

Original Article

Yonsei Med J 2024 Jan;65(1):34-41 https://doi.org/10.3349/ymj.2023.0115



Comparison of Physician-Controlled Maneuver and Assistant-Controlled Maneuver during Endoscopic Retrograde Cholangiopancreatography

Min Je Sung^{1*}, Jung Hyun Jo^{2*}, Hee Seung Lee², Jeong Youp Park², Seungmin Bang², and Moon Jae Chung²

Purpose: Cannulation of the major papilla is the most challenging part of endoscopic retrograde cholangiopancreatography (ERCP) for which physician-controlled wire-guided cannulation (PCWGC) and assistant-controlled wire-guided cannulation (ACWGC) are used as the cannulation techniques. PCWGC can reportedly save up to about 30% of the labor cost by reducing the number of assistants. This study aims to compare the safety and efficacy of PCWGC and ACWGC.

Materials and Methods: Of the 2151 patients aged >20 years (4193 cases) who underwent ERCP at Yonsei University Medical Center between January 2015 and December 2016, 989 were included in this study.

Results: Among efficacy outcomes, cannulation success rate, rate of precut sphincterotomy (PCWGC vs. ACWGC: 21.3% vs. 25.9%), bile duct cannulation time (PCWGC vs. ACWGC: median 3.0 minutes vs. 3.6 minutes), and total procedure time (PCWGC vs. ACWGC: median 13.6 minutes vs. 13.1 minutes) were not significantly different. Among safety outcomes, lower rates of post-ERCP pancreatitis were observed with PCWGC than with ACWGC (PCWGC vs. ACWGC: 5.8% vs. 8.8%, p=0.128). Among other post-ERCP adverse events (bleeding, perforation, and cholangitis), the difference was not significant between the groups. Radiation exposure (total dose area product, PCWGC vs. ACWGC: median 1979.9 μ Gym² vs. 2062.0 μ Gym², p=0.194) and ERCP cost excluding labor cost (PCWGC vs. ACWGC: \$1576 vs. \$1547, p=0.606) were not significantly different.

Conclusion: Requiring less assistants, PCWGC showed comparable efficacy and safety to ACWGC. PCWGC can be considered as an alternative option, especially in facilities lacking manpower and resources.

Key Words: Endoscopic retrograde cholangiopancreatography, physician-controlled wire-guided cannulation, assistant-controlled wire-guided cannulation, post-ERCP pancreatitis

INTRODUCTION

Cannulation of the major papilla is the most challenging part of endoscopic retrograde cholangiopancreatography (ERCP), with a rate of selective cannulation failure up to 18%. Difficul-

Received: April 27, 2023 Revised: August 28, 2023
Accepted: September 7, 2023 Published online: December 13, 2023
Corresponding author: Moon Jae Chung, MD, PhD, Division of Gastroenterology, Department of Internal Medicine, Yonsei University College of Medicine, 50-1 Yonsei-ro, Seodaemun-gu, Seoul 03722, Korea.
E-mail: mjchung@yuhs.ac

- *Min Je Sung and Jung Hyun Jo contributed equally to this work.
- •The authors have no potential conflicts of interest to disclose.

© Copyright: Yonsei University College of Medicine 2024

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (https://creativecommons.org/licenses/by-nc/4.0) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ty in cannulating leads to prolonged papillary manipulation, and repeated attempts at cannulation are known to increase the risk of post-ERCP pancreatitis (PEP).² In addition, with an increase in procedure time, anesthesia time increases, which increases the risk of various adverse events, such as respiratory depression or heart failure, stemming from the use of anesthetic drugs. It also increases a physician's exposure to radiation, making them prone to radiation-related health problems.

Conventional cannulation techniques include contrast-induced cannulation. However, inadvertent injection of contrast agents into the pancreatic duct may lead to both chemical and hydrostatic injuries of the pancreas and can lead to pancreatitis. ^{1,3,4} In a previous study, guidewire-assisted cannulation was found to significantly reduce PEP, compared to the contrast-assisted cannulation technique [relative risk (RR) 0.51, 95% confidence interval (CI) 0.32 to 0.82]. ^{1,4} Guidewire-assisted

34 www.eymj.org

¹Digestive Disease Center, CHA Bundang Medical Center, CHA University School of Medicine, Seongnam;

²Division of Gastroenterology, Department of Internal Medicine, Yonsei University College of Medicine, Seoul, Korea.



