The Impact of Emergency Surgery versus Self-expanding Metallic Stents on Anal Function and Quality of Life in Patients with Complete Obstructing Left-sided Colon Cancer

GanBin Li (ligb0808@163.com)
Beijing Chaoyang Hospital https://orcid.org/0000-0002-2576-1100

Tao Yu
Beijing Chaoyang Hospital

Hao-Yu Zhang
Beijing Chaoyang Hospital

Zhen-Jun Wang
Beijing Chaoyang Hospital

Guang-Hui Wei
Beijing Chao-Yang Hospital: Beijing Chaoyang Hospital

Hao Qu
Beijing Chaoyang Hospital

Zhai-Wei Zhai
Beijing Chaoyang Hospital

Jia Gang Han
Beijing Chaoyang Hospital

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Abstract

Background: Emergence surgery (ES) and self-expanding metallic stents (SEMS) are traditional approaches for complete obstructing left-sided colon cancer. A strategy of “stents-chemotherapy-surgery” was applied in our center recently. Studies assessing the anal function and quality of life of patients with complete obstructing left-sided colon cancer are still lacking.

Methods: Patients with complete obstructing left-sided colon cancer were included, and three treatment strategies were used, including ES, SEMS, and SEMS followed by neoadjuvant chemotherapy (NAC) for patients with complete obstructing left-sided colon cancer. The Wexner, Vaizey, and low anterior resection syndrome (LARS) scores were used to assess anal function and the EORTC QLQ C30 score was used to assess quality of life. Logistic regression analysis was used to detect risk factors affecting short-term anal function of patients.

RESULTS: The Wexner scores were similar among the groups during the follow-up period. The Vaizey (H=18.415, P=0.001) and LARS scores (H=3.660, P=0.04) both revealed that anal function among patients receiving SEMS and NACwas significantly better than patients who underwent ES at the 1-month post-operative follow-up evaluation; no significant difference existed at the 6- and 12-month follow-up evaluations. The EORTC QLQ C30 score revealed that social function of patients receiving SEMS and NAC was also significantly better than patients undergoing ES (H=7.035, P=0.03). Logistic regression analysis suggested that a one-stage stoma in an emergent setting is an independent risk factor for short-term reduction of anal function among patients with complete obstructing left-sided colon cancer (OR=5.238, 95% CI: 1.569~17.484, P=0.007).

Conclusion: Compared to ES, SEMS might be able to improve the quality of life and short-term anal function in patients with complete obstructing left-sided colon cancer.

Background

According to previous studies, 8–29% of colorectal cancer patients present with acute obstruction and > 75% are located at left colon [1–2]. Of these patients, most are dehydrated with an electrolyte imbalance requiring immediate intervention [3]. Emergency surgery (ES) is the traditional treatment for complete obstructing left-sided colon cancer [4]. Since the first deployment of self-expanding metallic stents (SEMSs) for obstructing colon cancer by Tejero et al. [5], SEMSs have gained much popularity in clinical practice with the advantages of increased primary anastomosis and laparoscopic surgery rates, reduced rates of temporary or permanent stoma, and post-operative complications [6–7].

A strategy that involves SEMSs followed by neoadjuvant chemotherapy (NAC) and scheduled surgery was recently adopted for complete obstructing left-sided colon cancer in our center, with the purpose of increasing systemic control of disease at an early stage and improving the patient’s general physical condition and tolerance for surgery by increasing the interval between SEMS insertion and surgery. Our

preliminary results confirmed the short-term oncologic superiority of this strategy compared with ES and SEMS alone [8–9].

The current study focused on the short-term efficacy and survival outcomes of ES versus SEMSs for complete obstructing left-sided colon cancer, such as peri-operative safety and efficacy, SEMS-related complications, and the negative impact on long-term survival outcomes [10–11]. Apart from the oncologic efficacy of SEMSs, measuring anal function and quality of life in patients after surgery is also of great concern, however, no such studies have been published.

