight of patients may be attributed to a low incidence of aspiration pneumonia in patients with a PS score of 3 or 4 in this study. Furthermore, careful vital sign monitoring was performed during ERCP, particularly in patients with poor PS.

There are several limitations of this study. First, this was a retrospective study that included specialized centers in Japan. Second, although we balanced patients' characteristics using one-to-one propensity score matching, some unmeasured confounding factors may exist. Therefore, some selection bias may not be excluded. Third, long-term outcomes of ERCP were not examined in this study. Future multicenter studies including large patient cohorts from institutions with different ERCP experiences are warranted to confirm the safety and efficacy of ERCP for CBDS in patients with a PS score of 3 or 4.

Table 4 Predictive factors for endoscopic retrograde cholangiopancreatography (ERCP)-related complications after ERCP for common bile duct stones

	Univariate analysis		Multivariate analysis			
	With complications (n = 116)	Without complications (n = 1227)	P value	Odds ratio	95%CI	P value
Indications of ERCP for CBDS			< 0.001	1.1	1.05-1.2	< 0.001
Acute cholangitis (%)	44 (37.9)	757 (61.7)				
Biliary pancreatitis (%)	1 (0.9)	63 (5.1)				
Obstructive jaundice without cholangitis (%)	35 (30.2)	248 (20.2)				
Asymptomatic CBDS (%)	36 (31.0)	159 (13.0)				
Absence of antibiotics (%)	41 (35.3)	205 (16.7)	< 0.001	1.7	1.04-2.7	0.034
Mean procedure time, min [mean (SD)]	33.4 (17.3)	26.7 (15.5)	< 0.001	1.01	1.00-1.02	0.098
Difficult biliary cannulation (%)	50 (43.1)	307 (25.0)	< 0.001	1.3	0.74-2.3	0.36
Pancreatic injection (%)	69 (59.5)	537 (43.8)	0.001	1.4	0.85-2.1	0.20
Contrast-assisted cannulation (%)	68 (58.6)	872 (71.1)	0.008	0.90	0.47-1.7	0.74
Prophylactic pancreatic stent placement (%)	27 (23.3)	174 (14.2)	0.014	0.77	0.45-1.3	0.33
Normal serum bilirubin (%)	68 (58.6)	576 (46.9)	0.019	0.86	0.53-1.4	0.52
PGW-assisted cannulation (%)	24 (20.7)	162 (13.2)	0.034	1.0	0.77-1.3	0.98
Precut sphincterotomy (%)	11 (9.5)	61 (5.0)	0.050	0.96	0.76-1.2	0.76
Age [mean (SD)]	72.5 (14.8)	75.1 (13.9)	0.051	1.0	0.98-1.01	0.66
Non-dilated CBD (< 10 mm) (%)	55 (47.4)	469 (38.2)	0.058	1.3	0.82-1.9	0.30
Protease inhibitor (%)	51 (44.0)	467 (38.1)	0.23			
EPBD (%)	18 (15.5)	145 (11.8)	0.24			
Trainees (%)	24 (20.7)	202 (16.5)	0.24			
Use of basket catheter (%)	47 (40.5)	562 (45.8)	0.29			
EPLBD (%)	15 (12.9)	203 (16.5)	0.36			
Platelet counts [mean (SD)] (×10 ⁶ /L)	19.8 (9.8)	19.1 (7.4)	0.39			
EST (%)	97 (83.6)	1062 (86.6)	0.40			
Rectal NSAIDs (%)	8 (6.9)	119 (9.7)	0.41			
Biliary stent placement (%)	95 (81.9)	1042 (84.9)	0.42			
Number of CBD stones [mean (SD)]	2.1 (3.0)	2.2 (2.7)	0.52			
Post-cholecystectomy (%)	10 (8.6)	133 (10.8)	0.53			
Complete stone removal (%)	108 (93.1)	1156 (94.2)	0.54			
Mechanical lithotripsy (%)	21 (18.1)	201 (16.4)	0.60			
Use of balloon catheter (%)	94 (81.0)	969 (79.0)	0.72			
Wire-guided cannulation (%)	13 (11.2)	130 (10.6)	0.88			
Female (%)	55 (47.4)	589 (48.0)	0.92			
PT-INR [mean (SD)]	1.2 (0.90)	1.2 (0.85)	0.93			
Antithrombotic treatment	32 (27.6)	342 (27.9)	1.0			

Billroth-1 reconstruction (%)	3 (2.6)	31 (2.5)	1.0
Presence of gallstones (%)	75 (64.7)	787 (64.1)	1.0
Successful biliary cannulation (%)	115 (99.1)	1209 (98.5)	1.0
Large stones (> 10 mm) (%)	22 (19.0)	234 (19.1)	1.0

CBDS: Common bile duct stones; CBD: Common bile duct; ERCP: Endoscopic retrograde cholangiopancreatography; PT-EST: Endoscopic sphincterotomy; EPBD: Endoscopic papillary balloon dilation; EPLBD: Endoscopic papillary large balloon dilation; PGW: Pancreatic guidewire; NSAIDs: Nonsteroidal anti-inflammatory drugs; INR: Prothrombin time-international normalized ratio.