cannulation was shown to be associated with greater primary cannulation success (RR 1.07, 95% CI 1.00 to 1.15) and less precut sphincterotomy (RR 0.75, 95% CI 0.60 to 0.95).1 Assistant-controlled wire-guided cannulation (ACWGC), one method of guidewire-assisted cannulation, involves placing a cannula into the biliary orifice and inserting a guidewire controlled by the assistant. Physician-controlled wire-guided cannulation (PCWGC) is a specific technique in which the physician preforms the ERCP by manipulating not only the endoscope but also the guidewire for cannulation. The distal end of the sphincterotome used for PCWGC can be bent in various directions, which improves biliary access. "Physician-controlled" maneuvering using wire-guided cannulation provides a tactile feel of the anatomy of ampulla of Vater to the physicians as they manipulate the guidewire. In addition, PCWGC can potentially reduce procedure time, fluoroscopy time (FT), and sedation requirements for the patients.5

During PCWGC, help from an assistant is not required; this prevents various problems caused by inexperienced assistants. Furthermore, from the institution's perspective, as this procedure reduces the manpower required for controlling the guidewire during ERCP, labor costs can be reduced. Usually, two assistants are required for the ACWGC method; however, only one assistant, for the preparation of accessories, is re-

quired for the PCWGC method. If the total procedure time is similar between PCWGC and ACWGC, the resulting reduction in the number of assistants can reportedly save up to about 30% of the labor cost.⁶ Recently, Buxbaum, et al.⁷ performed a randomized controlled study that included 216 patients to compare ACWGC and PCWGC, and showed a significant difference in PEP. However, data for a comparison of these two methods in a large cohort are limited. Furthermore, the superiority of PCWGC over ACWGC in terms of efficacy and safety remains unclear. Thus, this study aimed to compare the safety and efficacy between PCWGC and ACWGC in a large single hospital cohort.

MATERIALS AND METHODS

Patients and study protocol

Between January 2015 and December 2016, consecutive patients older than 20 years who were scheduled to undergo diagnostic or therapeutic ERCP at Yonsei University Medical Center were enrolled in the study. The data of 2151 patients (4193 diagnostic or therapeutic biliary ERCP cases) were reviewed. Patients who had previously undergone ERCP with sphincterotomy (n=1041), had a history of ampullectomy

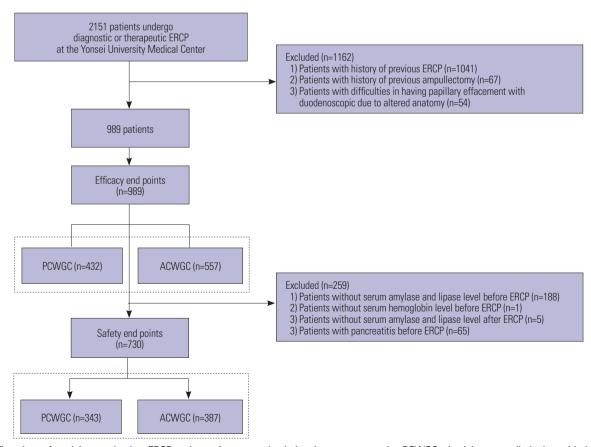


Fig. 1. Flowchart of participant selection. ERCP, endoscopic retrograde cholangiopancreatography; PCWGC, physician-controlled wire-guided cannulation; ACWGC, assistant-controlled wire-guided cannulation.

https://doi.org/10.3349/ymj.2023.0115



(n=67), or could not undergo papillary effacement with duodenoscope due to altered anatomy (n=54) were excluded. Overall, 989 patients were included (Fig. 1). Data on clinicopathologic characteristics were obtained from prospectively collected data. Patient demographics, procedure indications, vital signs, presence of comorbidities, such as diabetes mellitus and hypertension, laboratory results, and post-procedure clinical course were assessed. Serum amylase and lipase levels before ERCP were investigated to confirm the presence of pancreatitis before ERCP and to record differences in serum amylase and lipase levels before and after ERCP. Procedure indications included bile duct stones, biliary obstruction, biliary leak, chronic pancreatitis, acute pancreatitis, and primary sclerosing cholangitis. The protocol of the present study adhered to the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board (IRB) of Severance Hospital (IRB number: 1-2019-0056). The requirement for informed consent was waived by the IRB because of the retrospective study design.

ERCP procedure

All ERCP procedures were performed by three endoscopists (S.M.B., J.Y.P., and M.J.C.). S.M.B. and J.Y.P. had performed 3695 and 1439 ERCPs, respectively, from 2005 to 2014. M.J.C. had performed 2780 ERCPs from 2009 to 2014. PCWGC or ACWGC was chosen according to the physician's preference. ERCP was performed with patients under conscious sedation with propofol and remifentanil; patients were monitored by an anesthesiologist. Hyoscine-n-butyl (Buscopan; Boehringer Ingelheim Ltd., Bracknell, UK) was used as a smooth muscle relaxant at the discretion of the endoscopist.

