Newly-developed colonoscope (PCF-PQ260L) is useful for patients with difficult colons

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ABSTRACT

Background/Aims: *Preforming total colonoscopy (TCS) is sometimes difficult due to adhesions or long colons. The PCF-PQ260L (PQL) was developed to overcome TCS-related difficulties. The aim of this study was to investigate the performance and usefulness of PQL for difficult colon cases.*

Materials and Methods: *This was a retrospective single center observational cohort study investigating differences in patient characteristics and examination performance between patients examined with PQL, versus standard (SD), scopes. Secondly, we directly compared PQL and SD scopes in patients treated with both types of scope.*

Results: *The PQL was used with 105 patients and SD scopes were used with 1119 patients. Patients in the PQL group were significantly shorter (157cm vs 163cm, p< 0.01) and lighter, compared to the SD group (52 kg vs 58 kg, p< 0.01). There were no significant statistical differences with regard to cecal intubation rate, cecal intubation time, and adenoma detection. Direct comparison of use of PQL and SD scopes on the same patients revealed shorter average cecal intubation time (7 min vs 10 min, p< 0.01), and significantly increased numbers of patients reporting no pain (66 % vs 20 %, p< 0.01) and needing no sedative drugs (48% vs 25 %, p< 0.01) associated with PQL use.*

Conclusion: *The examination performance of the PQL scope was similar to the SD scope. The PQL may be a good option for patients who with difficult colons.*

Keywords: *Total colonoscopy, difficult colon, incomplete colonoscopy, cecal intubation rate, adenoma detection rate*

INTRODUCTION

Colonoscopy is an essential modality for colon cancer screening and surveillance, and several studies found that the removal of adenomatous polyps using colonoscopy decreased not only the incidence, but also the mortality, of colorectal cancer (1-3). Although colonoscopy is used widely in daily medical practice, performing high-quality colonoscopy is sometimes difficult. Some quality indicators of colonoscopy (4) include the adenoma detection rate (5-7), withdrawal time (8-10), and cecal intubation rate (11). Of these, the cecal intubation rate is correlated with both the technique of endoscopist and the patient's condition. Although endoscopists attempt to master the cognitive and technical skills required for colonoscopy, procedures characterized by an unsuccessful cecal intubation (called "incomplete" colonoscopies) reportedly range from 2% to 10% (12-14). An incomplete colonoscopy may increase the risk of interval cancer in patients due to an inability to examine regions of the colon (11).

Further, total colonoscopy (TCS) can be associated with prolonged procedure times in patients with difficult colons secondary to adhesions resulting from prior history of abdominal surgery, long colons, or those with small, thin bodies, even when the cecal intubation is barely achieved. Although sedation is one of solutions to overcome such situations, the use sedative drugs in high doses may increase the risk of sedation-associated side effects (15,16) and sometimes necessitate a prolonged recovery times. Besides, although there are several rescue methods used following incomplete colonoscopy, such as CT colonography (CTC), colon capsule endoscopy (CCE), and balloon overtube-assisted colonoscopy (BOAC), those procedures have disadvantages. For example, it is impossible to obtain tissue specimens using CCE or CTC, and BOAC requires a specialized endoscopic equipment and technique. Another solution is the development of an alternate colonosope. Olympus developed the ultra-thin colonoscopy PCF-PQ260 L/I and PCF-PH190 L/I. The PCF-PQ260L (PQL) (Figure 1) includes a small-cal-

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iber (9.2 mm) insertion tube with a long and soft body, a passive bending portion, and high-force transmission. These scopes are often used with patients who have severe adhesions of the colon due to surgery, or those with long colons or colon inflammation secondary to conditions such as diverticulitis. The PQL scopes are reportedly associated with less pain and a reduced need for sedatives (17-20).

Although PQL may be useful, its clinical utility for examining patients with difficult colons has not been fully examined. The aim of this study was to investigate the performance and usefulness of PQL in patients with difficult colons.

