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作成者（著者）	Saida, Yoshihisa
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Review Article

# A Review Historical Evolution, Current Status, and Future Prospects of Treatment for Obstructive Colorectal Cancer: Colonic Stent

Yoshihisa Saida\*

Department of Surgery, Toho University Ohashi Medical Center, Tokyo, Japan

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**ABSTRACT:** Colorectal obstruction, a common complication in colorectal cancer, often requires emergency surgery. Historical treatments including colostomy, three-staged resection, and the Hartmann operation had complications and high mortality rates. In 1965, a complex one-staged procedure involving subtotal colon resection and lavage was introduced but had limited adoption. Transanal decompression tubes offered relief but had limitations. Self-expandable metallic stents revolutionized treatment in the 1990s. Colonic stents improved the quality of life of patients, allowing normal eating habits and early discharge. Japan initially had limited stent use but approved WallFlex™ and Niti-STM stents. The Japan Colonic Stent Safe Procedure Research Group provided guidelines and conducted studies. The research group developed the Colorectal Obstruction Scoring System to assess stent indications and treatment effectiveness. Colonic stents are mainly used for malignant colorectal stenosis in Japan, including rectal stenosis post-surgery, palliative treatment, and as a bridge to surgery. Ongoing trials aim to establish evidence for stents as a bridge to surgery. Future prospects include stents for benign stenosis and improved design with reduced migration and removability. Researchers are developing absorbable or biodegradable stents and exploring drug-eluting and radioactive stents for preventing restenosis and controlling malignant stenosis. Studies on chemotherapy after colorectal stenting aim to improve high-risk cancer prognosis. I would like to conclude by emphasizing the need for safe placement of colonic stents and refer readers to the Mini-Guidelines provided by the Colorectal Stent Safety Procedures Research Group for reference.

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**KEYWORDS:** colorectal obstruction, colonic stents, obstructive colorectal cancer, japan colonic stent safe procedure research group, colorectal obstruction scoring system (CROSS)

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\*Corresponding Author: Yoshihisa Saida, 2-22-36 Ohashi, Meguro-Ku, Tokyo 153-8515, Japan, tel: +81-3-3468-1251  
e-mail: yoshisaida@nifty.com  
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## 1. Historical Evolution of Treatment of Obstructive Colorectal Cancer (Fig. 1)

Colorectal obstruction occurs in 8%-13% of colorectal cancer patients.<sup>1,3)</sup> It is the most common cause of emergency surgery/procedure in colorectal cancer patients.

Initially, as an emergency surgery, simple colostomy was performed.<sup>4)</sup> Later, in 1903, a three-staged surgical resection including tumor resection was reported.<sup>5)</sup>

In 1923, the Hartmann operation, a two-staged procedure including tumor resection and colostomy, was reported<sup>6)</sup> and became the surgical standard for a long time.

However, the complications and mortality rates were not low when these emergency surgeries were performed,<sup>7)</sup> and the quality of life (QOL) of patients could not be avoided because the colostomy often could not be closed, even if it made initially only temporarily.

To solve this problem, in 1965, a case report was published on 12 patients who underwent subtotal resection of the colon on the proximal side of the tumor, wherein the entire expanded proximal side of the tumor was resected and the small intestine was anastomosed with the distal side colon.<sup>8)</sup> This is the first one-staged procedure. In 1980, a surgical procedure wherein a one-stage intestinal anastomosis is performed after intraoperative lavage of fecal impaction was also reported.<sup>9)</sup> A meta-analysis of three articles, including a prospective study by the SCOTIA group, comparing the two one-staged surgical methods showed that subtotal colorectal resection was not preferable in terms of postoperative complications and

postoperative defecation function and its indication was limited to cases with multiple colorectal cancers or existing obstructive colitis.<sup>10)</sup>

However, intraoperative washing and anastomosis were also very complicated and time-consuming, and the risk of contamination of the surgical field was high, so they were not widely used. For a long time, therefore, the conventional Hartmann procedure was the mainstay of surgical practice. The major reason for the need of emergency surgery is that the colon cannot be easily decompressed by oral decompression through a long tube (naso-ileal tube, ileus tube) due to the presence of the ileocecal valve, which functions as an anti-reflux valve.