For ACWGC, the wire within the catheter lumen was controlled by the assistant under verbal direction from the endoscopist. A 0.035"×450-cm Hydra-Jagwire straight tip (Boston Scientific; Natick, MA, USA), an ERCP-catheter with a conical metal tip (MTW Endoskopie Manufaktur, Wesel Büderich, Germany), and a single-use 3-lumen sphincterotome V (Olympus, Tokyo, Japan) were used. Cannulation of the common bile duct (CBD) was initially attempted with a conventional cannula (MTW Endoskopie Manufaktur, Wesel Büderich, Germany).

For PCWGC, the wire was stripped from the tear-away catheter to convert it from a long- to a short-wire system and the wire was exclusively controlled by the endoscopist. A 0.035"× 260-cm Hydra-Jagwire straight tip (Boston Scientific), the Autotome Sphincterotome Rx Biliary system (Boston Scientific), and RX Locking Device (RX System, Boston Scientific) were used. Cannulation of the CBD was attempted first with a pull-type sphincterotome (Boston Scientific).

All equipment used in this study were purchased as part of the standard care of patients. TJF-260VF (V-scope), a duodenoscope with a V-shaped groove on the elevator that acts as the internal wire lock, was used for both methods. Precut papillotomy was typically employed using a needle knife (MicroKnife, Boston Scientific) if the first trial of cannulation using a conventional cannula or a pull-type sphincterotome failed.

After the procedure, patients continued fasting until the next morning. Serum amylase and lipase levels were measured at baseline and 18–24 hours after the procedure. If the investigation confirmed that a patient did not have PEP, then the patient resumed an oral diet.⁹

Fluoroscopy system

The fluoroscopy system (Artis zee; Siemens, Erlangen, Germany) is equipped with a floor-mounted C-arm, collimator, image receiver, and a digital image system, allowing automatic brightness/exposure control. The radiation data were automatically recorded by the Picture Archiving and Communication System (Artis Zee exam protocol, Siemens). This system automatically shows FT, air kerma (AK), and dose-area product (DAP). The frame rate for fluoroscopy was 15 frames per second. The fluoroscopy system was operated by an attending radiology technician stationed in the fluoroscopy room. Radiation recording protocols were implemented on January 1, 2016. Among the 479 patients who underwent ERCP in 2016, radiation exposure was compared among 472 patients, excluding seven without radiation exposure records (because of system errors, such as non-working data linkage). However, as the cumulative dose of radiation scatter measured by thermoluminescent dosimeters was measured once every 3 months, we could not measure the differences in radiation scatter for each case. Therefore, the outcomes related to radiation exposure included total FT (min), AK (mGy), DAP (μGym²), and the total number of images.

Cost of ERCP

In 2015, 97.3% of Koreans had national health insurance. The National Health Insurance Service (NHIS) of Korea pays health care providers on a fee-for-service basis. Total hospital charges are classified into the total insured charge (IC) and total noninsured charge (NIC), which are decided by the NHIS. When the NHIS accepts a certain treatment or medicine as an IC, it also determines the cost. Conversely, when the NHIS classifies the cost of a certain treatment or medicine as an NIC, such as the cost of new technology that has not been proven safe with level-1 evidence, the cost is set by each hospital. However, the ratio of personal charges considered IC depends on each patient's disease. Therefore, based on total hospital charges, we analyzed only the cost of ERCP, composed of the cost of sedation, devices, and service fees. However, service fees for ERCP were determined by the NHIS and did not include labor costs. All charges were converted to US dollars according to the June 2020 exchange rate (\$ 1=1200).

Definitions and primary outcome measures

The primary outcomes were the efficacy and safety of biliary cannulation. Total procedure time was defined as the time



from the first radiograph taken immediately before the insertion of the endoscope to the last radiograph taken immediately after the withdrawal of the endoscope. Time to deep cannulation of the CBD was considered from the first radiograph taken immediately before the insertion of the endoscope to the radiograph taken immediately after successful cannulation.

Safety outcomes included PEP and other post-ERCP adverse events of cholangitis, bleeding, and perforation. The 259 patients without pre-ERCP laboratory results were excluded from the analysis of safety outcomes. PEP included serum amylase or lipase levels ≥ 3 times the upper limit of normal at 24 hours after ERCP and new onset or worsened pancreatic-type abdominal pain and tenderness for more than 24 hours after ERCP. Cholangitis was defined as abdominal pain, fever, and an increased in total bilirubin by ≥ 3 times the pre-procedure levels. Bleeding was defined as post-procedure bleeding requiring blood transfusion, and perforation was defined as newly developed pain and retroperitoneal or intraperitoneal air.

Statistical analysis

Continuous variables are reported as medians with 25th-75th

percentiles, while categorical variables are reported as numbers and percentages. Given the non-normal distribution, continuous variables including cannulation and FT were compared using nonparametric tests (Mann–Whitney U-test for the comparisons). Categorical variables were examined by the chi-squared or Fisher's exact test. Adjustment was examined by linear regression analysis or logistic regression analysis. All hypothesis tests were two-sided, and p<0.05 indicated statistical significance. Calculations were performed with R version 3.6.0 (The R core development team, Vienna, Austria).

