Stoma

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CHALLENGES IN STOMA SURGERY AND PATIENT MANAGEMENT

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CHALLENGES IN STOMA SURGERY AND PATIENT MANAGEMENT

PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Universiteit Maastricht,
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Contents

Chapter 1

General introduction and outline of the thesis

Adaptation (in part) from*: The impact of an ostomy on older colorectal cancer patients: a cross-sectional survey.*

NM Verweij, ME Hamaker, DDE Zimmerman, YT van Loon, F van den Bos, A Pronk, IHM Borel Rinkes, AHW Schiphorst AHW

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Introduction

The first successful deliberate colostomy operation was performed over two hundred years ago.[1] It was created in 1793, in a newborn with an imperforate anus, who ultimately lived to the age of 45.[1-3] Colostomy operations carried high mortality rates at that time, mostly due to fatal peritonitis. Diverting colostomies were used increasingly often and became more common throughout the 20th century. At first, loop colostomies were primarily used to for fecal diversion in case of bowel obstruction when nonoperative remedies were deemed useless. It would take another almost 100 years before a "single barreled" stoma was described in 1882.[3]

Several surgeons have caused the increase in the use and popularity of a stoma. Miles was a true pioneer in rectal cancer surgery in his technique which is now known as abdominoperineal resection and secured the place for a colostomy - also known as 'abdominal anus' - as a cornerstone in the surgical treatment of rectal cancer.[4] Hartmann popularized the use of an end colostomy after a resection of sigmoid and proximal rectum with oversewing of the distal rectum stump for sigmoid carcinoma.[5] Re-anastomosis would be the delayed, second procedure. It is not known, if he himself used his eponymous procedure for complicated diverticulitis.[3] Even though over two centuries have passed since the first colostomy creation, indications and surgical techniques have remained relatively constant. Obstruction due to cancer or other causes, complicated diverticulitis, diversion of a newly formed anastomosis, radiation proctitis, and faecal incontinence are still the most frequent indications for a colostomy.

The development of the ileostomy took quite a bit longer and was first introduced in 1879 for the treatment of obstructing right colon cancer. These early 'flush' ileostomies were constructed as skin-level stomas and led to significant complications such as skin complications, retraction and stenosis. It was dr. Bryan Brooke who described the "Brooke ileostomy" in 1952 which dramatically changed and advanced stoma surgery. His "*more simple device to evaginate the ileal end at*

the time of operation and suture the mucosa to the skin; no complications have occurred from this" has significantly increased the outcomes for, but also the number of patients with ileostomies.[6] This has also led to the way in how we fashion our protruding stomas up until this day.

Surgeons were inventive in creating stomas; however, they were of little help in developing ways to manage the stomal output and stoma care. The first stoma patients were pioneers, there were no appliances available and no one to turn to for guidance or when problems were encountered. This changed when dr. Rupert Turnbull recruited one of his former ileostomy patient as "enterostomal therapist" in 1958.[7] Together they have developed reliable pouching systems and established stoma support systems and formal training programs. It is clear that especially those experts by experience are essential in their expertise, management and guidance for new stoma patients.

According to the Dutch stoma care nurses society, there are about 32,000 permanent ostomy carriers in the Netherlands (0.2% of the population) and approximately 7000 ostomies (temporary and permanent) are being placed each year (0.04% of the population). Due to increasing life expectancy, aging of the population and active screening programs for colorectal malignancies, both the overall number of ostomy carriers as well as the proportion of elderly ostomy carriers, is expected to rise even further in future years. Ostomies are being placed in 35% of the older colorectal surgery patients.[8] Decision-making regarding colorectal surgery is challenging, especially in the elderly. It is therefore important to have insight in the potential physical and mental impact, as well as care dependency and postoperative morbidity due to an ostomy in our patients. This information can be useful in preoperative patient counseling as well as in shared decision-making. Collecting such information was the primary goal of this thesis.

Outline of the thesis

The scope of the current thesis was to investigate the clinical aspects and "real-world" analyses of stoma use in colorectal surgery, in an effort to help stoma patients and to improve stoma-related morbidity. In **part I** we focus on postoperative results in stoma patients after benign and malignant colorectal surgery, critically appraising the added value of stomas and their effects in postoperative results. In **part II** we analyze the effect of easily implementable stoma pathways and their effectiveness in reducing readmissions and home care nursing services after discharge in new stoma patients, in an effort to reduce some of these well-known stoma-related problems. In **part III** we focus on the consolidation of the single port technique in stoma reversal surgery, exploring European experiences and highlighting its value compared to already existing techniques.

Part I - Use of stomas in colorectal surgery

The Hartmann's procedure has long been the mainstay for treating complicated diverticulitis. Complicated diverticular disease is defined as diverticulitis with associated abscess, phlegmon, fistula, obstruction, bleeding, or perforation.[9] Due to solid research in the past decades, other treatment options have been added. Tailored to the stage of the disease, several options are available, ranging from conservative treatment with observation and antibiotics, to primary anastomosis with or without deviating ostomy, to the original Hartmann's procedure.[10-13] Nevertheless, the debate on the optimal surgical treatment of complicated diverticulitis with peritonitis and sepsis is still not closed and the roles of laparoscopy, lavage as treatment and formation of anastomosis with or without ileostomy in emergency surgery are still under investigation.[10,14-16] **Chapter 2** investigates a decade-long single center experience of emergency surgery in complicated diverticulitis with its focus on laparoscopic Hartmann's procedures. Here we report "real-world" data in a field with conflicting results and where

randomized controlled trials are often ended prematurely due to the objective difficulties in enrolling patients in the emergency setting.

Stomas are not only used in emergency colorectal surgery for benign disorders, they are also widely accepted and propagated in elective colorectal cancer surgery. Up to 35% of the Dutch elderly patients still receive an ostomy after colorectal cancer surgery. In **chapter 3** we focus on the postoperative results and survival after left-sided colon cancer and proximal rectal cancer surgery in the elderly patient, comparing the outcomes of patients with a primary anastomosis compared to those with an end-ostomy. We explored in a nation-wide population-based study the non-inferiority of a primary anastomosis and whether differences in survival outcomes could be observed in stoma patients as compared to those with a primary anastomosis. Another well-known entity is the deviating stoma (DS), in an effort to reduce the anastomotic leakage related postoperative morbidity in patients after elective rectal cancer surgery. Our benchmark analysis showed unacceptably high rates of postoperative morbidity and complications in new ileostomy patients. This observation combined with the growing body of evidence about the disadvantages of ileostomies has led to a paradigm shift in our use of DS from 'diversion per protocol' to 'highly selective diversion' in our hospital. This policy is evaluated in **chapter 4**.

Part II - Effectiveness of pathways in new stoma patients

The care of patients with a stoma can be perceived both as an art and a science, as many of the commonly accepted interventions in stoma care are based on empirical evidence. However, the merits of clinical pathways have been reported before. The emphasis of this part of the thesis lies on the significant effects of small and easily implementable changes in our daily practice in the form of pathways, reducing morbidity and possible health care costs in patients with a stoma. In **chapter 5** we evaluate the efficacy and durability of an ileostomy pathway in an effort to reduce readmission rates for dehydration in new ileostomy patients. **Chapter 6** evaluates the effects of an easy in-hospital educational stoma pathway.

Teaching patients how to perform stoma care before and during their admission in which the stoma was created may lead to improved independence in their own stoma care and decrease of their need for home care nursing services after discharge. Whether this in-hospital educational stoma pathway is not only easily implementable in one pioneering hospital but also in others and whether the beneficial effects are reproducible is evaluated for the Dutch setting in **chapter 7**.

Part III - Use of single-port laparoscopy in stoma reversal surgery

Stoma reversal surgery of a left-sided colostomy is considered technically challenging, associated with a high risk of morbidity and even mortality. For these reasons and despite the introduction of modern surgical techniques, stoma reversal surgery is often not attempted or pursued by patients and their surgeons. Especially stoma patients who suffer from a complex abdominal wall defect are frequently discouraged in their wish for stoma reversal or hernia repair surgery due to the high rates of postoperative morbidity. Single port surgery is a technique that might limit the procedure to a confined compartment of the abdomen limiting unnecessary dissection and risks and facilitating the minimally invasive approach. First data have emerged suggesting its feasibility and safety.[17]

After these first promising results, the single-port technique was implemented and standardized as primary approach for reversal of left-sided colostomy in our hospital. These results of the biggest cohort known to date are evaluated in **Chapter 8**. In **chapter 9** we evaluate the experience of using this approach in multiple centers in Europe and offer an overview of the available literature on single-port reversal of left-sided colostomy procedures. **Chapter 10** discusses the feasibility and results of using this approach for stoma reversal in patients with concomitant complex abdominal wall defects. Specifically, this type of patients can benefit from the approach when the wish for stoma reversal exists without the specific need for hernia repair.

The thesis is concluded with a general summary and a vision on future perspectives.

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Part I

Use of stomas in colorectal surgery

Chapter 2

Time trends in emergency surgery for perforated diverticulitis: single center evaluation

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Submitted

Abstract

Purpose

Optimal surgical treatment for complicated sigmoid diverticulitis remains a subject of considerable debate, especially in the age of laparoscopy. This study evaluates the changes over time in emergency surgical treatment of perforated diverticulitis, including those after implementation of laparoscopy in a large community teaching hospital.

Methods

All patients undergoing emergency sigmoidectomy for perforated sigmoid diverticulitis in a single center from 2007 until 2018 were retrospectively analyzed. Primary outcomes were postoperative morbidity and mortality.

Results

A total of 104 patients (m:f, 58:44, median age 62.7 years, median BMI 28.4 kg/m^2) underwent emergency sigmoidectomy. Overall mortality rate was 4.8%, complication rate 66.3%, median length of stay 9.0 days. Significant rise in laparoscopic sigmoidectomy procedures was seen, resulting in 92.5% intended laparoscopic procedures from 2015 on compared to 0% in 2007-2010 and 50.0% in 2011-2014 (p<0.001). Over time significant decrease was seen in postoperative morbidity (p=0.01), in surgical site infections (p=0.001) and length of stay (p<0.001). Laparoscopic surgery also resulted in reduced postoperative morbidity (p=0.04) and shorter length of stay (p<0.001) compared to open surgery.

Conclusions

Midline laparotomy has made way for laparoscopic sigmoidectomy as the primary approach in emergency setting as treatment of choice for perforated colonic diverticulitis. A significant decrease in morbidity and length of stay over time and after laparoscopic surgery was noted.

Introduction

The optimal treatment for complicated colonic diverticulitis remains a subject of considerable debate. Advancing technologies and insights have introduced laparoscopy as new approach for different treatments such as intra-abdominal lavage and definitive treatment with a primary anastomosis as feasible therapeutic options.[1] Even though conservative treatment with observation and antibiotics have become one of the strategies for complicated diverticulitis, a Hartmann's procedure (HP, a (recto)sigmoid resection with formation of an end colostomy) continues to be a valuable procedure in the management of complicated diverticulitis to this day.[2]

Implementation of laparoscopy has led to reduction in postoperative morbidity, mortality and length of hospital stay in colorectal surgery, even in the era of enhanced recovery programs.[3] Therefore, it is not surprising that surgeons have been applying laparoscopy in the treatment of complicated diverticulitis, in an effort to reduce the high rates of morbidity and mortality of this disease. Studies have shown that laparoscopic sigmoidectomy in diverticulitis has led to faster recovery, less postoperative pain, reduction of major adverse events and improved quality of life.[4-6] Use of laparoscopy, however, still remains controversial, especially in hospitals without sufficient laparoscopic experience.[1]

Our center is a large community teaching hospital in the Netherlands. Implementation of laparoscopic surgery in 2011 resulted in a transition in all of our gastro-intestinal surgical procedures from a primarily open to primarily laparoscopic approach. Primary aim of this study was to evaluate the changes in surgical outcome defined as postoperative mortality, morbidity and length of stay after emergency sigmoidectomy for perforated diverticulitis in our hospital over time, also considering the period of implementation of laparoscopy. Moreover, we are interested in the stoma reversal rates of patients after HP in our center and if stoma reversal has increased over time, especially after introduction of laparoscopy. We postulated that the implementation of laparoscopy in emergency sigmoidectomy has improved our postoperative results by decreasing postoperative complication rates and length of stay.

Methods

All consecutive patients with perforated diverticulitis of the sigmoid colon undergoing emergency sigmoidectomy between 2007 and 2018 were included in this retrospective observational analysis. Hemodynamically unstable or septic patients were also included in this analysis. Perforated diverticulitis of the sigmoid colon was defined clinically by abdominal pain in the lower abdomen, local or generalized peritonitis during physical examination and confirmed with a radiological diagnosis defined by intra-abdominal free fluid and free air with presence of diverticulitis of the sigmoid colon on ultrasound or CT-scan of the abdomen.[7] Exclusion criteria were emergency sigmoidectomy due to other reasons such as obstructive ileus, fibrotic or stenotic diverticulitis, cancer, anastomotic leakage or colonic fistula.

Electronic patient records combined with the surgical procedure codes for open and laparoscopic sigmoidectomy were used for patient selection. Use of laparoscopy in colorectal surgery was introduced and implemented in 2011 by two colorectal surgeons specifically trained in minimally invasive surgery. This resulted in a pragmatic division of the group in periods of time from 2007-2010 (standard open approach), 2011-2014 (implementation of laparoscopy) and 2015-2018 (standard laparoscopic approach).

Primary outcomes were postoperative mortality and morbidity. Morbidity was defined by number of reinterventions, complications such as anastomotic leakage, surgical site infection, intra-abdominal abscess, ileus, infection of pulmonary or urogenital origin, intensive care unit (ICU) admission and readmissions within 30 days after discharge. Postoperative ileus as a complication was defined as a period of gastrointestinal inactivity after abdominal surgery, characterized by nausea, vomiting and delayed passage of flatus and stool, lasting for more than three days postoperatively or use of nasogastric tube.[8,9] Reinterventions were registered per patient during the admission and, if applicable, readmission period and classified under local or general anesthesia. Secondary outcomes were postoperative length of stay (LOS) and the rate of stoma reversal on last follow-up, if applicable. There was a minimum follow-up period of 12 months.

Statistical analysis

Univariate analysis, Fisher's exact test or Pearson's Chi-squared test were used to compare patient variables categorical variables. Mann-Whitney U test and Kruskal-Wallis test were used to compare continuous variables between groups. Statistical significance was defined as $p<0.05$. All statistical tests were performed with SPSS Statistics software (IBM Corp. version 26).
Approval of the institutional review board or ethics committee was not required because of the retrospective observational character of this study. The present report was prepared in concordance with STROBE guidelines.[10]

Results

Patient selection and characteristics

A total of 187 patients could be identified undergoing emergency abdominal surgery with sigmoidectomy for a variety of reasons between 2007 and 2018. All patients who underwent emergency sigmoidectomy for reasons other than perforated diverticulitis were excluded for this analysis. Flow chart about in- and exclusion can be found in Figure 2.1. Overall, 104 patients (m:f, 58:44, median age 62.7 years, median BMI 28.4 kg/m^2) were included. Detailed patient characteristics can be found in Table 2.1.

Surgical characteristics

All patients undergoing emergency sigmoidectomy received preoperative prophylactic single dose intravenous 2000mg Cefazolin and 500mg Metronidazole. All patients received postoperative intravenous Amoxicillin/clavulanic acid for at least 3 days, prolonged use of intravenous antibiotics was dependent on the clinical situation. All patients underwent a HP or sigmoidectomy with primary anastomosis (PA) with or without a deviating ileostomy at the surgeon's preference. All patients

were operated by at least one attending certified gastro-intestinal or colorectal surgeon.

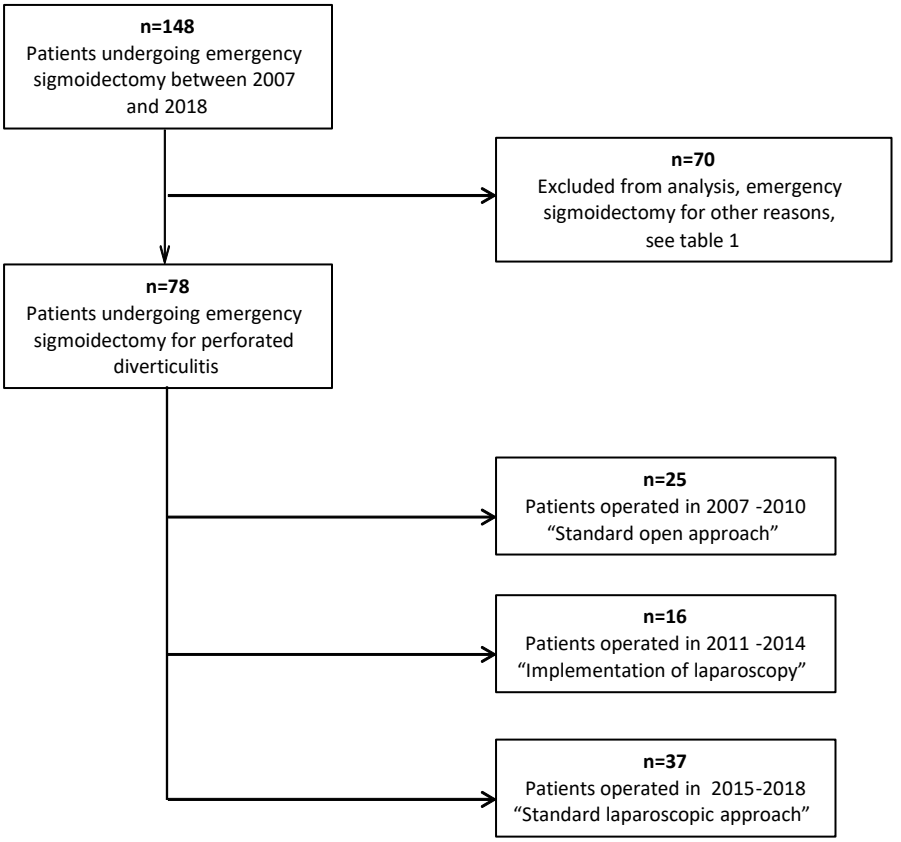

Figure 2.1 Flow chart with detailed patient selection of this study.

Table 2.1 Patient characteristics of patients who underwent emergency surgery for perforated diverticulitis.

	Total (n=104)	2007-2010 (n=25)	2011-2014 (n=26)	2015-2018 (n=53)
Gender, n (%)				
Male Female	58 (55.8)	8 (32.0)	18 (69.2)	32 (60.4)
	46 (44.2)	17 (68.0)	8 (30.8)	21 (39.6)
Median age (range)	62.7 (27.1 - 86.6)	62.7 (31.7 - 86.6)	59.9 (27.1 - 85.0)	62.9 (31.1 - 85.5)
Median BMI (range)	28.4 (17.0 - 37.8)	26.0 (19.0 - 37.8)	28.4 (19.6 - 34.7)	27.7 (17.0 - 36.4)
ASA, n (%)				
1	31 (29.8)	7 (28.0)	9 (34.6)	15 (28.3)
2	33 (31.7)	9 (36.0)	5 (19.2)	19 (35.8)
3	34 (32.7)	8 (32.0)	12 (46.2)	14 (26.4)
4	6 (5.8)	1 (4.0)	-	5 (9.4)

All procedures between 2007 and 2010 were performed via laparotomy, the first emergency laparoscopic sigmoidectomy was performed in 2011. A significant rise in the laparoscopic sigmoidectomy procedures afterwards was seen, resulting in 92.5% intended laparoscopic procedures from 2015 on, $p<0.001$. Overall, 40.4% of the procedures were performed by laparotomy, 40.3% (25/62) of the laparoscopic procedures were converted to open. Conversion from laparoscopy to open dropped significantly between 2011-2014 and 2015-2018, $p=0.002$. Variation between open, laparoscopic and converted to open emergency sigmoidectomy per category and per year can be found in Figure 2.2ab.

Overall PA was performed in 18.3% (19/104) of the patients of which 7 patients (7/19, 36.8%) received a deviating ileostomy. HP was performed in the remaining 81.7% of the patients, a slight increase from 68.0% to 86.8% was observed. Mean overall operative time was 116 minutes without significant differences over the time periods. More details can be found in Table 2.2.

Primary outcomes

Overall postoperative 30 day in-hospital mortality after emergency sigmoidectomy for perforated diverticulitis was 4.8% (n=5) and was not significantly different over time. One patient died due to irreversible severe abdominal sepsis, two patients

after acute myocardial infarction. The other two patients died due to pulmonary complications, one after aspiration during intubation, the other declined intubation for pneumonia induced respiratory failure.

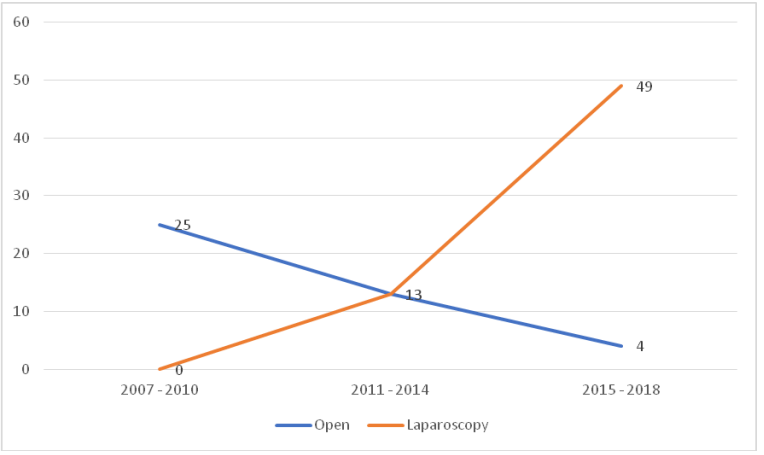

Figure 2.2a Overview of used technique for emergency sigmoidectomy per category.

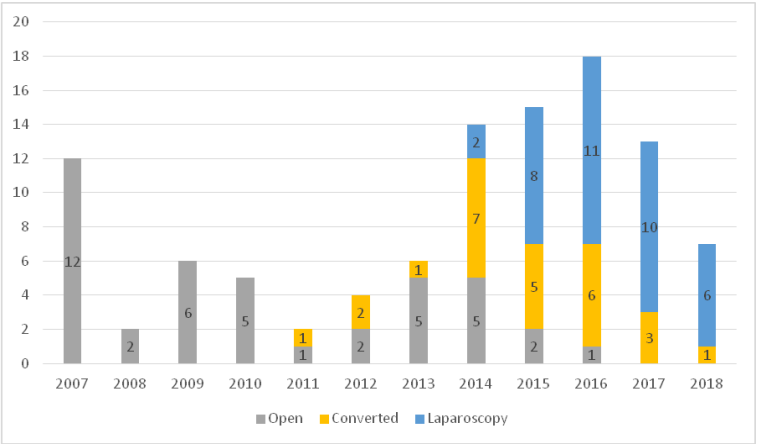

Figure 2.2b Overview of used technique for emergency sigmoidectomy per year.

