Clinics in Oncology

Research Article
Published: 16 Feb, 2024

Surgical Safety and Efficacy of Self-Expandable Metal Stents in Left and Right-Side Malignant Obstruction Colon

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Abstract

Objective: The purpose of this study was to compare the safety, short-term and long-term efficacy of self-expandable metallic stent in left-sided Colon Malignant Obstruction (MOLC) and right-sided Colon Malignant Obstruction (MORC).

Methods: Retrospective analysis of 186 patients diagnosed with Malignant Obstruction in Colon (MOC) who underwent surgical treatment in our hospital from January 2013 to March 2019. The data of each group were collected and compared. Statistical software was SPSS 25.0 and P<0.05 was considered statistically significant.

Results: SEMS implantation can significantly increase the rate of stoma-free surgery and laparoscopic surgery in MOLC patients, and reduce the incidence of incision infection and anastomotic leakage. SEMS implantation has no effect on the long-term treatment effect of MOC.

Conclusion: SEMS is a safe and feasible treatment for MOC patients. For MOC patients, SEMS implantation can significantly improve the rate of laparoscopic surgery, reduce intraoperative bleeding, and reduce postoperative complications such as anastomotic leakage and incision infection.

Keywords: Malignant obstruction colon; Malignant obstruction in right-sided colon; Malignant obstruction in left-sided colon; Primary surgery; Bridge to surgery

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Received Date: *29 Jan 2024*
Accepted Date: *11 Feb 2024*
Published Date: *16 Feb 2024*

Citation:
Wang PC, Ye K. Surgical Safety and Efficacy of Self-Expandable Metal Stents in Left and Right-Side Malignant Obstruction Colon. Clin Oncol. 2024; 9: 2058.

ISSN: 2474-1663

Abbreviations

MOC: Malignant Obstruction in Colon; SEMS: Self-Expandable Metallic Stent; BTS: Bridge to Surgery; MORC: Malignant Obstruction in Right-Sided Colon; MOLC: Malignant Obstruction in Left-Sided Colon; PS: Primary Surgery; R-SEMS: Malignant Obstruction in Right-Sided Colon Patients Accepted Self-Expandable Metallic Stent Implantation; R-PS: Malignant Obstruction in Right-Sided Colon Patients Accepted Primary Surgery; L-SEMS: Malignant Obstruction in Left-Sided Colon Patients Accepted Self-Expandable Metallic Stent Implantation; L-PS: Malignant Obstruction in Left-Sided Colon Patients Accepted Primary Surgery; CT: Computed Tomography; CEA: Carcinoembryonic Antigen; CA199: Carbohydrate Antigen 19-9; PR: Primary Resection; PRA: Primary Anastomosis Resection; OS: Overall Survival; DFS: Disease-Free Survival; BTS: Bridge to Surgery; ASA: American Society of Anesthesiologists; TNM: Tumor Node Metastasis; ASCRS: American Society of Colorectal Surgeons; NCCN: National Comprehensive Cancer Network

Introduction

As early as 1990, Bufill [1] proposed that left and right colon cancer should be regarded as two different diseases. Although it's embryological origin, biological behavior, carcinogenic mechanism and blood supply source are very different. But even so, most studies still regard left and right colon cancer as a disease. At present, the most commonly used definition of right and left colon cancer is based on the distance from the spleen. The tumor is located in the spleen near the mouth side as the right colon cancer, and the spleen anal side is the left colon cancer [2,3].

According to relevant studies, the incidence of obstruction in patients with colon cancer is about 7% to 47%, and about 85% of them requiring emergency treatment [4,5]. Moreover, MOC patients are generally accompanied by high mortality, high complication rate and high stoma rate after emergency surgery [6]. The high incidence of complications and high mortality after these emergency operations can be avoided by using SEMS and ileostomy decompression, so as to obtain the time to restore and improve the general condition of patients.

