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Safety of high-carbohydrate fluid diet 2 h versus overnight fasting before non-emergency endoscopic retrograde cholangiopancreatography: A single-blind, multicenter, randomized controlled trial

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Abstract

Background: Although overnight fasting is recommended prior to endoscopic retrograde cholangiopancreatography (ERCP), the benefits and safety of high-carbohydrate fluid diet (CFD) intake 2 h before ERCP remain unclear. This study aimed to analyze whether high-CFD intake 2 h before ERCP can be safe and accelerate patients' recovery.

Methods: This prospective, multicenter, randomized controlled trial involved 15 tertiary ERCP centers. A total of 1330 patients

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were randomized into CFD group ($n = 665$) and fasting group ($n = 665$). The CFD group received 400 mL of maltodextrin orally 2 h before ERCP, while the control group abstained from food/water overnight (>6 h) before ERCP. All ERCP procedures were performed using deep sedation with intravenous propofol. The investigators were blinded but not the patients. The primary outcomes included postoperative fatigue and abdominal pain score, and the secondary outcomes included complications and changes in metabolic indicators. The outcomes were analyzed according to a modified intention-to-treat principle.

Results: The post-ERCP fatigue scores were significantly lower at 4 h (4.1 ± 2.6 *vs.* 4.8 ± 2.8, $t = 4.23$, $P < 0.001$) and 20 h (2.4 ± 2.1 *vs.* 3.4 ± 2.4, $t = 7.94$, $P < 0.001$) in the CFD group, with least-squares mean differences of 0.48 (95% confidence interval [CI]: 0.26–0.71, $P < 0.001$) and 0.76 (95% CI: 0.57–0.95, $P < 0.001$), respectively. The 4-h pain scores (2.1 ± 1.7 *vs.* 2.2 ± 1.7, $t = 2.60$, $P = 0.009$, with a least-squares mean difference of 0.21 [95% CI: 0.05–0.37]) and positive urine ketone levels (7.7% [39/509] *vs.* 15.4% [82/533], $\chi^2 = 15.13$, $P < 0.001$) were lower in the CFD group. The CFD group had significantly less cholangitis (2.1% [13/634] *vs.* 4.0% [26/658], $\chi^2 = 3.99$, $P = 0.046$) but not pancreatitis (5.5% [35/634] *vs.* 6.5% [43/658], $\chi^2 = 0.59$, $P = 0.444$). Subgroup analysis revealed that CFD reduced the incidence of complications in patients with native papilla (odds ratio [OR]: 0.61, 95% CI: 0.39–0.95, $P = 0.028$) in the multivariable models.

Conclusion: Ingesting 400 mL of CFD 2 h before ERCP is safe, with a reduction in post-ERCP fatigue, abdominal pain, and cholangitis during recovery.

Trail Registration: ClinicalTrials.gov, No. NCT03075280.

Keywords: Endoscopic retrograde cholangiopancreatography; ERCP; Carbohydrate; Fasting; Safety; Complications; Enhanced recovery after surgery; Randomized controlled trial

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has substantially improved the non-surgical management of pancreaticobiliary disorders.[1–3] Similar to other upper gastrointestinal procedures, patients undergoing ERCP are often instructed to fast overnight as part of the preprocedural preparation to minimize the risk of aspiration associated with sedation or anesthesia assisted procedures. This preoperative strategy may potentially affect the metabolic balance of patients and increase the need for fluid replenishment during the procedure, especially for patients scheduled for an afternoon procedure after overnight fasting. Moreover, prolonged fasting for more than 12 h can affect patient recovery after ERCP.[4,5]

The current instructions for gastrointestinal surgery entail abstention from solid food for 6 h before surgery, although fluid intake is permitted 2 h before the procedure.[6] Preoperative carbohydrate loading has been demonstrated to reduce preoperative stress and anxiety of patients, attenuate the stress response to surgery, reduce postoperative complications, and promote early recovery.[7,8] Furthermore, studies have demonstrated that the stomach remained empty for 90 min after taking a liquid carbohydrate, without an increased risk of pulmonary aspiration.[9,10] Moreover, carbohydrate loading may reduce inflammation, increase insulin sensitivity, and preserve postoperative muscle mass.[11,12] However, there was no consensus regarding dietary restriction instructions before the procedure. Little information was available on the use of preoperative carbohydrate loading for patients undergoing ERCP. This study hypothesized that intake of a high-carbohydrate fluid diet (CFD) 2 h before ERCP in non-emergency patients would be as safe as overnight fasting.

We conducted a prospective, multicenter, single-blinded randomized controlled study to determine the safety of intake of a high-CFD 2 h before ERCP and its effects on postoperative recovery.

Methods

Ethical approval

This trial was conducted at 15 tertiary ERCP centers in China. The trial conformed to the International Conference on Harmonization Good Clinical Practice Guidelines and the *Declaration of Helsinki*. The protocol was approved by the independent local ethics committee at each study center. The patients or their legal representatives provided written informed consent. This study was registered with ClinicalTrials.gov (No. NCT03075280).

