Surgical Science, 2015, 6, 91-99
Published Online March 2015 in SciRes. http://www.scirp.org/journal/ss
http://dx.doi.org/10.4236/ss.2015.63015

Safety and Feasibility of Oral Rehydration Solution Prior to Endoscopic Retrograde Cholangiopancreatography

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Received 2 February 2015; accepted 26 February 2015; published 28 February 2015

Abstract

Purpose: The safety of oral rehydration therapy before endoscopic screening with respect to vital signs and complications after the screening procedure was assessed in patients undergoing endoscopic retrograde cholangiopancreatography (ERCP). Methods: A total of 107 patients scheduled for ERCP were assigned to either the intravenous drip injection (DIV) group during fasting (56 patients) or ORS group given oral rehydration solution (51 patients) prior to endoscopy. Vital signs after ERCP, including blood pressure and temperature, blood biochemical data and the incidence of post-ERCP complications were compared between the groups. Results: No cases of aspiration pneumonia were detected in either groups. Moreover, there were no statistically significant differences between the DIV group and ORS group in terms of the biochemical data and vital signs after ERCP. The intergroup difference in the development of pancreatitis after ERCP was 2.3% [95% CI: −5.7, 10.3], which was not statistically significant. Conclusions: The safety of oral rehydration therapy was found to be equivalent to that of the customary practice of infusion as a method for managing hydration and replenishing electrolytes in patients receiving ERCP. Oral rehydration therapy may be easily utilized as rehydration therapy prior to endoscopic screening for ERCP and other procedures.

Keywords

Endoscopic Retrograde Cholangiopancreatography, Oral Rehydration Therapy, Oral Rehydration Solution, Post-ERCP Pancreatitis, Complication

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How to cite this paper: Sasaki, T., Kato, D., Sakamoto, R., Shinya, S., Shiwaku, H., Yamashita, K., Nakashima, R. and Yamashita, Y. (2015) Safety and Feasibility of Oral Rehydration Solution Prior to Endoscopic Retrograde Cholangiopancreatography. *Surgical Science*, **6**, 91-99. http://dx.doi.org/10.4236/ss.2015.63015

1. Introduction

Fasting starting the night before endoscopy remains the customary practice for preventing aspiration pneumonia. Therefore, it is inevitable that the patient will become thirsty and hungry. In addition, it has been demonstrated that this approach has no scientific basis; thus, the need for fasting is being reconsidered.

Endoscopic retrograde cholangiopancreatography (ERCP) is an endoscopic procedure essential for the close diagnosis and treatment of pancreatobiliary diseases. However, this technique is invasive and the incidence of complications is not low. In particular, ERCP-induced pancreatitis is a severe complication, with a reported frequency of 2% - 15% [1] [2].

Patients receiving ERCP are also often instructed to fast starting the night before in the same manner as that used for standard endoscopy. Hence, the patient is often dehydrated during screening, which raises concerns regarding the potential development of pancreatitis, a common ERCP complication, as well as the vasovagal reflex.

In recent years, the use of oral rehydration therapy (ORT) has drawn increasing attention and its efficacy in preventing dehydration and as a treatment for mild dehydration has been reevaluated. OS-1 is an oral rehydration solution (ORS), a special purpose food product, used for rehydration and to replenish electrolytes in patients experiencing diarrhea, vomiting or fever. Some studies have reported the efficacy of this treatment in patients exhibiting mild dehydration in daily practice and as a rehydration therapy before and after invasive procedures. However, no previous reports related to the use of this technique in clinical trials of endoscopic screening have been published.

The purpose of our research was to examine the effects of ORT before endoscopy on vital signs and complications in patients undergoing ERCP.

2. Methods

2.1. Patients

The subjects of this study included patients admitted or making outpatients visits to the department of gastroenterological surgery from January 2012 to December 2013, at Fukuoka University Hospital for ERCP. Among these individuals, those 20 years of age or older who agreed in writing to participate in this study were registered. Patients who did not receive oral rehydration or had a previous history of laparotomy for gastroesophageal surgery and those whose participation was assessed by the physician to be inappropriate were excluded. The present study was conducted in accordance with the principles of the Declaration of Helsinki. Sample collection and all administrative procedures in this study were carried out in accordance with the code of ethics specified by the Institutional Ethics Committee of Fukuoka University Hospital.

