



Is a small-caliber or large-caliber endoscope more suitable for colonic self-expandable metallic stent placement? A randomized controlled study

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Abstract

Objectives: The colonic self-expandable metallic stent (C-SEMS) with a 9-French (Fr) delivery system allows for a small-caliber endoscope (SCE) to be used to treat malignant colonic obstruction. Despite the lack of evidence, the SCE has become popular because it is considered easier to insert than the large-caliber endoscope (LCE). We aimed to determine whether the SCE is more suitable than the LCE for C-SEMS placement.

Methods: Between July 2018 and November 2019, 50 consecutive patients who were scheduled to undergo C-SEMS for colon obstruction were recruited in this study. Patients were randomized to the SCE or LCE group. The SCE and LCE were used with 9-Fr and 10-Fr delivery systems, respectively. The primary outcome was the total procedure time. Secondary outcomes were the technical success rate, complication rate, clinical success rate, insertion time, guidewire-passage time, stent-deployment time, and colonic obstruction-scoring-system score.

Results: Forty-five patients (SCE group, $n=22$; LCE group, $n=23$) were analyzed. The procedure time in the LCE group (median, 20.5 min) was significantly ($p=0.024$) shorter than that in the SCE group (median, 25.1 min). The insertion time in the LCE group (median, 2.0 min) was significantly ($p=0.0049$) shorter than that in the SCE group (median, 6.0 min). A sub-analysis of the procedure difficulties showed that the insertion time in the LCE group (median, 5.0 min) was significantly shorter than that in the SCE group (median, 8.5 min).

Conclusion: Both LCE and SCE can be used for C-SEMS; however, LCE is more suitable than SCE as it achieved a faster and equally efficacious C-SEMS placement as that of SCE.

Clinical trial registration number: University Hospital Medical Information Network Clinical Trials Registry (UMIN 32748)

Keywords: colonoscopy, endoscopes, intestinal obstruction, self-expandable metallic stents, stents

Received: 16 August 2021; revised manuscript accepted: 19 November 2021.

Introduction

Colonic obstruction is an emergency medical condition that requires immediate treatment; one treatment option is the colonic self-expandable

metallic stent (C-SEMS).^{1–8} Because patients indicated for C-SEMS often have serious medical conditions, its placement is associated with adverse events. It is important to maintain a short

Ther Adv Gastroenterol

2022, Vol. 15: 1–10

DOI: 10.1177/
17562848211065331

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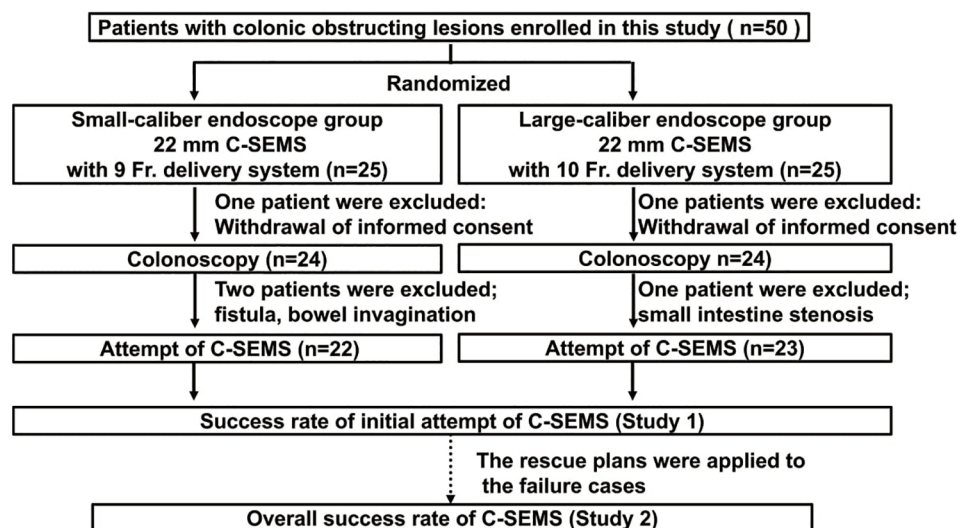


Figure 1. Flowchart.
 C-SEMS, colonic self-expandable metallic stent.