Since Lelcuk et al. inserted a balloon tube in sigmoid colon cancer in 1986,<sup>11)</sup> various tubes such as Nelaton catheter, biliary tubes, and nasogastric tubes have been tried and reported in order to decompress the pressure through a transanal approach for obstructive colorectal cancer patients who have failed nasal or oral decompression. In Japan, a specialized transanal decompression tube (ileus tube) was launched and many experiences with its use have been published. The success rate of insertion was reported to be 60%-100%, and in cases where insertion was possible, the rate of removal of bowel obstruction was reported to be 80%-100%, showing relatively good results.<sup>12-14)</sup> Since the 1990s, transanal decompression tubes from three companies (Create Medic, Nihon Sherwood, and Sumitomo Bakelite) have been commercially available and widely used in Japan and were the standard treatment for obstructive colorectal cancer in the

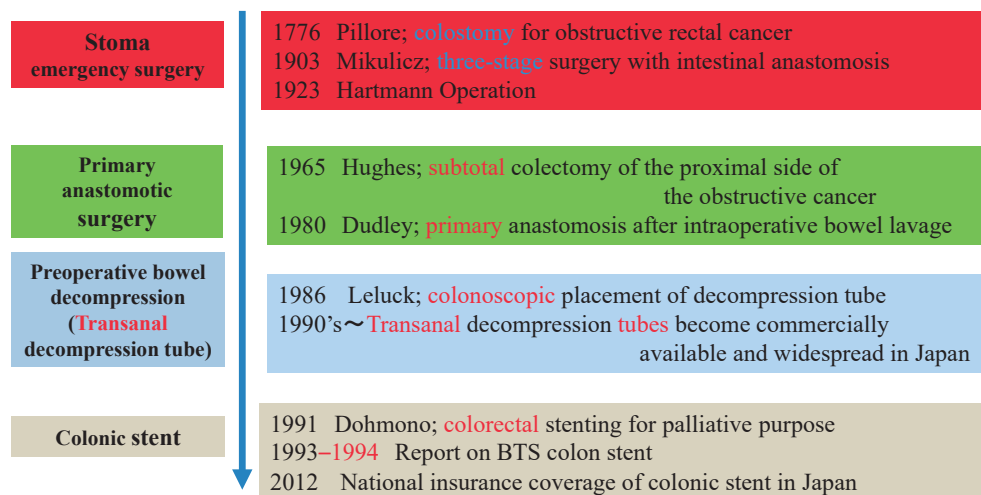


Fig. 1 Historical evolution of obstructive colorectal cancer treatment

1990s and 2000s. However, there were many problems in terms of the QOL of patients, such as inadequate decompression effect and difficulty in food intake, as well as strong discomfort for the patient.

Endoscopic stents [SEMS] for the gastrointestinal tract were introduced in the 1990s as palliative treatment for malignant obstruction of the esophagus and other digestive tracts and biliary tract and have been proven to be useful and have a high clinical success rate. For the colon, the colonic stent was introduced in the early 1990s by Dr. Dohmoto in Japan for palliative decompression of rectal obstruction in patients who could not undergo radical surgery.<sup>15)</sup> Later, the indication was expanded to bridge to surgery (BTS) for preoperative decompression.<sup>16, 17)</sup>

Compared to the transanal decompression tubes, colonic stenting has dramatically improved the QOL of patients by allowing them to eat freely after decompression and to be discharged from the hospital.

In 2010, the American Society for Gastrointestinal Endoscopy and the World Society of Emergency Surgery guidelines also stated that colonic stent decompression is standard for malignant stenosis of the colon.<sup>18, 19)</sup>

## **2. Introduction of Colorectal Stents in Japan and Establishment of the Japan Colonic Stent Safe Procedure Research Group**

Colonic stenting in Japan was introduced and included in the 2006 guidelines of the Japanese Society of Gastrointestinal Endoscopy;<sup>20)</sup> however, it was neither approved by the Japanese government for pharmaceutical use nor covered by health insurance. Therefore, the procedure was performed as a clinical study at a very limited number of institutions, using diverted stents for the esophagus or importing stents for the colon from overseas on a personal basis.

