Decompressing stoma as bridge to elective surgery is an effective strategy for left-sided obstructive colon cancer: a national, propensity-score matched study

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Decompressing Stoma as Bridge to Elective Surgery is an Effective Strategy for Left-sided Obstructive Colon Cancer

A National, Propensity-score Matched Study

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Objective: The purpose of this population-based study was to compare decompressing stoma (DS) as bridge to surgery (BTS) with emergency resection (ER) for left-sided obstructive colon cancer (LSOCC) using propensity-score matching.

Summary Background Data: Recently, an increased use of DS as BTS for LSOCC has been observed in the Netherlands. Unfortunately, good quality comparative analyses with ER are scarce.

Methods: Patients diagnosed with nonlocally advanced LSOCC between 2009 and 2016 in 75 Dutch hospitals, who underwent DS or ER in the curative setting, were propensity-score matched in a 1:2 ratio. The primary outcome measure was 90-day mortality, and main secondary outcomes were 3-year overall survival and permanent stoma rate.

Results: Of 2048 eligible patients, 236 patients who underwent DS were matched with 472 patients undergoing ER. After DS, more laparoscopic resections were performed (56.8% vs 9.2%, $P < 0.001$) and more primary anastomoses were constructed (88.5% vs 40.7%, $P < 0.001$). DS resulted in significantly lower 90-day mortality compared to ER (1.7% vs 7.2%, $P = 0.006$), and this effect could be mainly attributed to the subgroup of patients over 70 years (3.5% vs 13.7%, $P = 0.027$). Patients treated with DS as BTS had better 3-year overall survival (79.4% vs 73.3%, hazard ratio 0.36, 95% confidence interval 0.20-0.65) and fewer permanent stomas (23.4% vs 42.4%, $P < 0.001$).

Conclusions: In this nationwide propensity-score matched study, DS as a BTS for LSOCC was associated with lower 90-day mortality and better 3-year overall survival compared to ER, especially in patients over 70 years of age.

Keywords: decompressing stoma, emergency resection, obstructive colon cancer, propensity score matching

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Approximately 10% of patients with colorectal cancer present with an acute colonic obstruction.[1] In the Netherlands, obstructive left-sided colon cancer (LSOCC) is most frequently treated with emergency resection (ER) in the curative setting.[2] However, many of

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these patients have a deteriorated physical condition after several days of reduced intake and vomiting before presentation. Especially in elderly and frail patients, ER is associated with a high risk of mortality and morbidity.[3]

Initial decompression of the distended colon is an attractive approach to overcome the risks of an ER. This allows for optimization of the clinical condition of the patient, and facilitates a laparoscopic resection with primary anastomosis. Colonic decompression can be accomplished by either a stoma or placement of a selfexpandable metal stent (SEMS). SEMS as bridge to surgery (BTS) has been recommended as an alternative to ER in the elderly and frail patients.[4] However, the implementation of SEMS has been hampered by uncertainty about long-term oncological risks, especially after SEMS-related (micro-)perforation.[5–7] In addition, stenting experience is not always available in each center.

Decompressing stoma (DS) has been the historical BTS approach before the SEMS era and has recently regained popularity, likely due to the ongoing debate on oncological safety of SEMS in the curative setting. In the Netherlands, the use of DS as BTS increased from only 5% in 2009 to 23% in 2016, in line with the revised national colorectal cancer guideline of 2014.[2] However, quality of evidence supporting this recommendation was low. Literature on DS as an alternative to ER for obstructing colon cancer is limited, with most of the studies published before 1995.[8] This lack of data might reflect the infrequent use of DS, likely due to the need for a 3-stage procedure to restore bowel continuity and the difficulties in stoma care of emergency colostomies.

The aim of the current population-based study was to compare DS as BTS with ER using propensity-score matching for patients with nonlocally advanced LSOCC in the curative setting with 90-day mortality as the primary outcome parameter.