procedure time to prevent exacerbation and adverse events.⁹ Prolonged stent placement not only compromises the safety of the procedure, but also may worsen the post-procedural prognosis, such as causing septic shock due to obstructive colitis. It has been reported that it occurs in approximately 0.5–7% of patients with colorectal stenosis due to colorectal cancer.^{10–13} To reduce the procedure time and complications of colorectal stenting, stent-wire materials have been refined recently, and the newly developed 9-French (Fr) delivery system allows easier placement of the SEMS. In particular, the C-SEMS with a 9-Fr delivery system fits the small-caliber endoscope (SCE) with a 3.2-mm working channel as well as the large-caliber endoscope (LCE) with a 3.7-mm working channel; however, the C-SEMS with a 10-Fr delivery system fits only the LCE. Most operators choose the SCE based on their clinical experience and their impression that the SCE is easier to use.¹⁴ However, it is unclear whether the SCE is more appropriate than the LCE for C-SEMS placement. This study aimed to determine whether SCE or LCE is more suitable for C-SEMS placement, especially in terms of procedure time.

Methods

Study design

We performed a prospective, randomized, controlled study at seven medical centers (Kyushu

University Hospital, Kyushu Rosai Hospital, Aso Iizuka Hospital, Kyushu Medical Center, Fukuoka East Medical Center, Nakabaru Hospital, and Saiseikai Fukuoka General Hospital). A flowchart of this study is shown in Figure 1. All patients with colonic obstructive lesions underwent computed tomography (CT) before colonoscopy and were scheduled to undergo C-SEMS placement. After obtaining written informed consent, the patients were randomized to the SCE or LCE group. All patients underwent colonoscopy using an assigned endoscope and stent placement for malignant colonic obstructive lesions (study 1). If the endoscope could not be inserted sufficiently to reach the obstructive lesion, then the endoscope was switched to a more appropriate type with a different caliber size based on the discretion of the attending endoscopist. To evaluate the clinical success rate and adverse events, all patients who underwent colonic stent placement of the C-SEMS were hospitalized for a minimum of 3 days after the procedure. Medical conditions of the patients were assessed mainly by radiography on 3 consecutive days after the procedure, regardless of the occurrence of any symptoms, and the patients were further followed up from a minimum of 5 days to a maximum of 28 days after the procedure, until the attending doctors judged that their medical conditions became stable (study 2). This study was approved by the Clinical Ethics Committee of each hospital in accordance

with the Declaration of Helsinki and is registered in the University Hospital Medical Information Network Clinical Trials Registry (UMIN 32748) following the CONSORT checklist. All patients provided written informed consent to undergo the procedures and participate in the study.

Patients, inclusion and exclusion criteria, and lesions

Between July 2018 and November 2019, 50 consecutive patients were recruited. Inclusion criteria were as follows: suspected colonic obstruction according to CT; scheduled to undergo colonoscopy for C-SEMS placement; provided written informed consent; and age older than 20 years. Exclusion criteria were as follows: no indication for colonoscopy and not eligible for this study according to the judgment of the attending physician because of underlying disease. The obstruction was evaluated using CT images and endoscopic images. Biopsy samples obtained at the time of endoscopic insertion were evaluated to determine the pathology of the lesion. The length of the obstructive lesion was assessed using fluoroscopy.

Colonoscopes used for the SCE and LCE groups

PCF-H260I, PCF-Q260ZI, or PCF-H290ZI (Olympus Corporation; Tokyo, Japan) was used in the SCE group; these have an endoscope diameter of 11.3 or 11.7 mm and a 3.2-mm working channel. CF-H260AI, CF-HQ290I, or CF-H290ZI (Olympus Corporation) was used in the LCE group; these have an endoscope diameter of 13.2 mm and a 3.7-mm working channel.

C-SEMS delivery system selection

To minimize the effects of the differences in working channel size, the 22-mm stent with a 9-Fr delivery system (Niti-S; Taewoong Medical Co., Ltd., Gimpo, South Korea) was selected for the SCE group, and the 22-mm stent with a 10-Fr delivery system (Niti-S; Taewoong Medical Co., Ltd.) was selected for the LCE group. The 22-mm stent with a 9-Fr delivery system was developed based on the 22-mm stent with a 10-Fr delivery system. There was no difference in the expanded stent; only the size of the delivery system differed. The 22-mm stents with a 9-Fr delivery system can be used with the SCE and LCE; however, the 22-mm stents with a 10-Fr delivery system can only be used with the LCE.