Currently, assessment of anal function in patients has been limited to the rectum. Several studies have suggested that anal function in patients receiving neoadjuvant chemoradiotherapy followed by low anterior resection is usually poor, while > 70% of rectal cancer patients developed mild-to-major low anterior resection syndrome (LARS) [12–13]. There are few studies involving anal function and quality of life in patients with left colon cancer, especially with complete obstructing left-sided colon cancer. Thus, based on an established retrospective database of patients in our center, this study aimed to evaluate the precise impact of ES versus SEMSs on anal function and quality of life in patients with complete obstructing left-sided colon cancer.

Patients And Methods

Patient Selection

Patients with complete obstructing left-sided colon cancer admitted into the General Surgery Department of Beijing Chaoyang Hospital from January 2017 to January 2019 were included. The inclusion criteria were as follows: (1) complete left-sided colonic obstruction, confirmed by clinical manifestations and abdominal computed tomography (CT); (2) tumors located at the distal splenic flexure and 15 cm above the anal verge; (3) adenocarcinoma confirmed by pathologic results; (4) patients who underwent ES with resection of the primary tumor and one-stage stoma, and reversal of stoma 6 ~ 18 months after surgery; (5) patients who underwent surgery after deployment of a SEMS without a stoma; and (6) patients who received a SEMS followed by NAC, then scheduled for surgery without a stoma. The exclusion criteria were as follows: (1) patients who underwent decompressing surgery only without radical resection of the primary tumor; (2) obstruction due to tumor recurrence or distant metastasis; and (3) incomplete clinical data. According to different treatment strategies, patients were divided into the ES, SEMSs, and SEMSs + NAC groups. This study was approved by the Institutional Research Ethics Committee of Beijing Chaoyang Hospital (Capital Medical University). Informed consent was obtained from all patients.

Treatment Strategies

ES group

Patients who sought evaluation in the Emergency Department with symptoms of acute obstruction immediately received an abdominal CT scan and pre-operative examination, then the patient was prepared for surgery as long as malignant left-sided colonic obstruction was accurately made. The standard protocol for ES was a radical resection of the primary tumor with primary anastomosis and ileostomy or Hartmann surgery with a colostomy, and reversal of the stoma 9 ~ 18 months after surgery.

SEMSs group

Based on an “intention-to-treat” strategy, patients diagnosed with complete obstructing left-sided colon cancer underwent deployment of SEMSs (WallFlex; Boston Scientific Corporation, Natick, MA, USA) under fluoroscopy guidance. Clinical success was defined as passage of feces through the anus and complete alleviation of acute obstruction. ES was indicated for SEMS failure. Radical resection of the primary tumor with primary anastomosis was then performed for patients 1 ~ 2 weeks after deployment of a SEMS.

SEMS + NAC group

Patients with complete obstructing left-sided colon cancer first received three cycles of fluorouracil, leucovorin and oxaliplatin (mFOLFOX6) or two cycles of capecitabine and oxaliplatin (CAPEOX) chemotherapy after successful deployment of a SEMS. Radical resection of the tumor with primary anastomosis was then performed 2 weeks after chemotherapy. Adjuvant chemotherapy was given based on the pathologic results and at the patient’s discretion.

Outcome Measures

The Wexner [14], Vaizey [15], and LARS [16] scales were used to assess anal function of patients at the 1-, 6- and 12-month follow-up evaluations, respectively. The Wexner scale has five items with a total score of 20, including solid, gas, liquid incontinence, use of a pad, and alteration of lifestyle. The Vaizey scale adds another two items (the need for drugs to facilitate defecation and control of feces within 30 min) on the basis of the Wexner scale. Reduced anal function was considered if the total Wexner or Vaizey score was > 10. The LARS scale also has five items, including general control of feces and gas, defecation time, and frequency and urgency. A total score of 0 ~ 20 represents no LARS, while 21 ~ 29 and 30 ~ 42 represent mild and severe LARS, respectively.

The EORTC QLQ C30 (version 3) questionnaire was used to assess the quality of life [17]. This scale has a total of 30 items, including 5 functional domains (physical, role, emotional, cognitive, and social functions), 3 symptom domains (fatigue, nausea and vomiting, and pain), and 1 overall healthy domain. In the functional and overall healthy domains, the higher the score, the better the quality of life; however, a relatively higher score indicated a poor quality of life in the symptom domains.

