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# Radiological Position and Clinical Outcome of Preoperative Self-Expanding Metal Stents for Obstructing Colonic Cancer: A Single-Centre Cohort Study

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## Key Words

Self-expanding metal stent · Colonic obstruction · Radiological position · Non-elective surgery and complications

## Abstract

**Background:** Preoperative placement of self-expanding metal stents is used in patients with obstructing colon carcinoma to prevent an emergency operation. The perceived benefits remain the subject of discussion. The data-evaluating function and complications of stents in relation to radiological position are limited. **Methods:** Patients receiving a preoperative stent between 2003 and 2013 were retrospectively analysed in this single-centre study. We analysed radiological deployment, eccentricity and angulation of the stent directly after placement. Endpoints were clinical success (resolution of ileus), complications needing non-elective surgery (blow-out, perforation, persistent ileus, dislocation) and other complications (bleeding, infiltrate). Associations were corrected for other potential influences. **Results:** Eighty-two patients were included. In 22 patients (26.8%), the stent was placed proximal to the splenic flexure. Clinical success was present in 85.4%. Twenty-two patients (26.8%) had a complication of which 16 (19.5%) underwent urgent surgery for insufficient functioning of the stent; there were

two blow-outs (2.4%). A more symmetrically placed stent was associated with clinical success ( $p = 0.042$ ), with large overlap between groups. However, no association was found with non-elective surgery or complications. Also, angulation and deployment were unassociated with these outcomes. **Conclusions:** We could not establish an association between symmetry, angulation or deployment of self-expandable colonic stents with clinical success and complications.

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## Introduction

In the early 1990s, placement of a self-expanding metal stent (which we will refer to as ‘stenting’ in this article) was introduced to restore luminal patency in patients with an acute colorectal obstruction. Since then, preoperative stenting has been gradually implemented for patients with malignant colorectal obstruction in order to avoid emergency surgery.

Emergency surgery has a higher risk of mortality, stoma creation, suboptimal oncological resection and cicatricial hernia, especially in elderly patients [1–3]. However, randomised controlled trials have not shown these perceived benefits, although operator-dependent factors (low volume) have not been ruled out [4–6].

Significant complications of stent placement include perforation and bleeding and overall complication rates have been reported in approximately 4–40% of cases [6–14]. Of particular concern is perforation of the tumor, since it could lead to peritoneal tumor spill and dissemination of tumor cells [6, 10, 13, 15–17].

Proximal colon stenting, obstruction from an extra-colonic malignancy, the presence of peritonitis carcinomatosa and operator in-experience with cannulation and stent deployment techniques (no ERCP experience) are negative factors on the outcome of colonic stent placement [10, 18].

Many variables may influence the success of stent placement, for instance, the radiological position of the stent, localisation of the stenosis or stent length. Despite numerous reports, there are virtually no studies that tried to assess these factors. The aim of this study was to determine the radiological factors that are associated with clinical outcome.

## Material and Methods

According to a local surgical protocol in the Deventer Hospital, every patient with a complete colonic obstruction undergoes an attempt to preoperative stent placement. The protocol is operational since 1999. Excluded are patients with overt peritonitis and perforation, patients with tumors that are palpable on rectal examination, and patients with complex obstructions at multiple sites. Obstruction should be confirmed by plain abdominal X-ray (1999–2003) or computed tomographic (CT) scan (after 2003). For inclusion in our study, radiological pictures from the stent procedure had to be present in the picture archiving and communication system (PACS).

This study focuses only on stents placed as bridge to surgery. Excluded from the analysis were all patients treated for palliation because of problematic follow-up data and often unspecified cause of death in a terminal situation at home, for instance, perforation as cause of death in a terminal setting at home could easily be missed.

All patients were prepared by fluid resuscitation, administration of two enemas and active nasogastric suction. All stents were placed on an emergency basis, that is, within 12 h.