C-SEMS placement

After 60 ml of glycerin enema was administered for preparation of distal colon, all procedures were performed by 12 expert endoscopists certified by the Japan Gastroenterological Endoscopy Society with experience in screening the results of more than 5000 colonoscopies and placing at least 10 C-SEMS. Unexperienced endoscopists did not participate in this study. Before this study began, the participating institutions had two meetings to discuss standardization of the C-SEMS placement procedure. Endoclips were placed at the anal side of the obstructive lesion as the landmark on radiographs before the guide-wire was advanced. Endoscopic dilation was not performed before C-SEMS placement. An assistant operator was assigned the duty of checking the radiography monitor. After each step of the procedure was completed, the endoscopic images including the clock time were obtained to measure the duration of each step.

Outcome measures and definitions

The primary outcome was the total procedure time (from the start of the colonoscopy to completion of C-SEMS placement) as reduction of the total procedure time is one of the most important factors in C-SEMS for patients with colonic obstruction. The secondary outcomes were the technical success rate, complication rate, clinical success rate, insertion time, guidewire-passage time, stent-deployment time, and colonic obstruction-scoring-system (CROSS) score after C-SEMS placement. The CROSS score was defined as follows: 0, required a continuous decompressive procedure; 1, no oral intake permitted; 2, liquid or enteral nutrients permitted; 3, soft solids, low-residue, or full diet permitted with symptoms of stricture; and 4, soft solids, low-residue, or full diet permitted without symptoms of stricture. Procedure difficulties were defined as the following: obstructive lesions longer than 5 cm, peritoneal carcinomatosis, tumor located in the right colon, and CROSS score of 0 before the procedure started. Technical success was defined as successful C-SEMS placement. Clinical success was defined as an improvement in symptoms after the procedure. Complications were defined as any deviation from the envisioned clinical course. In addition, bleeding, which occurred more frequently, was finely defined as a decrease in hemoglobin level of ≥ 2 g/dl. Insertion time was defined as the duration required from the

start of the colonoscopy until sufficient intubation of the endoscope to reach the obstructive lesion. The guidewire-passage time was defined as the duration from the placement of the C-SEMS delivery system in the working channel of the endoscope until the passage of the guidewire to the oral side of the obstructive lesion. Finally, stent-deployment time was defined as the duration from the passage of the guidewire through the lesion until the completion of stent deployment. In this study, antibiotics were not administered prophylactically, but were planned to be applied for medical care in case of complications such as perforation. As a result, no patients received antibiotics before, during, and after the procedure. The patients fasted until the completion of stent expansion was confirmed by radiography on the third day after the procedure.

Questionnaire

To evaluate the usability of the selected endoscopes and stents, a questionnaire was given to each examiner after the procedure. The questionnaire included the following questions: 'How difficult was it to insert the endoscope to the obstructive lesion?' 'How difficult was it to advance the guidewire to the oral side of the obstructive lesion?' 'How difficult was it to complete the passage of the 9-Fr or 10-Fr delivery system through the obstructive lesion?' 'How difficult was it to deploy the stent?' 'How difficult was it to recognize the stent on fluoroscopy?' and 'How poor was the endoscopic view during stent deployment?' A visual analog scale score of 0–10 (0, easy or good; 10, difficult or bad) was used as the rating system. All examiners replied to these questionnaires soon after finishing the procedure.

Randomization

Permuted block randomization was conducted at the study office of the Graduate School of Medical Sciences, Kyushu University; the block size was two. Patients were randomly allocated to the SCE or LCE group (1:1 ratio).

Data management

Endoscopists at each institution contacted the data center in the Department of Medicine and Bioregulatory Science of the Kyushu University for case entry. E.I. performed randomization and data management. Data for each case were

entered into the case report form immediately after the placement of the colonic stent and sent to the data center. E.I. was not involved in any endoscopic procedures or patient recruitment.

Statistical analyses

Mann–Whitney *U* test was used to compare the two groups. Pearson's chi-square test was used to analyze categorical variables. $P < 0.05$ indicated statistical significance. Where applicable, data are shown as median (interquartile range (IQR)). All statistical analyses were conducted using the JMP version 15.0 software (SAS Institute, Cary, NC, USA).