RESULTS

Patient characteristics

The baseline characteristics of the study population are summarized in Table 1. The median age of the study population was 66.5 years, and the proportion of female participants was 44.5%. The prevalences of hypertension and diabetes were 45.1% and 28.6%, respectively, while median hemoglobin, total bilirubin, amylase, and lipase levels before ERCP were 12.6

Table 1. Baseline Characteristics Classified According to Selective Bile Cannulation Method

	Total (n=989)	PCWGC (n=432, 43.7%)	ACWGC (n=557, 56.3%)	<i>p</i> value
Age, yr	66.5 (56.7–75.4)	66.0 (57.2–74.7)	66.5 (55.8–75.7)	0.712
Sex				0.290
Male	549 (55.5)	248 (57.4)	301 (54.0)	
Female	440 (44.5)	184 (42.6)	256 (46.0)	
HTN	446 (45.1)	212 (49.1)	234 (42.0)	0.027
DM	283 (28.6)	131 (30.3)	152 (27.3)	0.295
Periampullary diverticulum	198 (20.0)	102 (23.6)	96 (17.2)	0.013
Indication				0.177
Stone	480 (48.5)	226 (52.3)	254 (45.6)	
Obstruction	377 (38.1)	152 (35.2)	225 (40.4)	
Leak	9 (0.9)	3 (0.7)	6 (1.1)	
Chronic pancreatitis	6 (0.6)	4 (0.9)	2 (0.4)	
Other	117 (18.8)	47 (10.9)	70 (12.6)	
Stent				< 0.001
No	567 (57.3)	245 (56.8)	322 (57.8)	0.729
Plastic stent	342 (34.6)	168 (39.0)	174 (31.2)	0.012
Number of plastic stents (range)	1 (1–3)	1 (1–3)	1 (1–2)	0.759
Metal stent	80 (8.1)	19 (4.4)	61 (11.0)	< 0.001
Number of metal stent (range)	1 (1–2)	1 (1–2)	1 (1–2)	0.217
Pancreatic duct stent	25 (2.5)	11 (2.5)	14 (2.5)	0.974
Lab findings before procedures				
Hemoglobin, g/dL	12.6 (11.3-13.7)	12.7 (11.5–13.8)	12.4 (11.3–13.7)	0.366
Total bilirubin, mg/dL	2.6 (0.9-6.1)	2.2 (0.7-5.7)	3.1 (1.0-6.3)	0.011
Amylase, U/L	62 (44–102)	62 (62–96)	61 (44–110)	0.444
Lipase, U/L	44 (28–97)	47 (29–88)	43 (28–110)	0.934

PCWGC, physician-controlled wire-guided cannulation; ACWGC, assistant-controlled wire-guided cannulation; HTN, hypertension; DM, diabetes mellitus. Variables are expressed as medians (interquartile ranges) or n (%). Continuous variables were denoted by cont. with a unit, and categorical variables were denoted by its nominal groups. The Mann–Whitney U-test was used for continuous variables, and the chi-squared test or Fisher's exact test was used for categorical variables.



g/dL, 2.6 mg/dL, 62 U/L, and 44 U/L, respectively. The prevalence of periampullary diverticulum was 20.0%. Procedure indications consisted of biliary stones (480 cases, 48.5%), biliary obstructions (377 cases, 38.1%), bile leaks (9 cases, 0.9%), chronic pancreatitis (6 cases, 0.6%), and others (117 cases, 18.8%). Overall, 422 patients (42.7%) had stents inserted, for which 342 (34.6%) received plastic stents and 80 (8.1%) received metal stents. The occurrence of stenting of pancreatic ducts was 2.5%. Of the study participants, 432 patients (43.7%) underwent PCWGC and 557 patients (56.3%) underwent AC-WGC. There were no significant differences in basal characteristics between PCWGC and ACWGC. However, PCWGC had higher proportions of hypertension (49.1% vs. 42.0%, p=0.027), periampullary diverticulum (23.6% vs. 17.2%, p=0.013), and plastic stent use (39.0% vs. 31.2%, p=0.012); a lower proportion of metal stent use (4.4% vs. 11.0%, p < 0.001); and lower total bilirubin levels (median, 2.2 mg/dL vs. 3.1 mg/dL; p=0.011) (Table 1).