2.2. Oral Rehydration Therapy Prior to Endoscopy

The patients were allocated to two groups: the ORS group, who received 500 ml of oral rehydration solution (OS-1, Otsuka Pharmaceutical Factory, Tokushima, Japan) up to one hour prior to ERCP, and the DIV group, who remained under complete fasting on the day of ERCP and were treated with an intravenous drip (**Table 1**). The results obtained from interviews and data, such as vital signs, including blood pressure and temperature, blood biochemical findings and the incidence of post-ERCP complications, were compared (**Figure 1**).

2.3. Statistical Analysis

Continuous data are reported as the mean ± standard deviation (SD) if normally distributed and the median and interquartile range (IQR) if not normally distributed. Categorical data are presented as numbers (n) and percentages (%). Student's *t*-test was used for comparisons of the mean values between the two groups. Some of the data were not normally distributed; in these cases, the nonparametric Mann-Whitney U test was used instead of the *t*-test. Categorical variables were evaluated using Fisher's exact test. Previous reports have shown the incidence of ERCP-induced pancreatitis to range from 2% to 15%. Therefore, we determined that a significant medical risk was present when the difference in the incidence of ERCP-induced pancreatitis between the intravenous drip group and the ORS group was more than 13%. A P value of less than 0.05 was considered to be statistically significant. All statistical analyses were performed with the SPSS v22.0 package for Windows (IBM Japan, Ltd., Tokyo, Japan).

Table 1. Composition of the oral rehydration solution (OS-1).

Volume (ml)	500
Energy (kcal)	50
Carbohydrate (%)	2.5 (glucose, 1.8)
Electrolytes ($mEq \cdot l^{-1}$)	
Sodium	50
Potassium	20
Magnesium	2
Chloride	50
Lactate	31
Phosphorus ($mmol \cdot l^{-1}$)	2
pH	3.9
Osmolarity ($mOsm \cdot l^{-1}$)	270

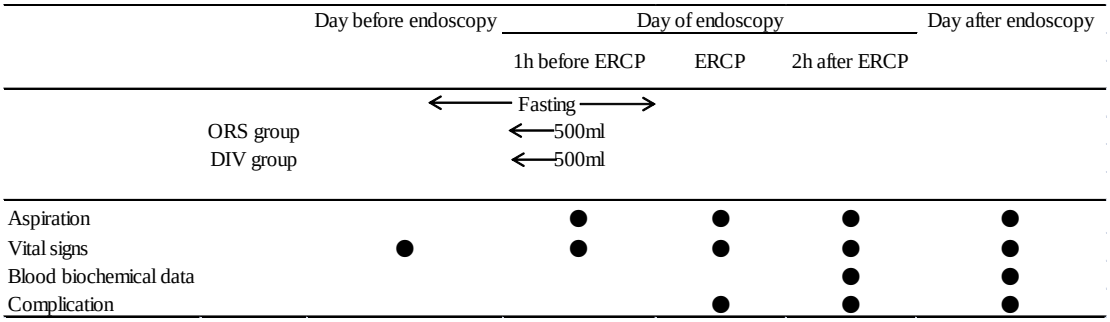

Figure 1. Schedule of treatment in the current study. ORS group, oral rehydration solution group (OS-1; oral rehydration solution: Otsuka Pharmaceutical Factory, Tokushima, Japan). DIV group, underwent complete fasting on the day of ERCP and given treatment with an intravenous drip.

3. Results

3.1. Baseline Characteristics of the Study Subjects

A total of 107 patients scheduled for ERCP between January 2012 and December 2013 were assigned to either the DIV group who received treatment with an intravenous drip while fasting (56 patients) or the ORS group who was given oral rehydration solution (51 patients) prior to endoscopy, and the two groups were compared.

As shown in **Table 2**, the drip group and the ORS group demonstrated no significant differences in terms of gender (drip group: 31 males and 25 females; ORS group: 25 males and 26 females), age (drip group: 68.9 ± 10.2; OS-1 group: 70.5 ± 10.8) or diagnosis.