Results

Enrolled patients

During the study period, 50 consecutive patients (SCE group, $n = 25$; LCE group, $n = 25$) were recruited in the study. Two patients were excluded because they withdrew their informed consent before undergoing the procedure. Three patients were excluded after insertion of the endoscope because they were ineligible for the C-SEMS (SCE group: one patient with a fistula and one with bowel invagination; LCE group: one patient with small intestine stenosis). As a result, 45 patients (SCE group: $n = 22$; LCE group: $n = 23$) were analyzed. There were no significant differences in patient demographics and lesion characteristics of the two groups (Table 1).

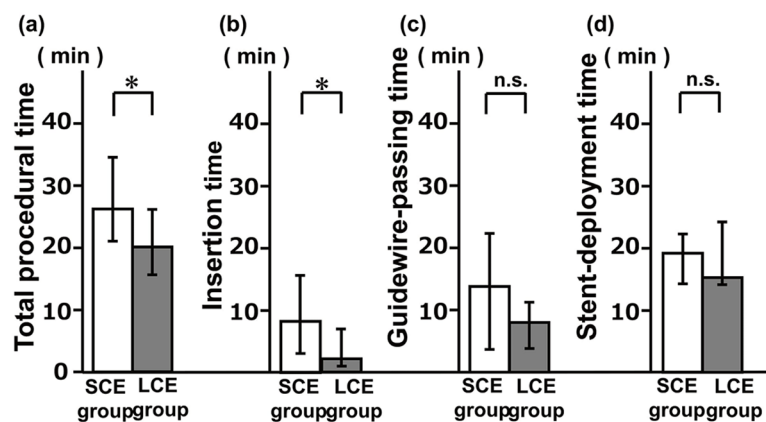
Primary and secondary outcomes of the study

The primary and secondary study outcomes are summarized in Figure 2 and Table 2. The procedure time in the LCE group (median, 20.5 min; IQR, 16.8–28 min; $n = 23$) was significantly ($p = 0.024$) shorter (approximately 22% shorter) than that in the SCE group (median, 25.1 min; IQR, 21–34 min; $n = 22$). The insertion time in the LCE group (median, 2.0 min; IQR, 1.0–6.0 min; $n = 23$) was also significantly ($p = 0.0049$) shorter than that in the SCE group (median, 6.0 min; IQR, 3.0–15.0 min; $n = 22$). There was no significant difference in the guidewire-passage time and stent-deployment time of the two groups. There was no significant difference in the technical success rate of the initial stent placement attempt in the two groups (SCE, 90.9%; LCE, 86.9%; $p = 0.67$). All patients who

Table 1. Characteristics of the patients and obstructive lesions in this study.

	SCE group (<i>n</i> = 24)	LCE group (<i>n</i> = 24)	<i>p</i> value
Male/female	18/6	13/11	n.s., <i>p</i> = 0.13
Age, years	70 (66–82)	77 (66–84.8)	n.s., <i>p</i> = 0.21
Stenosis location			n.s., <i>p</i> = 0.46
Rectum, <i>n</i>	2	3	
Sigmoid colon, <i>n</i>	12	12	
Descending colon, <i>n</i>	5	3	
Transverse colon, <i>n</i>	4	4	
Ascending colon, <i>n</i>	1	2	
Stenosis length, mm	52.5 (40–71)	50 (40–70)	n.s., <i>p</i> = 0.96
Stenosis cause			n.s., <i>p</i> = 1.0
Colon cancer, <i>n</i>	20	20	
Peritoneal carcinomatosis, <i>n</i>	3	3	
Locally recurrent cancer, <i>n</i>	0	1	
Invagination, <i>n</i>	1	0	
CROSS score	1 (0–3)	0 (0–2)	n.s., <i>p</i> = 0.82

Data are presented as median (interquartile range) unless otherwise indicated. CROSS, colonic obstruction-scoring-system; LCE, large-caliber endoscope; n.s., not significant; SCE, small-caliber endoscope.

**Figure 2.** The primary and secondary outcomes of this study. The total procedure time (a) was the primary outcome. The secondary outcomes were insertion time (b), guidewire-passage time (c), and stent-deployment time (d).