Efficacy outcomes

Among the 2151 patients screened, 989 were included in the efficacy analysis (Fig. 1). The primary outcome of successful biliary cannulation was similar between PCWGC and ACW-GC (99.5% vs. 99.5%). The rate of precut sphincterotomy, reflecting difficulties with cannulation, after initial failure to access the bile duct, was lower for patients who underwent PCWGC than for patients who underwent ACWGC, although statistical significance was not reached (21.3% vs. 25.9%, p= 0.095). The time to bile duct cannulation (median, 3.0 minutes vs. 3.6 minutes; p=0.149) and total procedure time (median, 13.6 minutes vs. 13.1 minutes; p=0.362) also showed no significant differences between PCWGC and ACWGC (Table 2). After adjustment for hypertension, total bilirubin levels, procedure indication, and plastic or metal stent use, there was no significant difference in the time to bile duct cannulation (p=0.254, B=29.593, VIF=1.033) and total procedure time (p=0.888, B= 6.119, VIF=1.032).

Safety outcomes

Of the 989 patients, 730 patients were included in the final safety analysis (Fig. 1). The difference in post-ERCP adverse events was not statistically significant between PCWGC and ACWGC (p=0.615). We observed that the rate of PEP among patients who underwent PCWGC was lower than that among patients who underwent ACWGC (20 cases, 5.8% vs. 34 cases, 8.8%), although the difference was not statistically significant (p=0.128). There was also no difference in post-ERCP pain scale values between two methods (p=0.751) (Table 3). After adjustment for hypertension, total bilirubin levels, procedure indication, and plastic or metal stent uses, there was no significant difference in the rate of PEP (p=0.253, 95% CI 0.782–2.553, odds ratio=1.413).

Table 2. Efficacy Outcomes

	PCWGC (n=432, 43.7%)	ACWGC (n=557, 56.3%)	<i>p</i> value
Cannulation success	430 (99.5)	554 (99.5)	>0.999
Precut sphincterotomy	92 (21.3)	144 (25.9)	0.095
Procedure time, minute			
Bile duct cannulation	3.0 (1.4-6.4)	3.6 (1.6-7.1)	0.149
Total procedure time	13.6 (9.3-19.9)	13.1 (8.8-20.5)	0.362

Variables are expressed as medians (interquartile ranges) or n (%). PCWGC, physician-controlled wire-guided cannulation; ACWGC, assistant-controlled wire-guided cannulation.

Table 3. Safety Outcomes

	PCWGC (n=343, 47.0%)	ACWGC (n=387, 53.0%)	<i>p</i> value
Endoscopic adverse events	11 (3.2)	9 (2.3)	0.615
Bleeding	7 (2.0)	5 (1.3)	
Perforation	3 (0.9)	4 (1.0)	
Cholangitis	2 (0.6)	0 (0.0)	
Post-ERCP pancreatitis	20 (5.8)	34 (8.8)	0.128
Post-ERCP pain scales (0-10)	1.0 (0.0-4.0)	1.0 (0.0-5.0)	0.751

PCWGC, physician-controlled wire-guided cannulation; ACWGC, assistant-controlled wire-guided cannulation; ERCP, endoscopic retrograde cholangio-pancreatography.

Variables are expressed as median (interquartile range) or n (%).

Comparison of procedure time according to indications

For 473 biliary stone patients, the median procedure times for PCWGC (n=225) and ACWGC (n=248) were 12.2 [interquartile range (IQR), 8.6–18.5] and 12.8 (IQR, 8.8–18.0) minutes, respectively. The median procedure times in biliary obstruction patients who underwent PCWGC (n=152) and ACWGC (n=223) were 15.9 (IQR, 10.7–23.4) and 14.0 (IQR, 10.2–23.6) minutes, respectively. The differences in procedure times for biliary stones and obstructions were not statistically significant between PCWGC and ACWGC (Fig. 2).

Comparison of radiation exposure

Among 472 patients who underwent ERCP in 2016, 181 patients and 291 patients underwent ERCP with PCWGC and ACWGC, respectively. The FT for PCWGC was significantly lower than that for ACWGC (median, 2.8 minutes vs 3.0 minutes; p= 0.040). DAP and AK from fluoroscopy were not significantly different between the two methods (all p>0.05). From spot images, DAP (median, 235.3 μ Gym² vs. 158.1 μ Gym²), AK (median, 6.6 mGy vs. 4.2 mGy), and the total number of images (median, 8 vs. 5) were significantly different between PCWGC and ACWGC (all p<0.001). As sums of DAP and AK values for fluoroscopy and spot images, total DAP (median, 1979.9 μ Gym² vs. 2062.0 μ Gym²) and total AK (median, 59.1 vs. 60.9, p=0.835) values were not significantly different between PCWGC and ACWGC (Table 4).