3.2. ERCP-Related Procedures in the DIV and ORS Groups

No statistically significant differences in ERCP-related procedures, including screening of the papillary region, endoscopic retrograde pancreatography (ERP), balloon-ERP, pancreatic juice cytology, endoscopic retrograde cholangiography (ERC), endoscopic sphincterotomy (EST), lithotripsy using a wire basket, endoscopic biliary stenting (EBS), endoscopic nasobiliary drainage (ENBD), endoscopic papillectomy and endoscopic minor papilla sphincterotomy, were noted between the DIV group and the OS-1 group, as shown in **Table 3**.

3.3. Biochemical Data and Vital Signs after ERCP

As indicated in **Table 4**, the test data, including systolic blood pressure, diastolic blood pressure, pulse, body temperature, hemoglobin (Hb), hematocrit (Hct), blood urea nitrogen (BUN), serum creatinine (Cr), serum

Table 2. Baseline characteristics of the study subjects.

	DIV group (n = 56)		ORS group (n = 51)		P-value	
Age, years, mean ± SD	68.9 ± 10.2		70.5 ± 10.8		0.435	a
Gender (male/female)	31/25		25/26		0.564	c
Diagnosis					0.592	c
Choledocholithiasis	26	46.4	23	45.1		
Pancreatic adenocarcinoma	17	30.4	16	31.4		
Obstractive jaudice	5	8.9	8	15.7		
Chronic pancreatitis	1	1.8	2	3.9		
Distal cholangiocarcinoma	3	5.4	2	3.9		
Pancreas divism	3	5.4	0	0.0		
Pancreaticobiliary maljunction	1	1.8	0	0.0		

Note: mean ± SD, median [IQR]. n, %. a: Independent t test; b: Mann-Whitney U test; c: Fisher's exact test.

Table 3. ERCP-related procedures in the DIV and ORS groups.

	DIV group (n = 56)		ORS group (n = 51)		P-value
Screening papillary region	3	5.4	4	7.8	0.707
ERP	11	19.6	10	19.6	>0.999
Balloon-ERP	5	8.9	1	2.0	0.209
Pancreatic juice cytology	2	3.6	2	3.9	>0.999
ERC	3	5.4	5	9.8	0.474
EST	8	14.3	6	11.8	0.779
Lithotripsy	14	25.0	15	29.4	0.667
EBS	7	12.5	8	15.7	0.782
ENBD	0	0.0	0	0.0	-
Papillectomy	1	1.8	0	0.0	>0.999
Minor papilla sphincterotomy	2	3.6	0	0.0	0.496

Note: n, %. P-value: Fisher's exact test. ERP, endoscopic retrograde pancreatography; ERC, endoscopic retrograde cholangiograpy; EST, endoscopic sphincterotomy; EBS, endoscopic biliary stenting; ENBD, endoscopic nasobiliary drainage.

sodium (Na), serum potassium (K), serum chloride (Cl), blood glucose (Glu), white blood cells (WBCs), C-reactive protein (CRP) and serum amylase (AMY), obtained after ERCP showed no statistically significant differences between the DIV and ORS groups.

3.4. Incidence of Post-ERCP Pancreatitis in the DIV and ORS Groups

As shown in **Table 5**, the intergroup difference in the incidence of post-ERCP pancreatitis between the DIV group and the ORS group was 2.3% [95% CI: −5.7, 10.3], which did not rise to the level of statistical significance. In addition, the absolute value of the 95% confidence interval for the intergroup difference in the incidence of pancreatitis was less than 13%, defined as a medically significant difference in the Methods section. Therefore, the incidence of pancreatitis was not considered to be medically significant in the DIV or ORS group.

4. Discussion

Oral rehydration therapy (ORT) using oral rehydration solution (ORS) was originally developed to treat dehydration in developing nations. WHO-oral rehydration salt (WHO-ORS), developed by the World Health

Table 4. Biochemical data and vital signs after ERCP.