Data are shown as the median (interquartile range). LCE, large-caliber endoscope; n.s., no significant difference between the groups; SCE, small-caliber endoscope.

*Statistically significant difference between the groups (*p* < 0.05).

Table 2. Comparison of the success rate and procedure time of the small-caliber and large-caliber endoscope groups.

	SCE group (n=22)	LCE group (n=23)	p value
Initial technical success rate, %	90.9	86.9	n.s., $p=0.67$
Reason for failure			
Failure to reach to the lesion, n	2	2	
Failure to advance the guidewire, n	0	1	
Complication rate, %	0	0	n.s., $p=1.0$
Total technical success rate, %	95.5	87.0	n.s., $p=0.58$
Total clinical success rate, %	95.5	87.0	n.s., $p=0.58$
CROSS score after stenting	4.0 (4.0–4.0)	4.0 (4.0–4.0)	n.s., $p=0.85$

Data are shown as the median (interquartile range) unless otherwise indicated. CROSS, colonic obstruction-scoring-system; LCE, large-caliber endoscope; n.s., not significant; SCE, small-caliber endoscope.

underwent successful C-SEMS placement had improved clinical symptoms. The CROSS score of the SCE group after C-SEMS (median, 4.0; IQR, 4.0–4.0; $n=22$) was comparable with that of the LCE group (median, 4.0; IQR, 4.0–4.0; $n=23$) ($p=0.85$). The insertion time of the LCE group was significantly shorter than that in the SCE group, regardless of the presence or absence of difficulties (Table 3). Furthermore, there were no differences in the results of any questionnaire items between the groups (question 1: $p=0.54$; question 2: $p=0.94$; question 3: $p=0.53$; question 4: $p=0.92$; question 5: $p=0.73$; question 6: $p=0.20$) (Supplementary Figure 1) (study 1). The overall success rate, including the rate of successful cases with rescue plans, was not significantly ($p=0.67$) different between the SCE (95.5%) and LCE groups (86.7%) (Figure 3). No complications were observed in either group (Figure 3) (study 2).

Comparison of the outcomes of the SCE and LCE groups

We conducted sub-analyses of cases with and without procedure difficulties. There were no significant differences in the types of difficulties experienced by the two groups and the overall success rates in the SCE (84.6%; $n=13$) and LCE groups (81.3%; $n=16$) (Table 3). The insertion time in the LCE group (median, 5.0 min;

IQR, 1.5–7.0 min; $n=16$) was significantly shorter than that in the SCE group (median, 8.5 min; IQR, 3.8–17.8 min; $n=13$). There were no differences in the total procedure time, guidewire-passage time, stent-deployment time, and CROSS score of the two groups. In contrast, in patients without procedure difficulties (Table 3), there was no significant difference in the overall success rates of the SCE (100%; $n=9$) and LCE groups (100%; $n=7$). No differences were observed in the total procedure time, insertion time, guidewire-passage time, and stent-deployment time. All failures occurred in patients with procedure difficulties. One failed initial attempt was rescued by switching the colonoscope to a gastroscope; however, the other three failures could not be rescued because switching to a gastroscope did not allow for a sufficiently close insertion to the target obstructive lesions. In one of these cases, we were able to advance a guidewire to the oral side of the obstructive lesion; however, placing the delivery system in the working channel reduced the maneuverability of the endoscope and made it difficult to maintain a position that allowed completion of the procedure and insertion of the endoscope close to the target obstructive lesion. Therefore, the success rate of C-SEMS placement depended on whether the endoscope could be inserted close to the target obstructive lesion (insertion: 100%, 1/1; no insertion: 0%, 0/3; $p=0.045$).

Table 3. Comparison of the success rate and procedure time of the small-caliber endoscope and large-caliber endoscope groups with and without difficulties.