In recent years, more and more studies have applied SEMS as a Bridge to Surgery (BTS) for MOC patients. At present, SEMS is more used in MOLC patients, but few literatures have reported the use of SEMS implantation as BTS in the treatment of MORC [7]. There are limited data on the safety and feasibility of SEMS implantation in MORC patients. Although approximately 32% to 54% of MOC are located in the proximal colon, only 5% of colon stenting cases have been reported involving the right colon [8-10]. The purpose of this study was to evaluate the safety and feasibility of SEMS implantation by comparing the short-term clinical and long-term efficacy of MORC and MOLC in selecting SEMS implantation as BTS.

Materials and Methods

Research object

We retrospectively analyzed 186 patients diagnosed with MOC and underwent surgical treatment in our hospital from January 2013 to March 2022, including 118 cases of MOLC, 68 cases of MORC, 73 cases of SEMS placement, and 113 cases of PS treatment. According to the location of tumor obstruction and whether SEMS was implanted, eligible patients were further subdivided into four groups: R-SEMS group (n=23), R-PS group (n=45), L-SEMS group (n=50), L-PS group (n=68). In this study, the splenic flexure of the colon was selected as the boundary between the left half (including the splenic flexure) and the right half colon, and all positioning was based on intraoperative exploration and positioning. When initial decompression failed with SEMS placement or ileal tube, the patient underwent emergency resection and was classified according to initial treatment.

Inclusion criteria

(1) Pathologically confirmed colon cancer; (2) Imaging examinations such as abdominal CT suggested that MOC caused intestinal obstruction; (3) abdominal pain, bloating, stop exhaust defecation and other symptoms; (4) Preoperative evaluation of patients with stable vital signs, no shock, heart failure and other manifestations.

Exclusion criteria

(1) Patients with intestinal perforation or secondary peritonitis; (2) The tumor had distant metastasis or combined with other tumors; (3) Patients or their families refused further treatment; (4) Patients with palliative treatment;

SEMS implantation process

The SEMS placement procedure consists of four steps: (1) Identify the location and cause of acute intestinal obstruction by colonoscopy and abdominal CT; (2) A hydrophilic biliary tract guide wire passed through the tumor and crossed the obstruction point; (Figure 1) (3) Select the appropriate model of SEMS and open it; (4) Air and liquid feces immediately escaped through SEMS, indicating successful stent implantation (Figure 2).

Preoperative preparation

PS group: (1) Detailed medical history and physical examination and improve the relevant auxiliary examination; (2) To fasting, rehydration, nutritional support, preoperative prevention of infection, and actively improve the preoperative cardiopulmonary function assessment; (3) The use of preoperative prophylactic antibiotics.

SEMS group: Continue to actively improve the preoperative examination, fluid feeding bowel preparation, nutritional support, anti-infective treatment, etc. In general, polyethylene glycol or sodium phosphate is used for mechanical bowel preparation 7 to 14 days after remission of colorectal obstruction. For patients with hypertension and diabetes, blood pressure should be controlled below 160 mmHg to 100 mmHg and blood glucose should be controlled at 6 mmol to L-8 mmol/L before operation.

All the subjects were completed by the same gastrointestinal surgery team in our hospital. The surgeon has many years of experience in laparoscopic and open surgery. All the surgical procedures strictly abide by the principles of surgical sterility and standard surgical methods.

Observation indicators

We compared the two groups of stent placement, short-term surgical results, long-term efficacy, stent placement including technical success rate, clinical success rate, stent-related complications (perforation, displacement, re-obstruction); short-term surgical outcomes included Primary Resection Rate (PR), Primary Anastomosis Resection (PRA), stoma rate, laparoscopic surgery rate, operation time, blood loss, mortality and overall complication rate, total hospitalization time (including SEMS implantation and operation), postoperative hospitalization time; the long-term efficacy including 3-year DFS and 3-year OS were compared.

Postoperative follow-up suggested that patients should visit once a month in the first half of the year, once every 3 months in the next 2 years, and once every 6 months after 2 years. During the follow-up period, it is recommended that patients undergo a series of assessments, including clinical examination, carcinoembryonic antigen level test, CT and colonoscopy once a year after surgery.

Follow-up methods: Telephone follow-up, outpatient follow-up and inpatient medical records. The starting time of follow-up was the operation time. The deadline was March 2022, and the end point of follow-up was death.

