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Single-Operator Wire-Guided Cannulation Technique for Endoscopic Retrograde Cholangiopancreatography

Authors' Contribution:
 Study Design A
 Data Collection B
 Statistical Analysis C
 Data Interpretation D
 Manuscript Preparation E
 Literature Search F
 Funds Collection G

ABC 1 **Bin Wang***
 BD 2 **Yangrong Chen***
 DEFG 1 **Shumin Zhang**

1 Department of Gastroenterology, The 4th People's Hospital of Jinan, Jinan, Shandong, P.R. China
 2 Department of Hepatobiliary Surgery, Zhuji People's Hospital, Zhuji, Zhejiang, P.R. China

Corresponding Author:
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* Bin Wang and Yangrong Chen contributed equally to this work
 Shumin Zhang, e-mail: 64117926@qq.com
 Departmental sources

Background: The aim of this prospective study was to evaluate the clinical application value of single-operator cannulation technology (SOCT) for endoscopic retrograde cholangiopancreatography (ERCP).





Material/Methods: Sixty-nine patients prepared for ERCP were prospectively recruited from February 2014 to January 2017 in the 4th People's Hospital of Jinan. The included 69 patients were randomly divided into an experiment group (n=36) and a control group (n=33). Patients in the experiment group underwent SOCT procedure of ERCP and patients in the control group received the regular procedure of ERCP. The cannulation time, number of cannulations, number of attempts at cannulation, and ERCP procedure-relevant complications were recorded and compared between the 2 groups.

Results: All of the included 69 patients successfully finished the ERCP procedure, with no peri-operative deaths. The median duration of cannulation for the experiment group was 7.4 (2.3~35.1) min and 7.1 (2.9~26.1) min for the control group, with no significant difference (p>0.05). The distribution of different cannulation periods and cannulation attempts were not significantly different between the 2 groups (p>0.05). The major complications relevant ERCP procedure were pancreatitis and infection. The incidence rate of pancreatitis and infection were 2.8% and 2.8% in the experiment group and 3.0% and 0.0% in control group, and the difference between groups was not significant (p>0.05).

Conclusions: Compared with regular ERCP, SOCT achieved the same effects without the help of an experienced assistant, which could make the procedure useful in primary hospitals.

MeSH Keywords: **Catheterization • Cholangiopancreatography, Endoscopic Retrograde • Pancreatitis**

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Background

Endoscopic retrograde cholangiopancreatography (ERCP) is a contrast technique that provides a retrograde display of the pancreaticobiliary duct by injecting contrast agent through duodenal papillary intubation under endoscopic guidance [1,2]. ERCP considered as the criterion standard for diagnosis of pancreaticobiliary diseases. Based on ERCP, interventional therapies such as endoscopic sphincterotomy (EST), endoscopic nasal bile drainage (ENBD), and endoscopic retrograde biliary drainage (ERBD) are carried out [3,4]. ERCP has become an effective method for the diagnosis and minimally invasive treatment of liver, biliary, and pancreatic diseases [5–7]. Duodenal papillary intubation has also changed from the catheter method to guide wire method during ERCP. The traditional guide wire method is limited by use of a catheter or a knife incision in intubation. The operator cannot manipulate the guide wire directly while holding the incision knife at the same time. Therefore, the guide wire is usually manipulated by an assistant. The duodenal papilla intubation with traditional guide wire method is manipulated by 2 people because its success depends on tacit and close coordination between the operator and the assistant. The skill and competence of the assistant directly affect the success rate and papilla intubation time. During the 1990s, the advent of the fast switching system (short guide wire system) made it possible for the guide wire in duodenal papilla intubation to be operated by just 1 person [8]. Through improvement of endoscopy and appendages, the fast switching system makes the wire operation side closer to the endoscopy operation part, so operators can empty their right hands to manipulate the guide wire to achieve a one-person operation, which does not require close coordination with an assistant, and thus helps shorten intubation time, reduce papilla damage, and decrease line exposure time [9]. Although this technology has been used for a long time, it has not been widely applied [10]. In this study, a prospective randomized clinical contrast method was used to compare intubation time and postoperative complications between SOCT technology and conventional ERCP papilla intubation technology.