Study design and participants

Eligible patients aged 18–85 years who underwent ERCP participated voluntarily in this study. The exclusion criteria included contraindications for ERCP; coagulopathy (international normalized ratio >1.3) and thrombocytopenia (platelet count $<50 \times 10^9$ cells/L) or use of anti-coagulant drugs; preoperative comorbidities including acute pancreatitis, gastrointestinal tract bleeding, severe liver disease, shock, and liver or kidney failure; uncontrolled diabetes with or without complications; intestinal obstruction or other contraindications to oral feeding and hydration; a history of prior Billroth II and Roux-en-Y gastrectomy; unwillingness or inability to provide informed consent for the study; and pregnant or lactating women. Besides, we excluded patients who received local pharyngeal anesthesia. In addition, 31 patients in the CFD group who waited for more than 3 h after taking the high-CFD before undergoing ERCP for any reason were excluded to avoid potential bias because of longer waiting time, and 7 patients in the control group who did not receive the allocated intervention were also excluded. There were no data collected after randomization of these 38 patients.

Sample size determination

Sample size was calculated based on the fatigue score in a recent study.[13] This study assumed that the fatigue scale score in the control group would be 5.0 and was

reduced to 4.5 in patients in the study group, with a standard deviation of 2.7. To achieve the target difference by treatment between two groups with a power of 90% (at a two-sided α level of 0.05), 614 patients were needed in each group. Allowing for an 8% loss to follow-up, 665 patients were required in each group. Therefore, the total sample size needed was 1330.

Randomization and masking

The patients were randomized (1:1) either to receive a high-CFD (study group) or to undergo routine overnight fasting before ERCP (control group). The randomization procedure, which was computer-generated, was conducted by an independent biostatistician using a block size of 10. There was no masking of the patients to the treatment allocation. The investigators were blinded to the group assignment. The blinded independent assessors evaluated the primary and secondary outcomes.

Procedures

The patients in the study group received 400 mL of a high-CFD (Maltodextrin, Era Food for Special Medical Purpose Co., Ltd., Shenzhen, China) 2 h before ERCP. The control group underwent conventional preoperative overnight fasting for more than 6 h. According to the guidelines of the American Society for Gastrointestinal Endoscopy (ASGE),[14] patients who had post-ERCP pancreatitis (PEP) risk factors such as prior PEP, female sex, previous recurrent pancreatitis, suspected sphincter of Oddi dysfunction, and younger patient age (<40 years old) were routinely administered preoperative rectal nonsteroidal anti-inflammatory drugs (NSAIDs). All ERCP procedures were performed with deep sedation using intravenous propofol.

The patients initially received wire-guided biliary or pancreatic cannulation with a sphincterotome (Dreamtome, Boston Scientific, Natick, MA, USA). If the target duct cannulation failed, the double-wire technique or precut sphincterotomy was performed when appropriate. If the guidewire entered the pancreatic duct (PD) more than thrice, a prophylactic PD stent was placed. Therapeutic manipulation (e.g., sphincterotomy, balloon dilation, stone extraction) was performed at the discretion of the endoscopists.[15]

Endoscopists and/or anesthesiologists reviewed the indications and contraindications for ERCP before performing the procedure. All investigators were experienced endoscopists, and each had performed >1200 ERCP procedures. The ERCP procedure was classified as level 1–4 complexity[16] and performed according to the indication of patient and the goals of treatment. Carbon dioxide was used for all procedures. The patients were placed in the left decubitus position during the ERCP procedure. The residual gastric juice was suctioned, and its volume was measured during scope insertion.

Intravenous fluid, oxygenation, and cardiac monitoring were continued for 6 h immediately after the ERCP. Antibiotics were not routinely given unless patients had pre- or post-operative fever and elevated white blood cell count. The patients without any abdominal pain started a liquid diet. They were observed closely for any fever, abdominal pain, vomiting, or bleeding. The patients with severe post ERCP-related abdominal pain were given analgesics after the pain scores were recorded. Blood and urine samples were collected and tested for their amylase levels at 2 h and 12 h after the procedure, and the levels were repeated again at 24 h after the procedure.

Outcomes

The primary outcomes, including postprocedural fatigue and pain, were assessed based on a survey questionnaire, including pre- and post-operative discomfort. The fatigue levels were assessed at 4 h and 20 h after ERCP using the Fatigue Scale, including a 14-point scoring system [Supplementary Table 1, http://links.lww.com/CM9/B684].[17] Abdominal pain was assessed at 4 h after ERCP (using 10-point numerical scores: 1–10; 0: painless; 1–3: mild pain; 4–6: moderate pain; and 7–10: severe pain).

The secondary outcomes included the total procedural time, successful cannulation time (from the first attempt to successful cannulation), post-ERCP abdominal distension, and frequency of nausea and vomiting over 24 h. The documented complications, including PEP, cholangitis, cholecystitis, bleeding, respiratory aspiration, perforation, and any adverse outcomes requiring hospital admission or a prolonged hospital stay for further management, were monitored as described previously. In addition, intraoperative and 2-h blood glucose after the procedure, volume of residual fluid in the stomach, time to resume oral feeding after the procedure, time to ambulation, and duration of hospitalization were documented. All of the above-mentioned time-related parameters were documented up to 1 week after ERCP. To further monitor for late complications, all patients were followed up at 1 month either by phone or in the outpatient clinic.