Statistical analysis

SPSS 25.0 and GraphPad Prism 8.0 were used for statistical analysis. The measurement data conforming to the normal distribution were described by mean ± standard deviation (X ± s), and the *t* test was used for comparison between groups. The measurement data that did not conform to the normal distribution were described by median (range), and the Mann-Whitney U test of non-parametric test was used for comparison between groups. Chi-square test or Fisher test was used for comparison of enumeration data between groups. The survival time was calculated by Kaplan-Meier method, and the survival difference between groups was tested by Log-rank method. $P<0.05$ was considered statistically significant.

Result

Comparison of general data of cases

A total of 186 patients diagnosed with MOC were included in this study. Table 1 summarizes the general conditions of the 186 patients, including age, gender, ASA grade, TNM stage, and chronic disease history. The location of the tumor is different between the R-SEMS group and the R-PS group. The reason is that the ileocecal tumor cannot be implanted by SEMS because of its special anatomical structure (Table 1).

SEMS placement

Table 2 shows the results of SEMS implantation. Among the 73 patients who underwent SEMS implantation, 3 patients failed

Table 1: General information of patients.

	R-PS	R-SEMS	L-PS	L-SEMS	P1	P2	P3	P4
	N=45	N=23	N=68	N=50				
Age (year)	60 ± 13	50 ± 14	60 ± 13	63 ± 10	0.541	0.187	0.988	0.098
Gender, n (%)								
Male	33 (73.3)	12 (52.2)	45 (66.2)	36 (72.0)	0.081	0.5	0.421	0.097
Female	12 (26.7)	11 (47.8)	23 (33.8)	14 (28.0)				
ASA class. n (%)								
ASA1	4 (8.9)	2 (8.6)	8 (11.8)	2 (4.0)	0.775	0.378	0.813	0.241
ASA2	27 (60.0)	15 (65.2)	31 (51.5)	28 (56.0)				
ASA3	13 (28.9)	5 (21.7)	25 (36.8)	19 (38.2)				
ASA4	1 (2.2)	1 (4.3)	0 (0)	1 (2.0)				
location, n (%)								
Ileocecal	6 (13.3)	0 (0)			0.041			
Ascending colon	25 (55.6)	18 (78.3)						
Descending colon	14 (31.1)	5 (21.7)						
Sigmoid			44 (64.7)	39 (76.0)		0.118		
TNM, n (%)			24 (35.3)	11 (22.0)				
I	1 (2.2)	0 (0)	2 (2.29)	1 (2.0)	0.267	0.152	0.081	0.172
II	12 (26.7)	10 (43.4)	29 (42.6)	29 (58.0)				
III	32 (71.1)	13 (56.5)	37 (54.4)	20 (40.0)				
Chronic diseases, n (%)								
Hypertension, n (%)	5 (11.1)	3 (13.0)	17 (25.0)	4 (8.0)	0.815	0.017	0.068	0.497
Diabetes, n (%)	7 (15.6)	4 (17.4)	7 (10.3)	7 (14.0)	0.846	0.538	0.406	0.707
Coronary heart disease, n (%)	2 (4.4)	1 (4.3)	2. (2.9)	0 (0)	0.985	0.221	0.672	0.138

Table 2: Placement of SEMS.

±	R-SEMS	L-SEMS	
±	N=23	N=50	P4
Technical success rate, n (%)	22 (95.7)	48 (96.0)	0.945
Clinical success rate, n (%)	21 (91.3)	46 (92.0)	0.92
Perforation rate, n (%)	0 (0)	2 (4.0)	0.331
Re-obstruction rate, n (%)	1 (4.3)	4 (8.0)	0.566
Shift rate, n (%)	1 (4.3)	2 (4.0)	0.945
Rate of other related complications (hematochezia, etc.), n (%)	0 (0)	2 (4.0)	0.331
Overall complication rate, n (%)	2 (8.7)	10 (20.0)	0.226

in SEMS implantation due to the inability of the tumor stenosis guide wire to clearly pass through the stenosis site. There was no significant difference in technical success rate, clinical success rate and complication rate between R-SEMS and L-SEM (Table 2).

