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Endoscopic Stenting at the Stages of Radical and Palliative Treatment in Patients with Obstructive Colorectal Cancer: Results from a Prospective Randomized Trial

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Aim: to compare the effectiveness and oncological safety of colon preparation for surgical treatment in patients with colorectal cancer complicated with obstructive colonic ileus using endoscopic stenting and protective ostomy.
Materials and methods. A prospective, single-center, randomized study was carried out. All patients with colorectal cancer complicated with obstructive colonic ileus consecutively admitted to the Proctology Clinic of the University Clinical Hospital No. 2 of the Sechenov University were included in the study. Patients were randomized into two groups: Group 1 (study group) included patients who underwent endoscopic placement of a self-expanding metal stent to resolve obstructive colonic ileus; Group 2 (control group) included patients who underwent protective ostomy.
Results. Endoscopic stenting requires less general anesthesia and can be performed outside the operating room. The duration of decompression surgery is statistically significantly shorter with stenting compared to ostomy: 23 [20–30] and 50 [40–60] min, respectively ($p < 0.001$). The rehabilitation period, which is also the period of preparation for the main surgical intervention, with stenting was 4 [3–5] days, which was statistically significantly shorter compared to the control group ($p < 0.001$). Satisfactory quality of colon preparation after decompression in the study group was noted in 92.9 % of cases, in the control group — in 50 % of cases ($p < 0.001$). The result of nutritional correction in both groups was assessed as positive, however, in intergroup comparison, the level of serum albumin was statistically significantly higher in the group of stented patients ($p = 0.015$). The duration of the main surgery was statistically significantly longer in the ostomy group than in the study group: 300 [270–320] vs. 180 [160–220] min, respectively ($p < 0.001$). The results of the data indicating the oncological safety of both decompression methods were similar.
Conclusion. Endoscopic stenting of tumor stenosis in obstructive colonic ileus may be considered a preferable option for preoperative colon decompression compared to unloading stoma in the treatment of complicated forms of colorectal cancer within a single hospitalization.
Keywords: colorectal cancer, obstructive colonic ileus, ostomy, self-expanding metal stents
Conflict of interest: the authors declare no conflicts of interest.

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Эндоскопическое стентирование на этапах радикального и паллиативного лечения больных стенозирующим колоректальным раком: результаты проспективного рандомизированного исследования

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Цель: сравнить эффективность и онкологическую безопасность подготовки толстой кишки к хирургическому лечению больных колоректальным раком, осложненным обтурационной толстокишечной непроходимостью (ОТКН), с помощью эндоскопического стентирования и формирования разгрузочной стомы.
Материалы и методы. Проведено проспективное одноцентровое рандомизированное исследование. В исследование включались все последовательно поступающие в клинику колопроктологии Университетской клинической больницы № 2 Сеченовского Университета пациенты с колоректальным раком, осложненным ОТКН. Пациенты, включенные в исследование, рандомизированы в две группы: в I группу (исследуемую) вошли пациенты, которым для разрешения ОТКН проводилась эндоскопическая установка саморасширяю-

щегося металлического стента; пациентам II группы (контрольной) выполнялось формирование разгрузочной кишечной стомы.
Результаты. Эндоскопическое стентирование в меньшей степени требует общей анестезии и может проводиться вне операционной. Длительность декомпрессионного вмешательства статистически значимо меньше при стентировании в сравнении со стомированием: 23 [20–30] и 50 [40–60] мин соответственно ($p < 0,001$). Реабилитационный период, он же период подготовки к основному хирургическому вмешательству, при стентировании составил 4 [3–5] дня, что было статистически значимо меньше в сравнении с контрольной группой ($p < 0,001$). Удовлетворительное качество подготовки толстой кишки после декомпрессии в исследуемой группе отмечено в 92,9 % случаев, в исследуемой — в 50 % ($p < 0,001$). Результат нутритивной коррекции в обеих группах расценен как положительный, однако при межгрупповом сравнении уровень сывороточного альбумина был статистически значимо выше в группе стентированных пациентов ($p = 0,015$). Этап основной хирургической операции был статистически значимо продолжительнее в группе стомированных пациентов, чем в исследуемой группе: 300 [270–320] vs. 180 [160–220] мин соответственно ($p < 0,001$). Результаты данных, свидетельствующих об онкологической безопасности обоих методов декомпрессии, были сходные.
Выводы. Эндоскопическое стентирование опухолевого стеноза при толстокишечной обтурационной непроходимости может рассматриваться как предпочтительный вариант предоперационной декомпрессии толстой кишки в сравнении с разгрузочным стомированием при лечении осложненных форм колоректального рака в рамках одной госпитализации.
Ключевые слова: колоректальный рак, обтурационная толстокишечная непроходимость, формирование стомы, саморасширяющиеся металлические стенты
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Introduction