An investigator who was very familiar with ERCP at each site but blinded to the treatment allocation recorded the procedure-related parameters, including cannulation methods, numbers of cannulation attempts, unintended PD cannulation, pancreatography, and prophylactic pancreatic stent placement of the PD stent. The same investigator also recorded the demographics of patients, potential post-ERCP adverse events caused by the ERCP procedure, and follow-up data. Procedure-related complications such as PEP, cholangitis, cholecystitis, hemorrhage, perforation, and their severity grading are defined in Supplementary Table 2, http://links.lww.com/CM9/B684.[18]

Statistical analysis

Outcome analyses were conducted based on a modified intention-to-treat analysis, which included all patients who were randomized and underwent the allocated intervention of ERCP. The primary outcomes were

analyzed using the linear mixed model and expressed as the mean and standard deviation, and the least-squares mean differences and 95% confidence interval (CI) at 4 h and 20 h were estimated. Baseline fatigue score, group, time since randomization, and group × time interaction was included in the mixed model, and the center was included as a random effect for the analysis of fatigue at 4 h and 20 h. The linear mixed model for the analysis of the secondary outcomes included the fixed effect of the group and random effect of center, except for glucose (before and after the procedure), which included group, time, and group × time interaction as fixed effects.

Continuous variables were presented as the mean ± standard deviations or median (interquartile ranges), and skewed dichotomous variables were presented as counts (percentages). Comparisons between the two groups were conducted using *t*-test, Wilcoxon test, Pearson chi-squared test, or Fisher exact test, as appropriate. The associations between complications and the clinical risk factors were analyzed using logistic regression. Variables with P <0.10 in the univariate analysis were considered for inclusion in the multivariable model. Subgroup analyses were conducted in patients with or without a native papilla or a prior history of ERCP. All tests were two-sided, and *P*-values <0.05 were considered statistically significant. Statistical software (SAS version 9.4, SAS Institute Inc., Cary, NC, USA) was used for analysis.

Results

The eligibility of 2205 patients admitted for ERCP between April 1, 2017 and April 17, 2021 for study inclusion was assessed. A total of 875 patients were excluded based on the inclusion and exclusion criteria. The remaining 1330 patients were randomly assigned to the CFD group (study group, $n = 665$) and fasting group (control group, $n = 665$). 38 patients were excluded from the two groups because they did not receive the allocated intervention, leaving 1292 patients included in the final analysis (CFD group, $n = 634$; fasting group, $n = 658$) [Figure 1]. The study population consisted of 53.4% (690/1292) men with a mean age of 61.1 ± 15.9 years. The baseline characteristics were well-balanced between the two groups [Table 1].

The mean fatigue scores for the CFD group at 4 h and 20 h after ERCP were 4.1 ± 2.6 and 2.4 ± 2.1, while those for the fasting group were 4.8 ± 2.8 and 3.4 ± 2.4, with least-squares mean differences of 0.48 (95% CI: 0.26–0.71, P <0.001) and 0.76 (95% CI: 0.57–0.95, P <0.001), respectively. The mean abdominal pain scores for the CFD group were significantly lower than those in the fasting group (2.1 ± 1.7 *vs.* 2.2 ± 1.7, $P = 0.009$), with a mean difference of 0.21 (95% CI: 0.05–0.37) [Table 2].

The secondary outcomes, including the time to resume oral feeding after the procedure (17.3 ± 10.5 h *vs.*