	DIV group (n = 56)	ORS group (n = 51)	Δ [DIV − ORS] (%)		P-value	
			Mean	95% CI		
Systoric blood pressure (mmHg)	129.6 ± 16.1	130.9 ± 20.6	1.2	−5.8 8.3	0.732	a
Diastolic blood pressure (mmHg)	77.2 ± 12.4	74.4 ± 12.1	−2.8	−7.5 1.9	0.233	a
Pulse	68.7 ± 10.7	67.3 ± 12.2	−1.4	−5.8 2.9	0.517	a
Body temperature	36.5 ± 0.6	36.6 ± 0.7	0.1	−0.2 0.3	0.645	a
Hemoglobin	12.5 ± 1.6	12.1 ± 1.4	−0.4	−1.0 0.2	0.170	a
Hematocrit	37.3 ± 4.2	36.5 ± 4.1	−0.8	−2.4 0.8	0.320	a
Blood urea nitrogen	12.1 ± 5.2	11.9 ± 5.1	−0.2	−2.1 1.8	0.880	a
Serum creatinine	0.8 ± 0.3	0.8 ± 0.2	−0.1	−0.1 0.0	0.253	a
Serum sodium ($mEq \cdot l^{-1}$)	139.7 ± 2.1	139.8 ± 3.2	0.1	−1.0 1.1	0.886	a
Serum potassium ($mEq \cdot l^{-1}$)	4.1 ± 0.4	4.0 ± 0.5	−0.1	−0.2 0.1	0.539	a
Serum chloride ($mEq \cdot l^{-1}$)	104.5 ± 2.6	103.6 ± 3.8	−0.8	−2.1 0.4	0.182	a
Blood glucose	136.9 ± 47.0	152.1 ± 53.8	15.2	−4.2 34.6	0.123	a
White blood cell	6271.4 ± 3247.6	6811.8 ± 2492.8	540.3	−577.5 1658.2	0.340	a
C-reactive protein	0.1 (0.0, 0.8)	0.2 (0.0, 1.6)			0.264	b
Serum amylase	100.5 (70.3, 133.5)	104.0 (70.0, 148.0)			0.635	b

Note: mean ± SD, median [IQR]. P-value: a: Independent t test; b: Mann-Whitney U test; 95% CI: 95% confidence interval.

Table 5. Incidence of post-ERCP pancreatitis in the DIV and ORS groups.

	DIV Group (n = 56)	ORS Group (n = 51)	Δ [DIV − ORS] (%)		P-value
			Mean	95% CI	
Post-ERCP pancreatitis					
Absent	54 , 96.4	48 , 94.1			
Present	2 , 3.6	3 , 5.9	2.3	−5.7 , 10.3	0.668
Mild	2 , 3.6	2 , 3.9			
Moderate	0 , 0.0	1 , 2.0			
Severe	0 , 0.0	0 ,			

Note: n, %. P-value: Fisher's exact test. [Post-ERCP pancreatitis (absent or present) vs. group (DIV or OS-1)].

Organization (WHO), demonstrates significant success in dehydrated patients experiencing acute diarrhea due to cholera and the efficacy of this treatment in developing nations is widely recognized [3] [4]. In recent years, the use of ORS has drawn attention in many countries, including Europe and the US, as an option for rehydration therapy to rehydrate the patient and replenish electrolytes and glucose at an equivalent volume to fluid therapy [4]-[6]. The guidelines of the Center for Disease Control and Prevention (CDC) recommend the application of ORS in cases of mild to moderate dehydration [5]. The OS-1 used in this study is a special purpose food product created based on the idea of ORT recommended by the WHO and whose composition is aligned with the policy of the American Academy of Pediatrics [6]. In comparison to regular soft drinks, the efficacy of this treatment in treating dehydration and achieving postoperative rehydration with electrolyte replenishment has been recognized [7].

In the current study, ORT was used to manage the levels of body fluids prior to ERCP and the safety and efficacy of this approach before endoscopy were examined. Consequently, no patients showed the pre-ERCP ORT-triggered accumulation of excess gastric fluid or experienced issues with testing. Furthermore, no complications of aspiration pneumonia were noted, and the post-ERCP vital signs, including blood pressure and temperature, blood biochemical data and the incidence of post-ERCP complications were not significantly different

between the group given ORT and the group given sufficient transfusion via infusion. Therefore, using ORT for the management of rehydration and electrolyte replenishment in ERCP patients was found to be feasible and safe as a customary method for achieving rehydration via infusion.