The incidence of stenosing colorectal cancer (CRC) with intestinal obstruction ranges from 15 to 30 % and has remained stable over the past 25 years. Postoperative mortality after tumor resection in cases with obstruction is 15.7—20.2 %, significantly higher than in patients without obstruction [1—5]. This is due to a high rate of severe postoperative complications.

The optimal approach for CRC with obstruction is two-stage treatment: initial colonic decompression followed by tumor resection. Traditionally, proximal stoma formation was used for decompression. However, recent guidelines have included self-expanding metallic sent (SEMS) placement as an alternative.

While stoma formation reduces mortality, it has several downsides. The intraoperative complication rates range between 10—20 % [6, 7]. It leads to reinterventions, increasing mortality risk, prolonging hospitalization, and raising costs [8, 9]. Stoma presence complicates reconstructive step of the surgery, and stoma closure carries specific risks, including mortality.

Advances in endoscopic techniques have introduced an alternative to stoma formation for colonic decompression — endoscopic stenting of the tumor stenosis. Stenting restores the colonic lumen by compressing the exophytic tumor component. This decompression method appears potentially less traumatic compared to the more invasive approach of decompressive stoma formation. A self-expanding stent reestablishes normal intestinal transit, eliminates metabolic consequences of obstruction, shortens preoperative preparation time for tumor resection, and allows simultaneous evaluation of the proximal colon segments [10—12].

However, oncological safety of stenting remains a topic of discussion. Some studies suggest that stenting increases the concentration of circulating tumor DNA due to mechanical tumor damage, comparing to those who receive decompressive stoma [13, 14].

Despite consensus on the need for decompression in obstructive CRC, the optimal method remains controversial. To this day there were no prospective randomized trials have directly compared stenting and stoma formation in preoperative preparation for CRC resection, making this study relevant globally.

Materials and methods

This was a single-center, randomized, prospective study. The clinical study protocol was registered and approved by the Local Ethics

Committee of Sechenov University (extract from Protocol No. 34-20 dated December 9, 2020). All patients provided written informed consent for participation. The study protocol was registered in the international registry of randomized controlled trials at https://clinicaltrials.gov under identifier NCT05643989.

The study included all consecutive patients admitted to the clinic with malignant colonic obstruction who required decompressive surgical intervention between 2019 and 2023. Randomization was performed using a cluster method via the "Random Allocation Software" program, dividing participants into two groups: Group 1 (study group) underwent placement of a self-expanding metal stent, while the Group 2 (control group) received a preventive decompressive stoma.

Surgical techniques

Decompressive stoma formation

The procedure was performed under combined anesthesia. Depending on the patient's body mass index and clinical condition, the intervention was conducted using laparoscopic techniques or a local approach. The optimal stoma placement was considered to be 10 cm proximal to the tumor stenosis. The intestinal loop brought to the abdominal wall was secured with a fixation device, and the intestinal wall was anchored to the skin with separate seromuscular sutures. The stoma was opened on the operating table, and patency of afferent and efferent limbs was verified.

Endoscopic stenting

Placement of a self-expanding metal stent was performed under dual fluoroscopic and endoscopic guidance. Stent selection was based on computed tomography data using the following formula: tumor length + 4 cm (i.e., a 2 cm extension of the stent both proximal and distal to the tumor edges). A video colonoscope was advanced to the distal edge of the tumor stenosis. Under fluoroscopic guidance, an atraumatic metal guidewire was passed through the narrowed segment into the proximal colon, followed by stent deployment via a delivery system under fluoroscopic and endoscopic control. After placement, gas and fecal passage were visually assessed.