MATERIALS AND METHODS

Study design and patients

This is a retrospective single center observational cohort study that included 2425 consecutive patients who underwent TCS at a single center between April and September 2015. We excluded 435 patients with a history of colectomy, 506 patients in whom an unknown scope was used, 66 patients with familial adenomatous polyposis, 610 patients with no record of cecal intubation time, and 139 patients without TCS (Figure 1). Finally, 1224 patients were included in this study. Of these, the PQL was used in 105 patients, and a standard scope (SD) was used in 1119 patients. First, we investigated the difference in patient characteristics and examination performance associated with the PQL and SD scopes. Patient characteristics included patients' age, gender, height, and weight. The examination performance included cecal intubation rates, cecal intubation times, and adenoma detection rates (ADRs). Second, we investigated the examination performance of PQL in patients with a past history of colonoscopy using SD scopes. Of the 105 patients who underwent TCS with PQL from April to September 2015, 44 patients who underwent a previous colonoscopy at another hospital were excluded. This left 61 patients. We examined several factors, including cecal intubation time, patients' perceived pain, sedation, and endoscopist experience between examinations that used PQL and the previous examination, where an SD scope was used. The cecal intubation time, patients' perceived pain, and medications that were used during the colonscopy (including sedative drugs) were obtained from a database at our institution. All data were recorded prospectively in conformity with the Japan Endoscopy Database Project (21,22). This study was approved by National Cancer Center Hospital Institute's Ethics Committee (2016-245).

Figure 1. The PCF-PQ260L colonoscope has a small-caliber (9.2 mm) long and soft body.

Indications for the PQL scope

Indications for the PQL scope use include an incomplete colonoscopy with a SD scope, a difficult colonoscopy with a SD scope due to adhesions after surgery, excessive looping, estimated tumorous obstruction, pain intolerance, or severe general condition or comorbidity (gastrointestinal graft vs. host disease, etc.)

Definition of SD scopes

SD scopes include PCF-Q260ZI, PCF-Q260AZI, CF-H260AZI, CF-HQ290IZI, EC-L590ZP, EC-L590ZW, and EC-L600ZP.

RESULTS

Table 1 shows the indication for colonoscopy. The common indication for colonoscopy was screening in patients with cancers other than colorectal cancers (49% for PQL scope vs. 51% for SD scopes), and surveillance after endoscopic resection of colorectal tumors (33% vs. 21%). Other indications included therapeutic or preoperative colonoscopy, colonoscopy following a positive fecal immunochemical test, abdominal symptoms, and graft versus host disease (GVHD). Table 2 presents the indications for the use of PQL. The main reasons were ad-

Table 1. Indications for colonoscopy.

	PQL (n=105)	SD (n=1119)
Screening	51 (49%)	566 (51%)
Surveillance after endoscopic resection	35 (33%)	235 (21%)
Endoscopic treatment	2 (2%)	96 (9%)
Before treatment	5 (5%)	86 (8%)
FIT positive	5 (5%)	105 (9%)
Abdominal symptoms	2 (2%)	22 (2%)
GVHD	5 (5%)	0 (0%)
Other	0 (0%)	8 (1%)

PQL: PCF-PQ-260L; SD: standard type colonoscope; FIT: fecal immunochemical test; GVHD: graft versus host disease.

Table 2. Reasons for using PQL.

	PQL (n=105)
Adhesion(s)	49 (47%)
Long colon	28 (27%)
Poor performance status	6 (6%)
GVHD	5 (5%)
Stenosis or stricture	3 (3%)
Others	2 (2%)
Unknown	12 (11%)

PQL: PCF-PQ-260L; GVHD: graft versus host disease.

hesion (47%), long colon (27%), poor performance status (6%), GVHD (5%), and stenosis or stricture (3%). Table 3 presents the clinical characteristics of patients in the present study. The median age of patients were 70 years (PQL group) and 67 years (SD group). The PQL scopes were used with 41 males and 64 females, and SD scopes were used with 694 males and 425 females. The median height was significantly shorter for patients in the PQL group (157 cm vs. 163 cm, p<0.01), and the median body weight was significantly less for patients in the PQL group, compared with the SD group (52 kg vs. 58 kg, p<0.01). There were no statistically significant differences in cecal intubation times (7 min vs. 7 min, p=0.53), or ADRs (50% vs. 54%, p=0.11). No cases failed to achieve TCS. During a subgroup analysis, where we subdivided the patients according to the endoscopist's experience, we observed no differences relative to gender, median height, or body weight in patients treated by an expert endoscopist. In contrast, significant differences were observed relative to these factors in patients treated by a novice endoscopist (Supplemental Table 1).

