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Outcomes of Self-Expanding Metal Stents in Malignant Colonic Obstruction are Independent of Location or Length of the Stenosis: Results of a Retrospective, Single-Center Series

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Keywords
Self-expanding metallic stents · Colon cancer · Large bowel obstruction

Abstract
Aim: To evaluate the length and location of stenosis in the colon as predictors of technical and clinical outcomes of stent placement in patients presenting with obstructive colorectal cancer. ***Methods:*** A prospective single-center cohort study of patients treated with a colonic stent for malignant obstruction, regardless of stenosis length or location. Stenosis length was assessed globally on the appropriate CT slice as well as by 3D CT reconstruction. We analyzed whether outcomes were different in patients with a right sided-tumor and/or a stenosis >4 cm long. ***Results:*** One hundred forty-one patients were evaluated, 63 with a stenosis >4 cm, 48 with a stenosis proximal to the splenic flexure. Technical failure ($n = 9$) was mainly caused because of looping or due to the difficulty in engaging the stenosis precluding analysis of the relation between the stenosis length and technical success. Both measurement methods showed good agreement. Clinical outcomes were not associated with stenosis length or location. ***Conclusion:*** Clinical outcomes of stenting did not differ between groups regardless of stenosis length or location. Measuring stenosis length more precisely using 3D CT reconstructions is not of help.

Core Tip

Self-expanding metallic stents are a useful treatment option to restore the passage of feces. Few studies investigated whether stenosis length influences outcomes of stenting. According to Dutch interpretation, stent placement should not be undertaken in patients with a malignant stenosis length >4 cm or right-sided tumors (proximal to the splenic flexure); however, the quality of evidence is weak.

We demonstrated that clinical results and complications of colonic stenting did not differ between groups with a malignant stenosis ≤4 cm or >4 cm or between groups with right- or left-sided tumors. More precise objective measurement of stenosis length using 3D CT reconstructions did not change the results. We found no reason to exclude patients with an estimated stenosis length >4 cm and right-sided lesions from colonic stenting beforehand.

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P.K.S., P.G., E.H.B., O.A.D., and F.B.: The outcome of colonic stenting in patients with a malignant stenosis shorter or longer than 4 cm and either left or right sided is equivalent.

Introduction

Obstructive colorectal cancer can be treated with emergency surgery (either resection or decompression colostomy) or endoscopic placement of a self-expanding metal stent (SEMS). However, both methods have drawbacks. Emergency surgery leads to considerable morbidity and mortality, especially in patients aged 70 and above [1], has a high risk of a (temporary) colostomy (especially in palliative setting) [2], and it usually takes multiple operative steps before the tumor is removed and continuity restored [3]. Temporary colostomies also have a high rate of incisional hernia and restorative procedures [3]. On the other hand, colorectal stenting is difficult to perform and has a high rate of technical and clinical failure and complications when performed by inexperienced hands [4–6]. The most feared complication is perforation of the tumor with life-threatening abdominal sepsis and a possibility of oncological spillage. This is especially worrisome in patients with curative options, who are treated with a SEMS to resolve the ileus to optimize the general condition and the condition of the proximal colon before doing an oncological resection (Bridge to Surgery [BTS]). These controversies have been extensively reviewed in the European Guideline on Colorectal stenting [7]. The main issue is that treatment colorectal SEMS as BTS has not been shown to improve long-term outcomes, and is suspected to introduce an oncological risk [8], although evidence is of poor quality and other studies have shown no survival differences between patients treated with SEMS and deviating colostomy [3] or primary resection [9]. The only firmly established advantage of SEMS as BTS is less temporary stoma formation, which has been confirmed by a recent British randomized controlled trial [10]. For palliative indications, a broad consensus exists that colorectal SEMS is the preferred treatment [7]. These considerations have led to the advice to perform SEMS placement in BTS indications only by endoscopists having done at least 20 procedures in patients >70 years and/or ASA III status or more. In addition, tumors should be located in the left hemicolon (including the splenic flexure).

The Dutch interpretation of the European Guideline additionally states that a tumor stenosis longer than 4 cm should not be treated with a SEMS [8].

This criterion is based on 2 retrospective studies that revealed better outcomes in patients with the length of malignant stenosis not exceeding 4 cm [11, 12]. Manes et al. [11] reported about palliative stent placement and demonstrated that a stenosis longer than 4 cm was associated with lower technical and clinical success rates (OR 5.3 for technical failure and 2.4 for clinical failure). The other study showed that patients who received a stent shorter than 10 cm had better outcomes in terms of mean event-free survival. However, there is also a publication that did not confirm these associations [13].