In conclusion, ERCP for CBDS in patients with a PS score of 3 or 4 can be performed effectively. Thus, endoscopists should not be reluctant to perform ERCP for CBDS in patients with a PS score 3 or 4. Nevertheless, the indication of ERCP for CBDS, particularly in patients with asymptomatic CBDS, requires careful consideration, and antibiotics should be used before ERCP in patients with a PS score of 3 or 4.

CONCLUSION

ERCP for CBDS in patients with a PS score of 3 or 4 can be performed effectively. Thus, endoscopists should not be reluctant to perform ERCP for CBDS in patients with a PS score 3 or 4. Nevertheless, the indication of ERCP for CBDS, particularly in patients with asymptomatic CBDS, requires careful consideration, and antibiotics should be used before ERCP in patients with a PS score of 3 or 4.

ARTICLE HIGHLIGHTS

Research background

In parallel with the growing aging population worldwide, endoscopic retrograde cholangiopancreatography (ERCP) is being increasingly used in the treatment of common bile duct stones (CBDS) in patients with a poor performance status (PS). Therefore, determining the safety and efficacy of ERCP for CBDS in patients with a PS score of 3 or 4 is essential.

Research motivation

PS is an important tool to elucidate the indications and strategies of ERCP for CBDS in elderly patients. However, few studies examined the safety and efficacy of ERCP for CBDS in patients with a poor PS.

Research objectives

To examine the safety and efficacy of ERCP for CBDS in patients with poor PS, which is defined as a PS score of 3 or 4.

Research methods

We reviewed the medical records of three institutions in Japan from April 2012 to February 2020. The exclusion criteria were (1) failure to detect CBDS during ERCP; (2) history of therapeutic ERCP; and (3) an already surgically altered gastrointestinal tract including Billroth II or Roux-en-Y reconstruction. Finally, we identified 1343 patients with choledocholithiasis who met the inclusion criteria for the study, and 1113 and 230 patients had PS scores of 0-2 and 3 or 4, respectively. One-to-one propensity score matching was performed to compare the safety and efficacy of ERCP for CBDS between patients with PS scores of 0-2 and 3 or 4.

Research results

The overall ERCP-related complication rates in all patients with PS scores of 0-2 and 3 or 4 were 9.0% (100/1113) and 7.0% (16/230; $P = 0.37$), respectively. In the propensity score-matched group, the overall ERCP-related complication rates were 4.6% (9/196) and 6.6% (13/196; $P = 0.51$) among patients with PS scores of 0-2 and PS 3-4, respectively, and complications were significantly more severe in the group with a PS score of 3-4 than in the groups with a PS score of 0-2 ($P = 0.042$). In multivariate analysis, risk factors for ERCP-related complications were indication of ERCP and absence of antibiotics ($P < 0.001$ and $P = 0.034$, respectively). Particularly, absence of acute cholangitis including asymptomatic CBDS, was associated with increased risk of ERCP-related complications. Therapeutic success rates, including complete CBDS removal and permanent biliary stent placement, in propensity score-matched patients

with PS scores of 0-2 and 3 or 4 were 97.4% (191/196) and 97.4% (191/196), respectively ($P = 1.0$).

Research conclusions

ERCP for CBDS can be performed effectively in patients with a PS score of 3 or 4. The rates of ERCP-related complications were similar between the patients with PS scores of 0-2 and 3 or 4; however, their severity was higher in the group with a PS score of 3 or 4 than in the group with a PS score of 0-2. The indication of ERCP for CBDS, particularly in patients with asymptomatic CBDS, requires careful consideration, and antibiotics should be administered before ERCP in patients with a PS score of 3 or 4.

Research perspectives

The retrospective study design that included specialized centers in Japan was an important limitation of this study. Future multicenter studies including large patient cohorts from institutions with different ERCP experiences are warranted to confirm our findings.

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FOOTNOTES

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