No postoperative complication occurred in 33.7% of the patients during admission, nor in the 30 days after discharge. Postoperative overall complication rate was 66.3%, significant decrease in prevalence of complications were noted over time from 68% in 2007-2010 to 54.7% in 2015-2018 (p=0.01), see Table 2.2. No differences in prevalence of complications were noted between patients undergoing PA versus HP. Considerably less complications were noted in patients after laparoscopy compared to open approach, 58.7% and 78.0% respectively, p=0.04.

Table 2.2 Surgical details of patients who underwent emergency surgery for perforated diverticulitis.

	Total (n=104)	2007-2010 (n=25)	2011-2014 (n=26)	2015-2018 (n=53)	*p*-value
Mean OR time, minutes [range]	116 [54-235]	102 [56-226]	124 [81-235]	120 [54-207]	NS
Open approach, n (%)	42 (40.4)	25 (100)	13 (50.0)	4 (7.5)	<0.001
Laparoscopic approach, n (%)	62 (59.6)	-	13 (50.0)	49 (92.5)	
Conversion to open, n	25	-	10	15	0.002
PA, n (%)	19 (18.3)	8 (32.0)	4 (15.4)	7 (13.2)	NS
Ileostomy, n	7	5	1	1	
HP, n (%)	85 (81.7)	17 (68.0)	22 (84.6)	46 (86.8)	NS
Median LOS [range]	9.0 [2-54]	16.0 [2-54]	12.0 [5-48]	7.0 [2-29]	<0.001
No complication, n (%)	35 (33.7)	8 (32.0)	3 (11.5)	24 (45.3)	0.01
Overall complications, n	69 (66.3)	17 (68.0)	23 (88.5)	29 (54.7)	0.01
Surgical site infection	30 (28.8)	8 (32.0)	14 (53.8)	8 (15.1)	0.002
Intra-abdominal abscess	16 (15.4)	3 (12.0)	4 (15.4)	9 (17.0)	NS
Pulmonary	10 (9.6)	-	6 (23.1)	4 (7.5)	NS
Urogenital	7 (6.7)	2 (8.0)	3 (11.3)	2 (3.8)	NS
Ileus or gastroparesis	20 (19.2)	2 (8.0)	11 (42.3)	7 (13.2)	NS
Cardiac	12 (11.5)	2 (8.0)	4 (15.4)	6 (11.3)	NS
Rectal-stump leakage[!]	2 (2.4)	-	-	2 / 46	NS
Anastomotic leakage[*]	3 (15.8)	2 / 9	-	1 / 7	NS
Reinterventions	20 (19.2)	5 (20.0)	7 (26.9)	8 (15.1)	NS
Local anesthesia	8	1	2	5	
General anesthesia	12	4	5	3	
ICU admission	9 (8.7)	1 (4.0)	5 (19.2)	3 (5.7)	NS
Mortality, n (%)	5 (4.8)	1 (4.0)	1 (3.8)	3 (5.7)	NS
Readmissions, n (%)	18 (17.3)	2 (8.0)	6 (23.1)	10 (18.9)	NS

PA = Primary Anastomosis; HP = Hartmann's Procedure;LOS = length of stay; ICU = Intensive Care Unit; ! Percentage calculated over patients with HP; * Percentage calculated over patients with PA.

Surgical site infection (SSI) was the most frequent complication and occurred in 30 patients (28.8%). The incidence dropped from 32.0% in 2007–2010 to 14.5% in 2015-2018 (p=0.001). Subgroup analysis showed no statistically (of clinically) significant differences in SSI between patients undergoing PA versus HP nor between open versus laparoscopic approach. In the patients suffering from SSI 10% was after laparoscopy (3/30), 53.3% (16/30) after open surgery and 36.7% (11/30) after conversion from laparoscopy to open surgery.
Overall postoperative ileus rate was 19.2%, no significant difference was observed over time, nor in further subgroup analysis. Anastomotic leakage rate was 15.8% (3/19 patients) and rectal-stump leakage 2.4% (2/85 patients). Detailed overview of surgical details and postoperative complications and different subgroup analyses can be found in Table 2.2-2.4.

Table 2.3 Subgroup analysis of patients undergoing emergency sigmoidectomy with primary anastomosis versus Hartmann's procedure.

	Primary anastomosis (n=19)	Hartmann'sprocedure (n=85)	
Mean OR time, minutes [range]	112 [56-235]	115 [54-226]	NS
Open approach, n (%)	9 (47.4)	32 (37.6)	NS
Laparoscopic approach, n (%)	10 (52.6)	53 (62.4)	NS
Conversion to open, n	4 (25.0)	21 (39.6)	NS
Ileostomy, n	7 (36.8)	-	-
Median LOS [range]	13.0 [3-54]	9.0 [2-48]	NS
No complication, n (%)	6 (31.6)	29 (34.1)	NS
Overall complications, n	13 (68.4)	56 (65.9)	NS
Surgical site infection	7 (36.8)	23 (27.1)	NS
Intra-abdominal abscess	2 (10.5)	14 (16.5)	NS
Pulmonary	-	10 (11.8)	NS
Urogenital	2 (10.5)	5 (5.9)	NS
Ileus and gastroparesis	3 (15.7)	17 (20.0)	NS
Cardiac	2 (10.5)	10 (11.8)	NS
Rectal-stump leakage	-	2 (2.4)	-
Anastomotic leakage	3 (15.8)	-	-
Reinterventions	3 (15.8)	17 (20.0)	NS
local anesthesia	-	8	
general anesthesia	3	9	
ICU admission	-	9 (10.6)	NS
Mortality, n (%)	1 (5.3)	4 (4.7)	NS
Readmissions, n (%)	5 (26.3)	13 (15.3)	NS

HP = Hartmann's Procedure; LOS = length of stay; ICU = intensive care unit.

Overall reintervention, ICU admission and readmission rates were 19.2%, 8.7% and 17.3% respectively. There were no significant differences over time or in different subgroup analyses. A trend of increasing reinterventions under local anesthesia (25.0% in 2007-2010 versus 62.5% in 2015-2018) compared to decreasing reinterventions under general anesthesia (75.0% in 2007-2010 versus 37.5% in 2015-2018) can be seen over time and also in the subgroup analysis.

Secondary outcomes

Overall median LOS was 9.0 days; a statistically significant decrease of the median LOS over time was observed. Median LOS was 16 days in 2007-2014 versus 7.0 days in 2015–2018, $p<0.001$. Patients after laparoscopic surgery also had a statistically significant lower median LOS of 8 days compared to 14 days after open surgery, $p<0.001$.

Deviating ileostomy was placed in 36.8% (n=7) of the patients with PA. All of them had their ileostomy reversed (7/7, 100%) after median 111 days (71-3177), 71.4% (5/7) had no postoperative complications after restoration of continuity. Three patients with PA suffered from an anastomotic leakage. One of them died in the short-term postoperative period, the other two patients were treated with a colostomy, both of them were reversed. Overall stoma prevalence in patients with PA is 47.4% (9/19) with stoma reversal rate of 100% (9/9) and morbidity after stoma reversal of 33.3% (3/9).

In patients after HP (n=85), 10 patients were excluded from stoma reversal due to death in postoperative period (n=4), death due to unrelated metastatic disease after discharge (n=4) and death due to reasons unrelated to their previous perforated diverticulitis (n=2). Of the remaining patients, 72.0% (54/75) underwent colostomy reversal after median 219 days (40-1279), 68.5% (37/54) had no postoperative complications after their Hartmann's reversal. Rates of stoma reversal over time ranged from 60.0% (9/15) to 73.7% (14/19) to 75.6% (31/41) from the patients in 2007-2010, 2011-2014 and 2015-2018 respectively ($p=0.506$). Reasons for not restoring continuity was not always clear (4/21). Main reasons for

not pursuing stoma reversal were patients' comorbidity and/or patients' poor clinical conditions (9/21) and patients' own wish (8/21).

Table 2.4 Subgroup analysis of patients undergoing emergency sigmoidectomy via open versus laparoscopy.

	Open (n=41)	Laparoscopy[@] (n=63)	*p*-value
Mean OR time, minutes [range]	103 [56-226]	124 [54-235]	0.03
Conversion to open, n (%)	-	25 (39.7)	
PA, n (%)	10 (24.4)	10 (15.9)	NS
Ileostomy, n	6	1	0.01
HP, n (%)	31 (75.6)	53 (84.1)	NS
Median LOS [range]	14.0 [2-54]	8.0 [2-48]	<0.001
No complication, n (%)	9 (22.0)	26 (41.3)	0.04
Overall complications, n (%)	32 (78.0)	37 (58.7)	
Superficial site infection	16 (39.0)	14 (22.2)	NS
Intra-abdominal abscess	7 (17.1)	9 (14.3)	NS
Pulmonary	4 (9,8)	6 (9.5)	NS
Urogenital	4 (9.8)	3 (4.8)	NS
Ileus or gastroparesis	9 (22.0)	11 (17.4)	NS
Cardiac	5 (12.2)	7 (11.1)	NS
Rectal-stump leakage	-	2/53[!]	
Anastomotic leakage	2/10*	1/10*	NS
Reinterventions	11 (26.8)	9 (14.3)	NS
Local anesthesia	3	5	
General anesthesia	8	4	
ICU admission	5 (12.2)	4 (6.3)	NS
Mortality, n (%)	2 (4.9)	3 (4.8)	NS
Readmissions, n (%)	6 (14.6)	12 (19.0)	NS

PA = Primary Anastomosis; HP = Hartmann's Procedure; LOS = length of stay. [@] Percentages analyzed by intention to treat principle. ! Calculated over patients with HP. * Calculated over patients with PA.

Discussion

Our views and treatment for perforated or complicated diverticulitis have changed over time. Complicated diverticulitis would result in emergency surgery, mostly an HP via laparotomy, at the beginning of the 21st century. Treatments evolved further

to emergency surgery via laparoscopy to the use of percutaneous drainage, to even conservative treatment with antibiotics and careful close observation in a specific subset of patients with complicated diverticulitis.[11] We have also observed this change over time in our hospital. Use of laparoscopy in emergency surgery in patients with complicated sigmoid diverticulitis has become our standard of care. From 2014 on, almost all emergency procedures were performed via laparoscopy.

This study is, to our knowledge, one of the largest single center series including all consecutive patients, including the hemodynamically instable and septic patients, with perforated diverticulitis undergoing emergency sigmoidectomy as treatment. A significant reduction was seen in median LOS and postoperative complications over time. Even though the present study covers a long time, we believe that the implementation of laparoscopy is one of the reasons that the median LOS has significantly dropped from median 16.0 to 7.0 days over time.

We admit that as time progressed, knowledge and further sub specialization in gastrointestinal surgery have increased. Patients after gastrointestinal surgery are cared for in differentiated wards, by accompanying dedicated health care personnel. Besides this and the implementation of laparoscopy, the entrance and adherence of ERAS protocols[12] could also have contributed to the decrease in our LOS and postoperative morbidity.

Our way of aggressive surgical treatment, where patients with free air subsequently meant immediate emergency surgery, has made way for a progressively conservative mindset. Nowadays, we only tend to perform emergency surgery for complicated perforated diverticulitis in case of diffuse peritonitis combined with evident signs of sepsis. Those patients without signs of sepsis will be admitted for close observation with or without intravenous antibiotics.[13] This has led to our suspicion that operated patients for complicated diverticulitis these past years, might be patients in a worse baseline situation compared to the patients at the beginning of our observational cohort. A trend towards increase in ASA 4 patients over time can be seen in our cohort, but these numbers are too small to draw any meaningful conclusions. Other factors supporting this suspicion are difficult to find due to the retrospective nature of this cohort, but could be an interesting topic of further research.

Laparoscopic lavage is feasible for Hinchey III diverticulitis, but is not yet proven superior as treatment over a sigmoidectomy.[14-16] A multicenter, parallel-group, open label, randomized trial on laparoscopic peritoneal lavage (the LOLA-arm within the LADIES trial) has been terminated early, due to safety reasons after significant increase of morbidity and mortality.[17] Laparoscopic lavage has become an unfavorable treatment option by the majority of the surgeons in the Netherlands ever since. The LADIES trial has shown that laparoscopic sigmoidectomy with PA as treatment for Hinchey III and IV diverticulitis in hemodynamically stable and immunocompetent patients is feasible and it is being described as the appropriate surgical strategy. No differences were seen in postoperative morbidity, mortality or quality of life between HP or PA, but patients with a PA had a better stoma-free survival.[18]

Our results are in line with these results, with similar complication and mortality rates after PA or HP without differences in LOS. Another similarity is the higher rate of stoma reversal in patients after PA compared to those after HP. Our experiences with single-port reversal of HP, with favorable postoperative results, have resulted in our lower threshold to perform colostomy reversal.[19] Benefits of the single-port technique such as steering clear from midline adhesions and incisional hernias are especially prominent in patients after laparotomy and prior complicated postoperative course.[20] Remarkably, all of the patients with deviating ileostomy pursued or were offered restoration of intestinal continuity surgery in contrast to the patients after HP. The overall high morbidity, stoma related complications and impaired quality of life of ileostomy patients might influence the patients' or surgeons' decision to pursue ileostomy reversal surgery.[21,22] The fact that a third of the HP patients do not pursue colostomy reversal surgery, might imply that they are satisfied with their current situation with a permanent stoma and choose this over possible morbidity after reversal surgery. This is an interesting avenue of further research, to quantify patients' motivations to pursue or decline stoma reversal surgery.

Significant reduction can be seen in SSI over time and in subgroup analysis in favor of laparoscopy. A trend in reduction in reinterventions can be seen in favor of laparoscopy and a trend of increasing reinterventions under local anesthesia

compared to decreasing reinterventions under general anesthesia can be seen over time and also in the subgroup analysis. These numbers are too small to reach statistical significance, but are clinically important. Less invasive reinterventions such as percutaneous drainage instead of relaparotomy or reintervention under general anesthesia might be another reason for the overall reduction of LOS.
A major limitation of this study is its retrospective observational character. Identifying patients through patient electronic records and surgical procedure codes might result in missing patients in this present study. Patients were not stratified or case matched for HP or PA, these decisions were left at the surgeon's discretion, which must have resulted a certain selection and treatment bias especially for the PA group. Another limitation of this study is the introduction of ERAS protocols with increasing adherence over time on our dedicated colorectal surgical wards during the time of the study, which leads to difficulty interpreting or finding the cause of the improvements in postoperative results we have seen over time.

Conclusions

Surgical treatment of perforated sigmoid diverticulitis is ever evolving. Laparoscopic sigmoidectomy has become our primary treatment for patients with perforated diverticulitis in need of surgery. Over time, significant decrease in postoperative morbidity and length of stay was noted in our hospital, without changes in mortality. A significant decrease in morbidity and length of stay over time and after laparoscopic surgery was noted.

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Chapter 3

Primary anastomosis versus end-ostomy in left-sided colonic and proximal rectal cancer surgery in the elderly Dutch population: a propensity score matched analysis

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Abstract

Background
Primary anastomosis (PA) in left-sided colorectal cancer (CRC) surgery in elderly patients is disputed. The aim of our study was to evaluate the differences in postoperative outcomes after left-sided CRC surgery in elderly patients in The Netherlands, comparing patients with PA and those who underwent end-ostomy (EO).

Methods
Patients aged C 75 years with stage I–III leftsided CRC, diagnosed and surgically treated in 2015–2017 were selected from the Netherlands Cancer Registry (n=3286). Postoperative outcomes, short-term (30-, 60-, and 90-day) mortality and 3-year overall and relative survival were analyzed, stratified by surgical resection with PA versus EO. Propensity score matching (PSM) and multivariable logistic regression analysis were conducted.

Results
Patients with higher age, higher American Society of Anesthesiologists classification and higher tumor stage, a perforation, ileus or tumor located in the proximal rectum, and after open or converted surgery were more likely to receive EO. No difference in anastomotic leakage was seen in PA patients with or without defunctioning stoma (6.2% vs. 7.0%, p=0.680). Postoperative hospital stay was longer (7.0 vs. 6.0 days, p<0.0001) and more often prolonged (19% vs. 13%, p=0.03) in EO patients. Sixty-day mortality (2.9% vs. 6.4%, p<0.0001), 90-day mortality (3.4% vs. 7.7%, p<0.0001), and crude 3-year survival (81.2% vs. 58.7%, p<0.0001) were significantly higher in EO patients, remaining significant after multivariable and PSM analysis.

Conclusion
There are significant differences between elderly patients after left-sided CRC surgery with PA versus EO in terms of postoperative length of stay, shortterm survival, 3-year overall survival, and relative survival at disadvantage of EO patients. This information could be important for decision making regarding surgical treatment in the elderly.

Introduction

The incidence of colorectal cancer (CRC) is still increasing in Eastern Europe, Asia, and South America; however, the incidence rate and mortality is stabilizing or even declining in the US, New Zealand, Australia, and several Western European countries, including The Netherlands.[1,2] Approximately 50% of patients with CRC in Europe and the US are older than 70 years,[3] and hence elderly patients are therefore rapidly becoming the 'new normal' CRC surgical population and our surgical treatment should be adapted to these patients accordingly.

Few surgeons prefer the morbidity of an ileostomy over the low risk of an anastomotic leakage after right hemicolectomy. In a recent international audit, 95% of the patients after right hemicolectomy received a primary anastomosis (PA);[4] however, the choice of an anastomosis in left-sided CRC used to be heavily disputed. The retrospective Dutch Total Mesorectal Excision trial showed a mortality rate of 57% in elderly patients, compared with 8.2% in younger patients, when there was an anastomotic leakage.[5] Age is an important risk factor for 30-day mortality and all types of general complications, but not for anastomotic leakage.[6] Despite this, up to 35% of Dutch elderly patients still receive an ostomy after CRC surgery.[7] Older Dutch patients with an ostomy do not experience more ostomy-related limitations, nor a decrease in quality of life compared with their younger counterparts.[8] Nevertheless, according to the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) surgical risk calculator, this population benefits from less postoperative morbidity and mortality after a PA compared with patients who were treated with an end-ostomy (EO).[9] Unfortunately, no Dutch or European equivalent of this risk calculator is available for CRC surgery.

More information on the use and effect of ostomies can be useful in preoperative patient counseling and shared decision making. The aim of our study was to evaluate the differences in postoperative outcomes, hospital admission, short-term mortality, and 3-year overall and relative survival after left-sided colon cancer and rectal cancer surgery in elderly patients in The Netherlands, comparing the outcomes of patients after PA with those with EO.

Methods

Data collection

Data from the Netherlands Cancer Registry (NCR), a population-based registry covering all newly diagnosed malignancies in The Netherlands as notified by the automated pathological archive (PALGA) and the National Registry of Hospital Discharge Diagnoses (LMR), were used. Information on patient and tumor characteristics, diagnosis, and treatment are routinely extracted from the medical records by trained administrators of the NCR. The anatomical site of the tumor is registered according to the International Classification of Diseases for Oncology (ICDO). The UICC TNM (Union for International Cancer Control tumor-node-metastasis) classification is used for stage notification of the primary tumor, according to the edition valid at the time of diagnosis, and performance status is (re)coded according to the WHO, as described by Ma et al.[10] Comorbidity is registered according to a modified version of the Charlson Comorbidity Index and for a subgroup only, i.e. for all patients diagnosed in 2015 and for patients from one region in The Netherlands from 2016 onwards. The collected data includes patient and tumor characteristics, American Society of Anesthesiologists (ASA) classification, performance status, comorbidity, postoperative length of stay, anastomotic leakage, and postoperative and long-term mortality. Anastomotic leakage is defined as leakage of intestinal fluids or abscess formation at the place of the anastomosis that requires either a surgical or radiological reintervention, or treatment with an endosponge, within 60 days postoperatively. As a proxy for a complicated postoperative course, a prolonged postoperative hospital admission (defined as >14 days) was used. Patients' vital status is obtained by annual linkage of the NCR to the Municipal Personal Records Database, which records information on the vital status of Dutch inhabitants. Follow-up on vital status was complete to 31 January 2020.

Study population

The present study included patients aged ≥75 years with stage I–III left-sided colon cancer or proximal rectal cancer, who were diagnosed in 2015–2017 and underwent surgical resection of the tumor. Left-sided colon cancer was defined as being located in the left part of the transverse colon, and the descending or sigmoid colon (C18.4–18.7). Proximal rectal cancer encompassed tumors located in the rectosigmoid (C19.9) and tumors ≥10 cm from the anus in the rectum (C20.9). Only patients who underwent a single surgical resection, being a transverse colon resection, left hemicolectomy, sigmoidectomy (including Hartmann's resection), or low anterior resection were included. Furthermore, emergency resections and (extended) right hemicolectomy procedures were excluded. In case of multiple tumors per patient, only the tumor with the earliest date of diagnosis was selected. When the date of diagnosis was equal, the tumor with the most advanced stage was selected. For TNM stage, pathological stage was used. In case pathological stage was unknown or missing, clinical TNM stage was used.
Patients were categorized into two groups based on whether they received an anastomosis or an EO and, if so, which type. The first group entailed all patients with an anastomosis with or without a defunctioning ostomy and was labeled as 'primary anastomosis' (PA). The second group encompassed all patients who received an EO without PA and was labeled as such. Patients with an unknown type of ostomy were excluded.

Propensity score matched sample

Because of the population-based nature of the data, comparing outcomes of patients who received a PA with patients who received an EO is biased. Therefore, a subsample was created using propensity score matching (PSM), to reduce treatment assignment bias and create comparable groups. Propensity scores were determined using a logistic regression model in which the dependent variable was surgical resection with PA versus EO and the independent variables were factors potentially associated with this variable, i.e. sex, age, American Society of Anesthesiologists (ASA) classification, comorbidity, year of diagnosis, tumor

location, tumor stage, differentiation grade, ileus, perforation, surgical approach, and neoadjuvant treatment. The propensity score represented the probability that a patient would receive an EO. On the basis of the propensity scores, patients who received an EO were matched 1:3 to patients who received a PA, optimizing the closeness of the matches by assigning the closest matches first. Individuals were matched on propensity scores using a caliper width equal to 0.2 of the standard deviation of the logit propensity score.

