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**Name of Journal:** *World Journal of Clinical Oncology*

**Manuscript NO:** 79955

**Manuscript Type:** MINIREVIEWS

**Colonic <sup>2</sup>stent as bridge to surgery for acute left-sided malignant colonic obstruction, review of updated literature after 2020**

SEMS as bridge to surgery

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### **Abstract**

The 8%-29% of colorectal cancers are obstructive. <sup>2</sup>The use of “stent as bridge to surgery” is one of <sup>25</sup>the most debated topics in <sup>1</sup>obstructive left-sided colorectal cancer management. <sup>26</sup>The endoscopic placement of a self-expanding metallic stent (SEMS) as bridge to surgery (BTS) could turn an emergency surgery to an elective one, increasing the number of <sup>2</sup>primary anastomosis instead of stoma and facilitating the laparoscopic approach instead of open one. However, during the last years, the possible risk of perforations and microperforations facilitating cancer spread related to the use of SEMS as BTS has been highlighted. Therefore, despite the useful short-term outcomes related to BTS, the recent literature focus on <sup>2</sup>long-term outcomes investigating the <sup>2</sup>disease-free survival, the recurrence rate and the overall survival. Due to discordant data, international guidelines are still conflicting and the debate is still open. There is not agreement about using SEMS as BTS as gold standard.

**Key Words:** colorectal cancer obstruction; anastomosis; laparoscopy; recurrence rate; overall survival; guidelines

Binetti M, Lauro A, Tonini V. Colonic <sup>2</sup>stent as bridge to surgery for acute left-sided malignant colonic obstruction, review of updated literature after 2020. *World J Clin Oncol* 2022; In press

**Core Tip:** The aim of this review is to collect and to analyse <sup>1</sup>the most important articles about SEMS as BTS published after the 2020. Both the <sup>21</sup>short-term and long-term outcomes were analysed, focusing on the possible role of stent-related microperforations in worsening the disease-free and the overall survival. So, what do we know about SEMS as BTS in 2022? Despite the growing number of studies published in the last years, because of conflicting data, the use of SEMS as BTS is not considered as the gold standard in left-sided colorectal cancer obstruction. The publication of new meta-analysis, randomised studies and updated reviews should help to collect more and more specific and correct data, in order to draw up new international guidelines and a shared treatment flow-chart.

## INTRODUCTION

From 8 to 29% of colorectal cancers (CRC) are initially characterised by obstruction <sup>[1]</sup>. In the left-sided colonic obstruction's management there are two different options: emergency surgery (ES) and stent placement as bridge to surgery (BTS).

Historically, an emergent surgery was first considered for distal malignant obstruction <sup>[2]</sup>. In this context, three different surgical options could be considered <sup>[3]</sup>:

- three-stage management, in which the first intervention is a proximal stoma formation, followed by colonic resection and stoma reversal;
- two-stage management (Hartmann's intervention);
- one-stage management, that consists in resection and primary anastomosis.

About 20 years ago the SEMS placement was first used to decompress neoplastic stenosis <sup>[4]</sup>.

The ES is often conducted with open approach, because a distended bowel may hamper laparoscopy <sup>[5]</sup>. In addition to that, ES frequently concludes with stoma

formation that negatively impacts on patients' quality of life [6]. This is why the interest in BTS has become increasingly important.

In fact, in the past authors were mainly focused on short-term outcomes of using SEMS as BTS, such as anastomosis and stoma rate, laparoscopic and open approach and post-operative hospital stay.

On the other hand, the recent BTS literature is focused on long-term outcomes, such as disease-free survival (DFS), overall survival (OS) and progression free survival (PFS). This was made possible because several years have already passed since it started using SEMS as BTS, therefore a lot of data have been collected.

However, despite a growing number of articles have been published about CRC obstruction, the use of SEMS as bridge to surgery is still debated. No uniform international guidelines have been published yet. This is especially because of the possible role of microperforations worsening the long-term outcomes hypothesized by some authors.

The purpose of this review is to collect the latest 2-3 years' updates about SEMS as BTS use. In one of the more updated systematic review and meta-analysis [7] only two studies published after the 2020 have been included: Arezzo *et al* multicentric study [8] and Elwan *et al* single center study [9].

Both the international guidelines and the short/Long-term outcomes focusing on the new data published after the 2020 have been analysed (the "update" part of each single chapter).

## **GUIDELINES**

While in left-sided colonic obstructions, colonic stenting in a palliative setting is commonly accepted, the best treatment in curative setting is still debated. There is still not agreement about which is the best choice between SEMS placement as bridge to surgery or upfront ES.