METHODS

Study Design

A national, retrospective study was performed in the Netherlands as described in a previous publication by the Dutch Snapshot Research Group (DSRG).[2] All patients who underwent resection of primary colon cancer with a left-sided location (splenic flexure, descending colon or sigmoid) and with a registered obstruction between 2009 and 2016 were identified from a prospective, national, mandatory registry, the Dutch Colorectal Audit (DCRA). Baseline characteristics, procedural parameters, and 30-day outcome data were retrieved from this registry. Subsequently, all hospitals in the Netherlands (N = 77) were asked to extend the short-term outcomes with additional procedural and long-term data through individual patient file review using a web-based tool for data-entry. Data collection was performed according to Dutch privacy regulations, and anonymized data were provided to the research team by Medical Research Data Management (MRDM, Deventer, the Netherlands).

Under the supervision of consultant surgeons, surgical residents from each participating hospital added the additionally requested data to the DCRA database using the previously mentioned web-based tool. Subsequently, the supplied data was checked for discrepancies and missing values by 2 independent research fellows, where after these discrepancies were communicated back to the collaborators to re-check and complete the data.[2]

Study Population

Patients were included if they had a symptomatic colonic obstruction with abdominal distention, nausea and/or vomiting, and X-ray or computed tomography (CT) showed a dilated colon with or without dilatation of the small bowel. The tumor had to be proven malignant by histology and treated with either DS as BTS or ER.

Exclusion criteria were palliative treatment intent (as decided by the local multidisciplinary team), signs of bowel perforation on CT (free air), and locally advanced tumor disease defined as a registered cT4 tumor stage, neoadjuvant treatment, and/or multivisceral resection.

Outcomes and Definitions

The primary outcome parameter was 90-day mortality, defined as death within 90 days after resection of the primary tumor. The main secondary outcome parameters were 3-year overall survival and permanent stoma rate, the latter defined as the presence of a stoma at the end of follow-up.

Other outcomes included the number of laparoscopic resections, primary anastomoses, 90-day major complications (Clavien-Dindo score 3 of higher[9]), 3-year locoregional recurrence, 3-year disease-free survival, total complication rate (related to DS, resection, and postresection presence of a stoma), and total hospital stay (related to DS as BTS, resection, and any readmission).

Statistical Analysis

Before propensity-score matching, categorical variables were presented as percentages and compared with the X^2-test or the Fishers exact test. Normally distributed continuous variables were shown as means with standard deviations and compared with the Student t-test. Nonnormally distributed variables were reported as medians with interquartile ranges (IQR) and compared with the Mann-Whitney *U* test.

Missing data was imputed with R statistical software using the multiple imputation by chained equations (MICE package). One-to-two nearest neighbor matching without replacement was performed to balance baseline characteristics between the 2 groups within a caliper of 0.25 logit of the standard deviation of the propensity-score.[10] Propensity-score matching was performed according to the following baseline characteristics: sex, age, body mass index, American Society of Anaesthesiologists (ASA) score, previous abdominal surgery, tumor location, cM1 stage at presentation, length of the stenosis (on CT), year of resection, and pN stage. Due to the paired nature of the data, outcomes were compared with conditional logistic regression, with reporting of conditional odds ratios (cOR) and 95% confidence intervals. Kaplan-Meier survival curves were made, on which survival probabilities were compared between the 2 treatment groups with Cox proportional hazards with shared frailty. Subgroup analyses with stratification for age ($<$70 vs $\geq$70 years), ASA score (I-II vs III-IV), and primary tumor location (splenic flexure vs descending colon or sigmoid) were performed for the main outcome parameters and displayed using forest plots. A 2-sided *P*-value $<$0.05 was considered significant. All analyses were performed with R software version R3.3.2 (Matching and Frailtypack packages, R Foundation for Statistical Computing, Vienna, Austria) and IBM SPSS Statistics, version 25.0 (IBM Corp Amonk, NY, USA).

RESULTS

Patients and Baseline Characteristics

A total of 75 of 77 invited hospitals participated, leading to a registration of 3879 patients. After applying the exclusion criteria, 2048 eligible patients with nonlocally advanced LSOCC who underwent treatment with curative intent by either DS as BTS (N = 240) or ER (N = 1808) were included. One-to-two propensity-score matching led to a final inclusion of 236 DS and 472 ER patients (Supplemental Digital Content, Figure 1, http://links.lww.com/SLA/C521; Supplementary Table 1, http://links.lww.com/SLA/C299). The standardized mean difference was less than 10% for all baseline characteristics, except for stenosis length (4.2 vs 4.4 cm; Table 1).