Statistical analyses

For both the study population and the PSM sample, differences in patient, tumor, and treatment characteristics between patients who underwent a surgical resection with PA versus EO were analyzed using Chi-square tests.

In the total study population, multivariable logistic regression analysis was conducted to assess which patient, tumor, and treatment characteristics influenced the probability of receiving an EO. Variables included in this analysis were sex, age, ASA classification, performance status, year of diagnosis, location of the tumor, tumor stage, differentiation grade, ileus, perforation, resection type, surgical approach, and neoadjuvant treatment.

Between the groups of patients who underwent a surgical resection with PA versus EO, differences in length of hospital stay, prolonged hospital admission, and postoperative 30-, 60-, and 90-day mortality were calculated using the Wilcoxon rank-sum test, Chi-square test, or Fisher's exact test as appropriate. Multivariable logistic regressions were used to assess if an EO was associated with prolonged hospital admission and postoperative 90-day mortality after adjustment for other variables. These variables were the same patient, tumor, and treatment characteristics as listed in the logistic model above.

Within the PA group, differences in the occurrence of an anastomotic leakage and/or abscess between patients with no ostomy versus a defunctioning ostomy were assessed using the Chi-square test.

After stratification by surgical resection with PA versus EO, crude 3-year overall and relative survival rates were calculated. Relative survival is defined as the ratio of

the absolute survival observed among cancer patients and the survival that would have been expected for a comparable group from the general population (same age, sex, and period). Expected survival was calculated from population life tables from The Netherlands. Multivariable Cox regression was used to evaluate the independent impact of receiving an EO versus PA on the risk of death. For the calculation of relative excess risk of death (RER), multivariable regression models with a Poisson error structure were fitted. Both multivariable models were adjusted for the aforementioned characteristics and additionally for prolonged hospital admission and adjuvant treatment. Overall survival time was defined as the time between the date of resection to the date of death or last follow-up. Relative survival was measured from 90 days after surgery to overcome the higher-risk postsurgical period.

All analyses on short-term outcomes and survival were performed for both the total study population and the PSM sample. Furthermore, analyses were also repeated for the subgroup of patients from the total study population for whom comorbidity was registered.

P values<0.05 were considered statistically significant. SAS/STAT statistical software (version 9.4; SAS Institute Inc., Cary, NC, USA) was used for all analyses.

Results

The total study population consisted of 3286 patients (male/female: 1973/1313; median age 79 years), of whom 2661 (81%) received a PA and 625 (19%) received an EO. Within the PA group, a minority of patients received a defunctioning ostomy (n=227, 9%). Most patients had an ASA classification of II (54%) or III (33%). Performance status was known for 1351 (41%) patients, of whom half had a score of 0. Comorbidity was registered for 54% of patients, and a large majority (79%) had a tumor located in the left-sided colon. There were considerable differences in patient and tumor characteristics between patients who received a PA and patients who received an EO (Table 3.1). Defunctioning ostomies were mostly ileostomies, while almost all EO were colostomies.

The PSM sample consisted of 1392 patients: 348 (57%) of the EO patients could be matched to 1044 patients in the PA group. There were no differences in patient and tumor characteristics between both groups (Table 3.1).

Table 3.1 Patient, tumor and treatment characteristics of the total study population (n=3286) and the propensity score matched sample (n=1392) according to surgical resection with primary anastomosis versus end-ostomy.

	Total study population			PSM sample		
	Primary anastomosis	End-ostomy	*p*-value	Primary anastomosis	End-ostomy	*p*-value
Gender			0.229			0.660
Male	1611 (61%)	362 (58%)		620 (59%)	202 (58%)	
Female	1050 (39%)	263 (42%)		424 (41%)	146 (42%)	
Age			<0.0001			0.629
75-79 years	1525 (57%)	186 (30%)		392 (38%)	132 (38%)	
80-84 years	814 (31%)	242 (39%)		419 (40%)	131 (38%)	
≥85 years	322 (12%)	197 (31%)		233 (22%)	85 (24%)	
ASA classification			<0.0001			0.668
I	167 (6%)	16 (3%)		35 (3%)	8 (2%)	
II	1508 (57%)	259 (41%)		471 (45%)	163 (47%)	
III	807 (30%)	291 (47%)		444 (43%)	144 (42%)	
IV	39 (2%)	26 (4%)		32 (3%)	8 (2%)	
Unknown	140 (5%)	33 (5%)		62 (6%)	25 (7%)	
WHO performance status			<0.0001			0.946
0	599 (22%)	96 (15%)		182 (17%)	64 (19%)	
1	424 (16%)	88 (14%)		138 (13%)	43 (12%)	
2-4	102 (4%)	42 (7%)		50 (5%)	18 (5%)	
Unknown	1536 (58%)	399 (64%)		674 (65%)	223 (64%)	
Number of comorbidities[#]			0.0001			0.621
0	612 (42%)	96 (31%)		168 (31%)	62 (34%)	
1	521 (36%)	120 (38%)		215 (39%)	65 (36%)	
≥2	327 (22%)	99 (31%)		163 (30%)	55 (30%)	
Year of diagnosis			0.172			0.921
2015	943 (35%)	197 (32%)		357 (34%)	123 (35%)	
2016	869 (33%)	220 (35%)		342 (33%)	113 (33%)	
2017	849 (32%)	208 (33%)		345 (33%)	112 (32%)	
Location of the tumor			<0.0001			0.608
Left-sided colon	2164 (81%)	420 (67%)		879 (84%)	297 (85%)	
Proximal rectum	497 (19%)	205 (33%)		165 (16%)	51 (15%)	

Table 3.1 (continued)

	Total study population			PSM sample		
	Primary anastomosis	End-ostomy	*p*-value	Primary anastomosis	End-ostomy	*p*-value
Tumor stage			<0.0001			0.619
I	725 (27%)	107 (17%)		207 (20%)	61 (18%)	
II	1018 (38%)	276 (44%)		462 (44%)	161 (46%)	
III	998 (35%)	242 (39%)		375 (36%)	126 (36%)	
Differentiation grade			0.572			0.894
Well/moderate	2329 (87%)	549 (88%)		906 (87%)	299 (86%)	
Poor/undifferentiated	127 (5%)	34 (5%)		59 (6%)	20 (6%)	
Unknown	205 (8%)	42 (7%)		79 (7%)	29 (8%)	
Ileus			<0.0001			0.987
No	2441 (92%)	520 (83%)		899 (86%)	300 (86%)	
Yes	165 (6%)	100 (16%)		131 (13%)	43 (12%)	
Unknown	55 (2%)	5 (1%)		14 (1%)	5 (2%)	
Perforation			<0.0001			0.685
No	2485 (93%)	558 (89%)		962 (92%)	316 (90%)	
Yes	57 (2%)	44 (7%)		38 (4%)	16 (5%)	
Unknown	119 (5%)	23 (4%)		44 (4%)	16 (5%)	
Resection type			<0.0001			0.816
Transversum resection	159 (6%)	17 (3%)		50 (5%)	13 (4%)	
Left hemicolectomy	507 (19%)	93 (15%)		190 (18%)	68 (20%)	
Sigmoid resection	1275 (48%)	459 (73%)		649 (62%)	214 (61%)	
Low anterior resection	720 (27%)	56 (9%)		155 (15%)	53 (15%)	
Surgical approach			<0.0001			0.730
Laparoscopic	2035 (76%)	360 (57%)		657 (63%)	211 (61%)	
Laparoscopic converted to	262 (10%)	85 (14%)		146 (14%)	53 (15%)	
open	364 (14%)	180 (29%)		241 (23%)	84 (24%)	
Open						
Location stoma			<0.0001			<0.0001
Ileostomy	182 (7%)	15 (2%)		59 (6%)	12 (3%)	
Colostomy	45 (2%)	610 (98%)		29 (3%)	336 (97%)	
No stoma	2434 (91%)	0 (0%)		956 (91%)	0 (0%)	
Neo-adjuvant treatment			0.001			0.685
None	2463 (93%)	550 (88%)		976 (93%)	326 (94%)	
Radiotherapy	131 (5%)	47 (8%)		47 (5%)	13 (4%)	
Chemoradiation	67 (2%)	28 (4%)		21 (2%)	9 (2%)	
Adjuvant chemotherapy			<0.0001			0.063
No	2366 (89%)	598 (96%)		944 (90%)	326 (94%)	
Yes	295 (11%)	27 (4%)		100 (10%)	22 (6%)	

PSM: propensity score matched, [#]Comorbidity was available for a subgroup.

Factors associated with receiving an end-ostomy versus primary anastomosis

Table 3.2 presents the crude percentages and adjusted odds ratios (OR) for receiving an EO. Patients with advanced age, higher ASA classification, tumor located in the proximal rectum, tumor stage III, an ileus, or a perforation were more likely to receive an EO. Furthermore, patients who underwent a sigmoid resection and patients who underwent open or converted (from laparoscopic to open) surgery also had higher odds of receiving an EO. Additionally, in a subgroup analysis of patients for whom comorbidity was known, it was found that patients with two or more comorbidities were also more likely to receive an EO than patients without comorbidity [23% vs. 14%, adjusted OR 1.76, 95% confidence interval (CI) 1.19–2.62].

The proportion of patients receiving an EO varied considerably between hospitals: from 0 to 59% (median 18.4%, interquartile range 8.8–25.0%, calculated over 72/75 hospitals with ≥10 patients from the study population). There were no differences in EO between university versus non-university hospitals: 20.0% vs. 19.0% (*p*=0.767).

Table 3.2 Crude percentages and adjusted odds ratios for receiving an end-ostomy versus primary anastomosis among the total study population.

	Crude % end-ostomy	Adjusted odds ratio* (95% CI)
Gender		
Male	18%	1.00 (reference)
Female	20%	1.05 (0.84-1.30)
Age		
75-79 years	11%	1.00 (reference)
80-84 years	23%	1.93 (1.52-2.46)
≥85 years	38%	4.10 (3.11-5.39)
ASA classification		
I	9%	0.52 (0.27-0.97)
II	15%	1.00 (reference)
III	27%	1.91 (1.52-2.40)
IV	40%	3.17 (1.73-5.83)

Table 3.2 (continued)

	Crude % end-ostomy	Adjusted odds ratio* (95% CI)
Performance status		
0	14%	1.00 (reference)
1	17%	0.94 (0.64-1.38)
2-4	29%	1.57 (0.94-2.62)
Year of diagnosis		
2015	17%	1.00 (reference)
2016	20%	0.86 (0.67-1.12)
2017	20%	0.76 (0.59-0.99)
Location of the tumor		
Left-sided colon	16%	1.00 (reference)
Proximal rectum	29%	20.43 (13.27-31.47)
Tumor stage		
I	13%	1.00 (reference)
II	21%	1.48 (1.10-1.98)
III	21%	1.34 (0.98-1.82)
Differentiation grade		
Well/moderate	19%	1.00 (reference)
Poor/undifferentiated	21%	0.99 (0.62-1.58)
Ileus		
No	18%	1.00 (reference)
Yes	38%	1.91 (1.37-2.65)
Perforation		
No	18%	1.00 (reference)
Yes	44%	3.07 (1.86-5.07)
Resection type		
Transversum resection	10%	0.44 (0.25-0.80)
Left hemicolectomy	16%	1.00 (reference)
Sigmoid resection	26%	2.03 (1.53-2.71)
Low anterior resection	7%	0.06 (0.04-0.11)
Surgical approach		
Laparoscopic	15%	1.00 (reference)
Laparoscopic with conversion to open	25%	1.87 (1.36-2.57)
Open	33%	2.60 (1.98-3.39)
Neo-adjuvant treatment		
None	18%	1.00 (reference)
Radiotherapy	26%	0.83 (0.49-1.43)
Chemoradiation	29%	1.08 (0.54-2.17)

*Adjusted for all variables listed. ASA classification unknown, performance status unknown, differentiation grade unknown, ileus unknown and perforation unknown were included in the analysis but results not shown.

Short-term outcomes

The occurrence of an anastomotic leakage and/or abscess was known for 98% (n=2603) of patients with PA. There was no statistically significant difference in the occurrence of an anastomotic leakage and/or abscess between patients with or without a defunctioning stoma

Postoperative hospital stay was longer and more often prolonged (i.e. >14 days) in the EO group (Table 3.3), both in the total study population and in the PSM sample. In multivariable analysis, patients with EO were still more likely to have a prolonged hospital admission compared with patients with PA (adjusted OR 1.61, 95% CI 1.22-2.11). Furthermore, postoperative mortality 30, 60, and 90 days after surgery was higher in patients with EO (Table 3.3). However, the association with 90-day mortality was no longer significant in multivariable analysis in which correction for sex, age, ASA classification, performance status, year of diagnosis, location of the tumor, tumor stage, differentiation grade, ileus, perforation, resection type, surgical approach, and neoadjuvant treatment was undertaken (adjusted OR 1.29, 95% CI 0.84–1.99) [electronic supplementary Table S3.1]. Subgroup analyses among patients with known comorbidity provided similar results (data not shown).

In the PSM sample, postoperative mortality 30 days after surgery was no longer statistically significant; however, mortality 60 and 90 days after surgery remained statistically significantly higher in patients with EO (Table 3.3). Furthermore, in univariable and multivariable analysis, patients with ASA IV, a perforation, after open surgery, and with EO had higher odds of dying within 90 days compared with patients with PA (electronic supplementary Table S3.1).

Table 3.3 Length of hospital stay, prolonged hospital admission and postoperative mortality according to surgical resection with primary anastomosis versus end-ostomy among the total study population and the propensity score matched sample.

	Total study population			PSM sample		
	Primary anastomosis	End-ostomy	*p*-value	Primary anastomosis	End-ostomy	*p*-value
Length of hospital stay (days)			<0.0001			<0.0001
Median (interquartile range)	5 (4-8)	7 (6-13)		6 (4-9)	7 (5-13)	
Prolonged hospital admission			<0.0001			<0.0001
Yes	288 (11%)	124 (20%)		119 (11%)	72 (21%)	
No	2355 (88%)	494 (79%)		921 (88%)	273 (78%)	
Unknown	18 (1%)	7 (1%)		4 (1%)	3 (1%)	
Postoperative 30-day mortality % death	2.1%	4.6%	0.0004	2.8%	3.7%	0.366
Postoperative 60-day mortality % death	2.9%	6.4%	<0.0001	3.5%	6.0%	0.044
Postoperative 90-day mortality % death	3.4%	7.7%	<0.0001	4.0%	6.9%	0.029

PSM: propensity score matched.

Survival

In the total study population, the median follow-up time was 37 months. Crude 3-year overall survival was 81.2% for patients in the PA group versus 58.7% in the EO group (p<0.0001) (Figure 3.1). Furthermore, in multivariable analysis, the risk of death was higher in patients with EO compared with those with PA (Table 3.4). Subgroup analyses among (1) patients with known comorbidity and (2) patients who did not receive (neo)adjuvant treatment did not change this (results not shown). Differences between the PA and EO groups were still prominent in relative survival, with significantly higher relative survival among patients in the PA group, both in univariable and multivariable analyses (Figure 3.2, Table 3.4).

In the PSM sample, the median follow-up time was 35 months. Differences in crude 3-year overall and relative survival between patients in the PA group and patients who received an EO remained significant, also in multivariable analyses (Table 3.4).

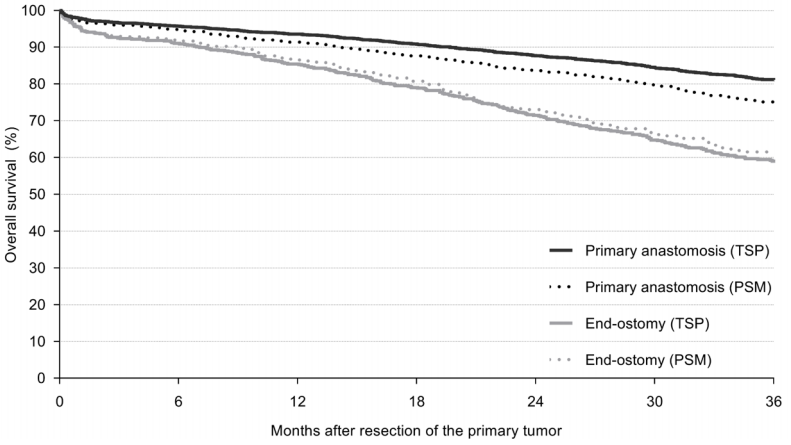

Figure 3.1 Three-year overall survival of the total study population and the propensity score matched sample according to surgical resection with primary anastomosis versus end-ostomy. TSP: total study population; PSM: propensity score matched sample.

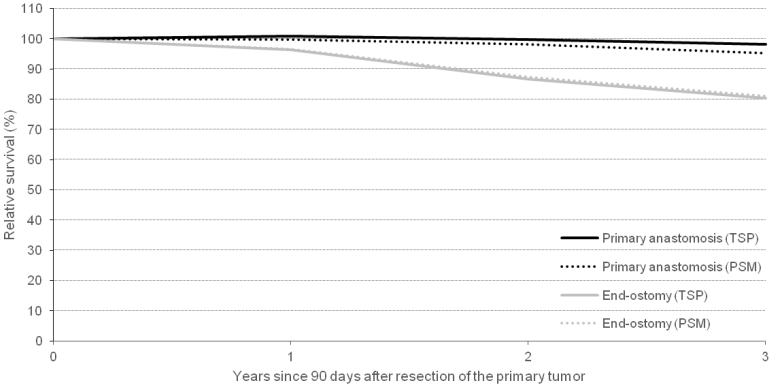

Figure 3.2 Three-year relative survival of the total study population and the propensity score matched sample according to surgical resection with primary anastomosis versus end-ostomy. TSP: total study population; PSM: propensity score matched sample. The lines for end-ostomy (TSP) and end-ostomy (PSM) are overlapping.

Table 3.4 Overall and relative survival and risks of death according to surgical resection with primary anastomosis versus end-ostomy.

		Overall survival		Relative survival	
		Crude 3-year OS %	Adjusted HR of death* (95% CI)	Crude 3-year RS %	RER of death* (95% CI)
Total study population	Primary anastomosis	81.2	1.00 (reference)	98.1	1.00 (reference)
	End-ostomy	58.7	1.59 (1.35-1.87)	80.3	2.55 (1.64-3.97)
PSM sample	Primary anastomosis	75.1	1.00 (reference)	95.3	1.00 (reference)
	End-ostomy	61.5	1.61 (1.32-1.97)	81.1	2.23 (1.34-3.72)

OS: overall survival; HR: hazard ratio; RS: relative survival; RER: relative excess risk of death; PSM: propensity score matched. *Adjusted for gender, age, ASA classification, performance status, year of diagnosis, tumor location, tumor stage, differentiation grade, resection type, surgical approach, prolonged hospital admission, neo-adjuvant and adjuvant treatment.

Discussion

To our knowledge, this is the first nationwide population-based study focused on the short-term outcomes and 3-year survival in elderly patients undergoing left-sided colon and proximal rectal cancer surgery with PSM. Our data suggest non-inferiority of PA compared to EO in mortality up to 90 days, analyzing PSM samples. Therefore, both patients and surgeons should evaluate the true benefits of an EO, based on alleged mortality risks, within the first month after surgery.

Postoperative hospital stay was longer and more often prolonged in EO patients, also after multivariable analysis and PSM. Pre-existent comorbidity or functional dependency may lead to an extended length of stay. Furthermore, increased length of stay in EO patients might be attributable to the fact that they are not independent in their stoma care when they are medically ready to be discharged. Arranging home-visiting nursing services often takes a couple of days.[11] Worth noting is that an easy standardized in-hospital educational stoma pathway improves the level of independence in new stoma patients and reduces the need for home-visiting nursing services.[12] Pre- and postoperative stoma education has shown to be effective in reducing the postoperative hospital stay in a younger population.[13] It is a challenge to achieve the same positive effects of stoma

educational pathways in the elderly population, and this may be an interesting subject for future research.

Deviating ostomies do not seem to influence the incidence of an anastomotic leakage in PA patients in our study. These findings, as well as the fact that deviating ostomies seem to ameliorate the consequences of a leak, have been previously reported.[14,15] Our registry did not encompass details such as postoperative reinterventions, intensive care unit (ICU) admissions, or readmissions after discharge; therefore, we cannot conclude that deviating ostomies reduce clinically relevant leakages or possible consequences of a leak in the Dutch elderly population. Furthermore, the fact that an anastomotic leakage is defined in many different ways, makes it hard to compare findings between studies. This database only registers anastomotic leakages based on radiological findings (as stated above), which might have resulted in an underrepresentation. However, the definition of anastomotic leakage for the NCR did not change over time, therefore any possible underrepresentation would be the same for the total study population.

A striking finding in our study is the difference in overall and relative long-term (3-year) survival in disadvantage of EO patients. The decreased overall and relative survival in EO compared with PA was significant in univariable, multivariable, and PSM analyses. Even though the impact of an ostomy on quality of life in elderly patients has been previously reported,[8,16] little can be found on the impact of an ostomy on the survival of elderly patients after CRC surgery. Our data show that patients with two or more comorbidities are more likely to receive an EO; however, univariable and multivariable analysis show that this degree of comorbidity does not influence survival.

Studies have shown that postoperative ostomy-related complications such as prolapse, necrosis, stenosis, retraction, leakage, and others can be as high as up to 70%.[17] The possible complications or reoperations may worsen quality of life, mental status, or social functioning and could be detrimental for the elderly patient. This effect may be an additional cause for the significantly higher 60- and 90-day postoperative mortality that we found in elderly EO patients. Multivariable analysis showed that age ≥85 years, ASA IV, perforation at the time of surgery, and

open surgery are not only risk factors for receiving an EO but also for dying within 90 days postoperatively. Various factors that may or may not be obvious, detected at the initial outpatient assessment but not included in the database, might have led to the surgeons' choice for an EO instead of an anastomosis. For example, the severity of comorbidities or the interplay between comorbidity and functional status might be such factors. Ultimately, no method reduces confounding by unmeasured variables. Indeed, frailty (vulnerability due to a decline of interrelated physiological systems), weight loss, and disability (presence of restriction in at least one activity of daily living) are a few examples of those factors that influence the vulnerability and survival of the elderly patient.[18,19] Specific preoperative assessment, such as a comprehensive geriatric assessment (CGA) helps in predicting postoperative morbidity and mortality.[20] In particular, dependency in instrumental activities of daily living, depression, polypharmacy, and impaired nutrition are important in predicting postoperative complications and early mortality.[20–23] Previous research has shown that the occurrence of complications was the strongest risk factor for reduced survival in octogenarians.[24] These results emphasize the importance of proper outpatient clinic consultation and the need for registration of the appropriate information regarding elderly patients beyond the standard given or measurable information that can be found in the medical charts. Performance scores, level of frailty, or CGA can be routinely assessed in clinical practice but unfortunately are not routinely documented in the charts or the data registries. In contrast, long-term survival is determined by a more complex interplay of non-surgical factors.