The introduction of stenting for colorectal stenosis in Japan started with the approval of the US-made colorectal stent, WallFlex™, in July 2011 and its national insurance coverage in 2012. Initially, the medical fee for lower gastrointestinal stenting was 9,100 points (K735-4), and the colorectal stent was Specified Insured Medical Material 157, Stent Set for Digestive Tract, without cover, 252,000 yen. In July 2013, the second colorectal stent, Niti-S™, made in South Korea, was added to the marketing list. Since then, colorectal stents have been widely used throughout Japan.

In 2012, after the long-awaited commercialization of the stent in Japan, I was eagerly awaiting its safe dissemination and planned to start a nationwide colon stent study group.

After consulting with many colorectal surgeons and endoscopists, I named the group the Japan Colonic Stent Safe Procedure Research Group to emphasize the purpose of spreading awareness of the safe procedure and received the cooperation of the leaders of gastrointestinal endoscopy and gastrointestinal surgery at the time. The group was founded in 2012 with the cooperation of the many leaders of gastrointestinal endoscopy and gastrointestinal surgery at the time.

The study group aims to discuss the safe procedure, followed by a prospective safety confirmation study, and through the report, to educate the public about the safe procedure of colonic stenting nationwide.

To increase the reliability of our activities and to receive support, we applied to become a side research group of the Japanese Society of Gastrointestinal Endoscopy. At the time, we just barely made it in time for the application period, and fortunately, we were registered as a side research group.

In 2012, the Colorectal Stent Safety Technique Study Group was approved as a side research group with the Japanese Society of Gastrointestinal Endoscopy, and its first task was to provide information on safe techniques for widespread use throughout the country. By gathering the opinions of many doctors and overseas researchers, we compiled information on preparation, tips, and techniques that should be followed for safe colonic stenting and published them as “Mini-Guidelines” on our website, where they can be viewed by anyone. This mini-guideline has been translated into English for international access and has been updated many times. We have also conducted many prospective and retrospective studies, including the WallFlex study, a multicenter prospective safety observational study of colorectal stents (UMIN study ID: UMIN000007953, 000011304),<sup>21)</sup> and other studies to confirm the safety of colorectal stents.

The activities as a side research group of the Japanese Society of Gastrointestinal Endoscopy ended in February 2015, after 3 years as a side research group. To sustain the research in the study group and to continue the distribution of information, it was approved as the first affiliated research group with the Japanese Society of Gastrointestinal Endoscopy, and it is still active as an

affiliated group. It still aims to educate the public about safe colorectal stenting procedures nationwide through reports on its activities.<sup>22)</sup>

To date, the WallFlex Prospective Study, Niti-S Prospective Study, CODOMO Backward-Looking Study, Jentily Prospective Study, and Naturfit Prospective Study are almost completed, the COBRA Trial is currently underway, and the COCORO study and CC-STEP study will soon begin (as of May 2023). Please refer to the website (<http://colon-stent.com/>) for details of each study.<sup>22)</sup>

### 3. Evaluation of Colonic Obstruction/Stenosis: CROSS (Table 1)

Gastric outlet obstruction scoring system (GOOSS)<sup>23)</sup> is widely used to evaluate symptoms of gastroduodenal stenosis, but there is no established method to evaluate colon obstruction.

Nagula et al. reported a scoring for the colon obstruction score,<sup>24)</sup> but it is based on a 0-15 point scale with scores ranging from 0 to 3 points for abdominal pain, abdominal distention, and frequency of bowel movements and is somewhat complicated, making it difficult to use in actual clinical practice. However, the evaluation of obstruction and stenosis was not easy to use in practice.

Without evaluation of obstruction and stenosis, it is difficult to determine the indication for colorectal stents and to evaluate them in clinical studies. Therefore, the members of the Colorectal Stent Safety Procedures Research Group, who are members of the Department of Gastroenterology and the Department of Surgery, created the basis for an evaluation method that is easy to use for both palliative and BTS (surgical) purposes and named it CROSS (Colorectal Obstruction Scoring System). CROSS was subsequently completed after incorporating the opinions of many doctors in the research group.