Stents were placed through the endoscope under radiological guidance by 4 gastroenterologists. Either the Wallstent™, Wallflex™ (Boston Scientific, One Boston Scientific Place, Natick, Mass., USA) or the Evolution™ (Cook, Europe Shared Service Centre, O'Halloran Road, National Technology Park, Limerick, Ireland) stent were used. No covered stents were used. Prophylactic antibiotics were not administered. Stricture dilatation either before or after stent placement was not performed.

The following data were prospectively registered: age, gender, date of stent placement, endoscopist, site of obstruction, stent brand and functioning of the stent after 24 h (clinical success).

The following outcome parameters were used: (1) clinical success, defined by the production of at least moderate amounts of feces after 24 h with clinical resolution of ileus. The production of

feces after 24 h was verified from the descriptions of the treating physician at follow-up; (2) complications needing surgery within 21 days after stent placement. A period of three weeks was chosen, because in our centre elective surgery after stent placement takes place within a maximum of three weeks (median 2 weeks). Non-elective surgery is actually a failure of intent, as the goal of stenting is to avoid this to happen. Complications not needing surgery, for instance, asymptomatic dislocation or self-limiting bleeding, were not used as an endpoint.

All stents were placed under fluoroscopic guidance, taking care that X-ray direction was most perpendicular to the distal end of the stent and the incurvation of the stenosis was positioned in the image plane. As a result, projection artifacts were minimised.

The fluoroscopy images from PACS were scrutinised by author EB to calculate the radiological parameters. In addition, a random sample of 25 patients was double-checked by author R.D.

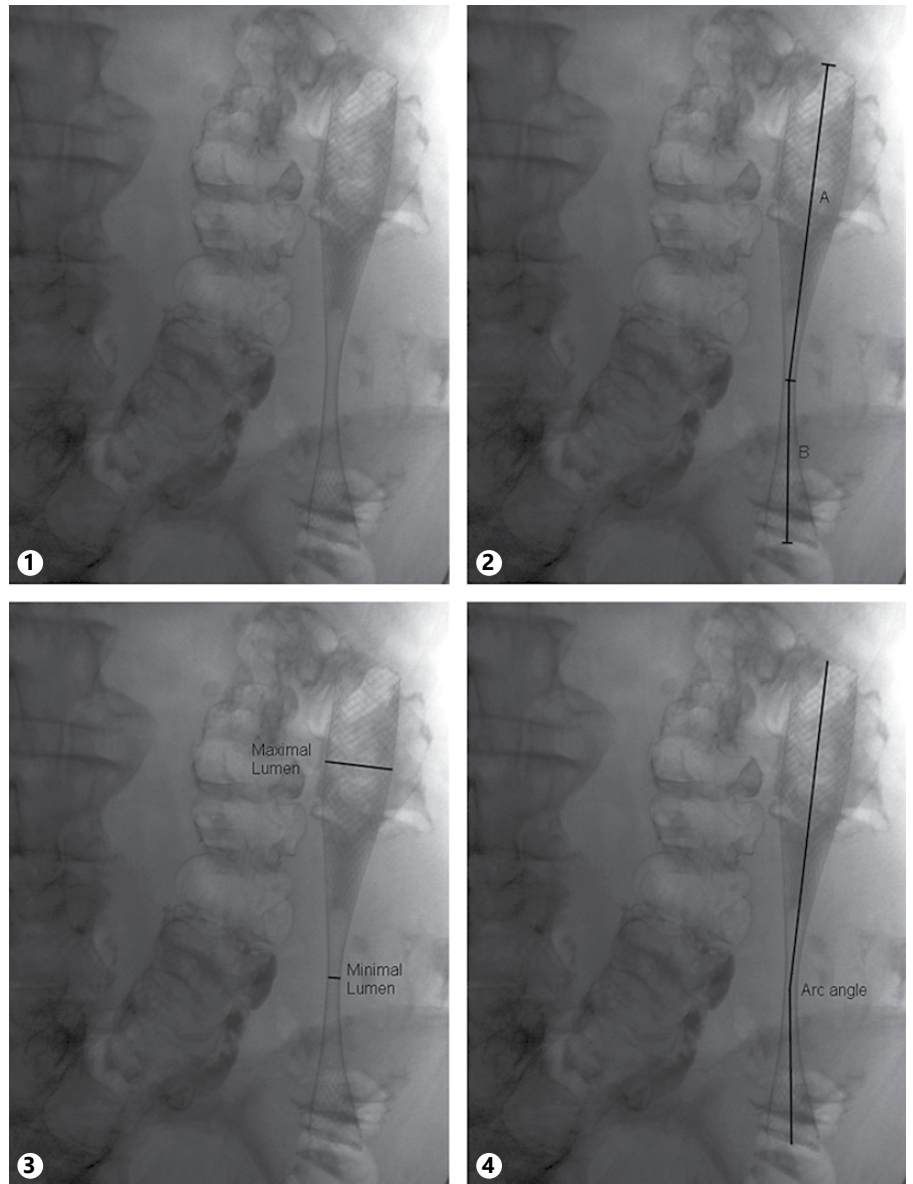
The following radiological parameters were used (fig. 1): (1) distance from the proximal margin of the stent to the point of maximum impression by the stenosis, divided by the total length (relative distance to impression, RDI). It should be noticed that a large RDI implies that the greater part of the stent has been deployed at the cecal side; (2) eccentricity: the relative distance of the impression from the centre of the stent. This is calculated by  $RDI - 0.5$  and taking the absolute value of the result. For instance, eccentricity is both 0.3 if the  $RDI = 0.8$  (meaning a proximal position of the stent) or if the  $RDI = 0.2$  (meaning a distal position of the stent). If  $RDI = 0.5$  the eccentricity is 0; (3) minimal luminal diameter: this is the luminal diameter at the point of maximum impression by the stenosis; (4) stent angle. This is the angle between the axis of the proximal and the distal end of the stent. The result was subtracted from 180°, so that a stent in a straight position had an angle of 0 degrees.