This study is also limited due to its retrospective, observational character and by the fact that occurrence of complications (other than anastomotic leakage and abscess) and causes of death are not registered in the NCR. The lack of complete information regarding the severity of comorbidities or performance scores are major limitations of this study, since both are important factors that can influence postoperative morbidity and survival. Relative survival was used in an effort to match cancer-specific survival as an estimation. This unfortunate shortcoming in the NCR data leaves many unknowns in our search for the exact causes of the survival differences in our elderly patients.

The downside of using PSM analysis is that the exclusion of patients from this analysis leads to loss of power. Nevertheless, PSM ensured the comparability of patients in both analyzed groups and provides additional information on subgroups in addition to the usual analysis in population-based data registries.
Relevant focus for further research would be to include more extensive data on performance scores, CGA, comorbidities, and postoperative complications that could lead to a European equivalent of the ACS NSQIP calculator and a better understanding of the survival and optimal treatment for our elderly patients with left-sided CRC. This information could be important for the decision making on surgical treatment in the elderly. Furthermore, repeating this analysis in 5 or 10 years, to evaluate the possible changes in EO rates and survival over time, as well as evaluation of interhospital variation in EO rates, would enrich the information for this decision making.
Despite the limitations of this study, one of its strengths is that it is based on the most comprehensive nationwide cancer registry with survival information that we have in The Netherlands. It shows real-life data and is a representation of our national elderly population with CRC. The discrepancies in 60- and 90-day mortality, as well as overall and relative survival, between patients with a PA and EO may be biased due to the different patient-specific factors, even though we have tried to correct for this using univariable, multivariable, and PSM analyses. Since there is significant difference in short-term mortality and overall and relative survival between patients with PA or EO in favor of PA, one might advocate that it is advisable to try to avoid the use of EO. A critical assessment on comorbidities, potential handling of an EO, age, and tumor stage will be necessary to argue in favor of an EO.

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Table S3.1 Crude percentages, univariable and multivariable odds ratios for postoperative 90-day mortality among the total study population and the propensity score matched sample.

	Total study population			Propensity score matched sample		
	%	Univariable OR (95% CI)	Multivariable OR* (95% CI)	%	Univariable OR (95% CI)	Multivariable OR* (95% CI)
Gender						
Male	4.5%	1.00 (reference)	1.00 (reference)	4.6%	1.00 (reference)	1.00 (reference)
Female	3.7%	0.82 (0.58-1.17)	0.64 (0.44-0.93)	4.9%	1.07 (0.65-1.76)	0.95 (0.56-1.63)
Age						
75-79 years	2.3%	1.00 (reference)	1.00 (reference)	2.1%	1.00 (reference)	1.00 (reference)
80-84 years	4.6%	2.09 (1.36-3.20)	1.71 (1.10-2.67)	5.1%	2.50 (1.23-5.08)	2.43 (1.16-5.07)
≥85 years	9.6%	4.57 (2.97-7.03)	3.53 (2.21-5.65)	8.5%	4.33 (2.12-8.85)	5.55 (2.58-11.92)
ASA classification						
I	0.6%	0.19 (0.03-1.37)	0.24 (0.03-1.78)	2.3%	0.77 (0.10-5.90)	1.24 (0.16-9.93)
II	2.8%	1.00 (reference)	1.00 (reference)	3.0%	1.00 (reference)	1.00 (reference)
III	5.8%	2.13 (1.46-3.10)	1.52 (1.02-2.27)	5.4%	1.86 (1.04-3.32)	1.79 (0.97-3.30)
IV	10.8%	4.14 (1.80-9.53)	2.44 (1.01-5.90)	15.0%	5.71 (2.14-15.23)	6.22 (2.13-18.17)
Performance status						
0	2.3%	1.00 (reference)	1.00 (reference)	2.4%	1.00 (reference)	1.00 (reference)
1	1.8%	0.76 (0.33-1.73)	0.62 (0.27-1.43)	2.2%	0.90 (0.25-3.25)	0.71 (0.19-2.65)
2-4	7.6%	3.51 (1.59-7.73)	2.14 (0.93-4.90)	5.9%	2.50 (0.69-9.13)	1.73 (0.44-6.83)
Year of diagnosis						
2015	4.3%	1.00 (reference)	1.00 (reference)	3.3%	1.00 (reference)	1.00 (reference)
2016	4.0%	0.92 (0.60-1.39)	0.91 (0.58-1.42)	5.1%	1.54 (0.81-2.96)	1.69 (0.83-3.42)
2017	4.4%	1.01 (0.67-1.53)	1.07 (0.68-1.68)	5.9%	1.82 (0.97-3.43)	1.94 (0.96-3.95)
Location of the tumor						
Left-sided colon	4.5%	1.00 (reference)	1.00 (reference)	4.9%	1.00 (reference)	1.00 (reference)
Proximal rectum	3.3%	0.73 (0.46-1.15)	1.09 (0.57-2.06)	3.7%	0.74 (0.35-1.58)	1.47 (0.35-6.25)
Tumor stage						
I	2.9%	1.00 (reference)	1.00 (reference)	4.1%	1.00 (reference)	1.00 (reference)
II	4.7%	1.67 (1.03-2.69)	1.05 (0.63-1.75)	5.1%	1.27 (0.63-2.55)	0.96 (0.46-2.03)
III	4.6%	1.61 (0.99-2.63)	1.26 (0.74-2.13)	4.6%	1.12 (0.54-2.34)	0.95 (0.43-2.11)

Table S3.1 (continued)

	Total study population			Propensity score matched sample		
	%	Univariable OR (95% CI)	Multivariable OR* (95% CI)	%	Univariable OR (95% CI)	Multivariable OR* (95% CI)
Differentiation grade						
Well/moderate	4.2%	1.00 (reference)	1.00 (reference)	4.7%	1.00 (reference)	1.00 (reference)
Poor/undifferentiated	6.8%	1.66 (0.88-3.14)	1.27 (0.64-2.53)	6.3%	1.36 (0.53-3.50)	1.09 (0.39-3.08)
Ileus						
No	4.0%	1.00 (reference)	1.00 (reference)	4.6%	1.00 (reference)	1.00 (reference)
Yes	7.6%	1.99 (1.21-3.25)	0.83 (0.47-1.46)	6.3%	1.40 (0.72-2.74)	0.89 (0.41-1.93)
Perforation						
No	4.0%	1.00 (reference)	1.00 (reference)	4.5%	1.00 (reference)	1.00 (reference)
Yes	10.9%	2.93 (2.53-5.62)	2.28 (1.12-4.66)	11.1%	2.63 (1.08-6.39)	3.09 (1.15-8.33)
Resection type						
Transversum resection	5.1%	0.82 (0.39-1.73)	0.73 (0.33-1.60)	3.2%	0.41 (0.09-1.82)	0.28 (0.06-1.34)
Left hemicolectomy	6.2%	1.00 (reference)	1.00 (reference)	7.4%	1.00 (reference)	1.00 (reference)
Sigmoid resection	4.2%	0.66 (0.44-0.99)	0.66 (0.42-1.03)	4.3%	0.56 (0.32-0.99)	0.73 (0.39-1.38)
Low anterior resection	2.6%	0.40 (0.23-0.70)	0.54 (0.27-1.10)	3.9%	0.50 (0.22-1.17)	0.61 (0.14-2.67)
Surgical approach						
Laparoscopic	3.2%	1.00 (reference)	1.00 (reference)	3.9%	1.00 (reference)	1.00 (reference)
Laparoscopic with conversion to open	4.6%	1.48 (0.85-2.56)	1.07 (0.60-1.91)	5.0%	1.30 (0.63-2.67)	1.14 (0.53-2.46)
Open	8.5%	2.82 (1.93-4.12)	1.87 (1.20-2.92)	6.8%	1.78 (1.03-3.09)	1.98 (1.03-3.79)
Neo-adjuvant treatment						
None	4.4%	1.00 (reference)	1.00 (reference)	4.9%	1.00 (reference)	1.00 (reference)
Radiotherapy	2.8%	0.64 (0.26-1.57)	0.86 (0.31-2.43)	1.7%	0.33 (0.05-2.40)	0.39 (0.04-3.36)
Chemoradiation	2.1%	0.47 (0.12-1.94)	1.03 (0.23-4.69)	3.3%	0.67 (0.09-4.97)	1.65 (0.18-15.09)
Ostomy group						
Primary anastomosis	3.4%	1.00 (reference)	1.00 (reference)	4.0%	1.00 (reference)	1.00 (reference)
End-ostomy	7.7%	2.38 (1.66-3.41)	1.29 (0.84-1.99)	6.9%	1.77 (1.05-2.96)	1.89 (1.10-3.26)

*Adjusted for all variables listed. ASA classification unknown, performance status unknown, differentiation grade unknown, ileus unknown and perforation unknown were included in the analysis but results not shown.

Chapter 4

From chicken to cowboy: Paradigm shift in the use of ileostomy in rectal cancer surgery

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Submitted

Abstract

Background

Use of deviating stomas (DS) to reduce morbidity after rectal cancer surgery remains a subject of debate. Aim is to evaluate postoperative complications after discontinuing standard use of DS in rectal cancer surgery in a single high-volume center.

Methods

All patients after rectal resection and primary anastomosis between 2012 and 2019 were included and categorized in two groups: 2012-2015 (routine DS) and 2016-2019 (highly selective DS). Primary outcomes were use of DS and postoperative complications such as anastomotic leakage (AL). Secondary outcomes were postoperative outcomes (length of stay (LOS), readmission and mortality rates) and stoma free survival one year after index surgery.

Results

A total of 247 patients were included (group A n=117, B n=130), 94 patients received ileostomy (66% vs 13%, $p<0.001$). Overall complication rate was 34%, significantly higher in group A (43.1% vs. 26.0%, $p=0.005$). Notable reduction was seen in complications (43% vs. 26%, $p=0.005$) and median length of stay (6 vs. 4 days, $p<0.001$) in favor of group B. No differences in leakage, mortality and reoperation rates were seen between the groups. One year stoma free survival was better in group B (87.1% vs. 95.4%, $p=0.022$).

Conclusions

This study shows that implementation of highly selective use of DS in rectal cancer surgery did not result in negative effects on the postoperative complications, nor reduced reoperations in the age of laparoscopic surgery and restricted neoadjuvant radiation therapy. Therefore, surgeons might need to re-evaluate their arguments and presumed benefits of using ileostomy in rectal cancer surgery in the current practice.

Introduction

Ileostomies have been used since the early 20th century as a deviating stoma (DS) to in order to "protect" colorectal anastomosis in an effort to reduce anastomotic leakage (AL) related morbidity.[1] Studies have suggested that the use of DS can decrease the incidence of a clinically relevant leakage and reduce the reoperation rates after AL. Use of DS is therefore recommended by many surgeons in rectal cancer surgery.[2-7] This has led to a steady increase in the use of DS up to 70% of the patients undergoing rectal resections in the Netherlands.[8]

Benchmark analysis performed at our hospital in 2014-2015 showed that almost 80% of the new ileostomy patients encountered postoperative complications (postoperative ileus 41%, renal impairment 28%, surgical site infection 24%, high output ileostomy 38%) and prolonged length of stay >14 days.[9] These results are in line with available literature about the disadvantages and high rates of postoperative morbidity, reintervention and readmission rates in patients with DS.[10-14] Also, a remarkable large variation from 0-100% use of DS between Dutch hospitals was shown, suggesting that the use of DS not necessarily leads to better outcomes and therefore, rightfully questioning if we should be 'chickens' (routine diversion) or 'cowboys' (highly selective diversion)[15]? These factors have led to a paradigm shift in our surgical practice. Our institution changed from routine diversion (before 2015) to highly selective diversion (after 2015) of an anastomosis with DS in elective rectal resections. So far, available data concerning highly selective DS after elective laparoscopic rectal cancer surgery is limited.[16,17]

Aim of the present study is to assess the impact of discontinuing the standard use of DS after elective rectal cancer surgery on the postoperative outcomes in a single center.

Materials and methods

This is a single center retrospective analysis of prospectively collected data observational study. Data input for the Dutch ColoRectal Audit (DCRA, former Dutch Surgical Colorectal Audit) was used. As only retrospective observational data is used, no ethical approval or informed consent was required under Dutch law for using these data.[8]

All patients surgically treated for rectal cancer at our hospital between 2012 and 2019 were included.
Inclusion criteria were patients undergoing partial or total mesorectal excision for resectable rectal cancer with a primary anastomosis. Exclusion criteria were patients with a stoma in prior medical history, after local excision of rectal carcinoma, a rectal resection without an anastomosis or abdominoperineal resection. Patients were categorized in two different time periods from 2012-2015 (group A, routine diversion with DS) and 2016-2019 (group B, highly selective diversion).

Primary outcomes were the use of DS and the postoperative complications after rectal cancer surgery. Postoperative complications were categorized as surgical, pulmonary, cardiac, infectious, neurologic, and other. DCRA categorized surgical complications in AL, abscess, ileus, postoperative hemorrhage and surgical site infection (SSI). AL was defined as extraluminal leakage of fluids or abscess formation at the anastomosis found perioperatively or seen on radiologic imaging or during endoscopic examination. Secondary outcomes were LOS, readmission rates within 90 days of discharge, mortality and stoma free survival one year after index surgery.

Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS), version 26.0 (IBM Corp., Armonk, NY, USA). Normality of the data was tested using the

Shapiro-Wilk test. Non parametric data were expressed as medians and ranges. Mann-Whitney U test and Kruskal-Wallis test were used for non-parametric data. Categorical data are given in absolute numbers with percentages and were compared using the Pearson Chi-Square test for nominal data (and the Fisher Exact test for binary variables). A *p*-value less than 0.05 was considered statistically significant.

Results

Patient characteristics

A total of 555 patients could be identified undergoing elective rectal cancer surgery between January 2012 and December 2019. Of those patients 308 were excluded (Figure 4.1). The remaining 247 patients (m:f 154:93, median age 65.3 years [34.1-83.0], median BMI 25.7 [16.2-44.1]) were included in this analysis and categorized in group A (n=117) and group B (n=130). Majority of patients were ASA 1 or ASA 2 patients. Majority of the patients received neoadjuvant radiotherapy (59.5%), although this percentage decreased over time (68.1% vs. 51.9%). Median distance between the anal verge and the tumor is 10 [0-25] cm, no differences were seen between the groups (Table 4.1).

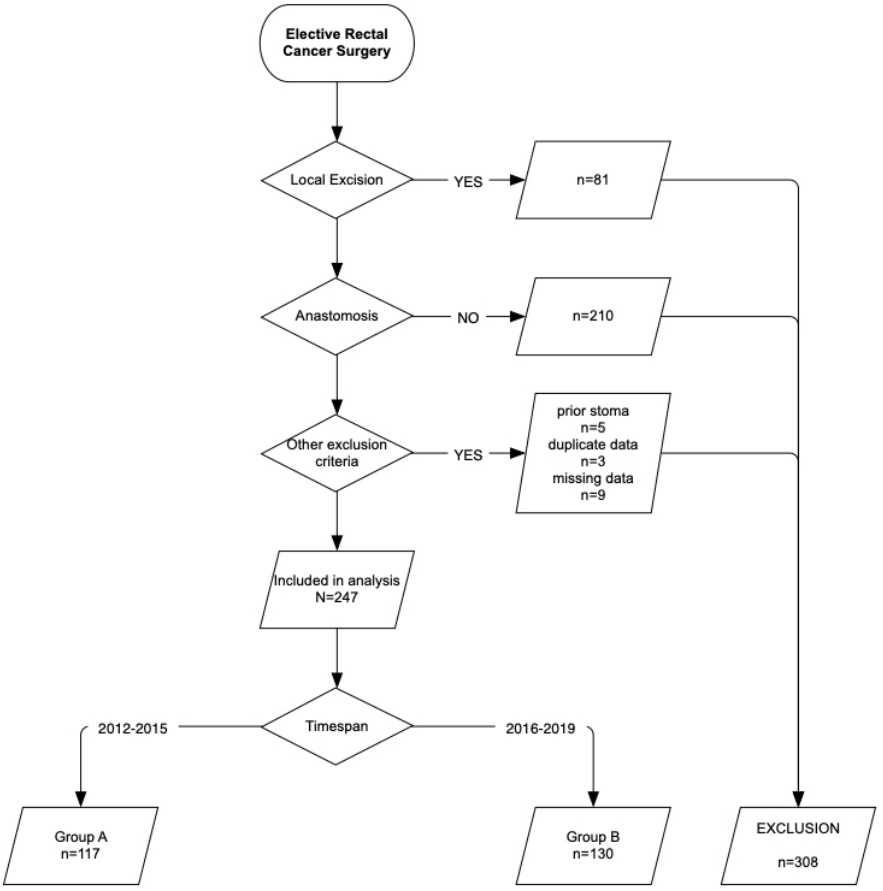

Figure 4.1 Flow chart of inclusion.

Table 4.1 Baseline patient characteristics.

	Total (n=247)	Group A 2012-2015 (n=116)	Group B 2016-2019 (n=131)	*p*-value
Male, n (%)	150 (60.7)	74 (63.8)	76 (58.0)	0.364
Female, n (%)	97 (39.3)	42 (36.2)	55 (42.0)	
Median age, years (range)	65.3 (34.1-82.3)	65.3 (34.1-82.3)	65.2 (42.6-81.0)	0.955
Median BMI, kg/m^2 (range)	25.7 (16.2-44.1)	25.8 (18.2-35.8)	25.7 (16.2-44.1)	0.275
Comorbidity, n (%)	146 (59.1)	71 (61.2)	75 (57.3)	0.604
ASA class, n (%)				0.076
ASA I	84 (34.0)	40 (34.5)	44 (33.6)	
ASA II	140 (56.7)	71 (61.2)	69 (52.7)	
ASA III	22 (8.9)	5 (4.3)	17 (13.0)	
ASA IV	1 (0.4)	0 (0.0)	1 (0.8)	
Pre-operative tumour related complications, n (%)	6 (2.4)	3 (2.6)	3 (2.3)	1.000
Neoadjuvant radiotherapy, n (%)	147 (59.5)	79 (68.1)	68 (51.9)	**0.013**
Neoadjuvant chemoradiation therapy, n (%)	40 (16.2)	22 (19.0)	18 (13.7)	0.301
Median distal margin, mm (range)	100 (0-250)	100 (30-200)	90 (0-250)	0.060

Surgical details and outcome

Majority of patients were operated laparoscopically (96.0%) with 1.3% conversion rate. Overall use of DS was 38.1% (n=94), there was a significant decrease in the use of DS from 66.4% in group A compared to 13.0% in group B, $p<0.001$ (Table 4.2, Figure 4.2).

Postoperative complications

The overall complication rate was 34%, which was notably higher in group A (43.1% vs. 26.0%, $p=0.005$). There was a decrease in overall surgical complications (29.3% vs. 17.6%, $p=0.034$), while the individual surgical complications stayed the same. Significant reduction in median LOS (6 vs. 4 days, $p<0.001$) and need for ICU admission (8.6% vs. 1.5%) was seen between the groups. No differences in the different categories of postoperative complications were observed between the two groups. No differences were seen between the two groups in readmission and mortality rates, Table 4.3.

Table 4.2 Overview of surgical outcomes over time

	Total (n=247)	Group A 2012-2015 (n=116)	Group B 2016-2019 (n=131)	*p*-value
Surgical approach, n (%)				**0.049**
Laparotomy	10 (4.0)	8 (6.9)	2 (1.5)	
Laparoscopy	237 (96.0)	108 (93.1)	129 (98.5)	
Conversion, n (%)	3 (1.3)	2 (1.9)	1 (0.8)	0.593
Deviating stoma, n (%)	94 (38.1)	77 (66.4)	17 (13.0)	**<0.001**
Resection margin, n (%)				0.102
Radical resection >1 mm	244 (98.8)	113 (97.4)	131 (100.0)	
Irradical resection	3 (1.2)	3 (2.6)	0 (0.0)	
T stage, n (%)				0.106
pTX	1 (0.4)	1 (0.9)	0 (0.0)	
pT0/ypT0	15 (6.1)	10 (8.6)	5 (3.8)	
pT1	21 (8.5)	13 (11.2)	8 (6.1)	
pT2	102 (41.3)	49 (42.2)	53 (40.5)	
pT3	107 (43.3)	43 (36.2)	65 (49.6)	
pT4	1 (0.4)	1 (0.9)	0 (0.0)	
N stage, n (%)				0.165
pN0	159 (64.4)	76 (65.5)	83 (63.4)	
pN1	84 (34.0)	40 (34.5)	44 (33.6)	
pN2	4 (1.6)	0 (0.0)	4 (3.1)	

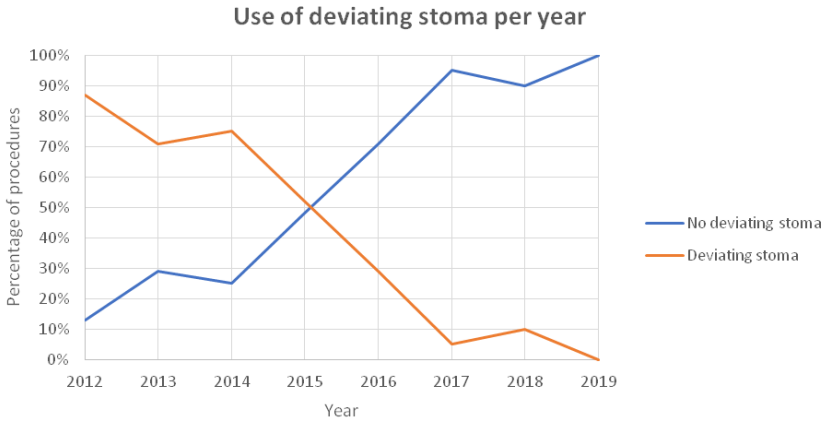

Figure 4.2 Use of deviating stoma per year in percentages. Blue line = no deviating stoma. Orange line = deviating stoma.