CROSS is a universally applicable and simple method of evaluating colorectal stenosis and obstruction and is available on the website (<http://colon-stent.com/>) (Table 1).<sup>22)</sup>

It is currently not only widely used in Japan but also addressed in European guidelines and evaluated internationally.<sup>25)</sup>

The CROSS is scored according to eating status and abdominal symptoms. For palliative treatment, the CROSS score is 0-3, and for BTS, the CROSS score is 0-1 (2), which is considered a good indication for preoperative stenosis release. The CROSS is easy to understand and to

Table 1 Colorectal Obstruction Scoring System (CROSS)

Level of oral intake	Score
Requiring continuous decompressive procedure	0
No oral intake	1
Liquid or enteral nutrient	2
Soft solids, low-residue, and full diet with symptoms of stricture <sup>†</sup>	3
Soft solids, low-residue, and full diet without symptoms of stricture <sup>†</sup>	4

<sup>†</sup> Symptoms of stricture contain abdominal pain/cramps, abdominal distension, nausea, vomiting, constipation, and diarrhea which are related to gastrointestinal transit.

evaluate the effectiveness of treatment for obstructive colorectal cancer.

### 4. Current Status of Colorectal Stents

The current indication for colon stents in Japan is malignant colorectal stenosis. The indications are rectal stenosis due to anastomotic recurrence or Schnitzler metastasis after colorectal cancer surgery, stenosis due to malignant diseases including unresectable colorectal cancer with stenosis symptoms (palliative treatment), and colorectal cancer with bowel obstruction symptoms to avoid emergency surgery (presurgical procedure BTS). Cases of very long or complicated stenosis, fistula formation, bleeding tendency, imminent rupture, or severe inflammation are not indicated.

In Japan, only malignant diseases are currently covered by the insurance, and the use of the procedure for benign stenosis is contraindicated.

Conventional emergency surgery for patients with colorectal obstruction has a high complication and mortality rate. Therefore, avoiding emergency surgery is a BTS. However, in 2014, the European Society for Gastrointestinal Endoscopy (ESGE) published a clinical guideline<sup>26)</sup> stating that BTS as standard treatment for left-sided obstructive colorectal cancer with clinical symptoms is not recommended due to the possibility of worse long-term outcome.

Subsequently, a meta-analysis of several papers reported no adverse effects of colonic stents on long-term prognosis, and the ESGE guidelines were updated in 2020, recommending BTS placement on both the right and left sides, with a particularly positive revision for the left side.<sup>25)</sup>

In Japan, the COBRA Trial (UMIN000026158), a pro-

spective, multicenter, randomized controlled trial RCT, was started in 2017 and is still ongoing.<sup>22)</sup> The trial aims to establish stronger evidence in BTS.

However, the 2022 edition of the Japanese Guidelines for the Treatment of Colorectal Cancer<sup>27)</sup> weakly recommends colonic stents for palliation of symptoms of bowel obstruction for palliative purposes but weakly recommends that they not be performed in patients eligible for chemotherapy, and they are not recommended as BTS due to the possibility of a worse long-term prognosis. However, we expect this to change in the future as evidence accumulates.

## 5. Future Prospects for Colorectal Stents

In the future, it is expected that stents suitable for benign stenosis, especially for anastomotic stenosis, will be developed.

There have already been reports on the use of stents as temporary treatment for suture failure and postoperative anastomotic stenosis,<sup>28, 29)</sup> and it is highly likely that current stents will be effective in the short term, and colonic stent options for benign stenosis will be explored in the future.

The covered stent, whose use in the colon has been limited due to its frequent migration, is also being considered for introduction mainly in BTS due to less pressure on the tumor and less invasiveness. The development of covered colonic stents with less migration is expected.

Removable gastrointestinal stents have been investigated in bariatric surgery and treatment of upper gastrointestinal anastomotic complications after esophageal surgery, and their application to the colon is also expected. However, even with such stents intended for removal, there are concerns about complications during removal and the risk of inability to remove the stent, so absorbable or biodegradable stents that do not require removal have been developed, but their weak expandability is a problem in the colon.