All analyses were done using IBM SPSS Statistics version 21.0. Cross tabulations were used with  $\chi^2$  statistics and Fisher's exact test for nominal (usually binary) and ordinal variables. Associations between binary outcomes and normally distributed variables such as the radiological parameters were investigated using the Student t-test. Associations between binary outcomes and non-normally distributed variables were investigated using the Mann-Whitney U test. Binary logistic regression analysis was used to assess multivariate relationships. All p values are two-sided and considered significant when less than 0.05.

## Results

From 18th July 2003 until 6th November 2013, preoperative stent placement was attempted in 94 patients with a first presentation of obstructing primary colorectal carcinoma.

Two patients from other hospitals were lost to follow-up. In 3 patients, radiological images had not been made during the procedure. From the remaining 89 patients, preoperative stent placement was successful in 82 patients (technical success rate of 92%). The 7 technical failed stent placements were in all cases caused by the inability to pass the stricture with a guide wire. These 7 patients were all



**Fig. 1.** Radiological measurements. **1** Fluoroscopy after placement of a stent in a stenosis in the proximal colon descendens. **2** Relative distance to impression (RDI) =  $A/A + B$ . **3** Minimal luminal diameter. **4** Stent angle (SA) =  $180 - \text{arc angle}$ .

**Table 1.** Localization of the tumour

	n	%
Proximal rectum	2	2.4
Sigmoid	43	52.4
Descending colon	9	11.0
Splenic flexure	6	7.3
Transverse colon	8	9.8
Hepatic flexure	4	4.9
Ascending colon	10	12.2
Total	82	100.0

subsequently operated upon in an emergency setting. The 82 patients with successful stent placement were included in our current analysis. There were 41 females (50%) and the mean age at the time of stent placement was 71.8 (range 34.7–92.3 years). In 45 patients (55%) the stent was placed in the rectum or sigmoid. The locations of the obstructions are given in table 1.