Stoma reversal

A total of 110 stoma patients could be identified, 80 versus 30 patients from group A and B respectively. There was an overall stoma reversal rate of 90.0% (99/110). At one year after index surgery significantly less patients in group B had a stoma compared to group A (4.6% vs. 12.9%, *p*=0.022). Complication rate after stoma reversal surgery was 19.2% with 1.0% mortality. There were no differences in postoperative outcomes between group A or B, Table 4.4.

Table 4.3 Overview postoperative complications.

	Total (n=247)	Group A 2012-2015 (n=116)	Group B 2016-2019 (n=131)	p-value
Overall complication, n (%)	84 (34.0)	50 (43.1)	34 (26.0)	**0.005**
Surgical complication, n (%)	57 (23.1)	34 (29.3)	23 (17.6)	**0.034**
Anastomotic leakage, n (%)	30 (12.1)	17 (14.7)	13 (9.9)	0.329
Abscess, n (%)	15 (6.1)	9 (7.8)	6 (4.6)	0.424
Ileus, n (%)	18 (7.3)	12 (10.3)	6 (4.6)	0.091
Postoperative hemorrhage, n (%)	3 (1.2)	0 (0.0)	3 (2.3)	0.250
Surgical Site Infection, n (%)	8 (3.2)	5 (4.3)	3 (2.3)	0.480
Pulmonary complication, n (%)	9 (3.6)	7 (6.0)	2 (1.5)	0.088
Cardiac complication, n (%)	4 (1.6)	2 (1.7)	2 (1.5)	1.000
Infectious complication, n (%)	12 (4.9)	9 (7.8)	3 (2.3)	0.072
Neurologic complication, n (%)	3 (1.2)	2 (1.7)	1 (0.8)	0.602
Other complications, n (%)	26 (10.5)	15 (12.9)	11 (8.4)	0.301
Re-operation, n (%)	33 (13.4)	17 (14.7)	16 (12.2)	0.581
Of whom stoma, n (%)	24 (66.7)	9 (52.9)	15 (93.8)	**0.017**
Ileostomy	19	7	12	
Colostomy	5	2	3	
ICU admission, n (%)	12 (4.9)	10 (8.6)	2 (1.5)	**0.015**
Days on ICU, median days (range)	0 (0-19)	0 (0-19)	0 (0-3)	**0.025**
LOS, median days (range)	4 (2-39)	6 (2-39)	4 (2-52)	**<0.001**
Readmission, n (%)	42 (17.0)	21 (18.1)	21 (16.0)	0.735
Mortality within 90 days, n (%)	2 (0.8)	2 (1.7)	0 (0.0)	0.220

A total of 11 patients never underwent stoma reversal surgery. In group A, 7 patients (7/80, 8.8%) never underwent stoma reversal surgery due to death since index surgery (2), metastatic disease (2), salvage proctectomy with end colostomy (1) and patients' preference (2). In group B 4 patients (4/30, 13.3%) never

underwent stoma reversal surgery due to patients' preference (3) and salvage proctectomy with end colostomy (1).

Table 4.4 Stoma reversal surgery related outcome.

	Total (n=247)	Group A 2012-2015 (n=116)	Group B 2016-2019 (n=131)	*p*-value
Never had a stoma	137 (55.5)	36 (31.0)	101 (77.1)	**<0.0001**
Stoma free at one year, n (%)	226 (91.5)	101 (87.1)	125 (95.4)	**0.022**
Stoma free after one year, n (%)	236 (95.6)	109 (94.0)	127 (96.9)	0.357
Median time to stoma reversal in days [range]	124 [34-783]	126 [34-783]	113 [34-509]	0.413
Complications after stoma reversal, n (%)[#]	19 (19.2)	15 (20.5)	4 (15.4)	0.773
Surgical Site Infection, n (%)[#]	8 (8.1)	7 (9.6)	1 (3.8)	0.449
Ileus, n (%)[#]	5 (5.0)	5 (6.8)	0 (0)	0.322
Readmission after stoma reversal, n (%)[#]	5 (5.0)	2 (2.7)	3 (11.5)	0.112
Re-intervention or operation, n (%)[#]	8 (8.0)	7 (9.6)	1 (3.8)	0.326
ICU admission, n (%)[#]	5 (5.0)	3 (4.1)	2 (7.7)	0.604
Mortality after stoma reversal, n (%)[#]	1 (1.0)	1 (1.4)	0 (0)	1.000

*Calculated over the patients who have had a stoma. [#] Calculated over the patients who underwent stoma reversal surgery, n=99, group A n=73, group B n=26.

Table 4.5 Stoma reversal surgery.

	Total (n=110)	Group A 2012-2015 (n=80)	Group B 2016-2019 (n=30)	*p*-value
Deviating stoma, n (%)	94 (85.5)	77 (96.3)	17 (56.7)	**<0.001**
Median time to stoma reversal in days [range]	124 [34-783]	126 [34-783]	113 [34-509]	0.413
Overall stoma reversal surgery, n (%)	99 (90.0)	73 (91.3)	26 (86.7)	0.724
Stoma reversal surgery within one year, n (%)	88 (80.0)	65 (81.3)	24 (80.0)	1.000
Overall complication, n (%)	19 (19.2)	15 (20.5)	4 (15.4)	0.773
Surgical Site Infection, n (%)	8 (8.1)	7 (9.6)	1 (3.8)	0.449
Ileus, n (%)	5 (5.0)	5 (6.8)	0 (0)	0.322
Readmission, n (%)	5 (5.0)	2 (2.7)	3 (11.5)	0.112
Re-intervention or operation, n (%)	8 (8.0)	7 (9.6)	1 (3.8)	0.326
ICU admission, n (%)	5 (5.0)	3 (4.1)	2 (7.6)	0.604
Mortality after stoma reversal, n (%)	1 (1.0)	1 (1.4)	0 (0)	1.000

Discussion

The present observational study evaluates the paradigm shift in the use of DS from routinely to highly selective DS after rectal cancer surgery in a single high-volume center. Meanwhile, important reduction in overall surgical and postoperative complications, postoperative ICU admission, median ICU LOS and hospital LOS was seen. These data support our hypothesis that the implementation of highly selective use of DS did not result in increased surgical or postoperative morbidity and had no negative influence in re-operation rates. Furthermore, one year stoma free survival was lower in patients with standard DS compared to patients with highly selective DS. These findings warrant a discussion between surgeons (and their patients) about the role of the use DS in rectal cancer surgery.

Many different risk factors for AL after rectal cancer surgery have been identified over the years, in an effort to optimize perioperative condition and lower the rates for AL.[18-22] However, it remains unclear if use of DS is warranted in only those patients with these risk factors or in all rectal cancer patients. Use of DS is still advised and considered beneficial in an effort to prevent or attenuate the possible postoperative morbidity and mortality and reduce re-operation rates after AL.[2-7,23] It is noteworthy that not only positive effects of DS usage but also stoma related morbidity and even mortality has been described. Also, stoma reversal surgery might not be feasible or offered in all patients after AL, while others might face significant morbidity and sometimes mortality pursuing stoma reversal surgery.[24-26] Moreover, it has also been suggested that having a DS may be associated with a higher incidence of low anterior resection syndrome, whereas timing of reversal or height of the anastomosis cannot explain the correlation between DS and the bad functional outcomes.[27-28] These factors leave colorectal surgeons in a search for the optimal strategy in rectal cancer surgery and seem to warrant that standard use of DS may not be the ‘one size fits all’ approach in our efforts to reduce AL and AL related morbidity. Because of this, combined with the results from our benchmark study, we decided to change our policy for rectal cancer surgery from standard

deviation to highly selective deviation and resulted in the present study evaluating the effects of this paradigm shift.

Discontinuing the standard use of DS was, however, a major significant surgical change in the evaluated timespan. Another important factor which influenced surgical decision-making and quite possibly our postoperative results, is the change in the Dutch colorectal treatment guideline in 2014, advocating a more restrictive use of neoadjuvant radiation therapy in rectal cancer patients.[29] These factors could be considered as beneficiary contributions in the observed decrease in surgical and postoperative complications and therefore as possible confounders.

The complication rate of stoma reversal surgery should, in our opinion, be included when assessing the complication rate of rectal cancer surgery in the presence of DS. In our study almost 20% of patients encountered postoperative complications after stoma reversal surgery. There are also increasingly different treatments options when AL is encountered. In the acute treatment of AL, albeit with or without the presence of DS, a surgeon can choose from re-laparoscopy with drain placement or percutaneous drain placement, endoluminal endo-sponge drainage systems, endoscopic (over-the-scope) clips, transanal closure / re-suture / re-do of the anastomotic defect or anastomosis, all depending on the level of expertise and experience of the surgeon and surgical team of the hospital.[30] These are all important factors to weigh in the decision whether or not to use routine DS and interesting topics for further research. It would be interesting to try to identify those surgeon and surgery related factors that influence perioperative decision-making and choices to pursue or withhold DS placement in the current time frame.

Aside from the factors mentioned before, this study is also limited by its observational, retrospective character. Especially when regarding the use of DS in rectal cancer surgery in patients, the reasons for DS cannot be always retraced in the database and were left to the surgeons' discretion and the perioperative findings. These exclusions and limitations may have resulted in a certain bias, which cannot be easily corrected for. The use of the nationwide DCRA definitions,

however, ensures uniformity; all patients in the Netherlands undergoing surgical treatment for colorectal cancer are prospectively registered. Despite the aforementioned limitations and contributing factors, these results show real life data and are a true reflection of achieved improvements in reducing postoperative morbidity in rectal cancer surgery.

Further focus for research would be to include nationwide data of all Dutch hospitals, to evaluate the evolution and change in the use of DS in the Netherlands and its subsequent results since the last nation-wide evaluation. As minimally invasive surgery has been accepted and incorporated across the world, more improvements are necessary to eliminate the incidence and the sequelae of AL. Some of these promising innovations are the implementation of transanal TME technique, integrating the transanal technique with a single stapled anastomosis,[31] use of intraoperative fluorescence imaging[32] and use of a ghost or virtual ileostomy after rectal cancer surgery.[33] These new techniques will surely show their merit (or lack thereof) in the coming years.

Conclusion

Ultimately, this analysis has evaluated the use of DS and the results in rectal cancer surgery in a single center, where a demonstrable paradigm shift has occurred in the use of DS. This change did not result in adverse effects in postoperative complications in patients without DS in the age of laparoscopic surgery and restricted neoadjuvant radiation therapy. Therefore, surgeons might need to re-evaluate their arguments and presumed benefits of using DS in rectal cancer surgery in the current practice.

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Part II

Effectiveness of pathways in new stoma patients

Chapter 5

Effectiveness of the ileostomy pathway in reducing readmissions for dehydration: does it stand the test of time?

YT van Loon, VY Poylin, D Nagle, DDE Zimmerman

Dis Colon Rectum 2020;63(8):1151-1155

Abstract

Background
The ileostomy pathway, introduced in 2011, has proved to be successful in eliminating hospital readmissions for high output ileostomy or dehydration in the following period of 7 months in a single institution. However, it is unclear whether this short-term success, immediately after the initiation of the program, can be sustainable in the long term.

Materials and methods
The aim of this study was to assess the efficacy and the durability of the ileostomy pathway in reducing readmissions for dehydration over a longer period of time. This was a retrospective review of the patients who entered into the ileostomy pathway, since its introduction on March 1, 2011, until January 31, 2015. This study was conducted at a tertiary academic center. Patients undergoing colorectal surgery with the creation of a new end- or loop ileostomy were included. To assess the long-term sustainability of the ileostomy pathway. The primary endpoint was readmission within 30 days after discharge for a high output ileostomy or dehydration.

Results
A total of 393 patients (male n=195, female n=198, median age 52 [18-87] years) were included, 161 pre-pathway and 232 on-pathway. Overall 30-day post-discharge readmission rates decreased from 35.4% to 25.9% (p=0.04). Readmissions due to high output and/or dehydration dropped from 15.5% to 3.9% (p<0.001). Readmissions due to small bowel obstructions dropped from 9.9% to 4.3%, (p=0.03).

Limitations
The possible limitations of the study included a non-randomized comparison of the patient groups and those patients who were possibly admitted to different institutions.

Conclusions
The present ileostomy pathway decreases readmissions for high output ileostomy and dehydration in new ileostomy patients and is durable in the long term.

Introduction

Despite significant improvements in surgical techniques in treating colorectal diseases, there continues to be a need for protective ileostomies in high-risk patients, in addition to patients who are in the need of a permanent ileostomy. Numerous studies have shown increased morbidity, including dehydration, electrolyte abnormalities, and especially high rates of readmission, in those patients with new ileostomies, leading to an increased utilization of resources and a decrease in patient satisfaction.[1-4]

Dehydration continues to be one of the main issues that new ileostomy patients are facing.[3] Besides frequent readmissions, patients also encounter difficulties with ostomy management, a loss in quality of life, lower physical and social functioning, lower global health status, and a worsened body image.[5,6] The patients' inability to demonstrate independent self-management of ostomy care, their need for information, their emotional support, and continuous nursing assistance in their ostomy care, makes them very dependent on ostomy nurses and allied health personnel.[7,8] All of this results in a significant social and financial burden for patients and society.[9]

The Beth Israel Deaconess Medical Center (BIDMC) Ileostomy Pathway was introduced on March 1, 2011, in an effort to decrease the high rates of readmissions for dehydration in new ileostomy patients. In the first 7 months, the BIDMC ileostomy pathway showed a significant decrease of readmissions from 15.5% to 0%, when compared to a historical control group that consisted of patients who had been operated on in the previous four years.[10] However, the long-term durability of the pathway was unclear. The goal of the present study was to assess the efficacy and the durability of this pathway, in reducing readmissions for dehydration over a longer period of time.

Materials and methods

The BIDMC Ileostomy Pathway has been described in detail in the researchers' earlier report.[10] In short, the key components of this pathway are: preoperative education about ileostomy, standardized teaching materials across the service line, direct in-hospital patient engagement with a strong emphasis on patient self-management in the hospital, observation of the patients' ostomy management and post-discharge tracking of intake and output. The ileostomy output target was between 500 and 1200 mL/day and the antimotility agents such as Loperamide, Metamucil wafers and Diphenoxylate/Atropine were titrated as needed. All of the patients were discharged after a short follow-up with enterostomal therapists in the clinic, and with visiting nurses to assist at home. This pathway, specifically designed to reduce readmissions for dehydration and not for other postoperative complications, has been initiated on March 1, 2011. For detailed information about this pathway, see appendix 5.A.[10]

The inclusion criteria were all patients who underwent colorectal surgery with the creation of a new end- or loop ileostomy between January 1, 2007 and January 31, 2015. The BIDMC Colectomy Database (BIDMC Institutional Review Board no. 2010-P-000263/1), the BIDMC Rectal Cancer Clinic database (Dana Farber Cancer Center Institutional Review Board no. 10280), and the Division of Colon and Rectal Surgery records were used for the patient identification. The exclusion criteria were patients with planned elective readmissions within 30 days after discharge and patients who had a second or repeated diversion with an ileostomy (after previous ileostomy take down). Patients with outpatient management of dehydration or readmissions in other hospitals were not included in this study.

The patients were divided into 2 groups: pre-pathway (January 1, 2007 until February 28, 2011) and on-pathway (March 1, 2011 until January 31, 2015). Main outcomes were readmissions within 30 days after discharge as an adverse event. The reasons for readmission were categorized as follows: dehydration, infection of any type (wound, urinary, pulmonary, or intra-abdominal), small bowel obstruction/ileus, vascular problems (bleeding and thromboembolic events), and others. Dehydration must not be a result of an identifiable cause such as intra-

abdominal infection, ileus or fever and it was confirmed by direct chart review. There is no international consensus on the definition of the complex entity of dehydration in the literature.[11] Dehydration has been defined throughout this entire study period by at least one of the following criteria: increased creatinine above normal values of their personal baseline, a decreased urine output, hypotension, persistent tachycardia (>110 per minute), or a (reported) increase in stoma output (>1500mL/24 hours). The latter was considered the most important objective marker for dehydration. Readmissions were categorized in only one specific category.

Statistical analysis

Univariate analyses, Fisher's exact test, and the Wilcoxon rank-sum test were used to compare the patients' categorical and continuous variables, respectively. The statistical significance was defined as $p<0.05$. All of the statistical tests were performed with SPSS Statistics software (IBM Corp. version 22).

Results

A total of 455 patients, in whom a new ileostomy was created during the study period, were identified. In 62 patients a second or repeated diversion was the reason for exclusion, leaving 393 patients to be included in the analysis. The BIDMC Ileostomy Pathway was initiated on March 1, 2011. Pre-pathway patients consisted of 161 patients, and 232 patients were on-pathway. The groups were comparable in gender and age. Detailed patient characteristics of the included patients are presented in Table 5.1.

Table 5.1 Patient demographics.

Category	Prepathway group (n=161)	On pathway group (n=232)	*p*-value
Age in years, mean (SD)	50.0 (15.9)	53.4 (15.9)	ns
Male, %	50.6	49.1	ns
Preoperative diagnosis, %			
Diverticulitis (n=17)	3.7	4.7	ns
IBD (n=180)	45.7	45.7	ns
Cancer (n=151)	44.4	34.5	ns
Other (n=46)	6.2	15.5	p=0.01

SD: Standard deviation, IBD: Inflammatory bowel disease, ns: not significant

The median length of stay of the patients who were on-pathway was 5.0 days. At least one postoperative complication occurred in 42.2% (98 of 232 patients) of these patients. The most frequent postoperative complications were due to infectious reasons in 31.5% (73 of 232 patients). Major complications, such as reoperations, or intensive care treatment, occurred in 7.3% (17 of 232 patients). Details of the postoperative results and complications of the on-pathway patients can be found in Table 5.2.

Overall, the 30-day post-discharge readmission rates for new ileostomy patients were reduced from 35.4% (57 of 161 patients) to 25.9% (60 of 232 patients) after introducing the pathway, and this difference was statistically significant (p=0.04). The readmission rates for dehydration dropped from 15.5% (25 of 161 patients) to 3.9% (9 of 232 patients) p<0.001. The readmission rates for small bowel obstruction dropped from 9.9% (16 of 161 patients) to 4.3% (10 of 232 patients, p=0.03). There were no statistically significant differences in the readmission rates in the new ileostomy patients after the initiation of the pathway due to infectious or vascular causes (Figure 5.1). The use of Loperamide at the time of discharge decreased over time from 55.6% in 2012 (40 of 72 patients) to 31.0% (13 out of 42 patients) in 2014.

Table 5.2 Postoperative outcomes and readmissions.

Outcome	Prepathway group (n=161)	On pathway group (n=232)	*p*-value
Mean LOS (days)	7.5	7.6	ns
Stoma, % (n)			
end ileostomy	30.3 (49)	32.3 (75)	ns
loop ileostomy	69.7 (112)	67.7 (157)	ns
Readmissions, % (n)			
any readmission	35.5 (57)	25.9 (60)	*p*=0.04
dehydration	15.5 (25)	3.9 (9)	*p*<0.001

LOS: length of stay, ns: not significant

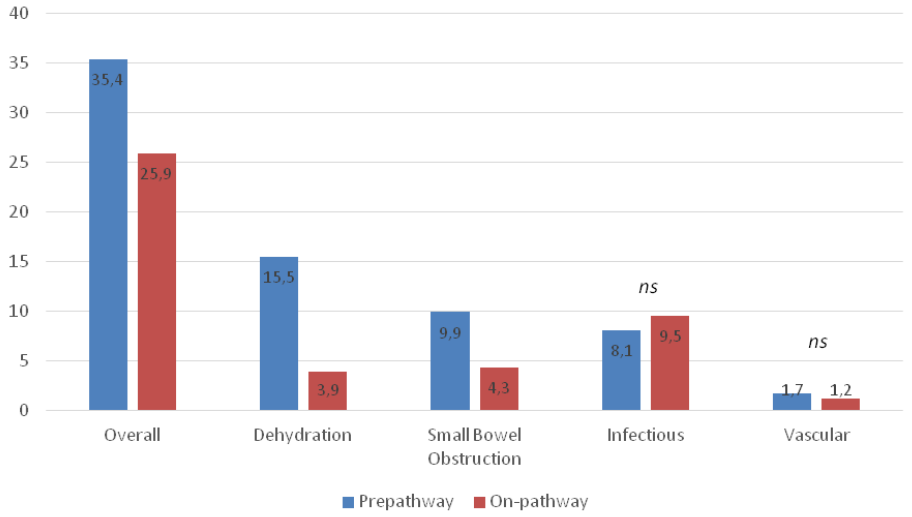

Figure 5.1 Readmission rates of prepathway and on-pathway patients divided per cause in percentages ns: not statistically significant.

Discussion

The present study has shown that the ileostomy pathway continues to be effective and successful in reducing readmission rates in general, as well as the readmission rates for dehydration, specifically years after the initiation of the project. Although the pathophysiology of high output ileostomy may vary, dehydration and subsequent readmission may be managed and prevented by this simple pathway.

Proactive intervention and education may reduce the rates of complications for new ileostomy patients. Moreover, other authors have identified the lack of postoperative ostomy education as an independent risk factor for readmission in new ileostomy patients.[12] Structured patient education aimed at their individual needs has been shown to have a positive effect on the quality of life, the length of the hospital stay and on health care costs.[13] Based on our prior data, as well as on the present study, it is postulated that patient education and guidance pre- and postoperatively are the cornerstones and the driving force why this pathway is effective in the short- as well as in the long term.

Surprisingly, the use of Loperamide at discharge has decreased over the years despite the pathway, while the readmission rates due to dehydration remain under 4%. Possibly, an increased use of Metamucil wafers is a reason why the use of Loperamide has decreased, however, this was not included in the present database. The literature shows that using Oral Rehydration Solution (ORS) might have a prophylactic effect on readmissions for dehydration.[14] These facts may be a confirmation that maintaining a well-balanced water homeostasis is mainly a result of the patients' comfort and knowledge, combined with their ability to manage their in- and outputs, instead of the use of antimotility agents.

Besides the reduction of overall readmissions and readmissions for dehydration, the readmissions for small bowel obstructions were also reduced after the introduction of this pathway (from 9.9% to 4.3%, p=0.03). It is unclear if this might be a result of other dietary regimens, a better patients' understanding, or improved water homeostasis in their new physical situation after an introduction of the pathway. This might also be the result of other influences, such as the introduction of minimally invasive surgery (laparoscopy or robot), other ways of pain

management (transversus abdominis plane block in stead of oral opioids), or the well known Enhanced Recovery After Surgery protocols.