Some of the most important published American Guidelines considered the stent insertion to solve the colonic obstruction as the first choice since 2010 [10] [11], while some

others consider both possibilities to be equally valid <sup>[12]</sup>. In general, the attitude of European Guidelines is more moderate, no guidelines consider the insertion of a stent as the only option <sup>[13]</sup> <sup>[14]</sup> <sup>[15]</sup>. Both approaches are also considered in the <sup>2</sup> World Society of Emergency Surgery (WSES) <sup>[16]</sup>.

In Webster work the high-quality international recommendations published between 2010 and 2019 have been analysed, only two studies considered the use of a stent as the gold standard <sup>[17]</sup>.

In this context, another discussed point is the “time to elective surgery” which is the time between stent insertion and elective surgery <sup>[18]</sup> <sup>[19]</sup>. Theoretically a delayed interval between SEMS placement and definitive surgery could allow better recovery and improve nutritional status, but it could be burdened by a high rate of local tumour infiltration and fibrosis <sup>[20]</sup>.

Not all guidelines indicate the ideal number of days between stent positioning and surgery. However, in the <sup>1</sup> American Society for Gastrointestinal Endoscopy (ASGE) about 6 days of time in elective surgery is considered as the best interval, after the sixth day the risk of perforation is increased <sup>[10]</sup>; while in the Eastern Association for the Surgery of Trauma an interval of 7 days is considered <sup>[21]</sup>.

#### Update:

Recently ESGE guidelines-Update 2020 has been published <sup>[22]</sup>. They recommend as strong recommendation and high quality of evidence stenting as BTS as an option in patient with potentially curable left-sided obstruction and it must represent a shared decision-making process. This main recommendation is different from 2014 ESGE guidelines, according to which the stent placement could be considered as an alternative only for in <sup>1</sup> patients with ASA  $\geq$  III and/or age > 70 years <sup>[23]</sup>. However both in 2014 and 2020 editions, the most important recommendation to use SEMS as BTS should be reserved for patients without sign of perforation (always strong recommendation) <sup>[22]</sup>.

In the recent ESGE guidelines a time interval of 2 wk until surgery is considered (weak recommendation, low quality evidence) <sup>[22]</sup>.

## **ENDOSCOPIC CONSIDERATIONS**

For patients suspected of having a neoplastic left-sided colonic obstruction, an urgent colonoscopy is usually performed [24]. It may be useful to identify other colonic lesions and to stage cancer with more accuracy [25].

The SEMS placement remains a challenging procedure. The technical success (TS) is defined as the endoscopic correct stent placement, while the clinical success (CS) is the resolution of the obstruction [26].

SEMS can be covered and uncovered. The uncovered ones can be divided into through-the-scope (TTS) and non-TTS [27]. The TTS SEMS is inserted through a guidewire. The diameter of the SEMS is about 18-22 mm [24]. In the majority of studies [24,25] the Wall-Flex enteral Colonic stent and the Niti-S enteral colonic stent was used.

The SEMS placement as BTS has been extensively studied for left-sided colonic obstruction, while limited data have been collected for the right-sided obstruction [28].

Despite severe endoscopic adverse events complicates less than <5% of the procedure [10], early and late complications can sometimes occur [29]. Some early complications (within 30 days) are migration, perforation and bleeding, while some late complications (after 30 days) are a late obstruction, migration and perforation.

The covered SEMS have a higher migration rate and lower obstruction rate; while uncovered SEMS have less migration rate [27].

Only few studies investigates the predictors of technical failure, but it seems that a stenosis > 8 cm may be associated with higher rate of technical failure [30].

### **Update:**

A central part of updated ESGE guideline is dedicated to endoscopic technical considerations. The colonic stenting should be performed directly or supervised by a medical figure both with colonoscopy and fluoroscopic expertise [22].

In 2021 a multicenter prospective cohort study affirmed that the WallFlex stent is the most globally used [31].



Some authors tried to compare the feasibility and safety of SEMS as BTS use based on the grade of colonic neoplastic obstruction, classified 0 to 2 by CROSS classification (Colorectal Obstruction Scoring System). No differences were found both in term of safety and short-term outcomes in 0, 1 and 2 patients [26].

In some other studies an effort to standardize the SEMS placement has been made. It has likely contributed to excellent short-term outcomes, technical success and low perforation rate [31].