TABLE 1. Baseline Characteristics

	Before PS Matching			After PS Matching		
	ER N = 1808 (%)	DS as BTS N = 240 (%)	SMD (%)	ER N = 472 (%)	DS as BTS N = 236 (%)	SMD (%)
Male sex	960 (53.1)	149 (62.1)	18.3	289 (61.2)	145 (61.4)	0.4
Mean age in years (SD)	70.2 (11.9)	68.5 (11.4)	14.1	68.6 (12.3)	68.5 (11.4)	1.0
Mean BMI (SD)	26.0 (10.9)	25.0 (4.2)	11.4	25.0 (3.8)	25.0 (4.1)	0.3
ASA score 3-4	612 (33.8)	53 (22.1)	26.4	105 (22.3)	53 (22.5)	0.3
Prior abdominal surgery	549 (30.4)	88 (36.7)	13.4	169 (35.9)	84 (35.6)	0.6
Tumor localization			11.1			1.1
Splenic flexure	246 (13.6)	42 (17.5)		80 (16.9)	40 (16.9)	
Descending colon	328 (18.1)	44 (18.3)		84 (17.8)	43 (18.2)	
Sigmoid	1234 (68.3)	154 (64.2)		308 (65.3)	153 (64.8)	
pN stage			15.2			6.5
pN0	828 (45.8)	95 (39.6)		193 (41.1)	95 (40.4)	
pN1	648 (35.8)	88 (36.7)		161 (34.3)	87 (37.0)	
pN2	332 (18.4)	57 (23.8)		116 (24.7)	53 (22.6)	
cM1 stage	165 (9.1)	16 (6.7)	9.1	32 (7.0)	16 (6.8)	0.9
Lung	20 (1.1)	1 (0.4)		3 (0.7)	1 (0.4)	
Liver	130 (7.5)	14 (5.8)		23 (5.0)	14 (5.9)	
Peritoneal	25 (1.4)	3 (1.3)		5 (1.1)	3 (1.3)	
Other	25 (1.4)	3 (1.3)		1 (0.4)	1 (0.2)	
Mean length of stenosis in cm (SD)	4.4 (2.0)	4.5 (2.0)	1.0	4.2 (1.8)	4.4 (1.9)	13.5
Median cecal diameter in cm (IQR)*				8.6 (7.4–10.0)	9.0 (7.8–10.0)	
Year of resection†			43.5			0.1
2009	149 (96.8)	5 (3.2)		14 (73.7)	5 (26.3)	
2010	164 (90.6)	17 (9.4)		22 (56.4)	17 (43.6)	
2011	236 (90.8)	24 (9.2)		41 (63.1)	24 (36.9)	
2012	270 (92.8)	21 (7.2)		50 (70.4)	21 (29.6)	
2013	269 (87.3)	39 (12.7)		70 (64.2)	39 (35.8)	
2014	301 (90.4)	32 (9.6)		108 (77.1)	32 (22.9)	
2015	233 (81.8)	52 (18.2)		88 (62.9)	52 (37.1)	
2016	185 (78.7)	50 (21.3)		79 (63.2)	46 (36.8)	

*Not used for propensity score matching, therefore only reported for patients included after matching (ER vs DS as BTS: $P = 0.127$).
†Percentage of row instead of column total.
BMI indicates body mass index; PS, propensity-score; SD, standard deviation; SMD, standardized mean difference.

Procedural Characteristics

Surgical treatment details are provided in Supplemental Digital Content, Table 1, http://links.lww.com/SLA/C520 and Supplementary Figure 1, http://links.lww.com/SLA/C292. More resections were performed laparoscopically in the DS group (56.8% vs 9.2%, $P < 0.001$). More primary anastomoses were constructed after initial DS compared to ER (88.5% vs 40.7%, $P < 0.001$). Although stoma rate directly after resection was similar (62.6% vs 66.2%, $P = 0.365$), this stoma was less often an end-colostomy in the DS group (6.0% vs 80.9%, $P < 0.001$). Median hospital stay after resection was 6 days (IQR 5–9) and 11 days (IQR 7–15) in the DS and ER groups, respectively ($P < 0.001$).