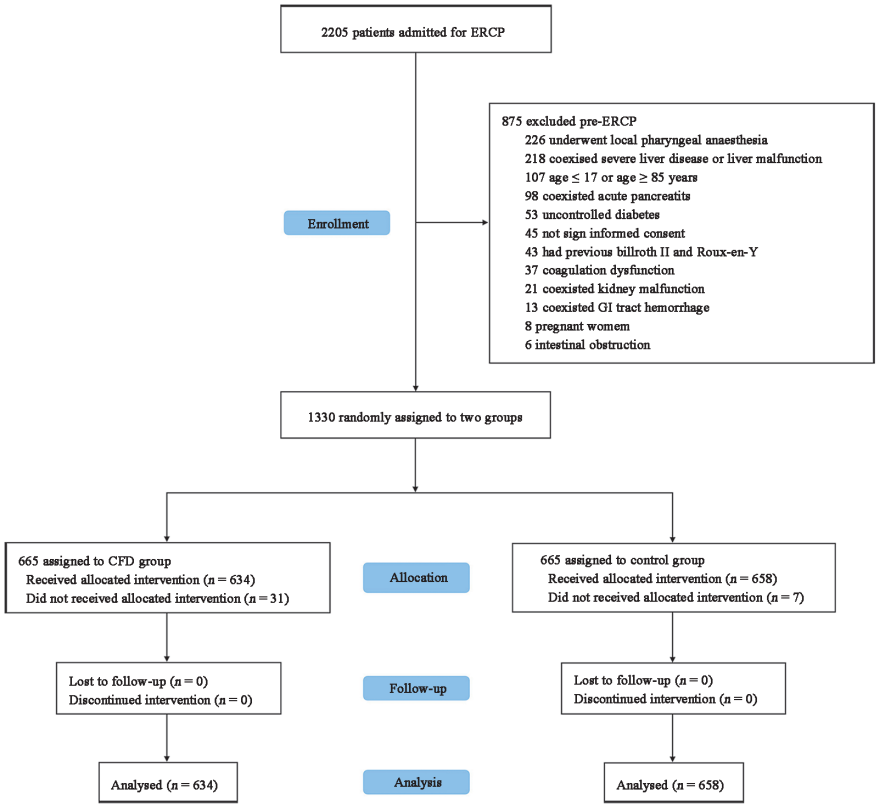

Figure 1: Flow chart of this high-CFD 2h *vs.* fasting overnight before non-emergency ERCP randomized controlled trial. CFD: Carbohydrate fluid diet; ERCP: Endoscopic retrograde cholangiopancreatography; GI: Gastrointestinal.

Table 1: Baseline characteristics of all participants in CFD gruop and fasting group.

Variables	CFD group (n = 634)	Fasting group (n = 658)	Statistical values	P-value	Variables	CFD group (n = 634)	Fasting group (n = 658)	Statistical values	P-value
Age (years)	60.3 ± 16.0	61.9 ± 15.8	–1.73*	0.084	Complex			1.28‡	0.199
Male	347 (54.7)	343 (52.1)	0.88†	0.348	1	23 (3.6)	27 (4.1)		
BMI (kg/m^2)	23.5 ± 3.5	23.2 ± 3.6	1.15*	0.250	2	123 (19.4)	145 (22.0)		
Diagnosis					3	470 (74.1)	469 (71.3)		
Choledocholithiasis	442 (69.7)	457 (69.5)	0.01†	0.918	4	18 (2.8)	17 (2.6)		
Gallstone	90 (14.2)	86 (13.1)	0.35†	0.555	Patient-related factors of PEP			0.27†	0.602
Benign biliarystricture	41 (6.5)	41 (6.2)	0.03†	0.862					
Chronic pancreatitis	12 (1.9)	11 (1.7)	0.09†	0.764	No	168 (26.5)	166 (25.2)		
Mirizzi syndrome	0	2 (0.3)	–	0.500	Yes	466 (73.5)	492 (74.8)		
Obstructive jaundice	124 (19.6)	156 (23.7)	3.28†	0.070	Laboratory tests before ERCP				
Previous biliary stent placement	32 (5.1)	33 (5.0)	0.00†	0.979	WBC (×10^9/L)	6.9 ± 3.6	6.8 ± 3.6	0.21*	0.831
Pancreaticobiliary malignancies	85 (13.4)	73 (11.1)	1.61†	0.205	NEUT%	66.5 ± 15.5	67.2 ± 16.5	–0.74*	0.459
					PLT (×10^9/L)	206.6 ± 86.2	212.3 ± 91.2	–1.16*	0.245
Co-morbidity					Urine amylase (U/L)	176.5 (104.0–320.0)	162.0 (100.0–263.0)	1.66‡	0.097
Hypertension	168 (26.5)	213 (32.4)	5.36†	0.021	Serum amylase (U/L)	55.5 (37.0–78.0)	53.0 (37.0–75.0)	0.77‡	0.440
Diabetes	74 (11.7)	85 (12.9)	0.46†	0.496	TBIL (μmol/L)	26.0 (13.8–83.0)	26.9 (14.0–75.0)	0.31‡	0.755
Coronary disease	59 (9.3)	70 (10.6)	0.64†	0.425	CRP (mg/L)	10.0 (4.6–36.2)	12.3 (5.0–40.5)	1.57‡	0.117
Chronic pulmonary disease	21 (3.3)	20 (3.0)	0.08†	0.780	PCT (ng/mL)	0.2 (0.1–0.5)	0.2 (0.1–0.5)	0.30‡	0.764
Liver cirrhosis	19 (3.0)	19 (2.9)	0.01†	0.908	Urine ketone			0.16†	0.692
Previous surgery					Negative	485 (86.5)	501 (85.6)		
ERCP	119 (18.8)	130 (19.8)	0.20†	0.653	Positive	76 (13.5)	84 (14.4)		
Cholecystectomy	169 (26.7)	177 (26.9)	0.01†	0.921					
CBD exploration	26 (4.1)	32 (4.9)	0.44†	0.508					
Bismuth I	2 (0.3)	0	–	0.241					

Data were presented as mean ± SD, n (%) or median (Q1,Q3). * t values; † χ^2 values; ‡ Z values; Complex: The difficulty of the ERCP procedure is graded in 4 levels, and as the level gets higher, the difficulty increases; –: Not available. BMI: Body mass index; CBD: Common bile duct; CFD: Carbohydrate fluid diet; CRP: C-reactive protein; ERCP: Endoscopic Retrograde Cholangiopancreatography; GLU: Glucose; IQR: Interquartile; NEUT%: Neutrophils percentage; PCT: Procalcitonin; PEP: Post-ERCP pancreatitis; PLT: Platelet; SD: Standard deviation; TBIL: Total bilirubin; WBC: White blood cell.