Statistical analysis

SPSS (version 25; IBM, Armonk, NY, USA) was used for statistical analysis. Consecutive variables are described as the mean ± standard deviation ($\bar{x}$± s) or median (range). Differences among groups was analyzed by one-way ANOVA or the Kruskal-Wallis H test. Categorical data are described as a number (percentage) and the chi-square or Fisher exact test was chosen for statistical analysis. Logistic regression analysis was applied to identify risk factors affecting anal function; the results are described as the odds ratio (OR) and 95% confidence interval (CI).

Results

Baseline Characteristics

Ninety consecutive patients meeting the inclusion criteria were analyzed. Of the patients, 18 were excluded for the following reasons: three patients underwent decompressive stoma only and nine patients did not receive stoma reversal in the ES group; five patients underwent stoma creation in the SEMSs and SEMSs + NAC groups; and one patient had incomplete clinical data. Seventy-two patients were included in this study. During the follow-up period, 15 patients were lost to follow-up (12 patients due to cancer-related deaths and three due to cardiovascular disease). Finally, a total of 57 consecutive patients with complete obstructing left-sided colon cancer were identified, including 18 (31.6%) in the ES group, 20 (35.1%) in the SEMSs group, and 19 (33.3%) in the SEMSs + NAC group (Fig. 1). Of these patients, 40 (67.8%) were male with a mean age of 67.5 ± 14.5 years. Of the tumors, 64.9% (37/57) were located at the sigmoid colon, while 26.3% (15/57) were located at the descending, and 8.8% (5/57) were located at the splenic flexure. The laparoscopic surgery rate was significantly higher in the SEMSs + NAC group than the ES and SEMSs groups (84.2% *vs.* 16.7% *vs.* 40.0%, respectively; $P < 0.001$). The baseline clinical characteristics were comparable among the groups (Table 1).

Table 1
Baseline characteristics of patients in the 3 groups (n = 57)

Clinical characteristics	ES (n = 18)	SEMS (n = 20)	SEMS + NAC (n = 19)	Statistics	*P* value
Age (year)	69.6 ± 16.4	66.8 ± 11.9	63.4 ± 8.3	$F = 1.149$	0.33
Gender (n %)				$\chi^2 = 2.328$	0.31
Male	13(72.2)	13(65.0)	11(57.9)		
Female	5(27.8)	7(35.0)	8(42.1)		
BMI(Kg/m^2)	23.4 ± 3.9	21.9 ± 3.5	23.4 ± 3.8	$F = 1.162$	0.32
ASA (n %)				$\chi^2 = 3.146$	0.21
□	7 (38.9)	13 (65.0)	8 (42.1)		
□	11 (61.1)	7 (35.0)	11 (57.9)		
ECOG score (n %)				$\chi^2 = 0.145$	0.93
0	11 (61.1)	11 (55.0)	11 (57.9)		
1	7 (38.9)	9 (45.0)	8 (42.1)		
Hypertension (n %)	5 (27.8)	10 (50.0)	3 (15.8)	$\chi^2 = 5.454$	0.07
Diabetes (n %)	1 (5.6)	1 (4.3)	4 (18.2)	$\chi^2 = 0.006$	0.97
Cardiovascular disease (n %)	3 (16.7)	3 (15.0)	1 (5.3)	$\chi^2 = 1.499$	0.47
Tumor location (n %)				$\chi^2 = 1.109$	0.90
Sigmoid	11(61.1)	14(70.0)	12(63.2)		
Descending	5(27.8)	4(20.0)	6(31.6)		
Splenic flexure	2(11.1)	2(10.0)	1 (5.3)		
Type of surgery (n %)				$\chi^2 = 17.390$	0.001
open	15 (83.3)	8 (40.0)	3 (15.8)		
laparoscopy	3 (16.7)	12 (60.0)	16 (84.2)		
Total blood loss (mL)	170 (30 ~ 1000)	145 (50 ~ 800)	124 (20 ~ 300)	$H = 0.613$	0.74

BMI: body mass index; ASA: America Society of Anesthesiologists; ECOG: Eastern Cooperative Oncology Group