	SCE group	LCE group	<i>p</i> value
Cases with difficulties			
Number of cases	13	16	
Technical success, %	84.6	81.3	n.s., <i>p</i> =0.81
Total procedural time, min	33.0 (24.0–38.5)	22.5 (18.5–35.5)	n.s., <i>p</i> =0.98
Insertion time, min	8.5 (3.8–17.8)	5.0 (1.5–7.0)	<i>p</i> = 0.013
Guidewire-passage time, min	20.0 (11.0–24.0)	10.0 (8.3–17.3)	n.s., <i>p</i> =0.93
Stent-deployment time, min	20.0 (17.5–26.0)	20.0 (15.0–29.3)	n.s., <i>p</i> =0.52
Type of difficulty and technical success rate			
Stenosis ≥ 5 cm, %	91.7	87.5	n.s., <i>p</i> =0.72
Peritoneal carcinoma, %	66.7	66.7	n.s., <i>p</i> =1.0
Right colon lesion, %	100	80.0	n.s., <i>p</i> =0.34
CROSS score of 0, %	90.0	81.8	n.s., <i>p</i> =0.59
Cases without difficulties			
Number of cases	9	7	
Technical success, %	100	100	n.s., <i>p</i> =1.0
Overall procedural time, min	21.0 (16.0–26.8)	15.0 (13.0–18.0)	<i>p</i> = 0.028
Insertion time, min	7.5 (3.0–10.0)	1.0 (0.8–2.0)	<i>p</i> = 0.015
Guidewire-passage time, min	11.0 (3.0–15.0)	6.0 (3.0–7.0)	n.s., <i>p</i> =0.13
Stent-deployment time, min	15.0 (13.0–18.3)	14.0 (12.8–16.0)	n.s., <i>p</i> =0.76
Data are presented as median (interquartile range) unless otherwise indicated. CROSS, colonic obstruction-scoring-system; LCE, large-caliber endoscope; n.s., not significant; SCE, small-caliber endoscope.			

Discussion

Contrary to our expectations, the use of the LCE resulted in a shorter total procedure time than the SCE because of its reduced insertion time; however, there were no significant differences in the guidewire-passage time and stent-deployment time between the groups. As a short total procedure time is important in patients with serious medical conditions, these findings indicate that the LCE should be selected for C-SMES placement. However, there were no significant differences in the technical success rate, complication rate, and perception of satisfaction by the endoscopists when the SCE and LCE were used.

We speculated that the SCE would be more appropriate for insertion and C-SEMS placement. The insertion time using the standard caliber endoscope is comparable with that of using the SCE.^{15–18} This discrepancy may be explained by the differences in colon preparations (good *versus* poor for C-SEMS placement). To successfully insert a colonoscope, it is necessary to straighten the colon. It is easier to maintain the axis of the LCE because of its better suction ability; therefore, LCE is considered more appropriate than the SCE for straightening a colon with a considerable amount of gas and contents. In the present study, to minimize the effects of different

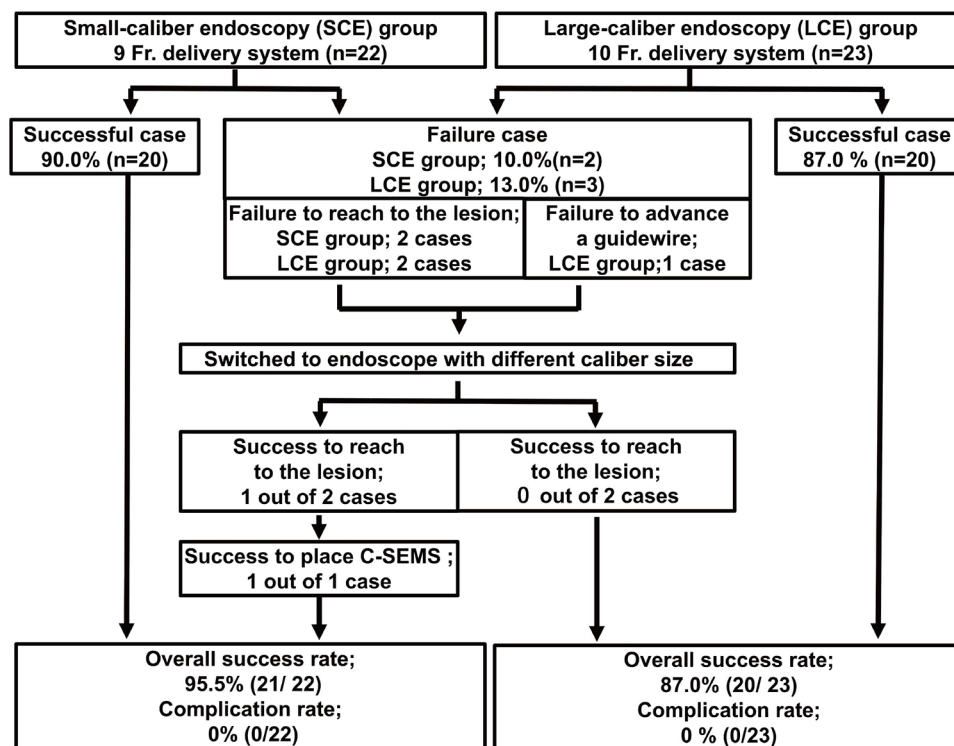


Figure 3. Summary of the study results.