18.4 ± 11.2 h, P = 0.004), time to sit up after the procedure (6.9 ± 4.8 h *vs.* 7.6 ± 4.8 h, P <0.001), and time to ambulate after the ERCP procedure (9.9 ± 5.5 h *vs.* 10.9 ± 5.6 h, P <0.001) were all significantly shorter for the CFD group than for the fasting group, with least-squares mean differences of 1.65 (95% CI: 0.54–2.75), 0.81 (95% CI: 0.35–1.27), and 1.19 (95% CI: 0.64–1.74), respectively. The intraoperative residual fluid in the stomach was higher in the CFD group than in the fasting group (39.2 ± 45.4 mL *vs.* 28.8 ± 28.5 mL, P <0.001), with a least-squares mean difference of –9.40 (95% CI: –13.10 – –5.71). The length of hospital stay was shorter in the CFD group than in the fasting group (4.8 ± 3.4 *vs.* 5.1 ± 4.1 days, P = 0.047). The cannulation time, total procedure time, glucose (baseline and 2 h post procedure), and night sleep duration were similar in the two groups. Analysis of the urinalysis results showed that the urine ketone levels were more stable in the CFD group than in the fasting group (negative rate: 92.3% [470/509] *vs.* 84.6% [451/533], χ^2 = 15.13, P <0.001).

There was no significant difference in the overall post-ERCP complications between the CFD group and the fasting group (7.9% [50/634] *vs.* 10.3% [68/658], χ^2 = 2.33, P = 0.127). There was no significant difference in post-ERCP pancreatitis between the CFD group and the fasting group (5.5% [35/634] *vs.* 6.5% [43/658], χ^2 = 0.59, P = 0.444), while less cholangitis was observed in the CFD group (2.1% [13/634] *vs.* 4.0% [26/658], χ^2 = 3.99, P = 0.046). Only one patient with gastrointestinal bleeding and one patient with cholecystitis were observed in the CFD group, and no aspiration pneumonia was observed in either group [Table 3].

During the procedures, only the rate of unintended PD cannulation was significantly higher in the CFD group (24.0% [152/634] *vs.* 18.8% [124/658], χ^2 = 5.06, P = 0.025) [Table 4]. There was no significant difference in the effects on white blood cells, neutrophils, procalcitonin, C-reactive protein (CRP), blood glucose, and albumin between the two groups [Supplementary Figure 1,http://links. lww. com/CM9/B684]. Multivariate analyses showed that unintended PD cannulation (odds ratio [OR]: 4.09, 95% CI: 2.65–6.33, P <0.001) and the need for lithotripsy (OR: 1.91, 95% CI: 1.07–3.40, P = 0.029) were associated with more post-ERCP complications [Table 5].

Subgroup analyses revealed that CFD reduced the risk of complications (OR: 0.61, 95% CI: 0.39–0.95, P = 0.028), but unintended PD cannulation (OR: 4.95, 95% CI: 3.15–7.78, P <0.001) and lithotripsy (OR: 2.75, 95% CI: 1.37–5.55, P = 0.005) increased the incidence of total complications in the patients without a prior history of ERCP (native papilla) [Supplementary Figure 2, http://links.lww.com/CM9/B684].

Table 2: Primary and secondary outcomes of all participants in CFD gruop and fasting group.

Variables	CFD group (*n* = 634)	Fasting group (*n* = 658)	Least squares mean difference (95% CI)*	*P*-value
Primary outcomes				
Fatigue score*				
Baseline	1.1 ± 0.8	1.2 ± 0.9		
4 h after procedure	4.1 ± 2.6	4.8 ± 2.8	0.48 (0.26–0.71)	<0.001
20 h after procedure	2.4 ± 2.1	3.4 ± 2.4	0.76 (0.57–0.95)	<0.001
Pain score†	2.1 ± 1.7	2.2 ± 1.7	0.21 (0.05–0.37)	0.009
Secondary outcomes				
Cannulation time (min)†	4.8 ± 6.6	4.2 ± 7.0	–0.39 (–1.10 – 0.32)	0.283
Total procedure time (min)†	39.4 ± 24.8	36.9 ± 23.2	–1.25 (–3.55 – 1.05)	0.286
GLU (mmol/L)*				
Baseline (mmol/L)	6.7 ± 5.1	6.6 ± 3.9		
Intraoperative (mmol/L)	7.0 ± 2.8	7.0 ± 3.4	–0.05 (–0.42 – 0.32)	0.796
2 h after procedure (mmol/L)	7.0 ± 2.2	7.2 ± 2.3	0.18 (–0.06 – 0.42)	0.151
Intraoperative residues in stomach (mL)†	39.2 ± 45.4	28.8 ± 28.5	–9.40 (–13.10 – –5.71)	<0.001
Time to resume diet after procedure (h)†	17.3 ± 10.5	18.4 ± 11.2	1.65 (0.54–2.75)	0.004
Length of hospital stay (days)†	4.8 ± 3.4	5.1 ± 4.1	0.39 (0.01–0.78)	0.047
Time to sit-up after procedure (h)†	6.9 ± 4.8	7.6 ± 4.8	0.81 (0.35–1.27)	<0.001
Time to ambulate after procedure (h)†	9.9 ± 5.5	10.9 ± 5.6	1.19 (0.64–1.74)	<0.001
Night sleep duration (h)†	6.9 ± 1.7	6.9 ± 1.8	–0.10 (–0.25 – 0.05)	0.186
Urine ketone				<0.001
Negative	470 (92.3)	451 (84.6)		
Positive	39 (7.7)	82 (15.4)		