Material and Methods

Patients

Sixty-nine patients who were prepared for ERCP were prospectively recruited from February 2014 to January 2017 in the 4th People's Hospital of Jinan. The study was approved by the Medical Ethics Committee of the 4th People's Hospital of Jinan. The included 69 patients were randomly divided into an experiment (n=36) and a control (n=33) group. The patient inclusion criteria were: (1) patients planned to receive the ERCP

examination and (2) signed informed consent was obtained from all the included patients. The patient exclusion criteria were: (1) patients with severe upper digestive tract obstruction and (2) patients with severe cardiopulmonary insufficiency, and those who could not afford the procedure.

Instrument and equipment

We used an X-ray imaging system (Philips Allura Xper FD20), the Image Processing Center (Evis Lucera, Olympus Cv-260) the Evis Lucera Xenon Light Source (Olympus Cv-260), and Electronic Endoscopy of the Duodenum (Evis Lucera Olympus Tjf Type 260v).

Single-operator cannulation technology

The operator placed the incision knife with the guide wire near the duodenal papilla or inserted it into the papilla opening before gently inserting the guide wire (Figure 1). By sensing the resistance encountered by the guide wire, the operator can confirm whether the guide wire has entered the pipe or not. If it fails to enter the pipe, the guide wire will be inserted again by changing the direction of the knife head until it enters the pipe. X-ray guidance is not needed in the process of intubating the guide wire. When the guide wire enters the pipe without obvious resistance, confirmation of whether the guide wire is in the target pipe is made by X-ray guidance. Due to different orientations of the guide wire in the pancreatic duct or the bile duct, we can judge whether it enters the target duct or not. Then, the incision knife is inserted by following the guide wire, and the contrast agent is injected to show the target duct. During the one-person operation of the guide wire in duodenal papilla intubation, the operator can manipulate the endoscope to adjust the position of the papilla, and obtain different angles of intubation by bending the incision knife [10]. The operator can also directly manipulate the guide wire to probe the openings of the pancreatic duct and the bile duct. All operations are performed by the operator independently (Figure 2). During the operation, the assistant only needs to pinch the guide wire to ensure that the long guide wire is not contaminated. After successful intubation, the assistant is still required to help prepare the devices and replace accessories.

Statistical analysis

All data were analyzed by SPSS 17.0 statistical software (SPSS, Inc., Chicago, IL, USA). Measurement data are expressed with $\bar{x} \pm s$ and the comparison between groups was analyzed by *t* test. Enumeration data are expressed with a relative number, and the comparison between groups was made by Fisher's exact test. $p < 0.05$ was regarded as a statistically significant difference.