#### Clinical Success

Clinical success after successful stenting was achieved in 70 patients (85.4%). Sixteen patients (19.5%) underwent urgent surgery. Twenty-two patients (26.8%) had a

**Table 2.** Complications and urgent surgery

Complications	n	%	Urgent surgery	%
No	60	73.2	66	80.5
Blow-out (perforations)	2	2.4	2	2.4
Persistent ileus and bleeding	2	2.4	2	2.4
Persistent/recurrent ileus	11	13.4	11	13.4
Dislocation – surgery	1	1.2	1	1.2
Dislocation – restenting	1	1.2	0	0
Inflammatory infiltrate	5	6.1	0	0

**Table 3.** Radiological parameters and their correlations

	RDI	Eccentricity	Smallest lumen	Stent angle
True dislocation	0.443	0.747	0.747	0.699
Clinical success	0.042	0.581	0.495	0.124
Complications needing urgent surgery	0.287	0.234	0.801	0.225
Infiltrate during surgery	0.424	0.139	0.238	0.866

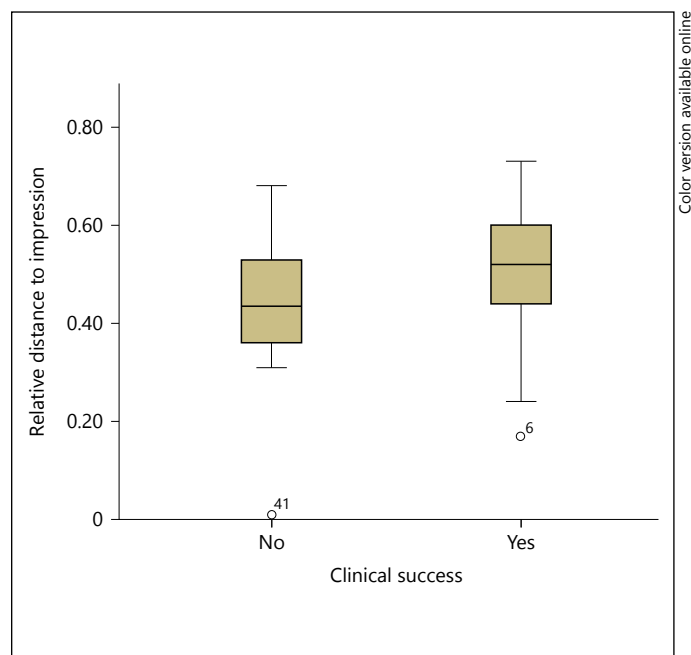
Radiological parameters and their correlations with clinical outcome (expressed in p values). Significance levels are two-tailed. RDI = Relative distance to impression. Notice that only RDI has a significant correlation with clinical success. However, given the large overlap as seen in figure 2, this might be a coincidence.

complication. The complications and reasons for urgent surgery are listed in table 2. No significant differences were found in clinical success and complications between the 4 performing endoscopists. Among the reasons for urgent surgery, insufficient functioning of the stent was always present. The most frequent non-surgical complication was an inflammatory infiltrate around the tumor.

### Stents

A Wallstent™ was inserted in 52 patients (63.4%), a Wallflex™ in 14 patients (17.1%) and an Evolution™ stent in 16 patients (19.5%). The different stents were not independently correlated to negative outcomes ( $p = 0.411$  for clinical success and  $p = 0.128$  for complications needing urgent surgery).

Different stent lengths were used, usually 60 mm ( $n = 59$ ), occasionally 80 mm ( $n = 3$ ), 90 mm ( $n = 10$ ) or 120 mm ( $n = 2$ ). Data about stent length could not be retrieved in the endoscopy report in 8 cases. In the remaining 74 patients, there were no significant associations with the insertion of a stent of 60 mm length as opposed



**Fig. 2.** Relative distance to impression and clinical success. Boxplot showing the distance from proximal stent margin to point of maximum impression by the tumor, divided by the total stent length (relative distance to impression, RDI), in the groups without and with clinical success. Although the means differ significantly ( $p = 0.042$ ), there is a large overlap and even patients with very asymmetrically placed stents such as case number 6 in the boxplot may do well.

to longer stents, clinical success ( $p = 1.00$ , OR 1.33, 95% CI 0.26–6.82) and complications needing urgent surgery ( $p = 0.28$ , OR 0.23, 95% CI 0.03–1.90).