Preparation for tumor resection after decompression

Following decompression, patients resumed a regular diet with a low-residue regimen. Bowel preparation was conducted using polyethylene glycol-based solutions. In Group 2, additional cleansing enemas were administered through the stoma outlet and rectum, as these segments were inaccessible to oral laxatives. A control colonoscopy was performed on day 5 post-decompression per study protocol to evaluate bowel preparation quality and inspect proximal colon segments for synchronous lesions or benign neoplasms requiring intervention.

Primary surgical intervention

Tumor resection was conducted in accordance with the RUSSCO (RUSsian Society of Clinical Oncology) 2025 Clinical Guidelines for Colorectal Cancer Treatment. In both groups, regardless of surgical approach, the first step involved abdominal cavity exploration, followed by peritoneal and pelvic lavage for cytological examination to detect malignant cells.

Primary endpoint — bowel preparation quality assessed using the Boston Bowel Preparation Scale.

Secondary Endpoints:

- time to malignant colonic obstruction treatment initiation (hospitalization and patient preparation requirements);
- operative duration (recorded by an anesthesiologist);
- early postoperative complications;
- length of hospital stay;
- time to malignant colonic obstruction resolution;
- tumor resection complications related to the stoma or stent;
- stoma formation during oncologic treatment in the study group;
- stoma closure during oncologic treatment in the control group.

Eligibility criteria

Inclusion criteria:

- patients aged ≥ 18 years with histologically confirmed stage I–IV colorectal cancer complicated by malignant colonic obstruction (COS (Colonic Obstruction Score) score ≥ 6);
- absence of decompensated comorbidities (ASA (American Society of Anesthesiologists) class < 4);
- scheduled tumor resection after obstruction relief;
- signed informed consent.

Exclusion criteria:

- inflammatory bowel disease;
- acute purulent infection near the tumor;
- severe psychiatric disorders precluding study participation.

Drop out the study: loss to follow-up, patient withdrawal of consent, or requirement for primary chemotherapy.

Statistical analysis

Data were analyzed using IBM SPSS Statistics 23 (IBM Corp., USA), with statistical significance set at $p \leq 0.05$.

Sample size calculation

To achieve 80 % study power with a type I error of 0.05 (analyzed using Fisher's exact and 2 tests), equal-sized groups of 28 patients each (total $n = 56$) were required.

Results

The analysis included treatment outcomes for 56 patients with confirmed colorectal cancer complicated by obstructive colonic obstruction. Following the randomization, two groups of 28 patients each were formed. Patients in Group 1 ('Stent') underwent endoscopic stenting of the tumor stenosis using self-expanding metal stents, while patients in Group 2 ('Stoma') received decompressive stoma formation. The groups were comparable in terms of gender, age, ASA classification, and anthropometric parameters, with no statistically significant differences in tumor location or extent of stenosis (Table 1).

A statistically significant shorter duration of decompressive intervention was noted in Group 1 compared to Group 2 (23 [20–30] vs. 50 [40–60] min, respectively; $p < 0.001$). All intestinal stomas were created under combined general anesthesia, while endoscopic stenting required only pharmacologic sedation in 64.3 % of cases ($p < 0.001$).

In Group 2, 3 (10.7 %) patients developed Clavien — Dindo Grade I complications characterized by parastomal wound infections. These complications did not prolong the preoperative preparation period. Group 1 had one complication (3.6 %) involving stent kinking and restenosis, requiring repeat colonoscopy for stent repositioning. The complication rates did not differ significantly between groups ($p = 0.611$).