Comparison of surgical conditions

Surgical situations: PRA, no stoma operation rate and Laparoscopic operation rate in L-SEMS group were significantly higher than those in L-PS group (92.0% *vs.* 70.6%, P2<0.05; 84.0% *vs.* 61.8%, P2<0.05; 86.0% *vs.* 66.2%, P2<0.05). In patients with PS, R-PS was superior to L-PS in PRA and no stoma operation rate (93.3% *vs.* 70.6%, P3<0.05; 95.6% *vs.* 61.8%, P3<0.05); there was no significant difference in the rate of PR and laparoscopic surgery. R-SEMS and L-SEMS have similar PR, PRA, No stoma operation rate and Laparoscopic operation rate. In MOLC patients, the operation time of the SEMS group was longer than that of the PS group, and the difference was statistically significant (median 138 min *vs.* 162 min, P2<0.05). There was no significant difference in blood loss between the two groups at the two tumor sites. However, in both MORC and MOLC, the SEMS group had less intraoperative bleeding than the PS group, and the difference was statistically significant (median 91 ml *vs.* 45 ml, P1<0.05; 101 ml *vs.* 60 ml, P2<0.05) (Table 3).

Comparison of postoperative complications

Postoperative complications: There was no significant difference in postoperative complications such as postoperative incision infection, postoperative intestinal obstruction, and anastomotic leakage and so on between the R-PS group and the R-SEMS group. The incidence of postoperative incision infection and anastomotic leakage in the L-PS group was significantly higher than that in the L-SEMS group, and the difference was statistically significant (17.0% *vs.* 8.0%, P2<0.05). 16.2% *vs.* 4.0%, P2<0.05) there was no significant

Table 3: Surgical condition.

	R-PS	R-SEMS	L-PS	L-SEMS	P1	P2	P3	P4
	N=45	N=23	N=68	N=50				
PR, n (%)	43 (95.6)	22 (95.7)	64 (94.1)	49 (98.0)	0.985	0.301	0.739	0.568
PRA, n (%)	42 (93.3)	21 (91.3)	48 (70.6)	46 (92.0)	0.762	0.004	0.003	0.92
No stoma surgery rate	42 (93.3)	20 (90.9)	42 (61.8)	42 (84.0)	0.451	0.008	0	0.435
Laparoscopic surgery rate, n (%)	33 (73.3)	22 (95.7)	45 (66.2)	43 (86.0)	0.027	0.015	0.421	0.22
Operation time, (Median, min)	133 (90-350)	134 (90-300)	138 (80-340)	162 (100-300)	0.285	0.006	0.154	0.005
blood loss, (median, ml)	91 (10-1000)	45 (20-600)	101 (20-1000)	60 (10-800)	0.009	0.001	0.15	0.763

Table 4: Postoperative complications.

	R-PS	R-SEMS	L-PS	L-SEMS	P1	P2	P3	P4
	N=45	N=23	N=68	N=50				
Hospital mortality, n (%)	0 (0)	0 (0)	1 (5)	0 (0)		0.389	0.414	
Wound infection, n (%)	12 (26.7)	3 (13.0)	17 (25.0)	4 (8.0)	0.2	0.017	0.843	0.494
Postoperative ileus, n (%)	4 (8.9)	0 (0)	5 (7.4)	4 (8.0)	0.141	0.896	0.768	0.163
Anastomotic leakage, n (%)	6 (13.3)	2 (8.7)	11 (16.2)	2 (4)	0.574	0.037	0.679	0.413
Anastomotic bleeding, n (%)	5 (11.1)	2 (8.7)	2 (2.9)	1 (2.0)	0.756	0.221	0.78	0.181
Abdominal infection, n (%)	4 (8.9)	2 (8.2)	6 (8.8)	6 (12.0)	0.979	0.573	0.99	0.675
Pulmonary infection, n (%)	10 (22.2)	1 (4.3)	9 (13.2)	4 (8.0)	0.058	0.369	0.211	0.566
Other complications, n (%)	1 (2.1)	2 (8.7)	2 (2.9)	2 (4.0)	0.219	0.753	0.816	0.413
Reoperation rate, n (%)	2 (4.4)	0 (0)	2 (2.9)	1 (2.0)	0.305	0.748	0.672	0.495
The days from SEMS implantation to operation (d) Hospital stay (d)		7 (4-132)		8 (0-28)				0.72
Hospital stay (d)	21 (8-44)	24 (12-53)	19 (10-47)	19.5 (12-69)	0.157	0.909	0.36	0.051
Postoperative hospital stay (d)	13 (7-32)	10 (5-42)	12 (8-32)	10 (6-26)	0.01	0.025	0.143	0.853