Following these conflicting results we studied whether the outcomes of colorectal SEMS placement different in groups with a malignant stenosis ≤4 cm (group A) or >4 cm (group B). As the European Guideline does not elaborate on how the length of the stenosis should be measured, we looked if 3D CT-reconstructed length yielded different results than global manual assessment on the appropriate CT slice, which is used in our clinic to assess the length of the SEMS before doing the procedure.

Patients and Methods

The study was based on a prospectively collected single-center cohort of patients with clinical and radiological evidence of malignant colonic obstruction, treated with a SEMS.

According to our local protocol, all patients who presented with clinical and radiological ileus due to an obstruction colonic carcinoma were preferably treated with an emergency SEMS procedure. This was regardless of age, ASA status, or (emergency) tumor staging.

Contraindications for stenting were peritonitis carcinomatosa, multiple stenoses, clinical, and/or radiological presentation of perforation, or very distal rectal tumors, defined as a palpable mass on rectal examination. In these patients, emergency surgery was performed.

Until the implementation of the European Guideline (2014) [7], SEMS – placement was the preferred treatment regardless of the tumor location in the colon [14], patient's age, and ASA-status. Also, no consideration was given to the length of the stenosis.

The choice for SEMS placement was discussed with the patient and family, which had to give its consent to initiate the procedure. The procedure itself has been described elsewhere and was performed by endoscopists who have had the experience of performing at least 20 procedures (after the introduction of the guideline).

The following data were prospectively recorded: date of SEMS placement, intent (palliative or BTS), stenosis localization, and SEMS type (58% Wall stent, 27% Wall flex, both Boston Scientific and 15% Evolution [Cook]). The choice was a matter of availability. Also, SEMS length, number of inserted SEMS, technical success (defined as accurate bridging of the stenosis), and clinical success (defined as resolution of ileus with production of at least moderate amounts of feces within 24 h) were prospectively recorded.

Data on adverse events were verified in retrospect using patient's charts. The circumstances of death in the palliative setting at home were often unclear, which made us decide to exclude the palliative group from the adverse event analysis.

CT scans were retrospectively assessed. Tumor stenosis length was estimated by authors P.K.S. and F.t.B., drawing 1 or 2 straight lines on the appropriate CT slices, using the measurement tool on the Picture Archiving and Communication System (Fig. 1). In a subset of patients, these results were compared with 3D CT reconstruction performed by radiologist PG using the General Electric Health care Advantage Workstation Volume Share 4, version 9.6.25b.

Patients were divided into groups A and B, having a stenosis length ≤4 and >4 cm respectively. Statistical analysis was done using Chi-Square statistics (using exact significance levels) and logistic regression analysis (SPSS software version 22).

Only the parameter age is expressed as mean ± SD of the mean. All tests were performed as two-sided tests. p values ≤0.05 were considered significant.

Results

The prospectively collected database consisted of 211 patients (July 2003–December 2014). A benign stenosis was found in 10 patients; a pre-procedural CT was not available in 60 patients. We, therefore, analyzed the records of 141 patients (54.6% male, mean age 73 years (range 34–94 years). In 57.4% of cases, the indication was BTS and the other patients had a palliative indication. In 66.0% of cases, the tumor was located in the left hemicolon (including the splenic flexure). There were 17 cases with recurrent tumor or metastasis, 3 still having curative options (BTS).

All endoscopists had a cumulative experience of >20 procedures when the Dutch version of the guideline was implemented. Technical failure occurred in 9 cases (6.3%). Reasons for technical failure were impossibility to reach the tumor because of looping of the endoscope (n = 2) or the presence of a severe angulation that it was impossible to engage the residual lumen with a guide wire (n = 6). There was only one case in which the length of the stenosis (89 mm) could have contributed to the inability to pass the stenosis with a guide wire. This number was too small to analyze the association between technical failure and stenosis length. Technical failure occurred in 5.4% of left-sided tumors and 8.3% of right-sided tumors (p = 0.49). Of the remaining 132 patients in whom a SEMS was successfully inserted, 48.5% had a stenosis length >4 cm.

Table 1 shows the general characteristics of group A (stenosis ≤4 cm) and group B (stenosis >4 cm). Noticeable, patients of group B had more often a palliative indication and were, on average, significantly older.