The postoperative recovery periods differed significantly between groups (Table 2). Stenting allowed earlier patient mobilization due to absence of postoperative wound pain and faster resolution of intestinal obstruction ($p < 0.001$). Visual Analogue Scale (VAS) pain scores were significantly higher in Group 2 both on postoperative day 1 (median — 6 vs. 3 points) and

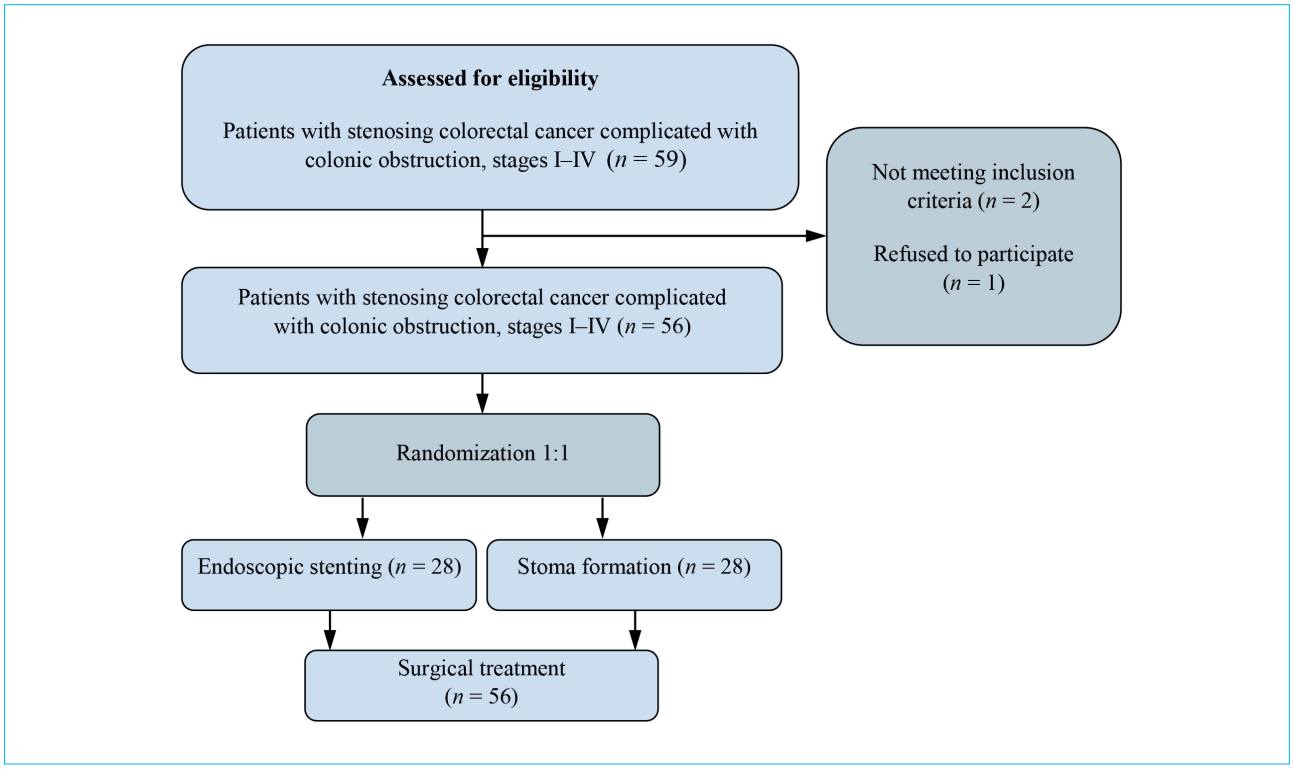

Figure. Flowchart of the study

Table 1. Clinical characteristics of patients in both groups

Parameters	Distribution into groups		*p*
	Group 1 ('Stent') (*n* = 28)	Group 2 ('Stoma') (*n* = 28)	
Age (years), *Me* [IQR]	66 [51–77]	59 [44–66]	0.088
Male, *n* (%)	12 (42.9)	14 (50.0)	0.592
OR [95% CI]	1.333 [0.465–3.822]		
ASA class, *n* (%)			
II	14 (50.0)	20 (71.4)	0.099
III	11 (39.3)	8 (28.6)	
IV	3 (10.7)	0 (0)	
Clinical stage, *n* (%)			
I	1 (3.6)	0 (0)	0.153
II	7 (25.0)	4 (13.4)	
III	13 (46.4)	21 (75.0)	
IV	7 (25.0)	3 (10.7)	
Tumor location, *n* (%)			
transverse colon	3 (10.7)	3 (10.7)	0.552
splenic flexure	2 (7.1)	2 (7.1)	
descending colon	6 (21.4)	2 (7.1)	
sigmoid colon	9 (32.1)	8 (28.6)	
rectosigmoid junction	4 (14.3)	4 (14.3)	
rectum	4 (14.3)	4 (14.3)	
Tumor length, *n* (%)			
≤ 3 cm	1 (3.6)	0 (0.0)	0.086
3–5 cm	8 (28.6)	6 (21.4)	
5.1–8 cm	9 (32.1)	13 (46.4)	
8.1–10 cm	10 (35.7)	5 (17.9)	
>10 cm	0 (0.)	4 (13.3)	
COS (points), *Me* [IQR]	8 [6.5–8]	8 [7–8]	0.429
VAS at admission (points), *Me* [IQR]	6 [6–8]	6 [6–7]	0.082
BMI (kg/m^2), *Me* [IQR]	24.94 [22.74–29.1]	23.15 [22.0–27.1]	0.130

Note: *Me — median; IQR — interquartile range; OR — odds ratio; 95% CI — 95 % confidence interval; ASA — American Society of Anesthesiologists; COS — Colonic Obstruction Score; VAS — Visual Analogue Scale; BMI — body mass index.*

day 3 (median — 4 vs. 0 points) ($p < 0.001$). The shorter recovery after stenting enabled faster preparation for the main surgery (4 [3–5] vs. 7 [5–8] days in Group 2; $p < 0.001$). Satisfactory bowel preparation (≥ 6 points on the Boston Bowel Preparation Scale) was achieved in 92.9 % of stented patients vs. 50 % in Group 2 ($p < 0.001$).