According to the most recent literature, the colonic stenting should be performed by endoscopists who demonstrate a good expertise as it represent a challenging procedure and in some articles a minimum number of procedures is indicated [32]. If stenting expertise is not available, decompressing stoma as a bridge to elective surgery should be considered [22].

Some authors showed how a delay of surgery bring to a significantly higher recurrence rate [33].

## **LABORATORY AND ANATOMOPATHOLOGICAL CONSIDERATIONS**

In the last 2-3 years, there has also been a growing interest about the possible association between SEMS as BTS using and worsening the long-term oncological outcome, such as perineural invasion (PNI), vascular and lymphatic invasion (LVI) [34].

The presence of PNI seems to decrease long-term survival [34]. The PNI negative impact recurrence and survival in colorectal cancers. In some studies, there was no difference in perineural invasion between ES group than in patients using SEMS as BTS [35].

The tumour stage and vascular invasion were found to be independent risk factor for PNI in patients with obstructing colonic stenting [36].

According to Wang *et al* [37] the PNI may be associated with obstruction, but not with stent insertion.

In some other articles, laboratory elements, such as circulating cell-free DNA (cfDNA) and circulating tumour DNA (ctDNA). During endoscopic procedure of colonic stenting the tumour manipulation could increase plasma rate of ctDNA and cfDNA [38]:

-ctDNA, tumour-derived DNA which indicates apoptotic or necrotic cells and it could contain gene mutation;

-cfDNA, which indicates cellular damage, derived by apoptotic or necrotic cells.

Among some authors the stent-induced neoplastic manipulation may lead malignant cells to local and distant invasion, worsening long-term outcomes [38].

In Brohholm *et al* study [39] a gene expression analysis was performed. The NanoString nCounter PanCancer IO 360 gene expression was used.

They observed that SEMS as BTS induces changes in gene expression in neoplastic microenvironment, related to progression in colorectal cancer and they may induce more aggressive phenotype. These changes seemed to be caused by mechanical pressure of the cancer and following inflammation of tissue. Six genes promoting angiogenesis were significantly upregulated. Tumour-promoting inflammation gene expression, such as IL-6 were involved. Some authors promote for the future the after-stenting use of anti-inflammatory drugs [39].

### **SHORT-TERM OUTCOMES**

In almost all the studies post-operative complications are analysed. Postoperative outcomes such as 30-day or 60-day mortality, anastomosis rate and laparoscopic rate are often considered.

The most important advantages of using a SEMS as BTS is transforming an urgent surgery to an elective one and it makes possible to maintain bowel continuity, avoiding the stoma creation [40] [14]. In fact, the elective setting allows to make a primary anastomosis more safely than in an urgent or emergent setting. Wang *et al* [41] in their meta-analysis also revealed that the use of colonic stenting could not increase the risk of anastomotic leakage incidence compared with emergency surgery.

Using a stent as BTS the surgical approach could be different too. Donlon *et al* in 2019 [42] reported a 78% rate of laparoscopic approach; but in the same year Boland *et al* reported only three studies (41%) in which the laparoscopic approach was successfully completed after the stent insertion [43].



According to De Ceglie *et al* [44] postsurgical complications like infections were less frequent in patients undergoing urgent surgery. In the same article hospitalization rate was similar in ES and BTS group. On the other hand, Consolo *et al* [45] obtained a different result, demonstrating a reduced hospital stay in BTS group.

In the Arezzo's high-quality meta-analysis [46] published in 2017 a significant lower rate of temporary and definitive stomas has been highlighted (33.9% vs 51.4%,  $p < 0.001$  and 22.2% vs 35.2%,  $P = 0.003$ ), while no difference in the 60-day mortality has been observed.

Only a few studies analyse the cost-effectiveness between using SEMS as BTS and emergency surgery [10]. In 2017 Allievi *et al* concluded considering that more data about cost-effectiveness are needed [47] [48].

#### Update:

The Cirocchi *et al* updated review also demonstrates that the use of SEMS is associated with low hospital mortality, higher rate of primary anastomosis and decreased stoma's rate [7] [49]. For this reasons, after colonic stenting as bridge to surgery patients often have a better quality of life, compared with immediate resection [50].

Better short-term outcomes of BTS group were confirmed in Spannenburg *et al* study: higher primary anastomosis, lower 30-days mortality rate, lower overall complications rate, shorter hospital stay are well reported [51].