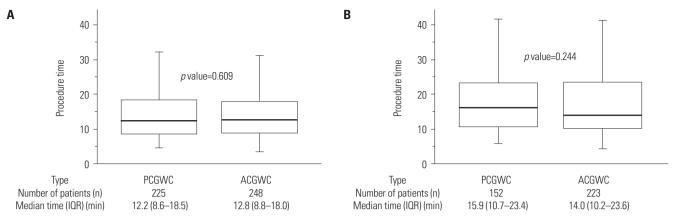


Fig. 2. Procedure times according to the ERCP technique in patients with biliary stone and biliary obstruction. (A) Comparison of procedure times in patient with biliary stone, PCWGC (n=225) vs. ACWGC (n=248): 12.2 min vs. 12.8 min (p=0.609). (B) Comparison of procedure times in patients with biliary obstruction, PCWGC (n=152) vs. ACWGC (n=223): 15.9 min vs. 14.0 min (p=0.224). The bold line indicates median values. A box denotes an interquartile range. Whiskers corresponds to 99.3% coverage. The Mann–Whitney U-test was used to calculate p-values for the comparison between two different cannulation methods. ERCP, endoscopic retrograde cholangiopancreatography; PCWGC, physician-controlled wire-guided cannulation; ACWGC, assistant-controlled wire-guided cannulation.

Table 4. Comparison of Radiation Exposure in 2016

	PCWGC (n=181, 38.3%)	ACWGC (n=291, 61.7%)	<i>p</i> value
Fluoroscopy			
DAP (µGym²)	1691.1 (856.7–3046.7)	1868.5 (1116.1–3845.7)	0.052
AK (mGy)	50.6 (26.6-97.6)	56.6 (29.4-104.5)	0.301
FT (minute)	2.8 (1.6-4.6)	3.0 (2.0-5.6)	0.040
Spot images			
DAP (µGym²)	235.3 (141.5-402.2)	158.1 (88.9–261.9)	<0.001
AK (mGy)	6.6 (3.9-12.4)	4.2 (2.3-7.3)	<0.001
Total number of images, n	8 (6–11)	5 (3–7)	<0.001
Total			
DAP (µGym²)	1979.9 (1040.3–3390.1)	2062.0 (1188.5–4208.3)	0.194
AK (mGy)	59.1 (32.5-107.4)	60.9 (32.6-119.0)	0.835

PCWGC, physician-controlled wire-guided cannulation; ACWGC, assistant-controlled wire-guided cannulation; DAP, dose-area product; AK, air kerma; FT, fluoroscopy time.

Variables are expressed as medians (interquartile ranges).

Comparison of ERCP cost

In cost analysis, we focused on the cost of ERCP and did not include the cost of inpatient hospitalization from date of procedure to discharge and laboratory or labor costs for medical staff. In our study, among the 989 patients who underwent ERCP, the cost of ERCP was not different between patients treated with PCWGC or ACWGC (median \$ 1376 vs. \$ 1347, p=0.606). The cost of a papillotome (\$ 200) was a flat rate during the study period (Supplementary Table 1, only online). It is expected that PCWGC may be cost effective if labor costs are included in the cost of ERCP because PCWGC requires relatively fewer medical staff members than ACWGC. Additional detailed analyses are required to evaluate cost effectiveness.

DISCUSSION

The present study compared the safety and efficacy between PCWGC and ACWGC performed in a large single-center cohort. We demonstrated that PCWGC is not inferior to ACWGC in terms of procedure time, success rate of biliary cannulation, rate of adverse events, and radiation exposure time, despite requiring less manpower (fewer assistants).

Key accessories essential for PCWGC are a short guidewire, devices compatible with the short guidewire, and a guidewire locking device. The short guidewire is preferred to overcome the limitations of "long-wire" systems. Long guidewires (450 cm) require increased time and precise coordination between the physician and assistant during device exchanges and therapeutic maneuvers. In addition, it is difficult to maintain access in long guidewire systems, and the procedure is dependent on a well-trained assistant resulting in limited physician control of the guidewire. The devices compatible with a shortwire system were designed to be exchanged over short wires while maintaining access. Short-wire systems allow the physicians to directly handle and manipulate the guidewire without the help of an assistant. For the application of devices compatible with a short-wire system, a guidewire locking device locks the wire in a position that maintains access during device exchange and intraductal manipulation of devices without guidewire control by the assistant. Thus, the procedure time can be shorter with PCWGC, and unexpected guidewire removal is prevented.