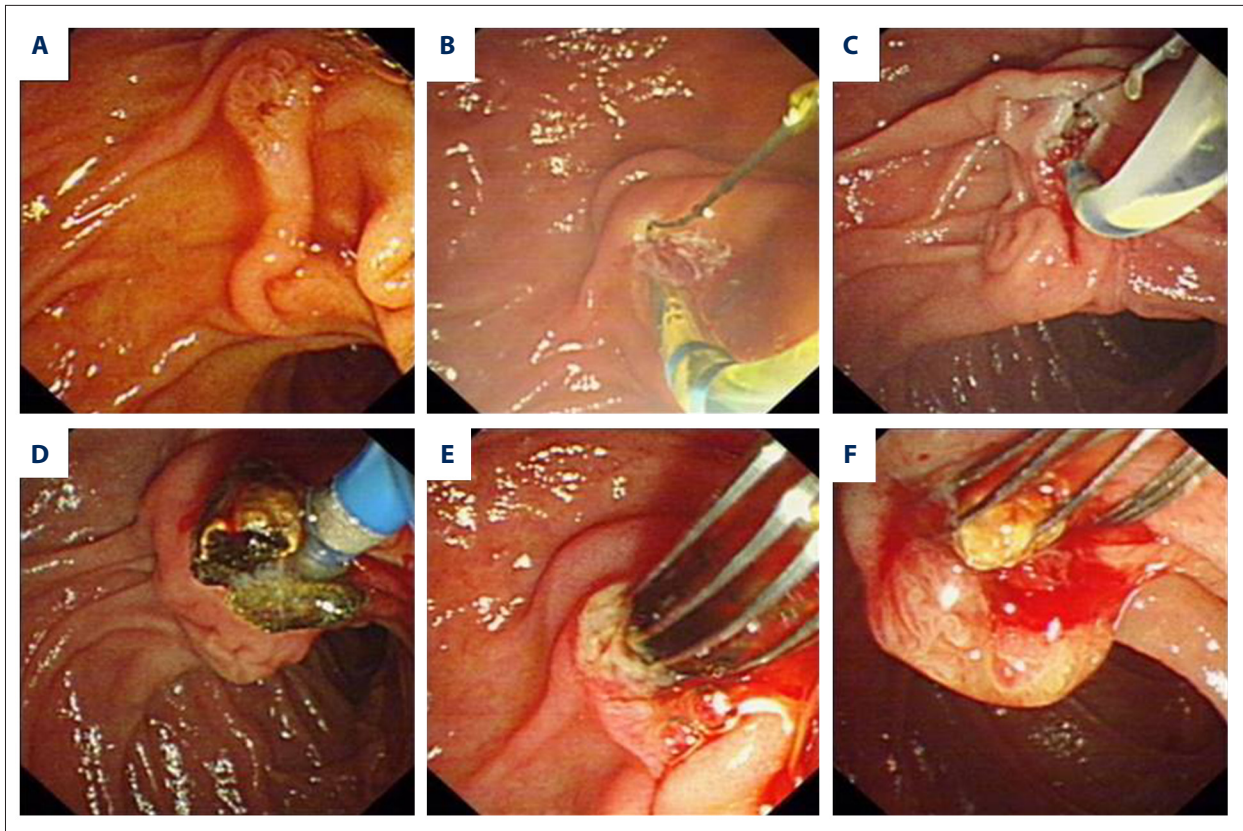


Figure 1. ERCP procedure in the treatment of choledocholithiasis (A: Exposing the papilla; B, C: Incision of the duodenal papilla; D: The choledocholithiasis was extracted by stone balloon; E, F: The choledocholithiasis was extracted by basket).