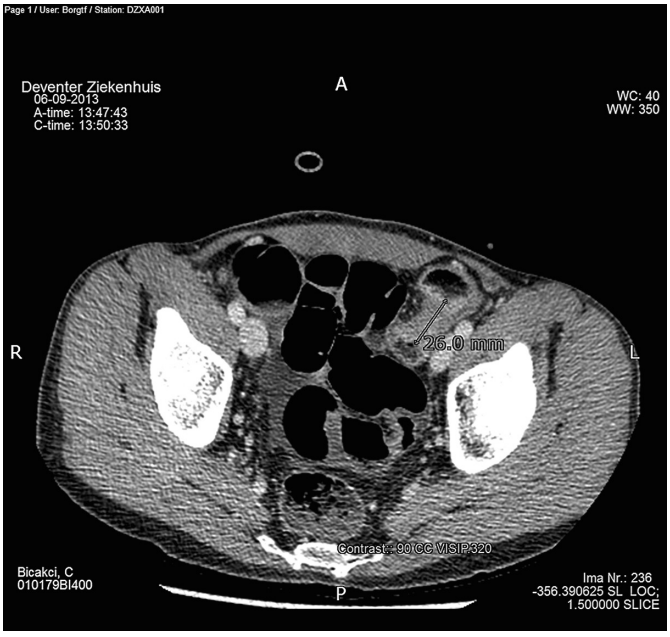

Fig. 1. Example of global assessment of stenosis length on the appropriate CT slice by drawing a straight line.

Table 2a shows the outcomes of group A and B. There were no differences in clinical success, premature operations, complications, or re-obstructions. Table 2b shows the outcomes related to the left- or right-sided location of the tumor. No differences in outcomes were found.

In 120 cases, the CT allowed for 3D reconstruction of the stenosis length. The results, as compared to the manual measurements are shown in Table 3, K = 0.59, indicating fair to good agreement. The outcomes in groups with a 3D-CT reconstructed stenosis length ≤ or >4 cm are shown in Table 4. Again, no significant differences are found. Multivariate logistic regression was performed using clinical success, urgent surgery after SEMS placement, perforation, bleeding, or re-obstruction as the dependent variable, and age, gender, intent (BTS or palliative), left-sided tumor or not, primary or recurrent CRC and stenosis length as the independent variable. This also revealed no association of a stenosis length >4 cm or left-sided location with these outcomes (all p values >0.27).

Discussion

After the poor results and high complication rates of the 2 Dutch randomized controlled trials [4, 8], the use of SEMS in the Netherlands has fallen dramatically. In 2009, 17.6% of patients with acute obstruction were treated

Table 1. Characteristics of total group, patients with a stenosis length ≤4 cm (group A) or >4 cm (group B)

	Total, *n* (%)	Group A	Group B	*p* value
Gender				0.294
Female	57 (45.4)	33 (57.9)	24 (42.1)	
Male	75 (54.6)	36 (48.0)	39 (52.0)	
Age, years, mean ± SD	72.9±11.8	70.3±12.4	75.8±10.3	0.006
Indication				0.437
Primary CRC	115 (87.1)	62 (53.9)	53 (46.1)	
Local recurrence	17 (12.9)	7 (41.2)	10 (58.8)	
Location of tumor				0.574
Left hemicolon	88 (66.7)	46 (52.3)	42 (47.7)	
Right hemicolon	44 (33.3)	23 (52.3)	21 (47.7)	
Purpose				0.014
BTS	76 (57.6)	47 (61.8)	29 (38.2)	
Palliative	56 (42.4)	22 (39.3)	34 (60.7)	
Stent length, mm				0.043
60	111 (84.1)	63 (56.8)	48 (43.2)	
80	3 (2.3)	2 (66.7)	1 (33.3)	
90	16 (12.1)	4 (25.0)	3 (75.0)	

Table 2. Clinical outcomes and complications in patients with respectively different stenosis length and location

a Clinical outcomes and complications in patients with a stenosis length <4 cm (group A) or >4 cm (group B)

	Group A, *n* (%)	Group B, *n* (%)	*p* value
Clinical resolution of ileus	40 (85.3)	26 (89.1)	0.61
Nonelective surgery	6 (11.8)	3 (9.4)	0.78
Perforation	2 (4.4)	1 (4.7)	1.00
Bleeding	1 (2.9)	1 (1.6)	1.00
Recurrence of obstruction	6 (13.2)	5 (17.2)	0.63

b Clinical outcomes and complications in patients with left-sided (including splenic flexure) and right-sided tumors