Clinical characteristics	ES (n = 18)	SEMS (n = 20)	SEMS + NAC (n = 19)	Statistics	*P* value
Operation time (min)	203.4 ± 52.8	189.5 ± 66.2	207.4 ± 67.5	F = = 0.438	0.65
Complications (n %)	10 (55.5)	7 (35.0)	4 (21.1)	χ^2 = 1.170	0.62
Adjuvant chemotherapy (n %)	11 (61.1)	12 (60.0)	13 (68.4)	χ^2 = 0.344	0.84
BMI: body mass index; ASA: America Society of Anesthesiologists; ECOG: Eastern Cooperative Oncology Group					

Assessment Of Anal Function And Quality Of Life

No significant differences existed in the Wexner scores during the follow-up period (Table 2). The results of Vaizey score revealed that the anal function of patients at the 1-month follow-up was significantly different among groups (H = 18.415, P = 0.001), a further comparison found that the anal function in SEMS group (P < 0.001) and SEMS + NAC group (P = 0.001) was significantly better than that in ES group, while no significant difference existed between SEMS and SEMS + NAC group. The results of LARS score also had a similar conclusion, at the 1-month follow-up, the median LARS scores in ES, SEMS and SEMS + NAC group were 20, 15 and 16 respectively with a significant difference level (H = 3.660, P = 0.04), a further analysis found that the anal function of patients in SEMS (P = 0.018) and SEMS + NAC group (P = 0.005) was better than that in ES group, but no significant difference existed at the 6- and 12-month follow-up evaluations thereafter. The rates of LARS at the 1-month follow-up were 50% (9/18) in the ES group, 20% (4/20) in the SEMSs group, and 26.3% (5/19) in the SEMSs + NAC group. No patients developed LARS at the 6- and 12-month follow-up evaluations in the 3 groups. No significant difference existing regarding anal function among patients in the SEMSs and SEMSs + NAC groups in this study.

Table 2
Assessment of anal function of patients in the 3 groups (n = 57)

Anal function	Follow-up	ES (n = 18)	SEMS (n = 20)	SEMS + NAC (n = 19)	*H*	*P* value
Wexner scale	1-month	4 (0 ~ 13)	3 (0 ~ 6)	4 (0 ~ 7)	3.632	0.16
	6-month	0 (0 ~ 9)	0 (0 ~ 2)	0 (0 ~ 3)	0.352	0.84
	12-month	0 (0 ~ 9)	0 (0 ~ 5)	0 (0 ~ 2)	0.083	0.96
Vaizey scale	1-month	7 (0 ~ 17)	3 (0 ~ 7)	4 (0 ~ 8)	18.415	0.001
	6-month	0 (0 ~ 13)	0 (0 ~ 3)	0 (0 ~ 4)	0.974	0.61
	12-month	0 (0 ~ 11)	0 (0 ~ 5)	0 (0 ~ 3)	0.685	0.71
LARS scale	1-month	20 (0 ~ 37)	15 (0 ~ 24)	16 (0 ~ 28)	3.660	0.04
	6-month	2.5 (0 ~ 25)	0 (0 ~ 14)	0 (0 ~ 13)	3.323	0.19
	12-month	5 (0 ~ 16)	1.5 (0 ~ 14)	0 (0 ~ 9)	2.897	0.11

According to the EORTC QLQ C30 scale, the social function of patients in the SEMSs (mean, 75.3; range, 16.7 ~ 100) and SEMSs + NAC groups (mean, 78.9; range, 16.7 ~ 100) was significantly better than the ES group (mean, 66.7; range, 25.2 ~ 100; $H = 7.035$, $P = 0.03$). No significant difference existed with respect to the physical, emotional, role, cognitive function, and general healthy domains (Table 3). The quality of life was similar between the SEMSs and SEMSs + NAC groups.

Table 3
Assessment of quality of life in the 3 groups (n = 57)