Nutritional status assessment revealed comparable baseline hypoalbuminemia in both groups ($p = 0.476$). Both groups showed significant improvement after nutritional correction, which included protein-enriched diet and sip feeding ($p < 0.001$). Although post-decompression albumin levels were significantly higher in Group 1 ($p = 0.015$) (Table 3).

The presence of a stoma significantly prolonged the duration of primary surgery due to the need for stoma reversal (180 [160–220] minutes in Group 1 vs. 300 [270–320] minutes in Group 2; $p < 0.001$). Surgical approaches were similar between groups. Malignant cells were detected in peritoneal lavage from one Group 1 patient and two Group 2 patients, with no intergroup difference in this oncological safety parameter. The rates of Clavien — Dindo Grade IIIa postoperative complications were comparable (Table 4).

Analysis of tumor markers (CA 19-9 (carbohydrate antigen 19-9) and CEA (carcinoembryonic antigen)) before and after decompression showed no values exceeding reference ranges, confirming the oncological safety of both methods. The observed CEA fluctuations remained within normal limits (< 5 ng/mL) (Table 5).

Table 2. Characteristics of decompression and preoperative preparation phases

Parameters	Distribution into groups		*p*
	Group 1 ('Stent') (*n* = 28)	Group 2 ('Stoma') (*n* = 28)	
Decompression procedure time (min), *Me* [IQR]	23 [20–30]	50 [40–60]	<0.001*
General anesthesia required, *n* (%)	18 (64.3)	28 (100.0)	0.001*
OR [95% CI]	2.556 [1.782–3.665]		
Post-decompression complications, abs. (%)	1 (3.6)	3 (10.7)	0.611
OR [95% CI]	0.309 [0.030–3.165]		
Time to mobilization (days), *Me* [IQR]	1 [1–1.5]	2 [2–3]	<0.001*
Decompression success rate, *n* (%)	28 (100.0)	28 (100.0)	1
Preparation time for primary surgery, *Me* [IQR]	4 [3–5]	7 [5–8]	<0.001*
The Boston Bowel Preparation, total (≥ 6 points), *n* (%)	26 (92.9)	14 (50.0)	0.001*
OR [95% CI]	13.0 [2.578–65.545]		
The Boston Bowel Preparation, right colon (≥ 2 points), *n* (%)	28 (100.0)	23 (82.1)	0.051*
OR [95% CI]	0.451 [0.333–0.610]		
Synchronous cancer detection, *n* (%)	1 (3.6)	1 (3.6)	1
	1.0 [0.059–16.822]		
VAS on day 2 after decompression (points), *Me* [IQR]	3 (3–4)	6 (4.25–6)	<0.001*
VAS on day 3 after decompression (points), *Me* [IQR]	0 (0–1)	4 (4–4)	<0.001*