The BIDMC ileostomy pathway is showing a continued effect for at least 4 years in significantly reducing readmissions of new ileostomy patients in general, and in readmissions for dehydration specifically. It might be worthwhile to consider introducing this approach in other clinics, where problems with readmissions due to dehydration exist. Some might advocate that the success of this pathway is the result of the highly specialized setting of the BIDMC, by having a dedicated colon and rectal surgery inpatient unit. A counter argument for this would be the fact that others have also shown a significant reduction of readmissions in new ileostomy patients, using not only patient education or checklists like this study's pathway, but also by daily telephone check-ups for 3 weeks and visiting home nursing services as tools.[15-18] All of this demonstrates that there is no one-size-fits-all solution to the frequently encountered and multifactorial problem of readmissions of ileostomy patients.

Recognizing those patients at risk for a readmission in a very heterogenous population remains important, while a dehydration readmission after an ileostomy prediction score might be really helpful.[19] The well-known various risk factors are an older age, the use of diuretics, high outputs during admission, the use of steroids, and the various comorbidities.[1,4,12,20] The incorporation of ORS instead of, or in addition to, the use of antimotility agents, possibly combined with a prediction score, are all interesting avenues of further research. Furthermore, the applicability and reproducibility of the pathway's success in other hospitals is currently being investigated by our researchgroup.

One of the limitations of this study was its retrospective character. Other limitations are that the data of patients who were possibly readmitted within 30 days after discharge in other institutions was not known, so they were not accounted for in the analysis. In addition, the frequency of use of other pharmacological therapeutics such as Metamucil wafers, or antimotility agents besides Loperamide were not registered in this study's database. Details about operative approach and postoperative complications of the prepathway patients were also not registered. The fact that there is no clear definition of dehydration

can be perceived by some as a limitation of the present study. We have chosen a definition that is practicable and used in everyday practice. Another possible limitation is that we unfortunately do not have data after January 2015. The fact that this pathway has been successful for at least 4 years after introduction, suggests that it is still very likely to remain effective in reducing readmissions for dehydration to this day.

Conclusion

In conclusion, this study has shown that the BIDMC ileostomy pathway is a feasible, effective and durable method to reduce readmission rates for dehydration and small bowel obstructions in ileostomy patients.

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Appendix 5.A

Detailed overview of Beth Israel Deaconess Medical Center Ileostomy Pathway[10]

The fundamental components of the pathway plan are as follows: preoperative education about ileostomy, standardized teaching materials across the service line, in-hospital direct patient engagement, observation of patient's ostomy management, and post discharge tracking of Is/Os. The critical difference in this approach was not the collation of the paper teaching materials, but our emphasis on patient self-management in the hospital.

Previously, patients were offered the opportunity to participate in their stoma care. In this new model, patients were asked to perform stoma care with direct nursing guidance and observation of their technique from postoperative day 1. In addition, we had realized that our patient care technicians were providing a lot of ostomy care, especially at night. This decreased the number of opportunities patients had to care for their stomas independently. We changed this process to allow the technicians to notify the nurse that the patient required pouch emptying so that the patient could be coached through the procedure. Finally, we asked the patients to chart their own Is/Os (Table S5.1).

The ileostomy output target was 1200 mL/day. We titrated antimotility agents for outputs greater than 1200 mL/day. Our typical dosing schedule began at 2 mg 3 times daily. All patients were referred for Visiting Nurse Association (VNA) services at discharge.

Each patient received a sheet and measurement tools in the hospital and instruction and support in charting his or her own stoma output. Dietary education was provided by registered nurses and wound ostomy and continence nurses (WOCN) to enhance the patient's understanding of foods that thicken ostomy output and support normal volume status. Teaching materials for patients were

developed and based on our current practice. Work flow checklists were developed to aid the nursing staff in the education of patients and optimization of patients for discharge (Table S5.2).

The document packet incorporated materials for the entire perioperative ostomy process, from preoperative site marking and education (Table S5.3) to discharge from the hospital with VNA services. All patients planned for surgery with a possible ileostomy continued to be seen preoperatively by one of the members of the WOCN team who explained what an ileostomy is, demonstrated pouching systems and techniques, and introduced the concepts of management of output with diet and antidiarrheals. We used the American Dietetic Association's "Ileostomy Nutrition Therapy" document and the United Ostomy Association of America's "How to Treat Ileostomy Blockage" and "Ostomates Food Reference Chart" for these purposes. The unit nurse educator sequentially in-serviced the nursing staff of the dedicated floor where patients undergoing colon and rectal surgery are primarily admitted in our hospital over the course of 1 month. Staff nurses were instructed to engage patients in ostomy teaching and management on postoperative day 1. Patients were expected to independently empty the pouching system by day 2 after surgery and were asked to be responsible for recording Is/Os and learning appliance change. Patients were discharged home with flow sheets and supplies for recording their Is/Os and with VNA services in place. We also created a VNA instruction sheet outlining our expectations for home care for the patients with ileostomies and asked the discharging nurse to directly communicate with the VNA service to reinforce management concepts (Table S5.4). We planned for early postoperative visits for the patients to see a WOCN and colon and rectal service nurse practitioner within 7 to 10 days after discharge.

Table S5.1 Ileostomy intake/output daily measurement chart.

Ileostomy intake/output daily measurement

Date	Time	Amount liquid consumed (mL)	Stool amount (mL)	Urine amount (mL)

Please use this form to record information about your daily intake and output. Anything less than 500 mL or more than 1200 mL out in 24 hours from your ileostomy, you need to call your doctor.

Table S5.2 Ileostomy discharge checklist.

Documents to review with patient during first hospital stay
• Ileostomy Care Instructions
• Taking Care of Your Ostomy booklet
• I & O Measurement Chart
Documents and supplies to give to patient on discharge
• Ileostomy Care Instructions
• Taking Care of Your Ostomy booklet
• Ostomy supplies (4 pouch changes)
• Prescriptions for ostomy supplies (Medicare patient only)
• I & O Measurement Chart
• A hat and urinal
Items to complete before discharge
• Give phone number to patient to make follow-up appointment with the ostomy RN (2–4 weeks postoperatively)
• Make follow-up appointment with the surgeon
• Resume and reconcile home medications
• Pain controlled with oral pain medicine
• Complete patient education regarding ostomy and/or wound care
• Fax referral to VNA for ostomy and/or wound care
• Give phone number to patient in the event they have any questions or concerns

I & O = inputs and outputs, RN = registered nurse; VNA = visiting nurse association.

Table S5.3 Ileostomy care instructions.

Ileostomy Care Instructions
You will likely be going home with a new ileostomy. You will be seen by a certified wound/ostomy nurse and participate in the care of your ostomy. In addition, other members of the team will also be involved in providing you with important information about your ostomy. The following instructions have been prepared to help ensure that you have the information that you need to help at home. If you have any questions, please ask your doctor or nurse. • Before you leave the hospital, the nurse should have reviewed with you: o This teaching sheet o Taking Care of Your Ostomy booklet o Ostomy supplies for 4 pouch changes o When or how to make your follow-up outpatient appointment with your surgeon o How to schedule a follow-up appointment with the ostomy nurse, call: 617-632-7060 • The nurse should have given you: o Prescriptions for ostomy supplies (if needed) o A chart to allow you to record your intake and output at home o A "hat" and "urinal" to help you measure your output • One major risk of having an ileostomy is dehydration. This is related to fluid loss through your stoma. • The signs and symptoms of dehydration include dry mouth or tongue, dizziness upon standing, weakness, a decrease in urination, urine darker in color, cramps in your abdomen and legs, and confusion. If you are having any signs of dehydration, please call your surgeon immediately. • To avoid dehydration, we instruct you to: o Drink 10 to 12 glasses of fluids daily, including electrolyte-enhanced beverages such as Gatorade, Pedialyte or Powerade. (This is especially important in warm weather, because you are perspiring more and losing more fluid from your body.) o Measure your fluid intake and ileostomy output. Use your "hat" or "urinal" as you were taught in the hospital to collect and measure the drainage in your ileostomy pouch. o Record these amounts on your measurement chart. If your ileostomy output is **less than 500 mL or greater than 1200 mL**, please inform your surgeon. Show this chart to your visiting nurse upon the visits. Bring this chart with you to your follow-up appointment with your surgeon and/or ostomy nurse. • If you have questions regarding the care of your ostomy at home, please contact the visiting nurse that is seeing you or contact the certified wound/ostomy nurse Monday to Friday @617-632-7060. You may also call your surgeon for any emergent concerns.

Doctor: Phone Number:

Table S5.4 Visiting nurse instructions.

To the Visiting Nurse:

Thank you for participating in the care of this patient. This patient has had multiple teaching sessions with both the wound/ostomy nurses and with the staff nurses and should have a good idea of how to care for their own ostomy. This patient has also been given several items that will assist them in their own care, such as instruction sheets, ostomy supplies, and ostomy output measuring tools. However, we would like to stress a few important points to assist you during your visits.

Bowel function:

- It is important to encourage the patient to monitor their bowel function closely every day. The patient should continue to record their ileostomy output and the amount of fluid they have taken in, just as they were taught in the hospital. A urinal or "hat" has been given to this patient for recording their ostomy output daily.
    - The patient has been instructed to show you their daily measurement chart at each visit, please ensure that they are completing this chart. If the ostomy output is less than 500 mL or greater than 1200 mL of liquid stool in a day, it is very important to call the doctor's office with this information.
    - Continue to reinforce to the patient that the major risk with an ileostomy is dehydration related to fluid loses. Daily fluid intake is 10 to 12 glasses of fluids, including electrolyte-enhanced beverages. During hot weather, encourage them to take in increased amounts of fluid and closely measure their ileostomy output.
    - Have the patient watch for signs and symptoms of dehydration, including dry mouth or tongue, decrease in urination, urine darker in color, dizzy when he/she stands, cramps in his/her abdomen or legs, dizziness, increased thirst, or weakness.

Stoma care:

- It is also important to monitor the appearance of the stoma. The tissue of the stoma should be moist, pink or red in color.
    - If the stoma has color changes from pink/red to dark purplish/blue in color, becomes swollen, or a large amount of continuous bleeding into the pouch, and or at the Mucocutaneous Junction (Stomal Incision), this is not normal. Call the patient's doctor's office for assistance.

If you or the patient has any questions regarding the care of the patient's ostomy, please refer to the instructions provided to the patient by the wound/ostomy nurses.

If the patient develops the following bowel symptoms please call the surgeon's office or go to the nearest emergency department, if severe: increasing abdominal distension and cramps, nausea, vomiting, inability to tolerate food or liquids, decrease in ostomy output, or has had no output from ostomy for 4 to 6 hours.

Chapter 6

Implementation of an easy in-hospital educational stoma pathway results in decrease of home nursing care services after discharge

YT van Loon, SHEM Clermonts, R Belt, DK Wasowicz, D Nagle, DDE Zimmerman

Colorectal Dis 2020;22(9):1175-1183

Abstract

Aim

New stoma patients often rely heavily on the assistance of the ward nursing staff during the hospital stay and on the availability of home nursing care services (HNCS) after discharge. An easily executable 4-day in-hospital educational stoma pathway was developed and implemented. Aim was to increase their level of independence (LOI) in order to reduce the need for HNCS after discharge.

Method

All new stoma patients on the gastrointestinal surgery ward, physically and psychologically capable to perform independent stoma care (SC), were enrolled in this pathway. They were compared to a retrospective control group of new stoma patients before the onset of the stoma pathway. Primary outcome is the need and frequency of HNCS for SC at the moment of discharge. Secondary outcome is LOI in SC at discharge.

Results

Total of 145 patients (m:f =102:43, median age 67 (range 27-90) years) were included in the present study. Patients requiring daily HNCS for SC decreased from 80% to 50%, $p<0.001$, patients discharged without HNCS for SC increased from 5% to 27%. Patients' independence in SC at discharge increased from 8% to 68%, $p<0.001$.

Conclusion

This study shows that a clinical 4-day in-hospital educational stoma pathway is feasible and effective in increasing the LOI in SC of new stoma patients and significantly reducing their need for HNCS. Cost-benefit analysis and applicability of this pathway in multicentre settings are currently being investigated.

Introduction

New stoma patients face significant physical, psychological and body image adaption with loss of personal physical function.[1] Clear and accurate information about life with a stoma and stoma care (SC) is important for acceptance of the situation, not just for the patient but also for their family members.[2] Insufficient preparation or education can lead to postoperative problems in accepting the new stoma or stoma management. Independent stoma management is advocated as a starting point in the acceptance of a new life with a stoma and is essential in their new postoperative life.[3,4] Adequately preparing patients to be independent in their SC starts with adequate education.[5] Physicians, surgeons, nurses and specialized stoma care nurses (SCN) are particularly important in these processes.

Frequently, patients otherwise ready for discharge, have their admission prolonged because independently emptying of their stoma pouch cannot be performed, increasing healthcare costs. Instead of independently managing their own SC, patients often rely heavily on either the assistance of the ward nursing staff during the hospital stay or on the availability of home nursing care services (HNCS) after discharge. These are well-established problems and have been described before by Chaudhri et.al. and Nagle et.al.[6,7]

There is a continued need for further reduction of postoperative complications, length of stay and use of HNCS in an effort to reduce overall health care costs. This highlights the obvious need for adequate in-hospital education and preparation of new stoma patients in an effort to increase independence. In order to reach these goals, we introduced an easily executable 4-day in-hospital educational stoma pathway. The aim of this pathway was to increase the level of independence (LOI) in new stoma patients, in an effort to reduce the need and dependency on HNCS after discharge. We postulate that well-educated and well-trained patients will be more proficient and independent in their SC and therefore less dependent on HNCS at discharge compared to patients who did not follow the stoma pathway.

Materials and methods

The study was undertaken within the gastrointestinal surgery department of Elisabeth-TweeSteden hospital in Tilburg, the Netherlands. All patients were treated by a team of certified staff nurses, physician assistants (PA) and SCN in a surgery department dedicated to colorectal surgery. Elective patients with a high probability of stoma formation received preoperative information and education about life with a stoma and the different aspects of SC. This was carried out by the PA and SCN utilizing standardized educational material during their outpatient clinic contact and included one session of hands-on stoma care practical supervised by a SCN. All the steps in SC were practiced with the help of an artificial Styrofoam stoma, which was provided by our local SC appliances manufacturer.

Baseline situation

A retrospective benchmark study was performed to evaluate the prevalence of HNCS use for SC at discharge. Data from all patients after elective or emergency gastrointestinal surgery with a new stoma from January 1, 2014 until December 31, 2014 was assessed for the LOI of their own stoma management and their need for HNCS for SC at the moment of discharge. These patients were not subjected to a standardized teaching program during their hospital stay, their SC was performed by the staff nurses or SCN. LOI is routinely assessed by the staff nurses or SCN during the admission and at discharge and is defined as the ability to perform an aspect of SC by themselves without help or assistance from someone else. These patients are defined as the baseline pre-pathway cohort, group A.

In an effort to standardize SC and improve patients LOI, a standardized in-hospital postoperative stoma pathway was designed by our team of surgeons, SCN and staff nurses. It was inspired by the Beth Israel Deaconess Medical Center's (BIDMC) ileostomy pathway[7] and made applicable to our local situation. This stoma pathway was developed with specific focus on patient education and engaging them and their family with the SC throughout their hospital stay.

Intervention

A 4-day in-hospital educational stoma pathway was introduced to improve independence in SC by new stoma patients. Fundamental components were active postoperative involvement of patients and their (family) caregivers about SC and life with a stoma. This was combined with adequate step-wise exposure to- and hands-on education in SC during the first 4 consecutive postoperative days. Nurses were instructed to engage patients and caregivers in their SC on postoperative day 1 and to accompany and guide them to become as independent in SC as possible. Introduction of this pathway was carried out by education with distribution of physical pocket cards (Figure 6.1a, 6.1b) to all the health care personnel of the gastrointestinal surgery department throughout January 2015. Onset of this pathway was February 1, 2015.

All new stoma patients before and after start of this pathway were treated within an established Enhanced Recovery After Surgery protocol.[8] All new ileostomy patients received the postoperative care and education according to the BIDMC ileostomy pathway.[7] All patients undergoing elective surgery received preoperative consultation by a SCN to determine the optimal stoma site. For patients undergoing emergency surgery at times when the SCN were not present, we relied on the staff nurses to preoperatively mark the optimal stoma site. The different types of stomas that were placed were end colostomies, loop- and end ileostomies. A loop colostomy is not common practice at our hospital.

The stoma pathway

Pre-operative outpatient clinic education by our PA and SCN stayed the same. Patients were notified at this time, informing and requesting them and their caregivers to partake in this new stoma pathway. Caregivers, if present, were asked to participate actively in SC and to be present on the ward during the educational moments. There was a strong emphasis on creating active patient engagement and dexterity throughout this entire process. In an effort to pursue complete independence, patients were encouraged to practice their stoma management as

often as they could, even during the evening and nights. This was purposely implemented to mimic home settings, when there is obviously no direct help from health care personnel. SC was divided into 3 steps: emptying the stoma pouch, changing the stoma pouch, adjustment and application of skin barrier (see Figure 6.1ab). No other interventions in peri- or postoperative care were implemented during this period of time.

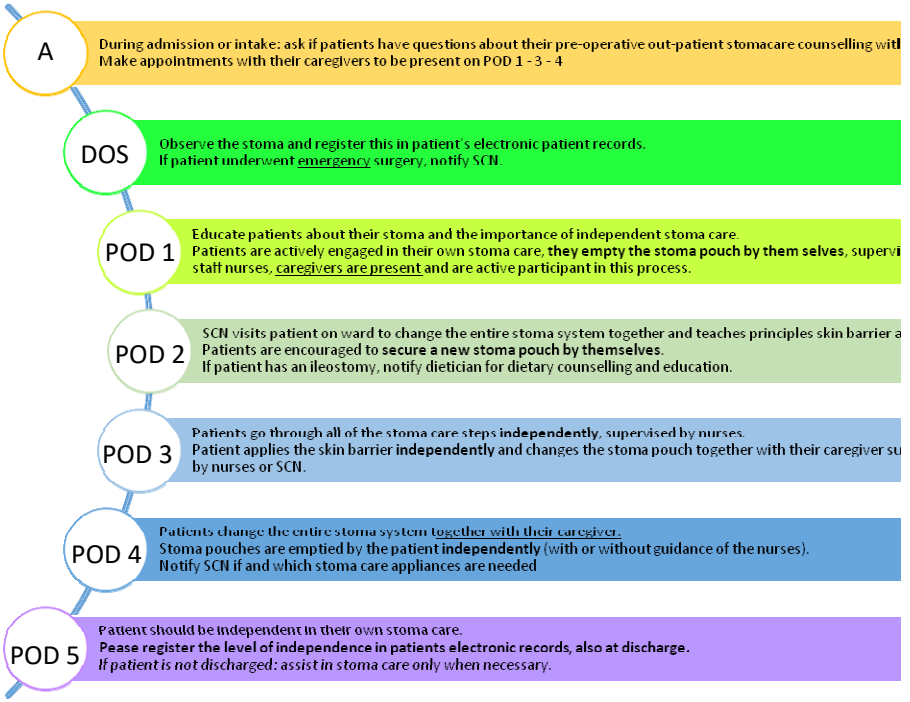

Figure 6.1a Translated English version of 4-day in-hospital educational stoma pathway, starting from the first postoperative day. A: at admission; DOS: day of surgery; POD: postoperative day; SCN: stoma care nurse.

It was our endeavour to make sure that all patients had gone through all the stoma pathway steps at the time of discharge and that the patients were at least

independent in emptying and changing the stoma pouch and how to adjust the skin barrier by themselves. The formal pathway always involved nursing support for the first 4 days. For the remainder of the admission nurses supported and rehearsed the steps of SC only when needed until discharge. Staff nurses and SCN routinely kept track of patients' progress, documented achieved LOI at every step in the pathway and at discharge. HNCS for SC at discharge was requested by staff nurses when needed in accordance with the patients and their caregivers.

Diëtiste: toestel 5763 | **Stomazorg:** toestel 3230

Dag van opname:	- Onduidelijkheden na gesprek met stomavpk? Vraag hiernaar. - Deel uit: geplastif ceerd blad stomazorg. - Maak afspraken met familie voor verplichte stomazorg op dag 1-3-4.
Dag van operatie:	- Observeer stoma en vul het stomaregistratieformulier in. - Bij een acute patiënt: licht stomaconsulente in.
Dag 1 postoperatief:	- Geef uitleg over het stoma en het belang van zelfzorg. - Patiënt **leegt zelf** stomazakje onder begeleiding. - Familie is hierbij aanwezig. - Rapporteer dagelijks mate van zelfstandigheid op stomaregistratieformulier.
Dag 2 postoperatief:	- Stomavpk wisselt met patiënt de stomaplaat. - Patiënt **bevestigt zelf** stomazakje op de stomaplaat. *(In weekend doet afdelingsvpk dit!)* - Vraag bij ileostoma diëtist in consult.
Dag 3 postoperatief:	- Patiënt **wisselt zelf** stomazakje onder begeleiding. - Patiënt **knipt zelf** stomaplaat met behulp van de mal. - Patiënt en familie legen overdag zelfstandig het zakje.
Dag 4 postoperatief:	- Patiënt en familie wisselen stomaplaat onder begeleiding. - Patiënt leegt stomazakje zelf zonder toezicht. - Laat stomavpk weten of materiaal besteld moet worden. - Patiënt wisselt in de avond **nogmaals zelf** het zakje.
Dag 5 postoperatief:	- Ontslag: patiënt wisselt stomaplaat en zakje zelf zonder hulp. - Geen ontslag: patiënt leegt en wisselt stomazakje zelf zonder hulp. - Vul stomaregistratieformulier in.
Aandachtspunten:	**Bij ontslag streven we naar:** *- Patiënt leegt en wisselt stomazakje zelf en kan stomaplaat op knippen.* *- Familie heeft stomazakje legen en wisselen en stomaplaat wissel gezien en geoefend.* **Bij ontslag: arts rapporteert in decursus welke stappen bij stomazorg al zijn doorlopen!**

Figure 6.1b The actual Dutch version of 4-day in-hospital educational stoma pathway.