Items	ES (n = 18)	SEMS (n = 20)	SEMS + NAC (n = 19)	*H*	*P*
Physical function	86.0 (56.1 ~ 91.3)	86.7 (60.0 ~ 93.3)	86.3 (52.8 ~ 93.1)	2.411	0.30
Emotion function	75.0 (50 ~ 100)	66.7 (50.0 ~ 100)	83.3 (16.7 ~ 100)	0.102	0.95
Role function	66.7 (25 ~ 91.7)	75.0 (33.3 ~ 91.7)	70.8 (25.0 ~ 91.7)	0.306	0.86
Cognitive function	66.7 (50 ~ 100)	66.7 (50.0 ~ 83.3)	83.3 (33.3 ~ 100)	1.559	0.46
Social function	66.7 (25.2 ~ 100)	75.3 (16.7 ~ 100)	78.9 (16.7 ~ 100)	7.035	0.03
General health	87.5 (58.3 ~ 91.7)	87.5 (58.3 ~ 100)	91.7 (66.7 ~ 100)	1.098	0.58
Fatigue	22.2 (11.1 ~ 44.4)	44.5 (11.1 ~ 55.6)	33.0 (11.1 ~ 66.7)	1.135	0.51
Nausea, vomiting	25.0 (16.7 ~ 50.0)	16.7 (0 ~ 50)	16.7 (0 ~ 66.7)	2.991	0.22
Pain	16.7 (0 ~ 50)	33.3 (0 ~ 50)	16.7 (0 ~ 50)	0.517	0.77

Patients were considered to have a reduction in anal function if the LARS score was > 20 or the Wexner or Vaizey score was > 10 at the 1-month follow-up evaluation. Patients were divided into normal (n = 37) and reduced anal function groups (n = 20) based on the total scores of the scales. Univariate analysis revealed that a BMI ≥ 24 kg/m^2 (χ^2 = 4.496, P = 0.03), one-stage stoma (χ^2 = 7.882, P = 0.005), and ES (χ^2 = 7.889, P = 0.02) were associated with reduced anal function (Table 4). Multivariate analysis further revealed that one-stage stoma in an emergent setting was an independent risk factor for short-term reduction of anal function of patients with complete obstructing left-sided colon cancer (OR = 5.238, 95% CI: 1.569 ~ 17.484, P = 0.007; Table 5).

Table 4
Univariate analysis of factors affecting anal function in patients (n = 57)

Factors	Normal group (n = 37)	Reduced group (n = 20)	χ^2	*P* value
Age (≥ 65 year)	20 (54.1%)	13 (65.0%)	0.638	0.56
Gender (Female)	12 (32.4%)	5 (25.0%)	0.343	0.42
Tumor location			3.278	0.09
Sigmoid	25 (67.6%)	13 (65.0%)		
Descending	11 (29.7%)	4 (20.0%)		
Splenic flexure	1 (2.7%)	3 (15.0%)		
BMI (≥ 24Kg/m^2)	18 (48.6%)	16 (80.0%)	4.496	0.03
ECOG (0)	19 (51.4%)	14 (70.0%)	1.852	0.17
ASA (Ⅱ)	18 (48.6%)	10 (50.0%)	0.009	0.99
Hypertension	10 (27.0%)	8 (40.0%)	1.011	0.31
Cardiovascular disease	5 (13.5%)	3 (15.0%)	0.024	0.88
Diabetes	5 (13.5%)	4 (20.0%)	0.400	0.53
Treatments			7.889	0.02
ES	7 (19.0%)	11 (55.0%)		
SEMS	15 (40.5%)	5 (25.0%)		
SEMS + NAC	15 (40.5%)	4 (20.0%)		
Laparoscopy surgery	23 (62.2%)	8 (40.0%)	2.570	0.11
Operation time (≥ 180 min)	26 (70.2%)	11 (55.0%)	1.329	0.25
Blood loss (≥ 100 mL)	29 (78.4%)	14 (70.0%)	0.492	0.48
Adjuvant chemotherapy	25 (67.6%)	11 (55.0%)	0.881	0.35
One-stage stoma	7 (18.9%)	11 (55.0%)	7.882	0.005
Post-operative complications	8 (21.6%)	2 (10.0%)	1.212	0.27

BMI: body mass index; ASA: America Society of Anesthesiologists; ECOG: Eastern Cooperative Oncology Group; ES: emergent surgery; SEMS: self-expanding metallic stent; NAC: neoadjuvant chemotherapy

Table 5
Logistic regression analysis of risk factors resulting in reduced anal function