Table 4 compares the performance between the PQL scope and the SD scope in 61 patients with a previous history of colonoscopy, using both the PQL and SD scopes, at our institution. The use of the PQL scope was associated with significantly shorter cecal intubation times, compared to SD scopes (7 min vs. 10 min, p<0.01). Further, a significantly greater number of patients who underwent colonoscopy with the PQL scope reported no pain, compared to the SD scope (66% vs. 21%, p<0.01). The proportion of patients who needed no sedatives was significantly lower with the PQL scope, compared to the SD scope (48% vs. 25%, p<0.01). There were no differences in the endoscopist's experience between the PQL and SD scope groups.

DISCUSSION

This was the first study investigating the intra-examination performance of PQL, a scope characterized by a small-caliber insertion tube with a passive bending portion and high-force transmission. Outside Japan, the same type of scope (called PCF-PH190L/I) is already being used in daily clinical practice. This study had two important findings. First, the use of a PQL scope enabled us to perform a less invasive TCS in patients with difficult colons. Second, PQL can be used as the standard screening scope in patients with difficult colons, considering the fact that there was no difference in cecal intubation rates and times, and the ADR between the PQL and SD scopes.

The use of a PQL scope in patients with a history of difficult colonoscopies achieved a TCS with a significantly shorter cecal intubation time, less pain, and less chance of sedative drugs use compared to an earlier examination that used SD scopes. More PQL procedures were performed with an expert endoscopist because, in patients with difficult colons, TCS often necessitates a sophisticated procedure. Shorter intubation times were likely influenced by the higher ratio of expert endoscopists performing PQL examinations. In this study, the main reasons for using a PQL scope included adhesions and observations of a long colon during a previous colonoscopy. Patients with colon adhesions due to prior surgeries or inflammation, such as diverticulosis or endometriosis, sometimes suffer from severe pain due to an acute bending sigmoid colon. The PQL scope has a uniquely small diameter and a passive bending portion that is soft and exists adjacent to the bending part. The radius of the curved, passive bending portion gets gradually larger as it approaches the anal side. This helps the colonoscope pass thorough the acute bending portion. This new technology can reduce pain and therefore decrease the need for sedation (15,16). It

Table 3. Patient characteristics.

	PQL (n=105)	SD (n=1119)	p
Age, median (range)	70 (26-87)	67 (25-91)	0.05
Gender, male/female	41/64	694/425	0.76
Height in cm (range)	157 (135-187)	163 (135-190)	<0.01
Weight in kg (range)	52 (33-100)	58 (28-98)	<0.01
Cecal intubation time, min (range)	7 (3-30)	7 (1-40)	0.53
Adenoma detection rate (%)	44 (48/110)	53 (606/1153)	0.11

PQL: PCF-PQ-260L; SD: standard type colonoscope.

Table 4. Performance comparison of PQL and SD scopes in the same patients.

n=61		PQL	SD	p
Cecal intubation time, min, median (range)		7 (3-30)	10 (4-30)	<0.01
Pain	A) none	40 (66%)	12 (21%)	<0.01
	B) mild	20 (33%)	38 (62%)	
	C) severe	1 (2%)	11 (17%)	
Sedation	No	29 (48%)	15 (25%)	<0.01
	Yes	32 (52%)	46 (75%)	
Endoscopist	Expert	52 (78%)	27 (44%)	<0.01
	Nonexpert	9 (22%)	34 (56%)	

PQL: PCF-PQ-260L; SD: standard type colonoscope.

may potentially reduce complications associated with sedation. Although, 52% of patients who used PQL to overcome difficult colonoscopy still needed sedation (Table 4), light or conscious sedation is usually used for routine colonoscopy in Japan. The use of PQL and a small amount of sedative drugs may become a good solution for difficult colonoscopy. Further, it is sometimes difficult to advance the colonoscope, even after successfully traversing the acute bending portion, due to the scope shape. The PQL scope features a high-force transmission, which enables endoscopists to maintain scope maneuverability even after making a relatively complex loop. This might lead to shorter intubation times, compared to previous examinations, despite less use of sedatives.