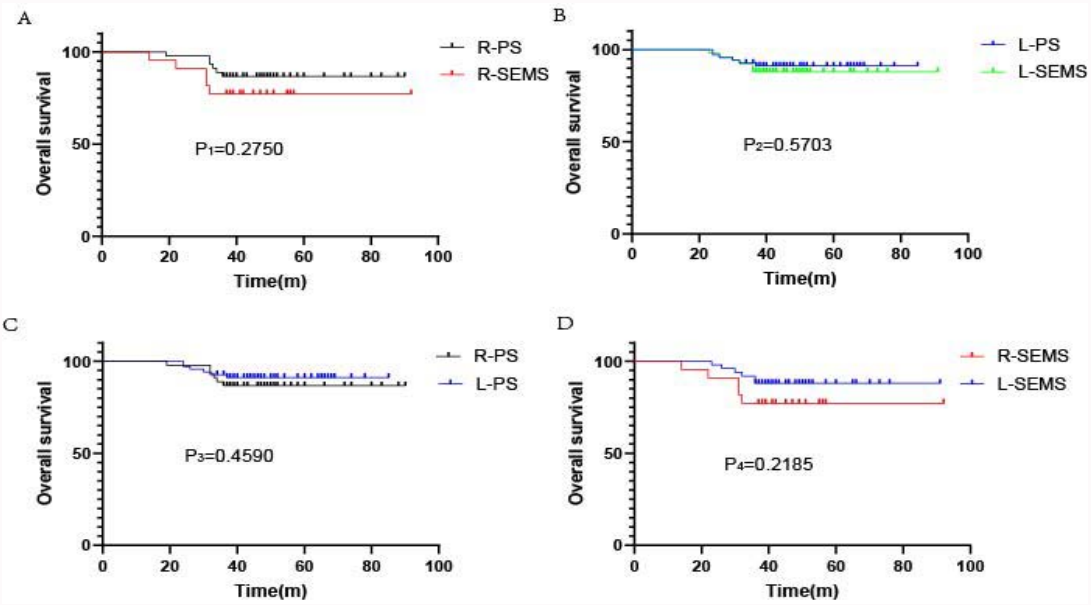

Figure 1: A hydrophilic biliary tract guide wire passed through the tumor and crossed the obstruction point.

difference in the incidence of postoperative intestinal obstruction, anastomotic bleeding, abdominal infection, pulmonary infection and other related complications between the two groups. There was no significant difference in postoperative complications between MORC and MOLC regardless of PS or SEMS. There was no significant difference between MORC and MOLC in total hospitalization time and secondary operation rate. SEMS implantation could not reduce the total hospitalization time and secondary operation rate of MOC patients, but in both MORC and MOLC, the postoperative hospitalization time of SEMS group was shorter than that of PS

Figure 2: Air and liquid feces immediately escaped through SEMS, indicating successful stent implantation.

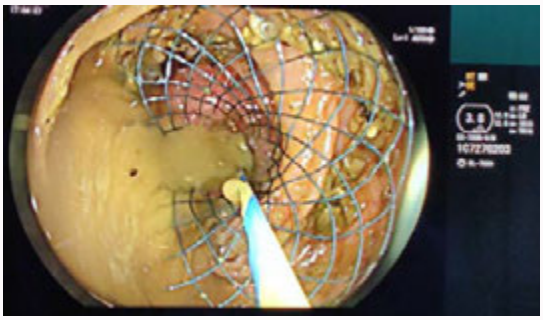

Figure 3: There was no significant difference in 3-year DFS between R-PS group, R-SEMS group, L-PS group and L-SEMS group (P>0.05**).**

group, and the difference was statistically significant (median 13d *vs.* 10d, P1<0.05; 12d *vs.* 10d, P2<0.05) (Table 4).