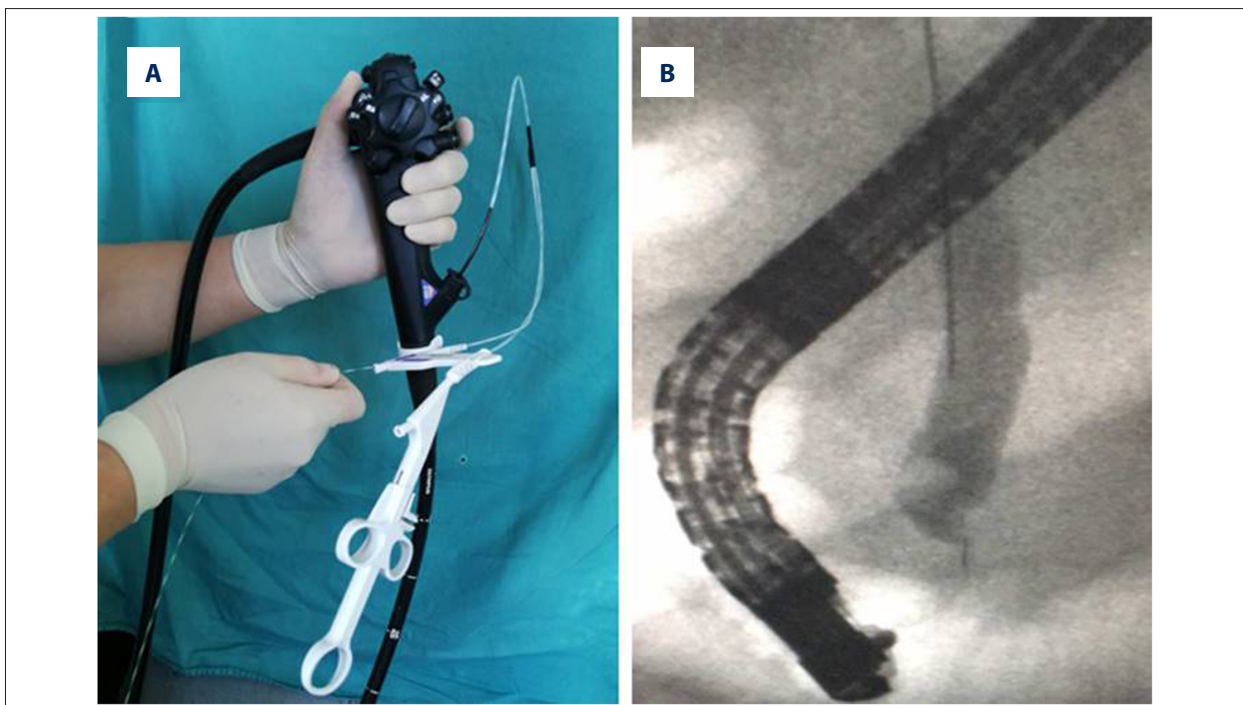


Figure 2. Intraoperative management of single-operator cannulation technology (A: single-operator cannulation technology; B: Angiography showed a filling defect at the lower end of the common bile duct).

Table 1. Base-line characteristics of the 2 groups of patients.

Characteristics	Experiment group (n=36)	Control (n=33)	t/chi-square	p-value
Age (years)			0.24	0.81
Mean ±SD	62.5±21.6	61.3±20.2		
Range	36~84	34~82		
Sex [n (%)]			0.10	0.75
Male	21 (58.3)	18 (54.6)		
Female	15 (41.7)	15 (45.4)		
Weight (kg)			0.39	0.70
Mean ±SD	66.2±9.6	65.3±9.4		
Range	46.3~92.1	45.8~90.7		
Height (cm)			0.33	0.74
Mean ±SD	171.2±10.5	172.0±9.5		
Range	152.0~188.0	150.0~187.0		
Basic disease [n (%)]			1.33	0.85
Cholelithiasis	16 (44.4)	13 (39.4)		
Biliary obstruction	12 (33.3)	12 (36.4)		
Carcinoma	3 (8.3)	4 (12.1)		
Acute suppurative cholangitis	4 (11.1)	2 (6.1)		
Pancreatitis	1 (2.8)	2 (6.1)		

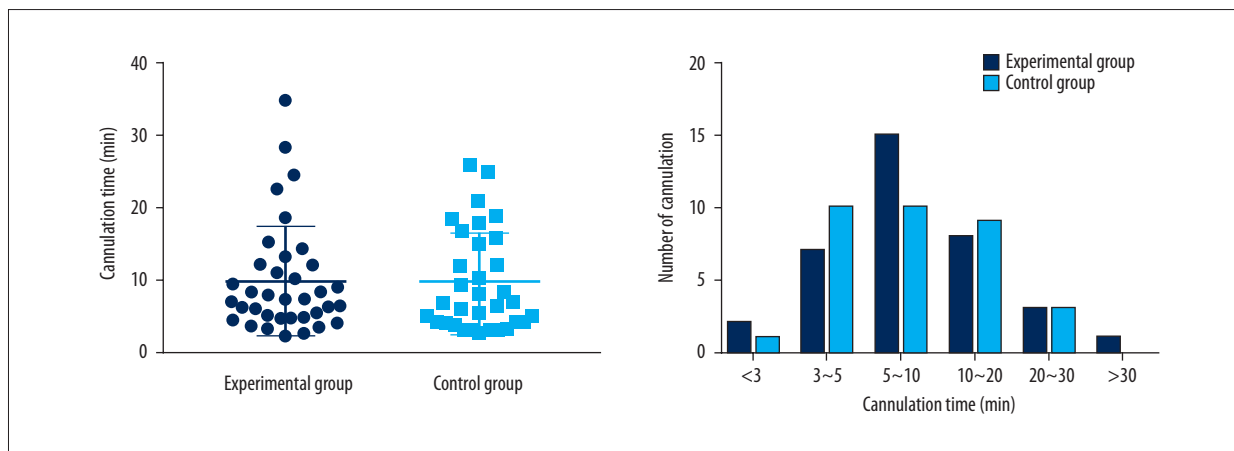


Figure 3. Scatter plot of cannulation time distribution of the 2 groups.

Results

General characteristics of 2 group patients

The general characteristics of the patients in the 2 groups are demonstrated in Table 1. There were no statistically significant differences between the 2 groups in age, sex, weight, height, or basic diseases ($p>0.05$).

Comparison of cannulation times and attempts

The median periods of cannulation were 7.4 (2.3~35.1) min and 7.1 (2.9~26.1) min (Figure 3A) for the experiment and control groups, respectively, without a statistically significant difference ($p>0.05$). The distribution of different cannulation periods (Figure 3B) and cannulation attempts were not statistically different between the 2 groups (Table 2).