There is no difference in cecal intubation rates and times between the PQL and SD scopes, even though the PQL scopes were used, especially in patients suspected of having difficult colons. This demonstrates the high maneuverability of the PQL scope. Further, a considerable number of patients who had easy colon were included in total and SD scopes were enough for them with a short cecal intubation time, then the difference in the intubation time between PQL and SD scopes became small. In contrast, as shown in Table 4, if the patients were restricted to those who have difficult colon, the difference in the cecal intubation time between the PQL and SD scopes became evident. Moreover, the ADR did not differ between the PQL and SD scope. ADR is an important quality indicator of effective colonoscopies. Our results confirmed an easy insertion and basic examination performance of the PQL scope in patients with difficult colons. Although some studies claimed that factors associated with difficult colonoscopy included an older age and female gender, procedures that were completed in a private office, thin body, and diverticular disease (23, 14), there were no significant differences in age and gender in the present study. We are uncertain of the reason for this, but it might be explained by differences in the patients' population. The present study was conducted at a tertiary referral center (cancer center hospital), and many patients had histories of abdominal surgery. Further, our facility treats a substantial number of young patients with malignant diseases, which might have affected our results. Currently, the PQL scope does not have a magnification function. Therefore, it is impossible to perform a detailed examination of early colorectal cancer using magnification. Endoscopic diagnosis using magnification is an important technique for deciding on a treatment strategy for colorectal tumors (24-26). The addition of a

magnification function to PQL scopes will be a substantial improvement.

There are several other modalities can be used as rescue methods, instead of PQL scopes, during incomplete colonoscopies. Those include CTC, CCE, and BOAC. Although CTC and CCE are useful as a less invasive methods, compared to colonoscopy, colonoscopy is the gold standard since tissue specimens cannot be obtained using CTC and CCE (27,28). Moreover, the detectability of CTC, especially for flat lesions, is unsatisfactory (29). Further, bowel preparation for CCE, using larger amounts of laxatives, puts a high burden on patients. Although BOAC is an important method following incomplete colonoscopy, it requires special devices and the technique of a sophisticated endoscopist (30). If the endoscopist is not familiar with BOAC, the procedure time will be prolonged. Considering the fact that the PQL is operated nearly identically to a SD scope and has an adequate ADR performance, it holds an advantage compared to CTC, CCE, and BOAC. If PQL fails, BOAC can be a secondary option.

This study had several limitations. First, this was a retrospective study in a single tertiary center. We excluded a substantial number of cases due to a lack of data. Second, endoscopists probably tried to insert the colonoscope more carefully, or a more skillful endoscopist performed the examination after it came to light that the patient had a difficult colon. This, in turn, might influence the cecal intubation time and the necessary dosage of the sedative drug. Third, this study did not reveal any improvements in cecal intubation rates since the cecal intubation rate with the SD scope is already 99% higher than in previous studies. This is probably because the present study was conducted at the referral center staffed by expert colonoscopists. Multicenter prospective studies are necessary to fully evaluate the efficacy of PQL.

In conclusion, the PQL showed an almost equivalent performance with SD scopes, and it may be a good option for patients with difficult colons.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of National Cancer Center Hospital (2016-245).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

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Conflict of Interest: The authors have no conflicts of interest to declare.

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Supplemental Table 1. Characteristics of patients according to an expert or novice endoscopists

	Expert endoscopists			Novice endoscopists		
	PQL (n=57)	SD (n=520)	p	PQL (n=48)	SD (n=599)	p
Age, median, (range)	70 (26-85)	66 (25-91)	0.28	69 (38-87)	67 (25-91)	0.37
Gender, male/female	27/30	317/203	0.06	14/304	377/222	<0.01
Height, cm, (range)	158 (146-187)	163 (135-187)	0.28	157 (135-178)	163 (135-190)	<0.01
Weight, kg, (range)	60 (40-91)	58 (30-98)	0.99	48 (33-100)	58 (28-98)	<0.01
Cecal intubation time, min (range)	6 (3-20)	7 (1-30)	0.92	6 (4-20)	7 (1-40)	0.26
Adenoma detection rate, %	53	54	0.98	46	54	0.32

PQL: PCF-PQ-260L; SD: standard type colonoscope.