Factors	*B*	*SE*	*Wald*	*OR(95%CI)*	*P*
Tumor location (sigmoid/desecnding, splenic flexure)	-0.294	0.477	0.381	0.745(0.293, 1.897)	0.537
One-stage stoma (Yes/No)	1.656	0.615	7.250	5.238(1.569, 17.484)	0.007
Treatments (ES/SEMS)	-0.238	0.783	0.093	0.788(0.170, 3.653)	0.761
BMI(≥24/<24Kg/m^2)	-0.179	0.628	0.081	0.836(0.244, 2.866)	0.776
ES: emergency surgery; SEMS: self-expanding metallic stent; BMI: body mass index					

Discussion

Complete left-sided colonic obstruction is an acute abdomen that is characterized by acute onset and severity. Acute obstruction is often combined with dehydration, electrolyte imbalance, or necrosis of the bowel and septic shock [1–2]. In this study we showed that social and short-term anal functions of patients with complete obstructing left-sided colon cancer were significantly better in the SEMSs and SEMSs + NAC groups than the ES group, while no significant difference was observed between the SEMSs and SEMSs + NAC groups. One-stage stoma in an emergent setting was associated with reduced short-term anal function post-operatively.

Anal resting pressure is mainly maintained by the anal sphincter (85%) and hemorrhoid venous plexus (15%). A reduced anal resting pressure is associated with fecal incontinence [18]. Generally, the anal sphincter is rarely involved in a left hemicolectomy and the procedure of trans-anal anastomosis might be considered only in a sigmoidectomy [19]. Consequently, regardless of the type of treatment strategy the impact on anal function is limited [20–21]. In the current study, the Vaizey and LARS scores revealed that the anal function of patients in the SEMSs and SEMSs + NAC groups were significantly better than the ES group at the 1-month follow-up evaluation. No significant difference was observed between the SEMSs and SEMSs + NAC groups, and the anal function was similar among groups thereafter, suggesting that the reduction of anal function in the ES group was temporary. Multivariate logistic regression analysis also concluded that a one-stage stoma in the emergent setting was an independent risk factor for temporary reduction of anal function in patients with acute obstruction. We speculate that the reduction in anal function in the ES group might be correlated with delayed reversion of the stoma [22–23]. A meta-analysis conducted by Croese et al. [23] revealed that the LARS rate increased as the interval between radical surgery and stoma reversal was prolonged in rectal cancer patients who underwent low anterior resection and protective ileostomy; the longer the interval, the worse the anal function. In the ES group, all patients received a one-stage stoma and the anal functions of these patients were analyzed until reversion of the stoma, and the interval between initial surgery and reversal in most patients was beyond

1 year. In addition, of the patients with reduced anal function, tumors were all located at the sigmoid colon, and it was observed that the Wexner and Vaizey scores decreased as the distance of the tumor above the anal verge increased, although no significant difference existed. As a result, we speculate that tumor location is also an important factor affecting anal function.

Several trials have suggested that quality of life of patients with colorectal cancer receiving a stoma is usually poor, especially with respect to the social function domain [10,24]. In our study, the EORTC QLQ C30 results revealed that patients in the SEMSs and SEMSs + NAC groups had better social function than the ES groups. We speculate that a poor quality of life among patients in the ES group was due to two reasons: these patients experienced worse social function, stoma-related complications, and inappropriate stoma nursing might cause a sense of self-abasement; and the psychological status and social function of patients might change with an alteration in defecation after creation of the stoma, thus individuals may be constantly cognizant of the disease state and more reluctant to engage in social contact [25–26]. During the follow-up period, we showed that social function of most patients recovered gradually after stoma reversion. Generally, we believe that the temporary adverse impact of ES on quality of life was acceptable and positive communication and appropriate stoma nursing might be helpful for those patients who experience social dysfunction [27–29].

This study had some limitations. First, due to its retrospective nature and small sample size in each group, the evidence supporting our conclusions still warrants additional clinical trials for confirmation. The overall follow-up was too short to perform further analyses. In addition, assessment of anal function was based on a series of scales without objective measurement of anal resting pressure, and selection bias might exist during the follow-up period.

Conclusion

Compared to ES, SEMSs might be helpful for improvement of short-time anal function and quality of life. A multicenter prospective clinical trial conducted in our center with the purpose of evaluating the oncologic efficacy and anal function of SEMSs followed by NAC is ongoing. We anticipate that the results will further confirm the safety and survival benefits of this strategy.