	Left-sided, *n* (%)	Right-sided, *n* (%)	*p* value
Clinical resolution of ileus	38 (80.4)	28 (85.4)	0.64
Nonelective surgery	7 (14.3)	2 (14.6)	1.00
Perforation	2 (4.3)	1 (4.2)	1.00
Bleeding	1 (2.1)	1 (2.2)	1.00
Recurrence of obstruction	8 (16.3)	3 (10.4)	0.45

Table 3. Results of 3D-CT reconstruction of stenosis length in a subset of 120 patients

	Group A	Group B	Total
3D-CT ≤4 cm	44	17	61
3D-CT >4 cm	9	50	59
	53	67	120

Table 4. Clinical outcomes in groups with a 3D-CT reconstructed stenosis length ≤ or >4 cm

	3D-CT ≤4 cm, *n* (%)	3D-CT >4 cm, *n* (%)	*p* value
Clinical resolution of ileus	33 (83.0)	28 (88.6)	0.41
Nonelective surgery	6 (15.1)	3 (9.0)	0.39
Perforation	1 (3.8)	2 (6.0)	0.69
Bleeding	1 (3.8)	1 (1.5)	0.58
Recurrence of obstruction	6 (13.2)	5 (14.9)	1.00

with a SEMS, while in 2012, this figure had dropped to 5.9% [15]

Given these problems and the diminished experience, in the Netherlands, the European Guideline was implemented in 2014, using training, certification, and a prospective national audit [11], so that results could be monitored. According to this guideline, a SEMS as BTS should be placed only in patients >75 year and/or ASA III status having a left-sided obstruction.

In addition, it was chosen to exclude patients with a stenosis longer than 4 cm from SEMS placement as BTS (the "Dutch" version of the European Guideline). We investigated these active restrictions in a large single-center cohort and looked whether right-sided location and/or a stenosis ≥4 cm is associated with more difficulties and/or a worse outcome. These patients were selected for SEMS placement regardless of the stenosis length and location.

Stenosis length can be assessed in several ways. The use of fluoroscopy is, in our experience, not appropriate. X-ray projection is often not perpendicular and injected contrast flows away in the dilated proximal colon [15]. Furthermore, it is difficult to calibrate the X-ray pictures during fluoroscopy and translate the size on the x-ray screen to real centimeters.

We therefore decided to evaluate this research question only in patients in whom a CT scan was available. Although this led to the exclusion of 60 patients, we considered the remaining number of 141 cases, a sufficiently large dataset for a valid exploration –actually it is the largest dataset published so far on this topic. Estimation of stenosis length on the appropriate CT-slice is operator-dependent and for this reason we compared this to 3D-CT.

We could not demonstrate any association between clinical success, re-obstruction, perforation, bleeding or urgent surgery after SEMS placement, and the presence of a stenosis >4 cm. Also, we did not find any association between the left- or right-sided location of the malignant stenosis and these outcomes. Measurement of stenosis length using 3D CT reconstruction did not change the results.

It is difficult to explain why a longer stenosis is not associated with more clinical or technical failure. One explanation could be that all of the endoscopists were experienced colonoscopists (as well as ERCP-ists). In our view, the ability to successfully perform colonic stenting is dependent on both a very fluent colonoscopy and ERCP-technique.

With regard to technical success, it should be noted that all but one technical failure were due to the inability to reach or cannulate the stenosis, and were not related to stenosis length, which could have played a role in only one case. Also right-sided location was not associated with technical failure.

The limitations of our study are that our data are from a single-center cohort.

Conclusion

We found that failure to insert a SEMS is largely due to other factors rather than the fact that it is difficult to pass the stenosis with a guide wire or right-sided location. Clinical outcomes of SEMS for malignant colonic obstruction were not related to location in the colon or length of the stenosis. Further refinement of measuring a stenosis with 3D-CT reconstruction is of no additional benefit when compared to the global assessment of the stenosis on the appropriate CT slice.

Disclosure Statement

The authors declare no conflicts of interest.

Ethics Statement

The study was reviewed and approved by the Medical Ethical Committee Isala Institutional Review Board. Technical appendix, statistical code, and data set are available from the corresponding author at paulschoonbeek@hotmail.com. Informed consent was not obtained, but the presented data are anonymized and risk of identification is low.

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