In June 2022 a study that compare BTS to diverting stoma (DS) was published [52]. Seven studies were included and 1358 patient have been recruited, 646 in the first group and 712 in the second one. A lower Clavien- Dindo I/II complication rate was highlighted in BTS group (8.68% vs 16.85%,  $P = 0.004$ ), while the III-IV grade were similar (7.69% vs 8.79%,  $P = 0.37$ ). There are no differences also in short-term mortality, 3-year OS and permanent stoma rate.

#### **LONG-TERM OUTCOMES**

Even though SEMS as BTS short-term outcomes have been quite established, the long-term ones still remain uncertain. In the last few years the literature about using SEMS as

BTS focused on oncological outcomes: the “disease free survival” (DFS) is the time between surgery and new cancer signs discovery, while the “overall survival” (OS) is the time between surgery to death.

In the early 2000s Kim JS *et al* [53] suspected that SEMS insertion could negatively impact on oncological outcome.

Some authors tried to explain the mechanism. Some of them sustain that SEMS manipulation could cause a microperforation that may lead to peritoneal carcinomatosis; some other sustain that tumour’s compression is cause of hematogenous diffusion [54].

Marutchalam *et al* (2007) tried to expose the biological basis and they found an increased expression of cytokeratin 20mRNA (marker of tumour cells) in patients after stent insertion [55].

In Amelung *et al*’s research no significant recurrence rate, 3-year and 5-year OS have been identified [56].

Neither in Pinto *et al* analysis differences in tumor recurrence, recurrence-free survival and OS between ES and BTS groups have been highlighted [57]. The same result was also obtained by Matsuda *et al* [6] and Gibor *et al* [58]. In none of these studies differences have been highlighted in term of long-term outcomes.

These results were strongly supported by two of the main articles in SEMS as BTS’s use literature. The first one published in 2017 by Arezzo *et al* [46] The second one published a year later by Amelung *et al* [56]. The first one is a multicentric prospective randomized trial, controlled by European Association for Endoscopic Surgery. The second one is a meta-analysis in which no differences between the two groups in terms of 3-year and 5-year DFS and neither in 3-year and 5-year OS were confirmed.

However, only a few studies showed differences in long-term oncological outcomes. In 2019 Foo *et al* [54] presented a higher BTS distant recurrence rate (25,3% vs 15,0%  $P = 0,046$ ) and BTS overall recurrence rate (37,0% vs 25,9%  $P = 0,049$ ).

A 5-years follow-up was usually described in all studies, whereas Verstockt *et al* [59] study presented a 1-year, 2-year, 3-year, 5-year and 10-year OS for all stage patients.

In recent literature, <sup>1</sup>the cost-effectiveness terms have also been considered <sup>[60]</sup>. The ASGE guidelines considered <sup>1</sup>the use of stent as BTS more cost-effectiveness than emergency surgery <sup>[10]</sup>. However, only a few data about this topic are available <sup>[47]</sup>.

#### Update:

According to Cirocchi *et al* point of view <sup>[7]</sup>, however, overall recurrence and 3-year OS rate is similar both in ES and BTS group. In another recent study <sup>8</sup>3-year and 5-year DFS and OS were no different, despite a higher <sup>15</sup>number of lymph nodes were harvested in BTS group than ES one <sup>[51]</sup>.

In ESCO trial <sup>[8]</sup> neither OS and DFS differ in BTS and ES groups in a 36 mo follow-up study. However, as it has been reported in this paper, one randomised trial showed an <sup>9</sup>increased rate of malignant recurrence <sup>[61]</sup>. All these contradictory data needed a well conducted prospective, randomized trial. ESCO's inclusion criteria was a colonic cancer sided <sup>2</sup>between the splenic flexure and 15 cm from the anal margin, diagnosed by computed tomography (CT). Similar long-term oncological outcomes were observed. A significant time to progression (TTP) has been observed in descending colon, maybe because it is <sup>9</sup>the easiest endoscopic procedure (compared with flexure's and sigmoid's ones). No differences in term of TTP, DFS and OS were observed considering different age, sex, BMI and ASA score <sup>[8]</sup>.

In February 2022 a multicentric study <sup>[62]</sup> including 564 patients was published. The results showed the "non inferiority" of BTS *vs* ES in terms of OS ( $P = 0.012$ ). However, in another a recent study <sup>23</sup><sup>[63]</sup> considering only II and III stages, a higher frequency of <sup>13</sup>distant metastatic recurrence has been shown in BTS group than in the surgery alone group (13.3% *vs* 30.4%  $P = 0.035$ ).