Outcome Parameters

Main Outcomes

Ninety-day mortality was significantly lower after DS as BTS compared to ER (1.7% vs 7.2%, $P = 0.006$). In subgroup analysis (Supplementary Fig. 2, http://links.lww.com/SLA/C293), 90-day mortality remained significantly different between DS and ER in patients of 70+ years (3.5% vs 13.7%, $P = 0.027$) and in patients with a tumor in the sigmoid or descending colon (1.5% vs 7.2%, $P = 0.019$).

Three-year overall survival was significantly higher after DS as BTS [hazard ratio (HR) 0.36 (0.20–0.65)] (Table 2, Fig. 1). This difference remained significant in patients of 70+ years (HR 0.39 (0.21–0.73)), patients with an ASA score of I-II [HR 0.44 (0.23–0.84)], and patients with a tumor in the sigmoid or descending colon [HR 0.36 (0.19–0.68)] (Supplementary Fig. 3, http://links.lww.com/SLA/C294).

Permanent stoma rate was significantly lower after DS as BTS compared to ER (23.4% vs 42.4%, $P < 0.001$), also in patients with a minimum follow-up of 12 months (18.8% vs 33.4%, $P < 0.001$). In subgroup analysis (Supplementary Fig. 4, http://links.lww.com/SLA/C295), the difference in permanent stoma rate between DS and ER remained significant in patients of 70+ years (21.3% vs 46.5%, $P < 0.001$), patients with an ASA score of I-II (17.5% vs 30.4%, $P = 0.008$), and patients with a tumor in the sigmoid or descending colon (19.3% vs 35.8%, $P = 0.001$).

Other Outcomes

In the DS group, significantly lower rates were found for postresection complications (cOR 0.50), major complications (cOR 0.56), anastomotic leakage (cOR 0.27), intra-abdominal abscess (cOR 0.28), and postoperative ileus (cOR 0.27) (Supplemental Digital Content, Table 1, http://links.lww.com/SLA/C520).

During complete follow-up, total hospital stay was longer in the DS group with a median of 15 days (IQR 11–23) versus 11 days (IQR 8–17) ($P < 0.001$). Total complication rate did not significantly differ between the DS and ER groups (45.8% and 45.3%, $P = 0.805$). Reinterventions were more often performed in the DS group (58.7%