Drug-eluting stents used in the cardiovascular system are also being investigated in the gastrointestinal tract, particularly in the esophagus and biliary tract, but their clinical application has not yet begun. Radioactive stents have also been developed, and their introduction in combination with drug-eluting stents is expected to prevent restenosis and provide local control of malignant stenosis.

Several stent-related studies have been initiated on chemotherapy after colorectal stenting, and some have

reported the benefit and safety of preoperative chemotherapy in BTS.<sup>30)</sup>

I look forward to the accumulation of further evidence to improve the prognosis of high-risk obstructive colorectal cancer.

## Conclusion

Although colonic stents have been covered by insurance in Japan for 10 years since 2012 and are a relatively popular treatment method, complications including perforation will undoubtedly have a negative impact not only on short-term prognosis but also on long-term prognosis; thus, care should be taken to ensure safe implementation of the procedure.

The Colorectal Stent Safety Procedures Research Group has provided “Mini-Guidelines” for safe procedures on its website (<http://colon-stent.com/>), which should be consulted for reference.

**Conflicts of interest:** Y.S. (Yoshihisa Saida) received research grants from Boston Scientific Japan, Co., Ltd., Century Medical, Inc., and JAPAN LIFELINE, Co., Ltd.

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## Yoshihisa Saida, Professor Curriculum Vitae



1980	Graduated from Azabu Gakuen High School
1986	Graduated from the School of Medicine, Toho University - Passed the 80th National Medical Examination
1987	Enrolled in the Doctoral Program, Graduate School of Medicine, Toho University - Major: Surgical Science, Surgical Department
1992	Obtained credits in the Doctoral Program, Graduate School of Medicine, Toho University - Research Assistant, Surgical Department, School of Medicine, Toho University - Training at Akita Red Cross Hospital Endoscopy Unit under Dr. Susumu Kudo
1993	Assistant Professor, Surgical Department, School of Medicine, Toho University
1998	Studied abroad at Cleveland Clinic Florida, Department of Colorectal Surgery, USA (under Dr. SD Wexner)
2000	Lecturer, Surgical Department, School of Medicine, Toho University
2008	Associate Professor, Surgical Department, School of Medicine, Toho University
2011	Received the Toho Medical Association Award (No. 81)
2013	Professor, General and Gastrointestinal Surgery, Surgical Department, School of Medicine, Toho University
2015	Director of Medical Safety Management Office of Toho University Ohashi Medical Center
2023	Chief Professor, Department of Surgery, Toho University Ohashi Medical Center

### Organizing conference

- 1) 19th Laparoscopic Colectomy Workshop, January 22, 2005
- 2) 25th Tokyo Colon Seminar, Tokyo Grand Hotel, September 22, 2006
- 3) 35th Colorectal Disease Surgical Therapy Research Group, Hotel Nikko Fukuoka, January 20, 2011
- 4) 31st Johnan Digestive Disease Symposium, Meguro Gajoen, Tokyo, September 9, 2011
- 5) 1st Colonic Stent Safety Techniques Research Meeting, Grand Prince Hotel New Takanawa, Tokyo, May 14, 2012
- 6) 6th NOTES Research Meeting, Pacifico Yokohama, December
- 7) 5th Johnan Digestive Endoscopy Surgery Research Meeting, Shibuya, February 20, 2015
- 8) 63rd International Surgical Society Japan Branch Meeting, Asakusa View Hotel, June 17, 2017
- 9) 17th Japan-China-Korea Colorectal Cancer Symposium, Toho University Ohashi Hospital, September 19-20, 2020
- 10) 57th Japanese Emergency Abdominal Medicine

Association Annual Meeting, Urban Center Hotel → Web, March 11-12, 2021

11) 40th Japan Gastrointestinal Endoscopy Society Kanto Seminar, Pacifico Yokohama Annex Hall, January 16, 2022

12) KSOA, Keio Plaza Hotel, February 26, 2022

This is the summary of the career and professional activities of the individual as of the specified date.