Five patients received a second stent for insufficient bridging of the stenosis during the procedure, clinical malfunctioning or for symptomatic dislocation. All patients receiving two stents had less clinical success rate (40.0 vs. 88.3%,  $p = 0.021$ , OR 0.09, 95% CI 0.01–0.60), but not significantly more urgent surgery (40.0 vs. 18.2%,  $p = 0.25$ , OR 3.00, 95% CI 0.46–19.67).

### Radiological Position

With regard to the radiological parameters of the stent position immediately after the procedure, we found none of the radiological parameters to be associated with clinical outcome parameters (table 3), with one exception: the RDI in the group with clinical success was significantly higher than in the group without clinical success (0.51 vs. 0.43,  $p = 0.042$ ), although there was a large overlap found between the groups with or without clinical success (fig. 2). Even stents with little or no expansion or with

large angulations did well. Binary logistic regression analyses showed that in a model predicting the probability of clinical success and complications needing urgent surgery, no radiological parameters were significantly associated.

### Complications

All five dislocations occurred in patients with a tumor in the rectosigmoid ( $p = 0.058$ , OR 0.51, 95% CI 0.40–0.64). There were no associations found between a lesion in the rectosigmoid and with clinical success ( $p = 0.713$ , OR 1.26, 95% CI 0.40–0.64), complications needing surgery ( $p = 0.495$ , OR 1.48, 95% CI 0.48–4.53) or the presence of an inflammatory infiltrate during laparotomy ( $p = 1.00$ , OR 1.25, 95% CI 0.20–7.91). Three out of five dislocations (60%) appeared to be silent and were found during surgery and pathological examination of the tumor afterwards. Out of the two symptomatic dislocations one patient was re-stented, and the other underwent urgent surgery.

In the whole group, there were two perforations (2.4%), which were all due to recurrent ileus leading to a blow-out of the proximal colon. Noticeably, in one of these patients, the production of feces after 24 h was judged clinically as moderate with sufficient resolution of complaints (rated as a clinical success), also in the following days. Despite this, she developed a blow-out on day 8 after stent placement. This patient died from intra-abdominal sepsis.

In 2 patients (2.4%), there was bleeding necessitating blood transfusion. One of them already presented with bleeding before stent placement due to a large tumor in the ascending colon. The bleeding deteriorated after stent placement and ileus did not resolve sufficiently, leading to urgent surgery. In the other patient, the bleeding could be managed conservatively but had to be operated upon urgently for persisting ileus at a later time.

In 5 patients (6.1%) an inflammatory infiltrate with or without abscess around the tumor was found during operation. One of these patients had a large, necrotising T4 tumor and four had a T3 tumor with invasion of the pericolic fat. In one case, concomitant diverticulitis was found as well. It is unclear to what extent the inflammation had been promoted by the presence of a stent and/or manipulation during stent placement. There were no reports on pathological examination (of the surgically removed obstructions during elective or non-elective surgery) of stent endings that perforated the bowel wall (micro-perforations).

In binary logistic regression, we found no associations between the occurrence of complications (bleeding, infiltrate and perforation), number of stents, performing endoscopist and radiological parameters.

### Discussion

The reported results of preoperative stent placement for obstructing colorectal malignancy have been quite variable and, at least in the Netherlands, subject to extensive criticism because two Dutch randomised trials were stopped prematurely and did not improve the final outcome with regard to stoma rate or survival [6, 17]. Furthermore, complications are feared and the long-term prognosis of oncological outcome is under discussion showing differences in overall and disease-free survival [17, 19–24]. However, data are inconsistent and this topic remains as yet unclear. A recent study comparing the oncological outcome in our hospital and the oncological outcome in a well-matched comparable hospital, where no stents are placed, showed no significant differences [25].