Note: *Me — median; IQR — interquartile range; OR — odds ratio; 95% CI — 95 % confidence interval; VAS — Visual Analogue Scale; * — statistically significant differences (p < 0.05).*

Discussion

Obstructive intestinal obstruction represents one of the most common complications in emergency surgery, with CRC accounting for over 60 % of cases. Intestinal obstruction develops in 10–15 % of CRC patients. Emergency surgeries for CRC complicated by obstruction are associated with mortality rates of 15.7–20.2 % [1–5].

The presence of colonic obstruction significantly complicates oncological resection due to high risks of postoperative complications and mortality, while simultaneously extending the diagnostic period beyond the 14-day window as stated in oncology guidelines [15].

Decompression methods are therefore considered a preparatory step for radical surgical treatment within a single hospitalization. Current decompression options include diverting colostomy, decompressive tube placement, and SEMS insertion.

Initial reports on SEMS for malignant obstruction emerged over 30 years ago, primarily describing palliative applications for unresectable or metastatic CRC. Early studies reported complication rates up to 12.5 %, with tumor perforation (5.4 %) and bleeding (2.7 %) being most frequent [16, 17]. Despite advancements in endoscopic techniques, recent publications still indicate substantial

Table 3. Dynamics of albumin level changes before and after decompression, g/L

Groups	Observation phase				*p*
	Before decompression		After decompression		
	Me	IQR	*Me*	IQR	
'Stent'	28.20	24.25–31.5	35.0	32.0–38.15	<0.001*
'Stoma'	28.0	25.0–32.0	31.35	29.0–35.2	<0.001*
p	0.476		*0.015		–

Note: *Me — median; IQR — interquartile range; * — statistically significant differences (p < 0.05).*

Table 4. Characteristics of the primary surgical phase

Parameters	Distribution into groups		*p*
	Group 1 ('Stent') (*n* = 28)	Group 2 ('Stoma') (*n* = 28)	
Duration of surgery (min), *Me* [IQR]	180 [160–220]	300 [270–320]	<0.001*
Open approach (laparotomy), *n* (%)	19 (67.9)	23 (82.1)	0.355
OR [95% CI]	0.459 [0.131–1.603]		
Laparoscopic approach, *n* (%)	9 (32.1)	5 (17.9)	0.355
OR [95% CI]	0.459 [0.131–1.603]		
Positive intraoperative lavage, *n* (%)	1 (3.6)	2 (7.1)	1
OR [95% CI]	0.356 [0.161–0.788]		
Clinically significant anastomotic leak, *n* (%)	1 (3.6)	2 (7.1)	1
OR [95% CI]	2.077 [0.177–24.313]		

Note: *Me — median; IQR — interquartile range; OR — odds ratio; 95% CI — 95 % confidence interval; * — statistically significant differences (p < 0.05).*

Table 5. Dynamics of tumor markers before and after decompression

Groups	CA 19,9, U/mL				*p*
	Before decompression		After decompression		
	Me	IQR	*Me*	IQR	
'Stent'	20.7	12.45–25.00	21.0	12.88–25.08	0.182
'Stoma'	21.5	13.13–25.30	21.5	13.75–25.30	0.108
p	0.374		0.396		–
Groups	**CEA, U/mL**				***p***
	Before decompression		**After decompression**		
	Me	**IQR**	***Me***	**IQR**	
'Stent'	1.20	0.55–2.72	1.40	0.84–3.05	<0.001*
'Stoma'	1.30	0.90–2.66	1.50	1.10–3.00	0.017*
p	0.492		0.485		

Note*: CA 19-9 — carbohydrate antigen 19-9; CEA — carcinoembryonic antigen); Me — median; IQR — interquartile range; * — statistically significant differences (p < 0.05).*

complication rates (17.1 % overall), with 10 % of cases requiring emergency surgery [18].