Postoperative follow-up

A total of 186 patients were included in the study. The follow-up time was 14 to 92 months, with a median follow-up time of 43 months. The follow-up deadline was March 2022. All 186 patients were followed up. There was no significant difference in 3-year DFS between R-PS group, R-SEMS group, L-PS group and L-SEMS group (P>0.05) (Figure 3). There was no significant difference in 3-year OS between R-PS group, R-SEMS group, L-PS group and L-SEMS group (P>0.05) (Figure 4).

Discussion

About 15% to 20% of patients with colon cancer have intestinal obstruction as the primary manifestation [11,12], and the incidence of MOLC is much higher than that of MORC [13,14]. Most patients with MOC need emergency surgery to relieve obstruction. Even with the progress of medicine and surgery, compared with limited surgery, intestinal obstruction leads to the inability to perform bowel preparation, colonic dilatation and edema, systemic infection, and malnutrition, which may lead to preoperative colonic necrosis and perforation, postoperative anastomotic leakage, and other serious postoperative complications, resulting in the need for permanent fistula or endangering the patient's life. In 1994, Tejero et al. [15] used SEMS for the first time in the treatment of MOC, and changed the original need for emergency surgery to ordinary limited-term surgery. They found that this can significantly reduce postoperative complications and reduce the rate of stoma.

It is usually suggested that for MORC patients, the tumor location is far away from the anus, and bending degree of the intestinal canal increases, the intestinal preparation such as cleaning enema cannot be carried out due to obstruction, which affects our judgment of the tumor or obstruction site through colonoscopy, increasing the difficulty of endoscopic SEMS placement. However, relevant studies by Moroi et al. [16,17] have shown that for experienced endoscopists, endoscopic SEMS placement is safe and feasible in patients with malignant obstruction of the right colon. The success rate is high, and the technical requirements may be lower than previously thought. Even a Japanese prospective multicenter study reported a clinical success rate of up to 96% in the proximal colon [18]. In fact, with the gradual development of endoscopic technology and the continuous accumulation of clinical experience of endoscopists, the safety of SEMS implantation in MORC patients has gradually improved. However, there are still few patients with SEMS implantation in MORC, which needs further study to prove.