channel sizes, the 9-Fr and 10-Fr delivery systems were combined with the SCE and LCE, respectively. The sectional areas of the working channel in the SCE and LCE are 8.0 and 10.7 mm², respectively, and the sizes of the gap area between the working channel and delivery system are approximately 0.9 and 2 mm², respectively. The 60% decrease (from 2.7 to 1.1 mm²) in the gap area might have reduced the difference in the suction ability of the SCE and LCE. However, this correction would have only affected the stent-deployment time. Because a reduction in the total procedure time was attributed to a reduction in the insertion time, the suction ability is an important factor in the C-SEMS procedure.

The factors associated with technical difficulties include long stenoses (≥ 5 cm), peritoneal carcinomatosis, tumor in the right colon, and a CROSS score of 0 before colonoscopy.¹ In this study, the procedure difficulties were defined using these factors. We showed that the insertion time of the LCE group was significantly shorter than that of the SCE group with or without difficulties. In contrast, among patients with difficulties, those with peritoneal carcinomatosis had the

lowest success rate; this rate was much lower than that observed during previous studies of colonic malignant obstruction. Therefore, we should focus attention on individual patients with peritoneal carcinomatosis. Unfortunately, we could not determine whether the SCE or LCE was more appropriate, especially when peritoneal carcinomatosis was involved. This study suggested that reaching the point of obstruction is associated with successful C-SEMS placement. Even if the guidewire manipulation technique is advanced, it will be difficult to achieve successful C-SEMS placement if the colonoscope is not sufficiently close to the target lesion. Controlling the air volume and changing the body position are also important factors when attempting to insert the endoscope close to the target lesion. We have experienced success by changing the colonoscope to a gastroscope. It is highly advantageous that the recently developed SEMS with a 9-Fr delivery system can fit not only colonoscopes, but also gastroscopes; therefore, the SEMS may be combined with several types of endoscopes.

This study has limitations. First, to focus on the caliber size of the endoscopes and minimize

different suction abilities, the 9-Fr and 10-Fr delivery systems were combined with the SCE and LCE, respectively. We did not assess the usefulness of the LCE combined with the 9-Fr delivery system. Because of the suction ability of the LCE, the stent-deployment time might be reduced when the LCE is combined with the 9-Fr delivery system. Second, it is unclear whether non-expert endoscopists can achieve the same results. Additional prospective studies are required to clarify these questions.

In conclusion, both LCE and SCE can be used for C-SEMS, while LCE is more suitable than SCE as it achieved a faster and equally efficacious C-SEMS placement as that of SCE. However, the SCE or even a gastroscope could be a good option in cases with procedure difficulties, such as peritoneal carcinomatosis.

Acknowledgements

We thank Junji Kishimoto, the statistical analysis specialist involved in this study.

Author contributions

YM designed the study, analyzed the data, and wrote the manuscript. HO analyzed the data and edited the manuscript. EI managed the data and critically reviewed the manuscript. The other authors collected the data. All authors have read and approved the manuscript.

Conflict of interest statement

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: EI belongs to an endowed course supported by the companies Ono Pharmaceutical Co., Ltd, Miyarisan Pharmaceutical Co. Ltd, Sanwa Kagaku Kenkyusho Co., Ltd, Otsuka Pharmaceutical Factory, Inc., Fujifilm Medical Co., Ltd, Terumo Corporation, FANCL Corporation, Ohga Pharmacy, and Abbott Japan, LLC. EI receives lecture honorarium from Takeda Pharmaceutical Company. YO conducts collaborative research with Fujifilm Medical Co., Ltd and FANCL Corporation. The authors declare no other conflicts of interest in association with this study.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

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Supplemental material

Supplemental material for this article is available online.

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