TABLE 2. Long-term Treatment Outcomes

	ER N = 472 (%)	DS as BTS N = 236 (%)	cOR	95% CI	*P*-value
Median follow-up in months (i.q.r.)	25.5 (11.0–40.0)	26.0 (14.0–47.5)	1.01	1.00–1.02	0.064
Permanent stoma at time of last follow-up	197/465 (42.4)	55/235 (23.4)	0.44	0.41–0.62	<0.001
In patients with a minimum follow-up of 12 mo	115/344 (33.4)	36/192 (18.8)	0.45	0.29–0.71	<0.001
Median total hospital stay in days (i.q.r.)*	11.0 (8.0–17.0)	15.0 (11.0–23.0)	1.03	1.01–1.05	<0.001
Total complication rate – entire follow-up†	210/464 (45.3)	103/225 (45.8)	1.04	0.75–1.44	0.805
Related to stoma after resection	63/307 (20.5)	43/147 (29.3)	1.61	0.95–2.73	0.078
Parastomal hernia	11/276 (4.0)	11/133 (8.3)	1.74	0.62–4.87	0.291
Incisional hernia	9/266 (3.4)	11/131 (8.4)	2.20	0.72–6.73	0.166
Stoma prolapse	1/277 (0.4)	17/132 (12.9)	18.41	2.39–141.90	0.005
Stoma necrosis	10/274 (3.6)	0/132 (0.0)	0.02	0.00–14.20	0.237
Ileus caused by stoma	3/275 (1.1)	2/131 (1.5)	0.62	0.06–7.00	0.697
Dehydration	3/272 (1.1)	2/132 (1.5)	1.41	0.09–23.57	0.809
High output	13/273 (4.8)	5/132 (3.8)	1.58	0.42–5.99	0.500
Stoma dehiscence	11/272 (4.0)	0/132 (0.0)	0.02	0.00–8.30	0.198
Stoma stricture	7/274 (2.6)	0/132 (0.0)	0.02	0.00–105.11	0.378
Reinterventions – entire follow-up					
Including stoma reversal‡	199/466 (42.7)	131/223 (58.7)	2.02	1.44–2.83	<0.001
Excluding stoma reversal§	96/465 (20.6)	48/218 (22.0)	1.18	0.79–1.76	0.421
Locoregional recurrence	60/456 (13.2)	31/230 (13.5)	1.00	0.63–1.58	0.984
Anastomotic	17/60 (28.3)	7/31 (22.6)			
Locoregional lymph node (s)	2/60 (3.3)	1/31 (3.2)			
Peritoneal metastasis	34/60 (56.7)	20/31 (64.5)			
Unknown	7/60 (11.7)	3/31 (9.7)			
Distant metastases	90/455 (19.8)	48/232 (20.7)	1.07	0.72–1.59	0.735
Liver	35/90 (38.9)	26/48 (54.2)			
Lung	19/90 (21.1)	3/48 (6.3)			
Brain	1/90 (1.1)	0/48 (0.0)			
Distant lymph node	1/90 (1.1)	0/48 (0.0)			
Other	2/90 (2.2)	2/48 (4.2)			
Combination	29/90 (32.2)	16/48 (33.3)			
Unknown	3/90 (3.3)	1/48 (2.1)			
3-yr locoregional recurrence (%)	16.4	14.1	–	–	0.860
Number of events after 36 mo of follow-up	50	25			
Number of patients at risk after 36 mo of follow-up	146	78			
3-yr disease-free survival (%)	58.1	63.3	–	–	0.170
Number of events after 36 mo of follow-up	162	68			
Number of patients at risk after 36 mo of follow-up	135	69			
3-yr overall survival (%)	73.3	79.4	–	–	<0.001
Number of events after 36 mo of follow-up	102	33			
Number of patients at risk after 36 mo of follow-up	157	82			

*Combination of hospital stay during BTS interval including readmissions and hospital stay after resection including readmissions.
†Combination of complications after BTS and resection including stoma-related complications occurring after resection during entire follow-up.
‡Reinterventions within the BTS interval or after resection due to complications and/or stoma reversal during entire follow-up.
§Reinterventions within the BTS interval or after resection solely due to complications during entire follow-up, excluding stoma reversal.
i.q.r. indicates interquartile range.

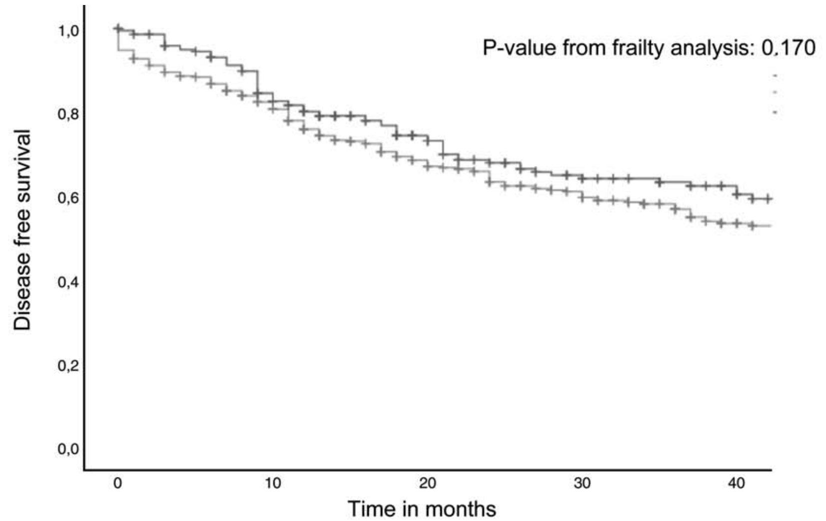
vs 42.7%, $P < 0.001$), due to more stoma reversals. No significant differences were found for 3-year locoregional recurrence and 3-year disease-free survival (Table 2, Fig. 1).