It has been widely accepted that PEP is the most frequent adverse event of ERCP and results in poor outcomes ranging from longer hospitalization to substantial morbidity. ^{1,11} The PEP occurrence rate reportedly ranges from 1%–7% to as high as 12%–31% of cases, and numerous patient- and procedure-related risk factors lead to this adverse event. ^{1,3,11-14} Many ap-



proaches, including the development of endoscopic interventions and training, have been employed to decrease the incidence and severity of PEP, especially through control of procedure-related factors. 1,3 In a prospective study that compared the post-procedure adverse events between PCWGC and ACWGC, significantly fewer endoscopic adverse events were reported for patients treated with PCWGC.7 Commonly used short guidewires for PCWGC are straight (185-270 cm) wires with a nitinol core and good tip flexibility. They provide good push ability and immediate tactile feedback directly to endoscopists while maintaining a very flexible and soft tip to reduce ampullary trauma. We assume that a physician-controlled maneuver can provide an additional benefit to guidewire-assisted cannulation by reducing the incidence of PEP. Our study showed that the rate of PEP among patients who underwent PCWGC tended to be lower than that among patients who underwent ACWGC, although the PCWGC group had a higher proportion of periampullary diverticulum.

PCWGC is an evolving technique that has been facilitated by the development of new tools to aid in cannulation. There are three prospective studies that have been conducted on the following devices for PCWGC: the V-scope system (2006), Fusion system (2010), and RX biliary system (2016).^{5,7,15} Papachristou, et al.15 showed that the exchange of short hydrophilic wires was quick and reliable (V-scope vs. standard scope; mean exchange time, 24 secs vs. 30 secs). In 2010, Draganov, et al.⁵ showed that the fusion short-wire system provided significantly shorter device exchange and stent insertion times than traditional longwire devices. In 2016, using the RX secondary system, Buxbaum, et al. showed that the use of the endoscopist-rather than assistant-controlled wire guidance for bile duct cannulation reduced adverse events of ERCP, including PEP [PCWGC vs. ACWGC; 3/109 (2.8%) vs. 10/107 (9.3%), p=0.049]. Thus, PCW-GC can reduce labor costs and shorten the procedure times as proficiency increases.

In terms of radiation exposure, the risks of medical radiation are split into two types: deterministic risks, determined by the threshold dose, as represented by skin injury, and stochastic risks, determined by a linear no-threshold model, such as cancer risk. Fluoroscopy performed during ERCP is associated with an evident risk of radiation exposure for patients, physicians, and assistants, with cancer being the most concerning potential long-term risk. However how a mentioned above, if the number of assistants is reduced with the use of PCWGC, we presume that the number of people exposed to radiation can be decreased.

Our study showed that the procedure times of PCWGC and ACWGC are similar. Additionally, we did not find a difference in adverse events rates, including PEP and radiation exposure, between PCWGC and ACWGC. The reason for no difference between PCWGC and ACWGC in terms of efficacy and safety can be attributed to the cannulation skills of the nurses work-

ing at the tertiary hospitals being comparable to those of the physicians; thus, there was little difference in the control of the guidewire between them. Therefore, we hypothesize that a comparison between PCWGC and ACWGC performed serially by physicians with less experience with ERCP might result in more meaningful findings.

There were limitations to our study. First, this study was the retrospective cohort study limited to one single center. Therefore, certain aspects regarding PEP, such as the proportion of double guidewire techniques, the exact number of cannulation attempts, and unintended pancreatic duct cannulation, could not be examined. Nevertheless, all of the PEP cases in this study were of mild severity. Validations in other races or ethnicities are also necessary to generalize the results of the present study to the overall population. Second, efforts such as propensity score matching are required to reduce bias due to variables that could confound estimates of the treatment effect. However, in our study, there was no significant difference in baseline characteristics, except for the portion of individuals with hypertension, the portion of patients who had periampullary diverticulum, total bilirubin levels, and proportions of plastic and metal stents used. After adjustment for hypertension, periampullary diverticulum, total bilirubin levels, procedure indication, and plastic or metal stents, there was no significant difference in the outcomes.

In conclusion, PCWGC showed comparable efficacy and acceptable safety to ACWGC and required fewer assistants. PCW-GC can thus be considered as an alternative option, especially in facilities lacking manpower and resources. Further prospective studies are needed to verify these findings.

AUTHOR CONTRIBUTIONS

Conceptualization: Moon Jae Chung. Data curation: Min Je Sung and Jung Hyun Jo. Formal analysis: Min Je Sung. Funding acquisition: Moon Jae Chung. Investigation: Min Je Sung and Jung Hyun Jo. Methodology: Min Je Sung and Moon Jae Chung. Project administration: Hee Seung Lee, Jeong Youp Park, Seungmin Bang, and Moon Jae Chung. Resources: Jeong Youp Park, Seungmin Bang, and Moon Jae Chung. Software: Min Je Sung. Supervision: Moon Jae Chung. Validation: Jung Hyun Jo. Visualization: Min Je Sung and Moon Jae Chung. Writing—original draft: Min Je Sung and Moon Jae Chung. Writing—review & editing: Min Je Sung, Jung Hyun Jo, and Moon Jae Chung. Approval of final manuscript: all authors.