For endoscopic screening, patients are normally instructed to fast for a certain period of time, with the goal of reducing the gastric fluid volume (GFV) in order to prevent vomiting and aspiration during the screening procedure. However, long-term fasting inflicts burdens on the patient, such as thirst and hunger, and dehydration has the potential to worsen the patient's condition in association with a low blood sugar level and perioperative complications. Previous studies have shown that food/fluid intake prior to surgery is safe when complying with guidelines regarding suggested contents and timing, which has led to a reevaluation of the need for fasting [8]. Various societies of anesthesiologists in both Europe and the US have revised their guidelines concerning preoperative fasting and proposed that the intake of clear fluids up to two to three hours before the operation is acceptable, with the exception of cases in which delayed gastric emptying is expected [9]-[12]. In addition, in recent years, Fearon *et al*. suggested the efficacy of ERAS (enhanced recovery after surgery) as a method for reducing the perioperative stress response and comprehensively decreasing the incidence of complications and demonstrated the adverse effects of perioperative fasting [13]. Moreover, various studies of ERAS have confirmed that carbohydrate (CHO) intake prior to surgery reduces insulin resistance in adult patients. Furthermore, it has been reported that thirst and hunger resulting from fasting increase the mental burden and level of anxiety in preoperative patients, whereas CHO intake overcomes these negative aspects [14].

Endoscopic retrograde cholangiopancreatography (ERCP) is a technique developed by McCune *et al*. in 1968 and Takagi *et al*. and Ohi in 1969 and subsequently became widely used worldwide [15]. Since then, as an extension of this technique, various treatment methodologies have been developed and evolved. However, adverse outcomes, such as pancreatitis, are not rare, and measures to reduce these complications remain challenging. As to the complications of ERCP, pancreatitis, hemorrhage and gastrointestinal perforation are the primary examples, among which pancreatitis may be severe and/or fatal. Various reports of high-risk groups regarding the development of ERCP-induced pancreatitis have been published. Fisk factors include a young age, female gender, normal pancreatogram findings, previous history of ERCP-induced pancreatitis, recurrent acute pancreatitis and sphincter of Oddi dysfunction (SOD), etc., while operative risk factors involve the level of experience of the physician performing the operation, frequent pancreatography, precut EST, endoscopic papillary balloon dilatation (EPBD) and difficult intubation [1] [16]-[20]. Currently, treatment protocols for the treatment of acute pancreatitis based on evidence-based medicine comprise the use of massive transfusions at the early stage of onset and the administration of prophylactic antibiotics only. Furthermore, evidence regarding the efficacy of protease inhibitor therapy does not support the use of continuous arterial drop therapy. Although identifying high-risk groups and administering treatments such as preventive medications and pancreatic duct stent placement have been attempted as preventive measures for reducing the incidence of ERCP-induced pancreatitis, no effective strategies have been confirmed [21]-[27]. Therefore, providing sufficient hydration to prevent the onset of dehydration around the time of testing due to the effects of fasting is more critical in patients undergoing endoscopic screening than in other cases. However, patients undergoing ERCP are normally instructed to fast starting the night before the procedure, similar to that required for normal endoscopy. Therefore, patients frequently complain of thirst and hunger at the time of testing and are often dehydrated, raising concern about the potential development of pancreatitis, a common ERCP complication, as well as the vasovagal reflex.

5. Conclusion

In this study, the safety of ORT was found to be equivalent to that of the customary practice of infusion as a method for managing hydration and replenishing electrolytes in patients receiving ERCP. Moreover, it is possible that the use of ORT may decrease unwanted feelings of thirst and hunger and reduce the psychological burden on the patient. Hence, oral rehydration therapy is thought to be an effective therapy for rehydration prior to ERCP and other endoscopic procedures.

Acknowledgements

The authors thank Hajime Yamakage (Satista Co. Ltd.) for providing assistance with the statistical analyses. Manuscript editing services were provided by Cactus Communications Pvt. Ltd.

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Conflicts of Interest

None of the authors have any potential conflicts of interest with regard to this study.

Financial Disclosures

The authors report no proprietary or commercial interests in any products mentioned or concepts discussed in this article.

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Abbreviations

ERCP: Endoscopic retrograde cholangiopancreatography;
DIV: Intravenous drip injection;
ORT: Oral rehydration therapy;
ORS: Oral rehydration solution;
ERP: Endoscopic retrograde pancreatography;
ERC: Endoscopic retrograde cholangiography;
EST: Endoscopic sphincterotomy;
EBS: Endoscopic biliary stenting;
ENBD: Endoscopic nasobiliary drainage;
EPBD: Endoscopic papillary balloon dilatation.

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