DISCUSSION

This population-based, propensity-score matched comparison between initial decompression of malignant colonic obstruction by a stoma followed by elective resection and immediate resection of the primary tumor in the acute setting revealed a lower 90-day mortality after DS, which translates into a better overall survival. In subgroup analyses, these observed differences between the two treatment strategies could be largely attributed to elderly patients (≥70 years). In addition, permanent stoma rate was lower after DS.

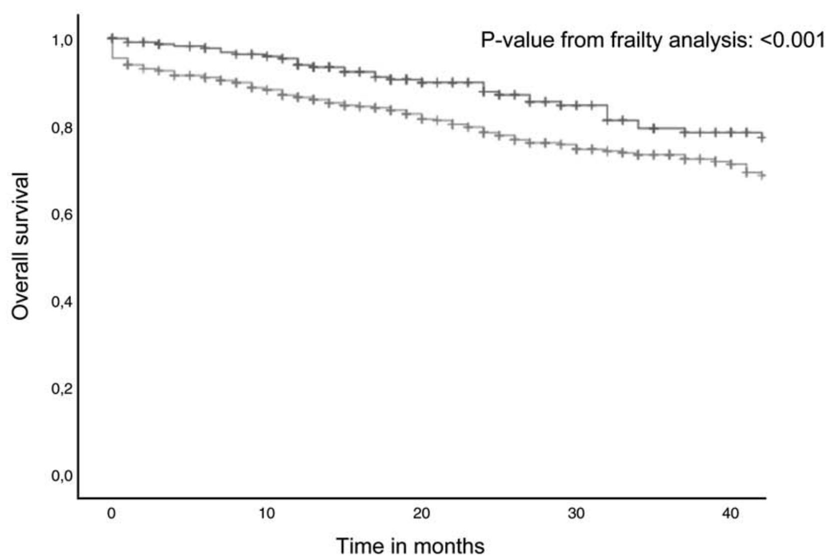
The primary aim of colonic decompression by SEMS or DS and delayed resection is to reduce postoperative mortality. Only 1 randomized trial comparing DS with ER has been performed so far, including 121 patients between 1978 and 1993.[11] No difference in mortality was found. Meta-analysis of 8 comparative studies published until 2015 resulted in an OR of 0.77 for mortality after DS compared to ER, but this was not significant (95% confidence interval 0.3–1.96).[8] Although initial meta-analyses of nonrandomized comparisons between SEMS as BTS and emergency surgery suggested a benefit regarding postoperative mortality in favor of SEMS,[12] this was not confirmed in subsequent meta-analyses including randomized trials.[13]

The present study demonstrated that DS effectively reduced the risk of mortality similar to a level as can be expected from primary elective colon cancer surgery (1.7%). The magnitude of the observed difference in mortality compared to ER was larger (cOR 0.50) than found in the meta-analysis by Amelung et al (OR 0.77),[8] and translated into better overall survival. Of important clinical



A

Number at risk					
Decompressing stoma	222	175	117	81	61
Emergency resection	446	335	233	172	95



B

Number at risk					
Decompressing stoma	228	203	140	100	73
Emergency resection	463	369	279	204	117

FIGURE 1. Disease free (A) and overall survival (B) for decompressing stoma as bridge to surgery versus emergency resection of left-sided obstructive colon cancer (propensity-score matched sample).

implication is that reduced mortality and improved survival are particularly seen in patients $\geq$70 years. The impact was similar and nonsignificant in both ASA 1-2 and ASA 3-4 patients with wide confidence intervals. ASA classification has been suggested to be less accurate in the emergency setting.[14] Interestingly, treatment strategy did not have a statistical impact on the main outcome parameters if the primary tumor was located in the splenic flexure, although this might be related to lack of power. Tumors in the splenic flexure are generally more difficult to approach surgically, but this does not seem to be a satisfactory explanation.