ORCID iDs

Min Je Sung Jung Hyun Jo Hee Seung Lee Jeong Youp Park Seungmin Bang Moon Jae Chung https://orcid.org/0000-0001-5395-8851 https://orcid.org/0000-0002-2641-8873 https://orcid.org/0000-0002-2825-3160 https://orcid.org/0000-0003-0110-8606 https://orcid.org/0000-0001-5209-8351 https://orcid.org/0000-0002-5920-8549



REFERENCES

- Tse F, Yuan Y, Moayyedi P, Leontiadis GI. Guidewire-assisted cannulation of the common bile duct for the prevention of post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis. Cochrane Database Syst Rev 2012;12:CD009662.
- Testoni PA, Mariani A, Aabakken L, Arvanitakis M, Bories E, Costamagna G, et al. Papillary cannulation and sphincterotomy techniques at ERCP: European Society of Gastrointestinal Endoscopy (ESGE) clinical guideline. Endoscopy 2016;48:657-83.
- 3. Freeman ML, Guda NM. Prevention of post-ERCP pancreatitis: a comprehensive review. Gastrointest Endosc 2004;59:845-64.
- Tse F, Yuan Y, Moayyedi P, Leontiadis GI. Guide wire-assisted cannulation for the prevention of post-ERCP pancreatitis: a systematic review and meta-analysis. Endoscopy 2013;45:605-18.
- Draganov PV, Kowalczyk L, Fazel A, Moezardalan K, Pan JJ, Forsmark CE. Prospective randomized blinded comparison of a shortwire endoscopic retrograde cholangiopancreatography system with traditional long-wire devices. Dig Dis Sci 2010;55:510-5.
- Van Steenbergen W, Van Aken L, Volders W, Kesteloot K. Cost analysis of ERCP in a university hospital. Gastrointest Endosc 2001; 53:152-60.
- Buxbaum J, Leonor P, Tung J, Lane C, Sahakian A, Laine L. Randomized trial of endoscopist-controlled vs. assistant-controlled wire-guided cannulation of the bile duct. Am J Gastroenterol 2016; 111:1841-7.
- Shah RJ, Somogyi L, Petersen BT, Tierney WM, Adler DG, Chand B, et al. Short-wire ERCP systems. Gastrointest Endosc 2007;66:650-7.
- Park SW, Chung MJ, Oh TG, Park JY, Bang S, Park SW, et al. Intramuscular diclofenac for the prevention of post-ERCP pancreatitis: a randomized trial. Endoscopy 2015;47:33-9.
- Cotton PB, Lehman G, Vennes J, Geenen JE, Russell RC, Meyers WC, et al. Endoscopic sphincterotomy complications and their management: an attempt at consensus. Gastrointest Endosc 1991;37:

- 383-93.
- 11. Chandrasekhara V, Khashab MA, Muthusamy VR, Acosta RD, Agrawal D, Bruining DH, et al. Adverse events associated with ERCP. Gastrointest Endosc 2017;85:32-47.
- 12. Kochar B, Akshintala VS, Afghani E, Elmunzer BJ, Kim KJ, Lennon AM, et al. Incidence, severity, and mortality of post-ERCP pancreatitis: a systematic review by using randomized, controlled trials. Gastrointest Endosc 2015;81:143-9.E9.
- Andriulli A, Loperfido S, Napolitano G, Niro G, Valvano MR, Spirito F, et al. Incidence rates of post-ERCP complications: a systematic survey of prospective studies. Am J Gastroenterol 2007; 102:1781-8.
- Masci E, Mariani A, Curioni S, Testoni PA. Risk factors for pancreatitis following endoscopic retrograde cholangiopancreatography: a meta-analysis. Endoscopy 2003;35:830-4.
- Papachristou GI, Baron TH, Gleeson F, Levy MJ, Topazian MD. Endoscopic retrograde cholangiopancreatography catheter and accessory exchange using a short hydrophilic guide wire: a prospective study. Endoscopy 2006;38:1133-6.
- Shore RE, Beck HL, Boice JD, Caffrey EA, Davis S, Grogan HA, et al. Implications of recent epidemiologic studies for the linear nonthreshold model and radiation protection. J Radiol Prot 2018;38: 1217-33
- Nishida T, Hayashi S, Takenaka M, Hosono M, Kogure H, Hasatani K, et al. Multicentre prospective observational study protocol for radiation exposure from gastrointestinal fluoroscopic procedures (REX-GI study). BMJ Open 2020;10:e033604.
- Selmaier M, Stillkrieg W, Müller RG, Hahn EG, Ell C. [Radiation burden in diagnostic and therapeutic endoscopic retrograde cholangiopancreatography (ERCP)]. Z Gastroenterol 1994;32:671-4. German
- 19. Larkin CJ, Workman A, Wright RE, Tham TC. Radiation doses to patients during ERCP. Gastrointest Endosc 2001;53:161-4.