Data were presented as mean ± SD or *n* (%). Least squares mean difference was estimated with a linear mixed model. *Mixed-effect model for repeated measures was used and the model included baseline fatigue score, group, time since randomization, and group × time interaction as fixed effects, and center as a random effect. †Mixed-effect model with random intercept was used, including fixed effect of group and random effect of center. CFD: Carbohydrate fluid diet; CI: Confidence interval; GLU: Glucose; SD: Standard deviation.

Discussion

This randomized controlled study investigated the benefits and safety of per oral intake of a high-carbohydrate liquid diet in patients before conventional ERCP procedures. The results showed that CFD administered 2 h before the procedure had a safety profile similar to that of a traditional overnight fasting plan and even reduced fatigue and abdominal pain after ERCP. Furthermore, the subgroup analysis revealed that CFD could reduce postoperative complications in patients with native papilla who did not have a previous ERCP. Factors such as the amount of propofol sedation, use of rectal NSAIDs, and prophylactic PD stents may more or less influence the fatigue score, pain scores, and even complications. There was no difference between the two groups, thus eliminating any potential bias caused by these factors.

As a routine protocol, patients are instructed to fast overnight before ERCP to avoid the risk of complications such as aspiration pneumonia during the procedure. Experiences gained by the observations gleaned from treating patients with enhanced recovery in patients with a presurgery protocol[19] showed that traditional preoperative fasting of 6–8 h is changed to oral CFD given 2–3 h before surgery which is safe and can benefit for patients' recovery.[20] Studies also reported that the intake of CFD before surgery could ensure stability of the blood glucose levels and circulation and potentially improve the tolerance of patients during surgery.[21] The current guidelines proposed by anesthesiology and perioperative care societies recommend that patients undergoing gastrointestinal or hepatobiliary surgery without gastrointestinal motility disorders can take solid food up to 6 h and drink clear fluids 2 h before anesthesia.[22,23] However, the current ERCP guidelines are not in agreement with these recommendations because of the potential risk of complications, including vomiting and aspiration pneumonia. Zhang *et al*[24] added CFD to the preoperative care of patients with choledocholithiasis who are scheduled to undergo ERCP, and patients were given 1000 mL of 10% glucose solution orally at night and 500 mL up to 4–6 h before ERCP in the morning. The results demonstrated that CFD was a safe and effective preoperative measure for patients before ERCP, which also improved their recovery. Wang *et al*[25] reported that the administration of 710 mL carbohydrate solution at night and 355 mL 2

Table 3: Summary of complications among all participants in CFD gruop and fasting group.

Variables	CFD group (n = 634)	Fasting group (n = 658)	χ^2	P-value
Post-ERCP complications	50 (7.9)	68 (10.3)	2.33	0.127
Complex 1	1 (4.3)	1 (3.7)	–	1.000
Complex 2	11 (8.9)	18 (12.4)	0.83	0.362
Complex 3	36 (7.7)	47 (10.0)	1.63	0.202
Complex 4	2 (11.1)	2 (11.8)	–	1.000
Pancreatitis	35 (5.5)	43 (6.5)	0.59	0.444
Cholangitis	13 (2.1)	26 (4.0)	3.99	0.046
Cholecystitis	1 (0.2)	0		
Aspiration pneumonia	0	0		
GI bleeding	1 (0.2)	0		
Post-ERCP complications in native papilla	42 (8.2)	59 (11.2)	2.72	0.099
Complex 1	1 (12.5)	0		
Complex 2	8 (8.0)	16 (12.9)	1.39	0.238
Complex 3	32 (8.1)	41 (10.7)	1.49	0.221
Complex 4	1 (7.1)	2 (15.4)	–	0.596
Pancreatitis	31 (6.0)	39 (7.4)	0.78	0.378
Cholangitis	9 (1.8)	20 (3.8)	4.01	0.045
Cholecystitis	1 (0.2)	0		
Aspiration	0	0		
GI bleeding	1 (0.2)	0		

Data were presented as n (%). CFD: Carbohydrate fluid diet; ERCP: Endoscopic retrograde cholangiopancreatography; GI: Gastrointestinal; –: Not available.

h before upper endoscopy procedures did not increase the risk of regurgitation but improved the sense of thirst, hunger, and xerostomia in patients who underwent endoscopic submucosal dissection. This study showed that although oral intake of carbohydrate solution 2 h before ERCP increased the volume of residual fluid in the stomach, adverse events such as aspiration pneumonia were not observed.