Abbreviations

ES
Emergency surgery; SEMSs:self-expanding metallic stents; NAC:neoadjuvant chemotherapy; LARS:low anterior resection syndrome; OR:odds ratio; CI:confidence interval; BMI:body mass index

Declarations

Acknowledgements

Not applicable

The contribution of each author: Study conception and design: Li, Wang, Han; Acquisition of data: Li, Tao, Zhang, Wang, Wei, Qu, Zhai, Han; Analysis and interpretation of data: Li, Wang, Han; Drafting of manuscript: Li, Tao, Zhang, Wang, Wei, Qu, Zhai, Han; Final approval: Li, Tao, Zhang, Wang, Wei, Qu, Zhai, Han; Critical reversion: Li, Tao, Zhang, Wang, Wei, Qu, Zhai, Han

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Availability of data and materials

Data is available from the corresponding author upon reasonable request

Ethics approval and consent to participate

The study was conducted in accordance with the guidelines of the International Conference on Harmonization for Good Clinical Practice and was approved by the Ethics Committee of Beijing Chaoyang Hospital, Capital Medical University (2016-scientific-161-1). The consent for study participation is informed and signed.

Consent for publication

Not applicable

Competing interests

None declared

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Figures

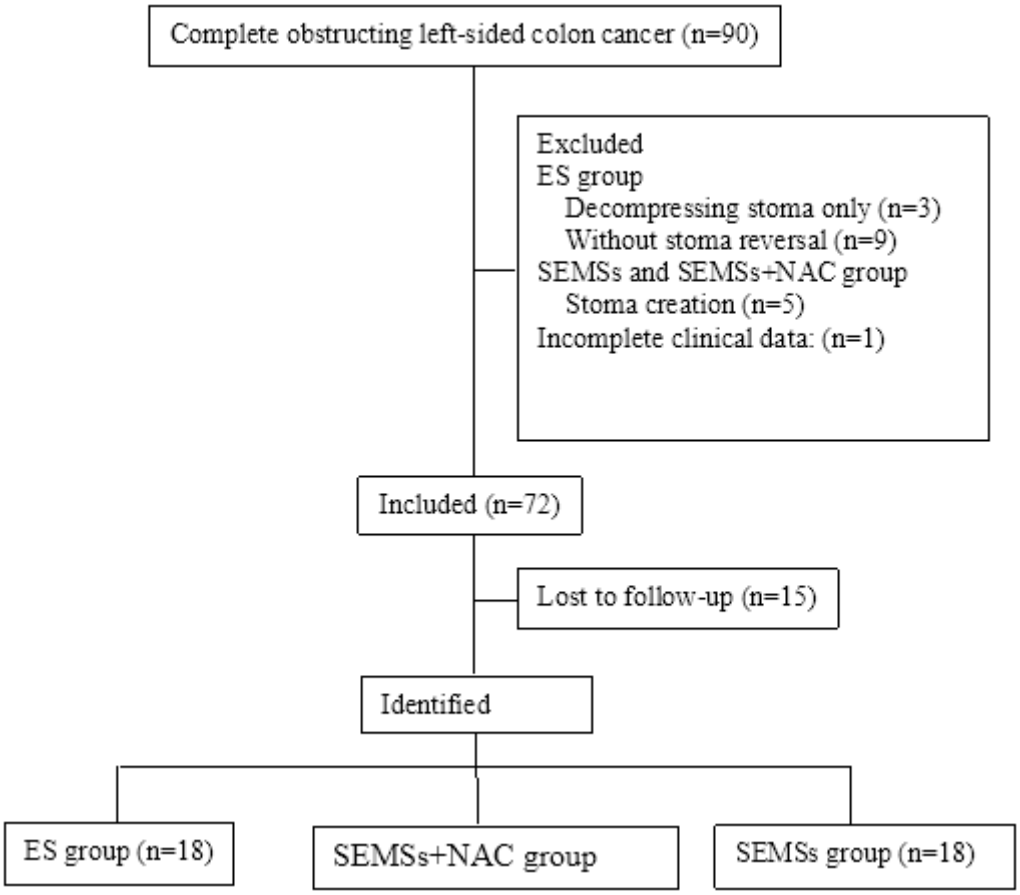

Figure 1

Flow diagram of patients included in this study