The department of gastroenterology and gastrointestinal surgery at the Deventer Hospital has a long-standing protocol of preoperative stent placement as first-line treatment for obstructing colorectal tumor and thus has built up a relatively large series, with published satisfactory results [26]. This is confirmed by the current analysis, showing a technical success rate of 92% and a clinical success rate of 85%. Both are comparable to the literature [9, 11, 12].

Several concepts in the current analysis are new: we used the occurrence of (semi-) urgent surgery as the main endpoint, because the goal of preoperative stenting is to avoid this to happen. Such intervention was necessary in 19.5% of ‘successfully’ stented patients, in all cases because of stent malfunctioning. Thus, the primary goal of avoiding urgent surgery was achieved only in 66 of 89 patients (74%). Although this figure seems rather high, it should be realised that this endpoint has not been used before, so comparison with the literature is not possible. Our other indicators such as technical and clinical success rates were comparable to other large single-centre series.

Using these stringent outcome parameters, we analysed several factors of potential influence, including an issue that has never been addressed before: the influence of the radiological positioning of the stent on stent functioning and complications.



We believe that we performed objective and measurable parameters of the radiological stent position. The measurement of the angulation and asymmetry of the SEMS can be of course affected by the projection during fluoroscopy and X-ray. For instance, when the direction of the X-ray is not perpendicular to the SEMS, but perpendicular to the plane of the arc angle, an overestimation will occur. When the direction of the X-ray is not perpendicular to the SEMS axis, the relative distance to the impression can be affected. However, it is likely that these effects have not played a major role because of the image optimisation prior to SEMS placement. Moreover, all measurements on plain abdominal X-ray were excluded to avoid these effects.

The rates of non-elective surgery (19.5%) and complications (26.8%) in our study might seem quite high compared with the reported literature. However, in this study all patients with a curative intent of treatment underwent an attempt of preoperative stent placement. Difficult procedures like stent placement in right-sided obstructions (26.8% of stent were placed proximal to the splenic flexure) were not excluded and looking at our technical success rate of 92% this was quite successful. Other studies showing lower complication rates often exclude difficult endoscopic stents placement in the right-sided colon [8, 13]. Looking at our complications, 8 out of the 22 complications can be seen as minor complications. Three were asymptomatic dislocations and all 5 patients with an infiltrate around the tumor had a T3 tumor with the invasion of the pericolic fat, necrotising T4 tumor or concomitant diverticulitis, where on pathological examination no micro-perforations were found. From pathological examination it is unclear to what extent the inflammation

had been promoted by the presence of a stent and/or manipulation during stent placement. As demonstrated in Sabbagh et al. we did not find associations with T4 tumors as risk factors for microscopic perforations [19].

## Conclusion

The primary findings of our study indicate that neither an eccentric position of the stent, a sharp angulation or little deployment after insertion of the SEMS had a negative impact on clinical success, complications and the occurrence of non-elective surgery. All of the previously mentioned variables turned out to have no real impact on stent functioning and complications, so even if the stent is not perfectly placed on radiological examination it could be clinically efficient. In discussions about stents, certain endoscopists may feel that shorter stents may be preferable, but we did not encounter any special problems when longer stents seemed necessary. We are not aware of any study that systematically addressed the effect of radiological deployment, asymmetry or angulation on stent functioning. Although again many endoscopists may feel that these factors may have negative impact, we could not find any associations with outcomes.

## Disclosure Statement

E.H. van den Berg, MD, J.F. Bergmann, MD, PhD, M. Ledebor, MD, PhD, R.A.J.M. van Dijk, MD, PhD, R.J.I. Bosker, MD and F. ter Borg, MD, PhD have no conflicts of interest or financial ties to disclose.

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