Currently, improved techniques have resulted in more stabilized body metabolism and rapid patient recovery. Previous studies have shown that prolonged fasting before surgery can lead to insulin resistance and increase breakdown of protein and glycogen, resulting in a state of negative nitrogen balance in the body, and consequently, patients were more likely to develop symptoms of fatigue or weakness.[12,22] A questionnaire survey showed that most patients were concerned with the discomfort of the procedure and the recovery after ERCP. Therefore, we chose postprocedural fatigue and pain as the primary outcomes. Carbohydrate intake 2–3 h before surgery can reduce preoperative thirst, hunger, and anxiety; reduce insulin resistance; and improve postoperative fatigue scores. [10,26] Mathur *et al*[27] found that preoperative oral intake of CFD does not have a significant effect on the postoperative tiredness of patients undergoing abdominal surgery. Hausel *et al*[11] conducted a trial comparing preoperative oral CFD and placebo in 252 abdominal surgery patients and discovered a significant improvement in the degree of tiredness among the oral CFD group. In our study, the patients in the CFD group required a shorter time to resume oral feeding and recovery. Fasting increases the breakdown of body fat and elevates the levels of free fatty acids and ketones, resulting in ketonuria.[28] Our data indicated that the frequency of positive postprocedural ketonuria was significantly lower in the CFD group than in the fasting group, suggesting that drinking a carbohydrate solution 2 h before ERCP significantly reduced the breakdown of fatty acids as well as the production and accumulation of ketones, thus reducing nausea and vomiting from ketoacidosis. Blood glucose monitoring before and after ERCP also demonstrated the stability of the blood glucose levels in the CFD group compared to the fasting group.[27,29,30] The present study also showed lower postoperative hemoglobin and albumin levels in the fasting group than in the CFD group, which could be a result of hemodilution due to the administration of a large amount of rehydration fluid in the fasting group.

In clinical practice, some specific conditions can cause complications during ERCP. For example, PEP and other complications may be more different in patients with a native papilla, while the observed probability of complications was lower in patients who had a history of prior ERCP.[31] A subgroup analysis was conducted considering the influence of no previous ERCP on the clinical outcomes. The results showed that the intake of CFD 2

Table 4: Comparation of ERCP procedures and laboratory test results after ERCP between CFD group and fasting group.

Variables	CFD group (*n* = 634)	Fasting group (*n* = 658)	Statistical values	*P*-value
Intravenous anesthesia	634 (100.0)	658 (100.0)		
Periampullary diverticula	133 (21.0)	138 (21.0)	0†	0.998
Cannulation methods				
Transpancreatic sphincterotomy	53 (8.4)	68 (10.3)	1.48†	0.223
Needle-knife fistulotomy	5 (0.8)	12 (1.8)	2.66†	0.103
ERCP procedures				
EST	490 (77.3)	509 (77.4)	0†	0.977
EPBD	312 (49.2)	268 (40.7)	9.39†	0.002
Stone extraction by basket	417 (65.8)	411 (62.5)	1.54†	0.215
Lithotripsy	59 (9.3)	55 (8.4)	0.36†	0.548
Unintended PD cannulation times	152 (24.0)	124 (18.8)	5.06†	0.025
1	54 (35.5)	47 (37.9)		
2–3	80 (52.6)	60 (48.4)		
>3	18 (11.8)	17 (13.7)		
Intraoperative bleeding	47 (7.4)	50 (7.6)	0.02†	0.899
PD stent placement	60 (9.5)	46 (7.0)	2.62†	0.105
Endoscopic nasobiliary drainage	401 (63.3)	395 (60.0)	1.41†	0.234
Laboratory tests after ERCP				
WBC ($\times10^9$/L)	7.9 ± 5.9	8.4 ± 6.4	–1.33*	0.185
NEUT%	73.1 ± 14.3	74.3 ± 14.2	–1.62*	0.104
HGB (g/L)	124.3 ± 19.5	122.8 ± 20.4	1.38*	0.169
PLT ($\times10^9$/L)	200.6 ± 81.3	201.2 ± 86.1	–0.13*	0.894
Urine amylase (U/L)	221.0 (119.0–554.0)	256.0 (134.0–506.5)	1.45‡	0.147
Serum amylase (U/L)	82.0 (53.0–157.0)	78.0 (50.0–164.0)	1.02‡	0.308
TBIL (μmol/L)	24.6 (14.7–47.0)	24.0 (14.8–52.0)	0.25‡	0.806
ALB (g/L)	35.7 ± 5.3	35.1 ± 5.5	1.89*	0.059
CRP (mg/L)	12.7 (5.5–33.6)	16.0 (7.9–44.8)	–2.94‡	0.003
PCT (ng/mL)	0.2 (0.1–0.5)	0.2 (0.1–0.5)	0.47‡	0.641
Urine SG			-0.64‡	0.524
<1.015	130 (23.8)	126 (22.3)		
1.015–1.025	368 (67.3)	386 (68.2)		
>1.025	49 (9.0)	54 (9.5)		
Hospitalization expenses (RMB Yuan)	31,000 (24,551–40,227)	32,000 (25,328–40,916)	–1.61‡	0.107