DS had almost been abandoned in the Netherlands, because there was no convincing evidence of any advantage over ER, and because these stomas are at high risk of prolapse. Furthermore, it was wrongly assumed that stoma closure always needs an additional intervention. However, restoration of continuity can already be achieved during resection in one third of patients (2-stage).[2] Constructing the DS close to the tumor location enables resection of the tumor and stoma site in one segment, thereby omitting a second anastomosis. The meta-analysis by Amelung et al already showed a lower permanent stoma rate for DS as BTS, which is confirmed by the present study.[8] Double loop stomas can be more easily closed than the often-constructed end colostomies after ER. Another benefit of a DS is its low surgical complexity in the emergency setting, especially a blowhole. Because of scarce literature, it is difficult to recommend either double loop or blowhole DS.[15,16]

Kronborg et al[11] showed a nonsignificant trend towards lower morbidity for DS ($P = 0.19$), being in line with the current study. However, the DS was constructed via a full midline laparotomy instead of a minimally invasive Trephine method, which might explain the nonsignificant result besides lack of statistical power. Furthermore, none of the subsequent elective resections were performed laparoscopically at that time, with half the duration of the bridging interval, and without perioperative care according to ERAS principles.[11]

In contrast to short-term morbidity, total complication rate did not differ between the 2 groups in the current study. This might be explained by the nonsignificant trend towards more stoma-related complications after resection in the DS group with more stoma prolapses (12.9% vs 0.4%, $P = 0.005$).

This study supports the Dutch guideline recommendation of 2014 and justifies the observed increase in the use of DS at a national level. ER still seems a valid option in patients below 70 years, but should be avoided in the elderly. The difference in stoma rate, and most of the other outcome parameters, indicates that DS should be the preferred intervention in patients over 70 years presenting with LSOCC. SEMS might be considered an alternative for DS based on a previously published comparison of these 2 bridging strategies from our group, provided that the lesion is considered eligible for stenting, sufficient stenting experience is available, and patients are well informed.[16,17] SEMS as BTS results in the lowest risk of having a stoma at any time during treatment. However, a nonsignificant trend towards better overall survival for DS compared to SEMS was observed.[16]

Limitations of the current study include its retrospective nature with a subsequent risk of missing data and selection bias. The degree of colonic distension might have influenced treatment choice regarding DS or ER. Motivation for either DS or ER could not be retrieved in 41% and 52% of patients, respectively. Whether surgery was performed during the evening or night-time hours was unknown, neither the expertise of the surgeon. Several surgical details were missing, such as splenic flexure mobilization, level of vascular ligation, anastomotic testing, and how stomas were reversed. In addition, our choice of variables for propensity-score matching might have influenced our results. Residual confounding by factors not taken into account might be present, and propensity-score matching may result in the loss of a considerable number of patients. However, only four patients in the DS group were excluded after matching, suggesting that at most small pretreatment differences were present between DS and ER patients. Furthermore, only patients who underwent tumor resection are included in the DCRA. DS patients who received subsequent palliative care or died during the bridging interval were therefore not included in this study. This might have resulted in a too optimistic outcome in the DS group. In a consecutive series of DS by Amelung et al, 146 patients underwent DS of whom 61 with palliative intent and 85 as BTS in the curative setting.[18] Mortality of only DS was 4/61 (6.6%) and of DS as BTS 2/85 (2.4%), resulting in an overall mortality of 4.1%. However, death within 30 days after only DS is likely occurring in palliative patients, and palliative intention of treatment was excluded in the present study in both the DS and ER groups. Finally, data on survival should be interpreted with caution as median follow-up was relatively short.

CONCLUSIONS

The current study revealed that initial colonic decompression by a stoma transformed high-risk acute surgery into minimally invasive restorative resections in a substantial proportion of patients, with corresponding benefits in outcome. Despite propensity-score matching, results might have been influenced by residual confounding.

Supplementary Figure 5, http://links.lww.com/SLA/C296, Supplementary Figure 6, http://links.lww.com/SLA/C297, Supplementary Figure 7, http://links.lww.com/SLA/C298.

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