Inclusion criteria

All patients undergoing gastrointestinal surgery with creation of a new stoma, either colostomy or ileostomy, from February 1, 2015 until December 31, 2015 were included in the present study and they were defined as the stoma pathway

cohort, group B. Patients had to be discharged to their own home and living independently without prior HNCS for other support or care and had to be willing to cooperate with this pathway.

Exclusion criteria

Patients under the age of 18, who had had a previous stoma, who were admitted on a different department than the gastrointestinal surgery department, who died during admission, who were discharged with HNCS for other care or support besides SC and patients with postoperative complications, existing comorbidity or previous medical history which made them incapable of independent SC such as visual impairment (e.g. partial blindness, hemianopsia, cataract), physical impairment (e.g. tremors, Parkinson's, paralysis) or intellectual disability (e.g. dementia, mental retardation) were excluded from this study. Patients who were not discharged to their own home but e.g. a rehabilitation centre or nursing home, are patients who were too frail, too ill (physically or psychologically) and unable to adhere to the stoma pathway and were therefore excluded. In order to minimize bias, patients who were operated between January 1 and January 30, 2015, during the educational period but before the official start of this pathway, were also excluded from this analysis.

Primary outcome measure was the need for HNCS for support in SC at home at discharge. Secondary outcome measure was the LOI in their own SC at discharge, the postoperative length of stay (LOS) and readmission rates after discharge.

Statistical analysis

Descriptive statistics were expressed as median and range (minimum, maximum) for continuous variables and tested using the Independent Samples medians test. Pearson Chi square test or Fisher exact tests, if appropriate, were used for categorical variables. Mann-Whitney-U test was used for ordinal variables.

Statistical analysis was performed using the SPSS software package version 22 (SPSS, Chicago, IL). All *p*-values <0.05 were considered statistically significant.

Results

Group A

One hundred patients were identified in the pre-pathway baseline control group, 60 patients (m:f =44:16, median age 67 (range 27-85) years) were included for analysis. Forty patients were excluded for several reasons: previous stoma in medical history (2), HNCS for other support and care than SC (14), discharge to somewhere other than their own home (12), died postoperatively (6), HNCS for reasons which were not clearly documented (3) and patients who had prolonged hospital stay due to complications and were therefore not able to learn own SC (3), Figure 6.2. Majority of the patients were operated electively (81.7%) for malignancy (76.7%) or diverticulitis (18.3%).

One hundred and sixty-three patients were identified in the stoma pathway group, of which 78 were excluded. A total of 85 new stoma patients (m:f =58:27, median age 67 (range 30-90) years) were included in group B for analysis. Reasons for exclusion were: previous stoma in medical history (7), HNCS for other support and care than their SC (18), postoperative admission to a different department other than the gastrointestinal surgery unit (6), comorbidity which made patients unable to perform independent SC (6), discharge to somewhere other than their own home (15), died postoperatively (6), HNCS for reasons which were not clearly documented (2), patients who had prolonged hospital stay due to complications and were therefor not able to learn own SC (5), patients receiving a palliative stoma (2) and patients who were operated between January 1 and January 30, 2015 (11), Figure 6.3. Majority of the patients were operated electively (74.1%) for malignancy (77.6%) or diverticulitis (12.9%). There were no patients who declined participation in the stoma pathway. See Table 6.1 for detailed overview of the patient characteristics.

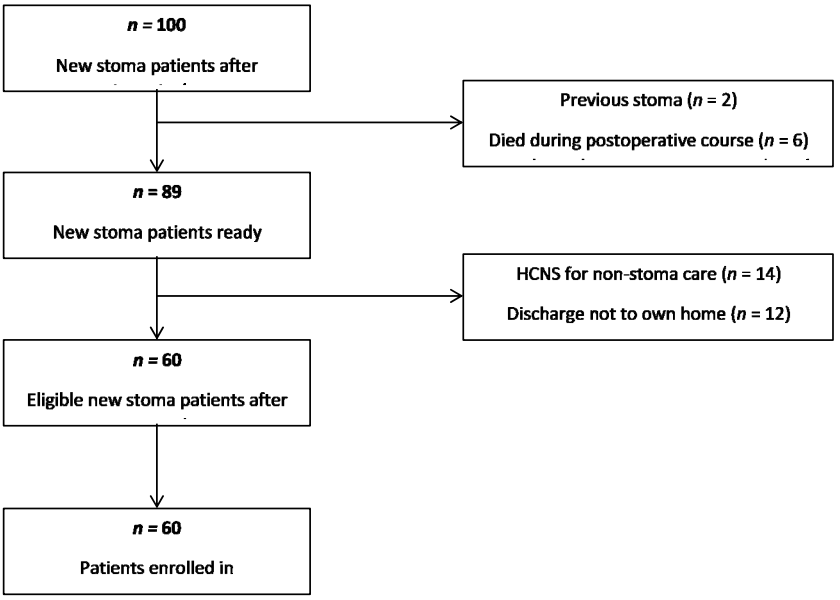

Figure 6.2 Flow chart with detailed patient selection of group A (pre-pathway baseline cohort group).

HNCS at discharge

In group A merely 3 patients (5.0%) were independent in their SC at discharge without the need for HNCS. The other patients needed HNCS for SC either three times a week (10/60, 16.7%) or daily (47/60, 78.3%). When comparing group A to group B, a difference in HNCS for SC at discharge was noted, this difference was statistically significant, $p<0.001$. The patients in group B without HNCS for SC at discharge increased from 5.0% to 27.1% (23/85) and those who needed daily HNCS decreased almost 30%, from 80.0% to 50.6% (Figure 6.4). There was no difference between the patients who underwent an emergency or elective surgery in their need for HNCS for SC at discharge either three times a week (11/22 vs. 32/63) or every day (5/22 vs. 14/63).

Group B

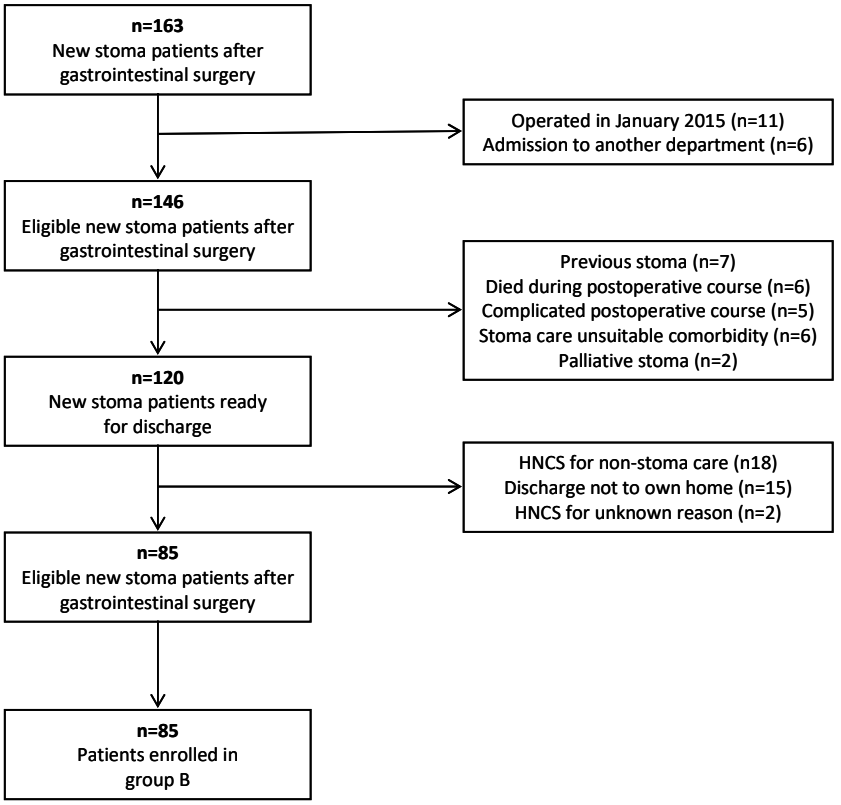

Figure 6.3 Flow chart with detailed patient selection of group B (stoma pathway group). HNCS = Home Nursing Care Services.

Table 6.1 Patient characteristics of the groups.

	Group A (n=60)	Group B (n=85)
Male, % (n)	73.3 (44)	68.2 (58)
Age in years, average (SD)	67.1 (13.5)	67.5 (11.0)
Elective surgery, % (n)	81.7 (49)	74.1 (63)
Type of stoma, % (n)		
Loop ileostomy	23.3 (14)	25.9 (22)
End ileostomy	10.0 (6)	7.1 (6)
Loop colostomy	5.0 (5)	12.9 (11)
End colostomy	61.7 (37)	54.1 (46)
ASA classification, % (n)		
ASA 1	21.7 (13)	10.6 (9)
ASA 2	50.0 (30)	60.0 (51)
ASA 3	23.3 (14)	23.5 (20)
ASA 4	5.0 (3)	5.9 (5)
Reason for surgery, % (n)		
Diverticulitis	18.3 (11)	12.9 (11)
Malignancy	76.7 (46)	77.6 (66)
IBD	1.7 (1)	4.7 (4)
Ileus	1.7 (1)	-
Anastomotic leakage	1.7 (1)	3.5 (3)
Iatrogenic perforation	-	1.2 (1)
Postoperative ICU, % (n)	20.0 (12)	11.7 (10)

Group A: baseline group, pre-pathway; Group B: intervention group, patients who enrolled the stoma pathway; SD: standard deviation; ASA: American Society of Anesthesiology; IBD: Inflammatory Bowel Disease
ICU: intensive care unit.

LOI at discharge

The achieved LOI by the new stoma patients showed a significant increase after introduction of the stoma pathway. Only 8.3% (5/60) of the patients in group A were able to independently perform their own SC compared to 68.2% (58/85) of the patients in group B, $p<0.001$. (Figure 6.5). In 60.3% (35/58) of the patients who were independent in their own SC at discharge still required HNCS; 48.6% of them (17/35) applied for 3 times a week and 51.4% (18/35) for daily HNCS.

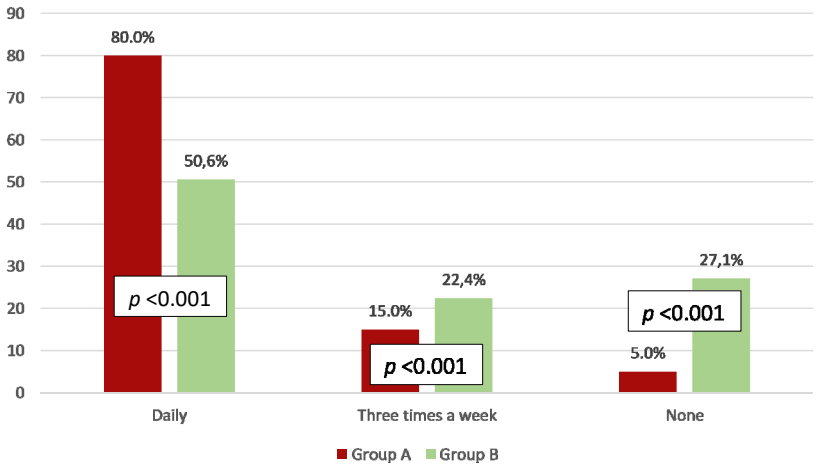

Figure 6.4 Percentage of home nursing care service use for stoma care at the moment of discharge per group.

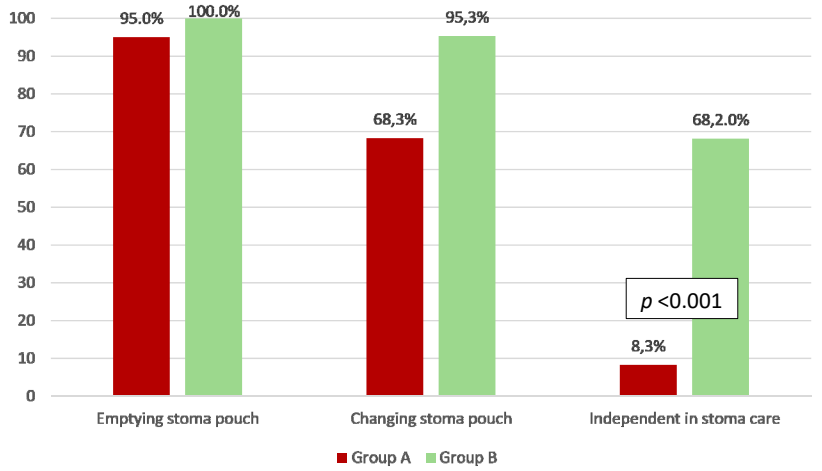

Figure 6.5 Percentage of achieved level of independence in their own stoma care by new stoma patients at the moment of discharge per group.

LOS and readmission rates

There was no statistically significant difference between the median LOS of both groups, 9.0 versus 7.0 days, *p*=0.173. Nor was there a difference between the readmission rates within 30 and 90 days, 5.0% and 11.7% versus 4.7% and 12.9%. See Table 6.2 for a detailed overview.

Table 6.2 Percentage of achieved level of independence and need for home nursing care services for stoma care at discharge.

	Group A (n=60)	Group B (n=85)	*p*-value
LOI at discharge, % (n)			
Emptying stoma pouch	95.0 (57)	100.0 (85)	
Change of stoma pouch	68.3 (41)	95.3 (81)	<0.001
Independent in stoma care	8.3 (5)	68.2 (58)	
HNCS at discharge			
None, % (n)	5.0 (3)	27.1 (23)	
Three times a week, % (n)	15.0 (9)	22.4 (19)	<0.001
Daily, % (n)	80.0 (48)	50.6 (43)	
LOS in days, median (range)	9.0 (4-56)	7.0 (3-35)	0.173
Readmission rates, % (n)			
Within 30 days	5.0 (3)	4.7 (4)	ns
Within 90 days	11.7 (7)	12.9 (11)	ns

LOI = level of independence; HNCS = home nursing care services; LOS = length of stay; ns = not significant.

Discussion

The care of patients with stoma can be perceived both as an art and a science, many of the commonly accepted interventions in SC are based on empirical evidence supported by little or no objective data.[9] However, merits of clinical pathways have been reported before and are widely accepted. Pathways are designed and capable to improve the quality of care, patient satisfaction and optimal efficiency in the use of resources.[10,11] We introduced a clinical pathway as a 4-day in-hospital educational stoma pathway trying to improve the quality of care for our stoma patients. This is, to the best of our knowledge, the only day to day

stoma pathway in the Netherlands for new stoma patients, aimed to improve independence and to reduce the need of HNCS in new stoma patients.

Our team of surgeons, staff and SCN observed that practically all of our new stoma patients were heavily dependent on daily HNCS at discharge for their SC. In an effort to improve this problem, we approached it in a stepwise manner. First, we confirmed our observations by a benchmark study, secondly identified possible points of improvement and questioned the concerned health care personnel about their thoughts and wishes. Lack of (standardized) postoperative in-hospital stoma training, absence of engagement of the patient with their own SC combined with the care provided by our staff nurses on the ward instead of letting the patients do it for themselves, were all identified as areas for potential improvement. After these steps, we developed a pathway which is heavily focused on education and hands-on practice with guidance and strong engagement of the patient and their caretakers with SC.

This present stoma pathway is easy to implement and execute in clinical practice. Implementation took as little time as one month, and caught on the enthusiasm throughout the entire line of health care personnel of our gastrointestinal surgery department. There were no patients who declined participation in the stoma pathway. We observed an obvious and significant increase in independence of our new stoma patients and concomitant significant reduction of their need of HNCS for SC after introduction of our stoma pathway. Need for daily HNCS decreased from 80% to 50%. Patients who were independent in SC at discharge increased from 8 to almost 70%, increasing the number of patients who did not need HNCS at discharge from 5 to 27%. Despite the significant increase in the new stoma patients' LOI, they still felt a need for HNCS at discharge. This might be due to uncertainty in their own ability or due to cultural or traditional reasons. In the Netherlands patients expect and are used to being discharged with HNCS, this has been tightly embedded and accepted in our locoregional and national health care system. The reasons for patients' dependence despite their independence in SC during admission and discharge are interesting avenues for further research.

We believe that the power of this pathway lies not only in the easily introducible interventions and better awareness by patients of their own situation, but also in the dedication and enthusiasm of all the health care personnel on the gastrointestinal surgery unit. Preoperative education is known to reduce postoperative adverse outcomes such as stoma-related cutaneous problems.[12] Specialized guidance and expertise can improve the quality of care for new stoma patients, increasing confidence, autonomy and problem-solving abilities.[13] Well prepared, trained and educated patients are more confident in their SC and are better adapted.[14] The fact that there is no difference in independence and HNCS at discharge, between patients who underwent elective surgery compared to those who underwent emergency surgery, suggest that the postoperative educational pathway is an undeniable important factor in teaching the patients their SC. The in-hospital pathway might be equally or even more important than the preoperative education in our hospital. It is our belief, but it was also reported before, that well-adjusted patients who are not dependent on others for their own SC are happier patients who experience higher (health related) quality of life and will lead to reduction in health care costs.[15]

There are some limitations to the present study. We did not perform patient selection at admission but instead chose to implement this pathway as a new standard of care on our gastrointestinal unit. Neither did we differentiate between patients who underwent elective planned or emergency surgery with a stoma. We did not record data on time to first stool, nor did we evaluate pre- or post-pathway quality of life scores. Also, we used a historical observational cohort as a baseline control group, we did not perform a case-matched analysis. This could all lead to a certain bias. However, we believe that we have limited the bias to a minimum by our strict exclusion criteria in both the baseline pre-pathway as well as the pathway cohort.

Interesting avenues of further research regarding this pathway are a cost-benefit analysis and the applicability of this pathway in a multicentre setting. These topics

together with a self-perceived quality of life in the postoperative follow-up of new stoma patients are being evaluated.

Conclusion

Proper stoma education will result in better adjusted new stoma patients, improving their proficiency and subsequently their independence in SC. This study shows that a clinical 4-day in-hospital educational stoma pathway is a feasible and effective method to increase the LOI in SC of new stoma patients and significantly reduces their need for HNCS, even when patients did not receive preoperative instruction. Cost-benefit analysis and applicability of this pathway in multicentre settings are currently being investigated.

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Chapter 7

Effects of a perioperative ostomy educational pathway on ostomy self-care, level of independence and the need for visiting nurse services in ostomates

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Submitted

Abstract

Background

Most new ostomates are not able to manage ostomy self-care when they are medically ready to be discharged. Consequently, the majority of new ostomates rely on visiting nurse services (VNS) for ostomy management. The aim of this study was to determine if a perioperative ostomy educational pathway increases the level of independence and decreases the need for VNS in new ostomates.

Methods

A prospective longitudinal study was conducted between July 2018 and February 2020. Patients following a perioperative ostomy educational pathway were compared to a historical control group. Patients aged ≥18 were included if they had received a colostomy or ileostomy in elective or emergency surgery and were treated on the general surgery ward. The primary outcome measure was the level of independence in ostomy care and the need for VNS.

Results

After discharge, 67.6% of the patients in the intervention group (n=244) were able to independently perform ostomy care and were therefore not relying on VNS, compared to 15.2% of the patients in the control group (n=33) (p<0.001). The need for VNS remains significantly higher in patients who did not attend the preoperative practice session and in patients aged ≥70 (p<0.01).

Conclusion

The perioperative ostomy educational pathway examined in this study effectively increased the level of independence in new ostomates and decreased the need for VNS. In addition, patients were satisfied with the received ostomy self-care guidance.

Introduction

While improved surgical techniques and treatment for colorectal cancer (CRC) have led to a decreased need for ostomies, over 25% of the patients diagnosed with CRC in 2019 still received a permanent or temporary ostomy.[2-3] An ostomy can be of great impact on quality of life (QoL) and is negatively associated with physical, psychological and social functioning.[4-6] Problems may arise during the process of acceptance, which subsequently may have a negative effect on self-management and self-efficacy.[7]

Most of these patients are not able to manage their ostomy self-care at the moment they are medically ready to be discharged, mostly because of lack of information and insufficient stimulation of the patient's self-efficacy concerning ostomy care during the perioperative phase.[5] In addition, ostomates may experience unnecessary ostomy-related uncertainties due to lack of knowledge.[5-7] This often leads to an increasing use of health care, including a higher demand for outpatient appointments and the need for continuous care by Visiting Nurse Services (VNS) after discharge.[8-9]

The difficulties that the majority of the new ostomates encounter after hospital discharge and the importance of guidance and follow up by an ostomy nurse have been well documented.[10-11] New ostomates are in need of information regarding their ostomy and emotional support, which can be provided by establishing a comprehensive plan of care. Such a plan should include information, technical expertise, psychosocial support, appointments with a surgeon and an ostomy nurse and sufficient guidance.[12] In addition, repetitive elements in educational plans have been proven effective to enhance the awareness of the need for self-care and adaptation to the new condition.[13] Sufficient guidance for ostomates is needed to ensure their independence in ostomy self-care.

Specialized guidance and expertise can improve the quality of care for new ostomates, increasing confidence, autonomy and problem solving abilities.[14] Developing this ostomy competency has been described for nurses, but surprisingly, hardly any protocol or pathway can be found in literature which promotes the establishment of this competence in new ostomy patients. Recently,

van Loon et al. described a 4-day in-hospital educational stoma pathway for patients with an ileostomy, which was shown to be feasible and effective in increasing the level of independence (LOI) in a selected patient population and decreasing their need for VNS.[15] This confirmed the merit of sufficient in-hospital education in achieving independence in ostomy self-care.
This study aimed to determine if a perioperative ostomy educational pathway increases the level of independence and decreases the need for VNS in new ostomates. Furthermore, factors influencing LOI and satisfaction of the patients were assessed.

Materials and methods

Research design

This prospective longitudinal study was conducted between July 2018 and February 2020 at Catharina Hospital Eindhoven, the Netherlands. The study included all the patients aged ≥18 who had received a colostomy or ileostomy, either in elective or emergency surgery, and were treated on the general surgery ward. Exclusion criteria were in-hospital deaths or further treatment in another hospital. All patients in the intervention group were provided with a perioperative ostomy educational pathway. Patients who had received an ostomy between January 2018 and March 2018 were used as a historical control group. Inclusion and exclusion criteria were the same as to those of the intervention group.
Based on an effect size of 0.5, an α of 0.05 and a β of 0.95 and a historical control group of 25 patients, at least 75 patients should be included in the intervention group to compare the control group and the intervention group. It was estimated that complete data could be obtained for 65% of the patients in the intervention group. Therefore, at least 102 patients should be included in the intervention group to correct for missing data in advance.