In 2022 Yamada *et al* <sup>[64]</sup> tried to explain how tumour manipulation may worsen the prognoses in CRC patients after SEMS insertion. 7 days after stent insertion the cfDNA related to ctDNA and serum lactate dehydrogenase level was significantly higher. This means that SEMS injures cancer and spread <sup>19</sup>DAMPs (damage-associated molecular patterns) released by necrotic cells, that induce sterile inflammation. In conclusion, SEMS placement seems to induce unfavorable genes circulation which result in

microenvironment associated with cancer progression. According to this last study angiogenesis too is induced by cancer manipulation, due to *via* miR-9 downregulation. According to some authors, using a standardized and reproducible SEMS insertion method is basic to reduce the perforation rate [31].

Otherwise, Veld JV *et al* [65] differently from the other studies tried to compare SEMS placement as BTS not with ES, but with decompressing stoma (DS) bridge to resection. The authors conclude that the two techniques have similar intermediate-term oncological outcome [65].

A comprehensive literature research compares SEMS as BTS long-term outcomes both with decompressing stoma as BTS and emergency surgery. Authors found that colonic stent and decompressing stoma may lead to better 5-year OS and DFS than emergency surgery. Otherwise, the decompressing stoma may bring to better 5-year OS than BTS strategy. According to these data, in Tan *et al* study decompressing stoma is considered the best choice for left-sided colonic obstruction [66].

## CONCLUSION

In 2022 the BTS strategy is considered a safe strategy and many studies have demonstrated better short-term outcomes than emergency surgery. Using a stent as BTS it is possible to obtain a more elevated rate of primary anastomosis *vs* stoma rate, laparoscopic approach *vs* open approach and a shorter post-operative stay.

The endoscopic stent placement is not a simple procedure and it requires specific skills[57]. The most recent ESGE guidelines recommend that colonic stenting should be performed by an operator with competence both in colonoscopy and fluoroscopic technique [22]. The stent insertion could be followed by early (< 30 days) or late complication (> 30 days), such as migration, perforation, bleeding and obstruction. However severe adverse events only occur in less than < 5% of procedures [10]. Stents could be covered and uncovered, covered stents have a lower obstruction rate[27].

The use of a stent as BTS makes an emergency surgery in elective one. The role of BTS has been analysed both in term of short-term and long-term outcomes.



The short-term outcomes are represented by higher laparoscopic approaches *vs open surgery* [42,43], higher rate of anastomosis *vs stoma rate* [41,46,67], 30-days after surgery complications and hospital stay [44]. The long-term outcomes include the disease-free survival, the progression-free survival and overall-survival.

Quite all the articles about SEMs as BTS starting from late 90s to about the first ten years of 2000 focused on the short-term outcomes. After stent placement, in elective setting, surgery can be completed with laparoscopic approach. In addition to that, a higher rate of primary anastomosis and lower rate of temporary or definitive stoma rates improve patients' quality of life [46].

Long-term outcomes are much more discussed than short-term ones. At the beginning both gastroenterologists and surgeons had a great enthusiasm in the excellent short-term results due the use of SEMs as BTS, but soon many conflicting data about a worsening of OS and DFS due to BTS stopped the initial enthusiasm [68]. Although there are many hypotheses, the exact biological mechanism has not been described. The use of a stent as bridge to surgery seems to be burdened by higher rate of perforations and microperforations resulting in cancer spreading [64].

Most articles only have 1-year to 3 or 5-year follow-up. Some rare cases have longer periods [59].

Because of all these contrasting data, international guidelines do not agree about considering the use of a stent as bridge to surgery as the gold standard. The American Guidelines suggest the use of a stent as bridge to surgery like the gold standard [10], while in the European Guidelines both suggest the surgical resection and the use of SEMs as BTS like possible treatments in patients with left-sided obstructing colonic cancer [22].

In this review, the most relevant articles about BTS published in the last two or three years have been reported. They especially focus on:

-long term outcomes, because of the increasing number of studies with a long follow-up are available [7,8,51,61-63];

-perforations and microperforations stents' related mechanism [64];

-national and international Guidelines <sup>[22]</sup>.

However, despite the large number of articles on BTS subject, almost all authors agree on the lack of randomised controlled studies (RCTs) <sup>[51]</sup>.

Some of the most important topic for further searches are the national and international agreement in therapeutic algorithm of treatment for patients with left-sided obstructive colonic cancer and more detailed cost-benefit analysis.

Furthermore, considering literature after the 2020, it could be interesting to prepare a specific study to understand COVID's pandemic impact on the use of SEMS as BTS.



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