Notable concerns include stent migration (22 %), restenosis (17 %), and procedure-related mortality (0.58–3.7 %). Some authors attribute complications to prolonged intervals between stenting and surgery [19, 20]. Our study design based on a "bridge-to-surgery" strategy, aimed to minimize preoperative preparation time and reduce complications. However, technical/clinical failure rates of endoscopic stenting may reach 25 % [21].

Quasi-elective surgery following SEMS placement demonstrates comparable long-term overall and recurrence-free survival to standard elective CRC surgery in uncomplicated cases [22]. Stenting also improves conditions for primary anastomosis, reducing preventive stoma rates (47.5 % vs. 67.9 %; $p = 0.003$) through better bowel preparation [23].

P. Gavriilidis et al. reported lowest mortality (10 %) when stoma formation served as initial decompression. Two-stage approaches (decompression followed by resection) showed superior immediate outcomes compared to single-stage procedures [24].

A systematic review by L. Tan et al. included 48 studies and favored two-stage management for malignant obstruction, noting longer hospital stays with stoma formation (odds ratio (OR) — 13.76; 95% confidence interval (95% CI): 9.13–18.03) but better 5-year survival (OR = 0.88; 95% CI: 0.80–0.98) compared to stenting [25].

Meta-analysis by F.J. Amelung et al. suggested SEMS as bridge-to-surgery may not adversely affect long-term oncological outcomes in left-sided obstruction, though sensitivity analysis revealed conflicting trends in three-year and overall survival between randomized and non-randomized groups [26]. M.F. Ho et al. found no survival difference whether surgery followed stenting within 4 weeks or later [18].

Controversially, T. Yamada et al. proposed SEMS induced gene circulation changes might

promote cancer progression through mechanical tumor compression and hematogenous dissemination [13, 27, 28]. Some advocate extending the stenting-to-surgery interval to 2 months and in that period, in order to mitigate dissemination risks, administer neoadjuvant chemotherapy. It was also observed that stent-related inflammation increases anastomotic leakage which leads to preventive stoma formation (34 %) [29].

Conversely, Z. Ni et al. detected no significant change in circulating tumor cells before and after stenting (34.90 vs. 38.33; $p = 0.90$) [30].

In our study, we analyzed changed in tumor markers along with peritoneal and pelvic cavity washings. The data showed no intergroup differences in CA 19-9/CEA levels or the detection rate of tumor cells during intraoperative peritoneal lavage ($p = 1$), supporting stenting's oncological safety.

P. Ferrada et al. recommend stenting as first-stage treatment if resection occurs within 6 days, as delayed surgery increases perforation risk [31]. Our findings align with global literature, identifying optimal preparation periods of 4 [3–5] days for stenting versus 7 [5–8] days for stoma formation.

Conclusion

Currently, the Russian Federation is experiencing a positive trend in the widespread adoption of endoscopic stenting in clinical practice. However, the variability in clinical and oncological outcomes necessitates further investigation. Our study has demonstrated the efficacy and safety of this decompression method within a single hospitalization period. Stenting of tumor stenosis showed statistically significant advantages in the duration of decompressive intervention, quality of bowel preparation, and time to primary surgical treatment, without increasing early complication rates. The endoscopic placement of self-expanding metal stents reduced the time to primary treatment by 43 %.

From an oncological safety perspective, our evaluation of risk factors including peritoneal washings and tumor markers (CA 19-9, CEA) revealed no statistically significant differences. Additionally, the stenting group demonstrated a tendency toward higher rates of laparoscopic interventions compared to the stoma group. The randomized approach employed in this study enhances its evidence level.

This study has certain limitations, including a relatively small sample size, its single-center design, and the lack of long-term oncological outcome data. Further investigation of long-term oncological parameters will enable more comprehensive conclusions regarding this decompression method. Continued research is needed to fully establish the role of endoscopic stenting in the management of malignant colonic obstruction.

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