A number of studies have confirmed that compared with

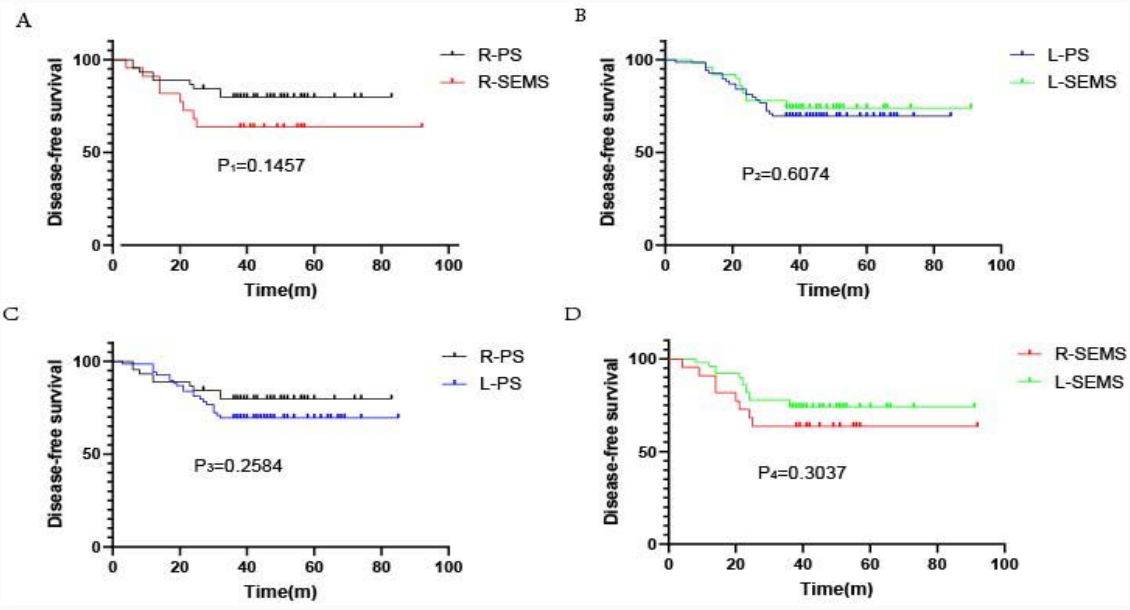

Figure 4: There was no significant difference in 3-year OS between R-PS group, R-SEMS group, L-PS group and L-SEMS group (P>0.05).

emergency surgery, SEMS implantation can improve the one-stage anastomosis rate of intestinal obstruction surgery and reduce the permanent stoma rate [19-21]. We believe that this and SEMS implantation as BTS can obtain more sufficient preoperative preparation time and more perfect preoperative evaluation, which is helpful to improve the nutritional status of patients, reduce intestinal edema, reduce perioperative complications, and promote postoperative recovery.

Previous studies [22,23] have shown that SEMS implantation can significantly increase the proportion of laparoscopic surgery in MOC patients by about 60% and reduce intraoperative blood loss. Compared with PS, prolonged waiting time after SEMS implantation can further promote the regression of intestinal wall edema, reduce the difficulty of surgery, and improve the proportion of minimally invasive surgery and surgical safety. SEMS implantation is beneficial to preoperative intestinal decompression. In order to improve the preoperative examination, sufficient preoperative examination is helpful to evaluate the tumor location, clinical stage and surrounding lymph nodes. Sufficient intestinal decompression can significantly reduce abdominal contents. Patients with better decompression effect can also carry out cleaning enema. More sufficient abdominal space and more sufficient preoperative examination are helpful to improve the rate of laparoscopic surgery. In terms of short-term surgical results, we believe that SEMS implantation as BTS can benefit both MORC and MOLC patients. Moroi et al. [24] believed that postoperative anastomotic leakage is the most common and serious postoperative complication of MOC. Anastomotic leakage can lead to complications such as abdominal infection and incision infection. Intestinal fluid corrosion of blood vessels can also lead to serious complications of abdominal bleeding. Effective control and reduction of postoperative anastomotic leakage can help patients recover. Our results suggest that SEMS placement can reduce anastomotic leakage after MOLC. Amelung et al. [9] and others observed that the total complication rate (27% in SEMS group, 40% in PS group) and mortality (2.4% in SEMS group, 8.8% in PS group) of MORC receiving SEMS placement as BTS were significantly lower than those in PS group. Therefore, SEMS implantation may be a feasible and beneficial treatment for MOC patients [25].

Although SEMS implantation as BTS has been widely used in the treatment of MOC patients. But its safety is controversial. Its safety mainly comes from two aspects: One is the risk of SEMS placement; second, there is the possibility of late complications [26]. Late complications mainly include local recurrence of tumors, distant metastasis of tumors, postoperative anastomotic inflammation, and postoperative recurrent intestinal obstruction. The results of this study are similar to those of Bae et al. [27,28]. From the existing evidence, it is not enough to prove that SEMS implantation will increase local recurrence, distant metastasis and reduce 3-year DFS of MOC patients.

The shortcomings of this study: First of all, this study is a retrospective cohort study, and the level of evidence is not high. Then, the number of MORC patients was small, which affected the comparison results. Finally, we hope to further complete the prospective, multi-center, large sample study for further explanation.

Conclusion

This study suggests that SEMS placement is a safe and feasible treatment for both MORC and MOLC patients. Although MOLC benefits more significantly, MORC can also benefit from it compared with PS. Therefore, we believe that SEMS implantation may be a helpful transitional treatment for MOC patients, and MOLC patients benefit more than MORC patients.

Funding

This study was supported by the Science and Technology Project of Fujian Provincial Health Commission (2021CXA028). Key Clinical Specialty Discipline Construction Program of Fujian, P.R.C (Fujian Health Medicine and Politics [2022]884). The second affiliated hospital of Fujian medical university doctor hospital special funds project (2022BD1601).

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