Data were presented as mean ± SD, *n* (%) or median (Q1, Q3). * *t* values; † χ^2 values; ‡ *Z* values. ALB: Albumin; CFD: Carbohydrate fluid diet; CRP: C-reactive protein; ERCP: Endoscopic retrograde cholangiopancreatography; EST: Endoscopic Sphincterotomy; EPBD: Endoscopic papillary balloon dilation; HGB: Hemoglobin; NEUT: Neutrophils; PCT: Procalcitonin; PD: Pancreatic duct; PLT: Platelet; SG: Specific gravity; TBIL: Total bilirubin; WBC: White blood cell.

h before ERCP may reduce the risk of postoperative complications, especially cholangitis, in prior patients without a history of ERCP. PEP is a well-known and the highest incidence complication of ERCP which is influenced by several risk factors, especially prolonged cannulation time, and repeated PD cannulation are the two main procedure-related risk factors. In this study, although the rate of unintended PD cannulation in the CFD group was higher than that in the fasting group (24.0% *vs*. 18.8%), it did not, surprisingly, increase the incidence of PEP. These could be a result of oral CFD intake causing gallbladder contraction and sphincter of Oddi relaxation by neurohumoral regulation in promoting bile flow. These changes could empty the biliary tract in an empty state, thus increasing cannulation difficulty and resulting in a relatively high rate of unintended PD cannulation. In addition, this study found that biliary decompression after cholangiography can avoid an increase in biliary pressure and that may reduce the occurrence of postoperative cholangitis. Further studies are needed to investigate these effects.

The present study has notable strengths. First, this randomized controlled trial included a large patient population and utilized a single-blind analysis to improve the study quality. Second, this multicenter study included 15 large ERCP centers in mainland China, which were spread over six regions of the country and involved different ethnic groups, thus increasing the generalizability of the results. However, this study also has limitations. First, there was no placebo control group, although it was not necessary in this study. Second, it was difficult to standardize the exact timing of CFD intake due to the different waiting times for ERCP. Third, more parameters were needed to monitor the inflammatory mediators or metabolism-related parameters before and after ERCP. Another limitation was that the patients were not blinded in the study, and

Table 5: Univariate and multivariate logistic regression for all complications.

Variables	Univariable analysis		Multivariable analysis	
	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Sex (male *vs*. female)	0.89 (0.61–1.31)	0.569		
Age (years)	1.00 (0.99–1.01)	0.551		
BMI (≤25 kg/m^2 *vs*. >25 kg/m^2)	1.25 (0.81–1.94)	0.316		
Previous ERCP (yes *vs*. no)	0.68 (0.40–1.17)	0.162		
Previous cholecystectomy (yes *vs*. no)	0.88 (0.57–1.37)	0.570		
EST (yes *vs*. no)	1.16 (0.73–1.86)	0.525		
EPBD (yes *vs*. no)	1.00 (0.68–1.47)	0.996		
Transpancreatic sphincterotomy (yes *vs*. no)	1.60 (0.91–2.81)	0.104		
Needle-knife fistulotomy (yes *vs*. no)	4.29 (1.48–12.38)	0.007	2.98 (0.96–9.25)	0.059
Cannulation time (min)	1.02 (1.00–1.04)	0.132		
Operation time (min)	1.01 (1.00–1.01)	0.105		
Unintended PD cannulation (yes *vs*. no)	4.08 (2.76–6.02)	<0.001	4.09 (2.65–6.33)	<0.001
PD stent (yes *vs*. no)	2.58 (1.52–4.38)	<0.001	0.93 (0.51–1.71)	0.820
Lithotripsy (yes *vs*. no)	1.87 (1.07–3.25)	0.027	1.91 (1.07–3.40)	0.029
Periampullary diverticula (yes *vs*. no)	0.96 (0.60–1.53)	0.859		
Complex				
1	1.00			
2	2.91(0.67–12.61)	0.254		
3	2.33 (0.56–9.74)	0.733		
4	3.10 (0.54–17.93)	0.402		
Patient-related factors of PEP (yes *vs*. no)	1.13 (0.73 – 1.77)	0.581		
CFD group (yes *vs*. no)	0.74 (0.51–1.09)	0.128		

BMI: Body mass index; CFD: Carbohydrate fluid diet; CI: Confidence interval; EPBD: Endoscopic papillary balloon dilation; ERCP: Endoscopic retrograde cholangiopancreatography; EST: Endoscopic Sphincterotomy; OR: Odd ratio; PD: Pancreatic duct.

evaluation of the fatigue score as the primary endpoint could be subject to potential bias.

In conclusion, comparing with the patients who underwent traditional preprocedural fasting, the non-emergency patients who were given 400 mL of CFD 2 h before ERCP had a similar clinical outcomes and an an equivalent safety profile. This 2-h CFD plan decreased the fatigue and pain score during recovery from ERCP and reduced the risk of cholangitis. It also reduced the total postoperative complications, especially for those with a native papilla.

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Conflicts of interest

None.

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