Table 2. Cannulation times and attempts distribution comparison between the 2 groups.

Index	Experiment group (n=36)	Control group (n=33)	t/chi-square	p-value
Cannulation time (min)			2.80	0.73
<3	2 (5.6)	1 (3.0)		
3~5	7 (19.4)	10 (30.3)		
5~10	15 (41.7)	10 (30.0)		
10~20	8 (22.2)	9 (27.3)		
20~30	3 (8.3)	3 (9.1)		
>30	1 (2.8)	0 (0.0)		
No. of attempts(n)			0.25	0.97
<5	6 (16.7)	4 (12.1)		
3~5	11 (30.6)	12 (36.4)		
5~10	15 (41.7)	14 (42.4)		
>10	4 (11.1)	3 (9.1)		

Table 3. Risk of complications in ERCP between the 2 groups.

Complications	Experiment group (n=36)	Control group (n=33)
Pancreatitis	1 (2.8)	1 (3.0)
Bleeding	0 (0.0)	0 (0.0)
Infection	1 (2.8)	0 (0.0)
Perforation	0 (0.0)	0 (0.0)
Total	2 (5.6)	1 (3.0)

Complications in ERCP

The major complications in ERCP were pancreatitis and infection. The incidence rates of pancreatitis and infection were 2.8% and 2.8%, respectively, in the experiment group and 3.0% and 0.0%, respectively, in the control group, and the differences were not statistically significant ($p>0.05$) (Table 3).

Discussion

Duodenal papilla intubation is limited by the guide duct or the incision knife during ERCP, wherein the operator cannot directly manipulate the guide wire simultaneously with the incision knife [11–13]. The guide wire is usually manipulated by an assistant [12,14,15]. Therefore, duodenal papilla intubation using the traditional guide wire method is manipulated by 2 persons, and is thus called a two-person operation method [16]. The assistant needs to sense whether the guide wire enters the pancreatic duct and the bile duct or not, and the result is told to the operator. Making a continuous ray

perspective observation is necessary while probing the opening of the bile duct by using the guide wire. The direction of the knife head is still adjusted by the operator [17]. The coordination between the operator and the assistant becomes very important. The skill or competence of the assistant directly affect the success rate and intubation time of papilla intubation [18]. The advent of SOCT technology has reduced dependence on the assistant in the ERCP operation, especially in papilla intubation. The operator can complete the ERCP operation almost independently. Therefore, SOCT technology can significantly reduce the difficulty in ERCP, and improve its popularity in primary health care units. Although SOCT technology has been proposed for 20 years, its clinical application is still not wide. Few studies have reported the advantages SOCT technology in the ERCP process and its effect on the success rate and time of intubation.

Li et al. [10] conducted a large-scale, single-center, prospective, randomized clinical study research to analyze the differences between SOCT technology and conventional two-person ERCP technology. Results show that SOCT technology is not significantly different in papilla intubation time and incidence of postoperative complications from conventional ERCP technology, suggesting that a successful duodenal papilla intubation with SOCT method does not require the highly tacit coordination of the assistant. SOCT is a safe, efficient, and feasible technology because it reduces the need for an assistant.

In this study, we selected 69 ERCP patients and analyzed the difference between SOCT technology and traditional duodenal papilla intubation in ERCP. Our results demonstrated that, compared with regular ERCP, SOCT achieved the same effects without an experience assistant during the procedure, which makes it more applicable in primary hospitals. Li et al. reported

that the duodenal papilla intubation time is less than 3 min. Our duodenal papilla intubation time was 3–10 min, which is significantly higher than that of Li et al. The reason may be related to the operator's experience. However, no obvious difference in ERCP-related complications between the 2 studies were observed, suggesting that SOCT technology is a safe, efficient, and feasible technology because it can reduce the dependence on an assistant. However, the sample size of the present work was small, with weak statistical power. Therefore, the results need to be confirmed by randomized trials with larger sample sizes.

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Conclusions

SOCT achieved the same effects without an experienced assistant, which could make it more useful in primary hospitals. However, the study has several limitations. The number of patients included was relatively small, and the statistical power was low. All patients were from a single medical unit, and because the operation was completed by 1 surgical team, selection bias may be present.

Conflict of interest

None.