Ostomy self-care reinforcement education

The perioperative ostomy educational pathway consists of several crucial elements, namely information, technical expertise, psychological support, referrals and surveillance (Figure 7.1).[12] This pathway was adapted from the 4-day in hospital educational stoma pathway by *van Loon et al.* and served as a guideline for patients to achieve independence regarding ostomy self-care [15] (Figure 7.2; Appendix 7.2).

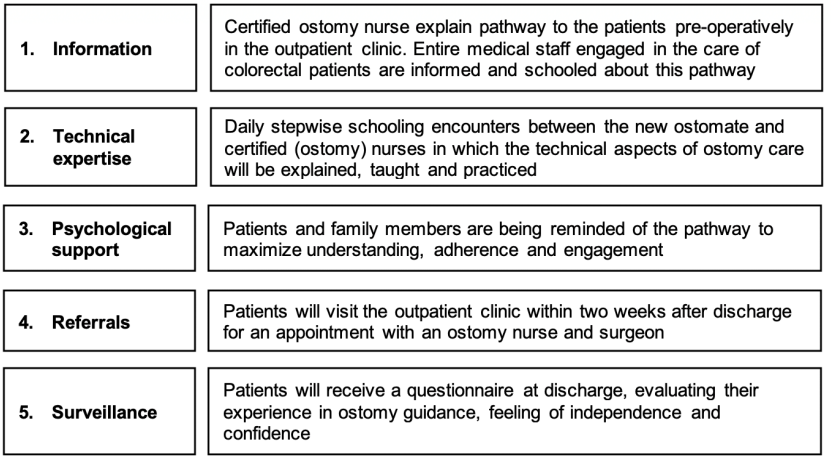

Figure 7.1 Schematic overview of the crucial elements incorporated in perioperative ostomy educational pathway.

Prior to admission to the hospital, patients had three appointments at the outpatient clinic. During the first appointment they received information from the operating surgeon. The second appointment was for an intake interview, and the third appointment was a preoperative practice session with an ostomy nurse for ostomy self-care. On the first postoperative day, patients were stimulated to practice with ostomy self-care, including unrolling and emptying the pouch. On the second postoperative day, patients practiced with replacing the ostomy pouch. On

the third day, patients were expected to be able to empty the pouch independently. Moreover, they had to lay out all the needed materials to change the pouch and to remove the ostomy material from the body. In addition, patients started to practice with alteration and placement of the skin barrier. On the fourth day, patients continued to practice with alteration and placement of the skin barrier and changing the materials in the presence of a family member or a caregiver. On the fifth day, patients independently took care of their ostomy. All steps were practiced under supervision of a nurse or an ostomy nurse. At discharge, each patient's LOI in ostomy self-care was assessed by medical staff.
Within two weeks after discharge, patients had two appointments at the outpatient clinic, one with the surgeon to evaluate the recovery and one with the ostomy nurse to evaluate ostomy self-care.

Efficacy measures

Primary outcome measure was the LOI in ostomy self-care observed by medical staff at discharge. In order to be independent, patients had to meet the following criteria: no need for VNS and being able to independently take care of their stoma, which involved emptying the pouch, alteration and placement of the skin barrier and replacing the materials.
Secondary outcome measures were the time points (quantified in the number of days postoperatively) at which the patients started with the different aspects of self-care (emptying the pouch and adjusting and replacing the ostomy materials), the length of stay (LOS) and the number of contact moments with an ostomy nurse within one month and three months after discharge. In addition, the patient's appreciation of the provided ostomy care guidance and the patient's subjective level of confidence were measured by means of a self-care and satisfaction questionnaire (Appendix 7.1).

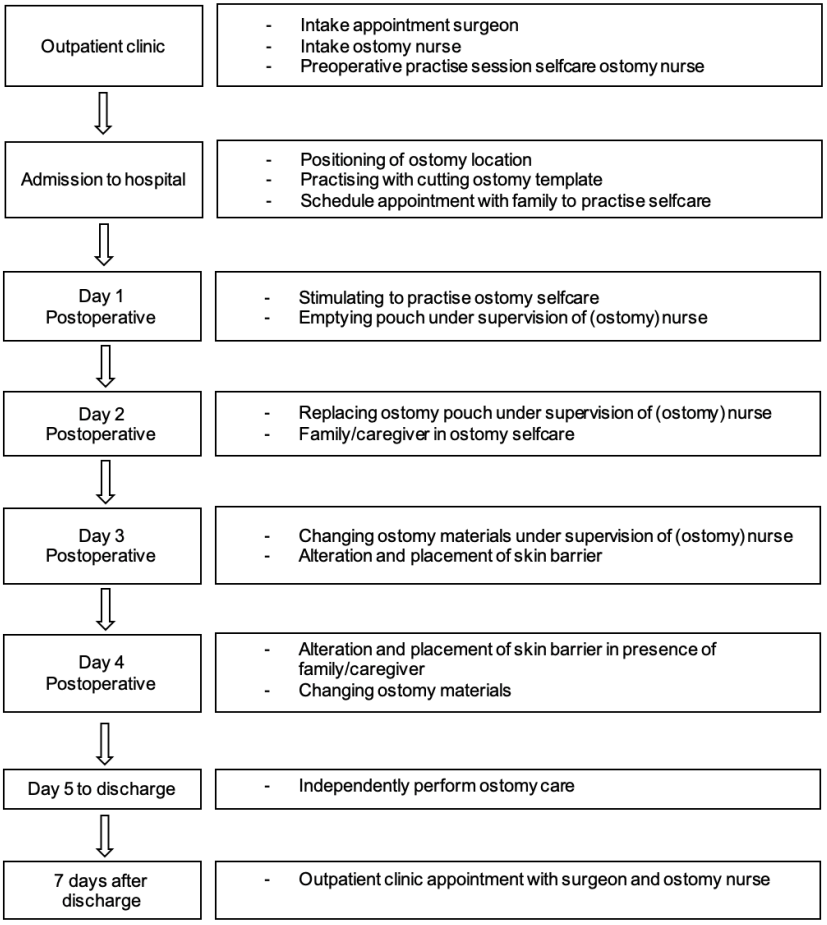

Figure 7.2 Educational ostomy pathway.

Data collection

The data were collected between July 2018 and February 2020. The data of the historical control group were collected retrospectively. Data regarding the

intervention were collected prospectively at several timepoints. The first timepoint was the moment at which a patient had the appointment with a surgeon and at which they attended the preoperative intake session with an ostomy nurse, followed by inclusion in this study. At this point, patient characteristics were collected (age, gender, BMI, medical history, type of surgery, type of stoma). After each post-operative practice sessions during hospitalization, the ostomy nurse collected data regarding the patient's ability to empty the ostomy pouch, alter and place the skin barrier and replace ostomy materials. At discharge, data regarding whether VNS was needed were collected. In addition, data were collected regarding contact with an ostomy nurse (outpatient clinic and by telephone) within one month and three months after discharge. To evaluate patient satisfaction, a self-care and satisfaction questionnaire was conducted in a group of patients who were operated between September 2019 and February 2020 (Appendix 7.1).

Data analysis

All statistical analyses were performed using SPSS ® Statistics (version 25.0, IBM Corp. Released 2017, Armonk, New York, USA). The primary outcome measure was analysed with the unpaired t-test. Patient characteristics of both groups (control and intervention) were compared using the unpaired t-test for continuous data and the chi-square test or Fisher's exact test and the Mann–Whitney U-test for categorical data. Secondary outcomes were analysed with the unpaired t-test or the Mann-Whitney U-test. Independent associations between patient and treatment characteristics and the need for VNS in the intervention group were analysed by means of univariate and multivariate binary logistic regression analyses. Significance was defined as a p value $p<0.05$.

Ethical considerations

The protocol for this study was approved by the Medical Ethics Review Committee (METC) Brabant (Trial number: nWMO-2019.105).

Results

A total of 33 patients were included in the historical control group. In the intervention group, a total of 244 eligible patients were included. The distribution of some variables of the baseline characteristics differed significantly between the control group and the intervention group (Table 7.1). The incidences of abdominoperineal resection (26.2% vs. 3.0%) and Hartmann's procedure (11.9% vs. 9.1%) were significantly higher in the intervention group (p=0.022). As a consequence, significantly more patients in the intervention group received an end colostomy (59.8% vs. 21.2%, p<0.001). All other baseline characteristics were distributed equally between groups.

Table 7.1 General characteristics of participants.

	Control group n=33 (%)	Intervention n=244 (%)	*p*-value
Gender			0.612
Male	21 (63.6)	144 (59.0)	
Female	12 (36.4)	100 (41.0)	
Age (years) *Mean (SD)*	62.67 (SD 13.32)	64.46 (SD 12.99)	0,459
Comorbidities			
Cardiac	11 (33.3)	131 (53.7)	
Pulmonary (COPD)	5 (15.2)	26 (10.6)	
Arthrosis	0 (0.00)	9 (3.7)	
Diabetes	6 (18.2)	23 (9.4)	
CVA/TIA	0 (0.0)	20 (8.1)	
Cognitive impairment	1 (3.0)	12 (4.9)	
BMI <20 kg/m^2	8 (24.2)	14 (5.7)	
BMI ≥30 kg/m^2	6 (18.2)	38 (15.6)	
ASA score			0.674
I	3 (9.1)	10 (4.1)	
II	15 (45.5)	147 (60.2)	
III	15 (45.5)	75 (30.8)	
IV	-	12 (4.9)	
Operation setting			0.540
Elective	25 (75.8)	196 (80.3)	
Emergency	8 (24.2)	48 (19.7)	

Table 7.1 (continued)

	Control group n=33 (%)	Intervention n=244 (%)	*p*-value
Type of operation			0.022*
APR	1 (3.0)	64 (26.2)	
LAR	8 (24.2)	49 (20.1)	
Sigmoid resection	3 (9.1)	29 (11.9)	
HIPEC	9 (27.3)	29 (11.9)	
Stoma construction	9 (27.3)	47 (19.2)	
Other	3 (9.1)	26 (10.7)	
Ostomy type 1			<0.001*
Transversostomy	19 (57.6)	72 (29.5)	
Ileostomy	6 (18.2)	17 (7.0)	
End (terminal) colostomy	7 (21.2)	146 (59.8)	
End (terminal) ileostomy	1 (3.0)	9 (3.7)	
Ostomy type 2			<0.001*
Temporary	26 (78.8)	99 (40.6)	
Permanent	7 (21.2)	145 (59.4)	
Ostomy history			0.743
Yes	8 (24.2)	53 (21.7)	
No	25 (75.8)	191 (78.3)	
Length of stay (days)			
Median (Q_1-Q_3)	10 (6.0-15.5)	8 (6.0-15.0)	0.641
IC admission			0.717
≤1 day	27 (81.8)	193 (79.1)	
≥2 days	6 (18.2)	51 (20.9)	
Complications (Clavien-Dindo)			0.607
Grade 0-2	26 (78.8)	191 (78.3)	
Grade 3	6 (18.2)	36 (14.8)	
Grade 4	1 (3.0)	16 (6.5)	

BMI = body mass index, IC = intensive care. APR = abdominal perineal resection, LAR = lower anterior resection. Significant differences ($p<0.05$) between groups are indicated by an asterisk (*).

Aspects of ostomy self-care and need for VNS

Several aspects of ostomy self-care were evaluated for both groups (Table 7.2). Patients in the intervention group were offered a preoperative practice session, which was attended by 32% of the patients. No comparison was made with the control group, since they were not given this opportunity.

Table 7.2 Aspects of ostomy selfcare and need for VNS.

	Control group n=33 (%)	Intervention n=244 (%)	*p*-value
Preoperative practice session			
Yes	NA	78 (32,0)	NA
No		266 (68,0)	
Stoma productive postoperative in days Median (Q_1-Q_3)	2.00 (1.00-4.00)	2.00 (1.00-4.00)	0.773
Postoperative day emptying pouch Mean ±SD	6.37 ±4.39	4.15 ±3.51	0.002*
Postoperative day alteration and placement of skin barrier and replacing pouch Mean ±SD	9.29 ±9.05	5.10 ±3.84	0.474
VNS			
No need	5 (15.2)	165 (67.6)	<0.001**
Daily	24 (72.7)	71 (29.1)	
Twice a week	4 (12.1)	8 (3.3)	

** High significance (p<0.01), *mild significance (p<0,05).

During admission, 90.7% in the intervention group emptied the ostomy pouch, compared to 84.4% of the control group (p=0.643) (Figure 7.3A). In the intervention group, 85.7% was able to perform alteration and placement of skin barrier and replaced the ostomy pouch during admission, compared to 21.1% of the patients in the control group (p<0.001) (Figure 7.3B). After discharge, 67.6% of the patients in the intervention group were independent in ostomy self-care and therefore able to go home without the need for VNS, compared to 15.2% of the patients in the control group (p<0.001) (Figure 7.3C).

In both groups, the ostomy started producing on average on day 2 postoperative (p=0.773). The control group started emptying the pouch on day 6, whereas the intervention group started emptying the pouch on day 4 postoperative (p=0.002). The intervention group started with alteration and placement of skin barrier and replacement of the pouch on average on day 5, while the control group started on day 9 (p=0.474).

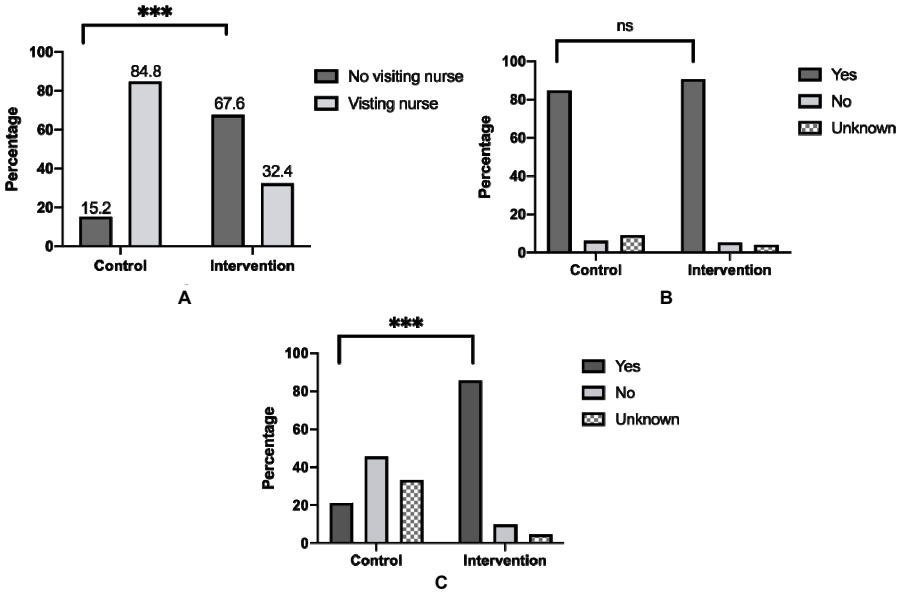

Figure 7.2 Different aspects of level of independence. A. Differences between control group and intervention group whether they were able to empty the stoma pouch during admission B. Differences between control group and intervention group whether they were able perform alteration and placement of skin barrier and replace pouch during admission C. Differences between control group and intervention group regarding need for VNS. *** = p<0.001 compared to control, NS = non-significant.

Contact moments with ostomy nurse after discharge

The average numbers of contact moments with an ostomy nurse within one and three months after discharge were assessed for each group (Table 7.3). There was no significant difference in the number of contacts the patients had with the ostomy nurse within one and three months after discharge between the groups. The number of consultations by telephone within one month after discharge was significantly higher in the intervention group (1.5 times vs. 1.0 times, p=0.018) and did not differ significantly within three months.

Table 7.3 Average number of contact moments with stoma nurse after discharge.

	Control group n=33	Intervention n=244	*p*-value
Contact moments with stoma nurse up until 1 month after discharge			
Total	2.39 ±1.77	2.70 ±1.91	0.380
Consults by telephone	1.03 ±1.02	1.52 ±1.37	0.018*
Contact moments with stoma nurse up until 3 months after discharge			
Total	3.91 ±3.19	4.37 ±3.16	0.434
Consults by telephone	1.94 ±1.85	2.35 ±1.97	0.263

Values are indicated as mean ±SD. * significant difference (p<0,05).

Factors associated with the need for VNS

In univariate analysis (Table 7.4), patients in need of VNS for ostomy care were more likely to be 70 years or older (p<0.001), to not have attended the preoperative ostomy practice session (p=0.003) and to have undergone emergency surgery (p=0.004).

Table 7.4 Independent associations between patient and treatment characteristics and the need for VNS in the intervention group.

	Patients n=244	OR (95% CI)	P-value	Adjusted OR (95% CI)	*p*-value
Age					
<70	152	Reference			
≥70	92	3,064 (1.756–5.347)	<0.001**	3.204 (1.762–5.827)	<0.001**
Gender					
Male	144	Reference			
Female	100	1.133 (0.658–1.952)	0.652	NS	NS
Stoma history					
No	191	1.625 (0.812–3.249)	0.170	NS	NS
Yes	53	Reference			
BMI					
<30	203	Reference		NS	NS
≥30	41	1.253 (0.622–2.526)	0.528		

Table 7.4 (continued)

	Patients n=244	OR (95% CI)	P-value	Adjusted OR (95% CI)	*p*-value
Preoperative practice session					
No	166	2.635 (1.384–5.018)	0.003**	3.015 (1.492–6.092)	0.002**
Yes	78	Reference			
Type of surgery					
Elective	196	Reference			
Emergency	48	2.564 (1.344–4.891)	0.004**	1.641 (0.788–3.417)	0.186
Ostomy type					
Permanent	99	Reference			
Temporary	145	0.996 (0.577–1.720)	0.988	NS	NS
IC admission					
<2 days	193	Reference			
≥2 days	51	1.180 (0.616–2.260)	0.617	NS	NS
ASA classification					
Grade I	10	Reference			
Grade II	147	1.204 (0.244–5.939)	0.820	NS	NS
Grade III-IV	87	3.909 (0.785–19.468)	0.096	NS	NS
Complications (Clavien-Dindo)					
Grade 0	121	Reference			
Grade I-II	70	1.545 (0,819–2.913)	0.179	1.795 (0,878–3.670)	0.109
Grade III-IV	52	2.040 (1.031–4.036)	0.041*	1.689 (0.762–3.744)	0.196
Cardiovascular disease					
No	113	Reference			
Yes	131	1.788 (1.032–3.099)	0.038*	1.127 (0.582–2.182)	0.723
Neurological					
No	224	Reference			
CVA	15	2.678 (0.933–7.683)	0.067	NS	
TIA	5	9.373 (1.028–85.434)	0.047*	10.221 (1.055–98.985)	0.045*
Arthrosis					
No	235	Reference			
Yes	9	1.707 (0.446–6.538)	0.435	NS	NS
Mild cognitive impairment					
No	232	Reference			
Yes	12	26.529 (3.359–209.515)	0.002**	28.981 (3.371–249.103)	0.002**

Reference values are indicated. Non-significant values ($p>0.05$) in the univariate analyses are indicated as NS in the multivariate analysis. ** High significance ($p<0.01$), *mild significance ($p<0.05$).

In addition, patients with severe postsurgical complications according to the Clavien-Dindo scale had a higher need for VNS (p=0.041). Furthermore, patients were more prone to need VNS if they suffered from cardiovascular disease (p=0.038), if they had a history of transient ischemic attack (TIA) (p=0.047) or if they were mildly cognitively impaired (p=0.002). Patients with a BMI higher than 30 did not have a significantly higher need for VNS (p=0.528). Furthermore, patients with a temporary ostomy were not more likely to need VNS (p=0.988).

Multivariate analyses showed that patients more likely to need VNS were patients aged 70 and older (OR =3.2, CI 1.76-5.83) and those who did not attend the preoperative practice session (OR =3.0, CI 1.49-6.09). In addition, patients with mild cognitive impairment (OR =29.0, CI 3.37-249.10) or a history of a TIA (OR =10.2, CI 1.06-98.96) had an increased need for VNS.

Self-care and satisfaction questionnaire

The self-care and satisfaction questionnaire was completed by 47 patients (response rate 70%) who underwent surgery between September 2019 and February 2020 (Table 7.5; Appendix 7.1).
Of the patients (n=47) who completed the questionnaire, 81% had undergone elective surgery and 19% emergency surgery. In total, 85% of these patients attended the preoperative practice session with an ostomy nurse. The patients rated this preoperative session with the ostomy nurse with a score of 7.9 out of 10 on a Likert scale. Of the nine patients (19%) undergoing emergency surgery, four (8%) patients had a short intake session with an ostomy nurse in order to determine the ostomy location. The guidance provided by the nurses on the surgical ward regarding ostomy self-care was rated with a score of 7.5 (Likert scale 1-10) by the patients. Furthermore, additional received information on the surgical ward was rated with a score of 7.7 (Likert scale 1-10). The majority of the patients (72%) thought that the moment at which the ostomy self-care education started after surgery was just right. However, 19% thought that the self-care education started too early. In contrast, 9% thought it started too late. At discharge, 94% of

the patients felt that they were able to empty the pouch independently, 60% felt able to change the pouch and 66% felt able to perform alteration and placement of the skin barrier. The experienced self-efficacy regarding independent ostomy self-care at discharge was rated with a score of 6.1 out of 10.

Table 7.5 Results from the self-care and satisfaction questionnaire.

	Questionnaire group n=47 (%)
Type of surgery	
Elective	38 (81)
Emergency	9 (19)
Preoperative session with stoma nurse	
Yes	40 (85)
No	7 (15)
Average rating preoperative session stoma nurse	
Mean ±SD (Scale 1-10 [1 = lowest, 10 = highest])	7.9 ±1.2
Average rating guidance stoma selfcare on surgical ward	
Mean ±SD (Scale 1-10 [1 = lowest, 10 = highest])	7.5 ±1.8
Average rating additional information regarding stoma selfcare on surgical ward	7.7 ±1.3
Mean ±SD (Scale 1-10 [1 = lowest, 10 = highest])	
Postoperative starting moment stoma selfcare	
Too early	9 (19)
Just right	34 (72)
Too late	4 (9)
Able to independently empty pouch at discharge	
Yes	44 (94)
No	3 (6)
Able to independently change pouch at discharge	
Yes	28 (60)
No	19 (40)
Able to independently alteration and placement of skin barrier at discharge	
Yes	31 (66)
No	16 (34)
Average rating self-efficacy regarding stoma selfcare at discharge	
Mean ±SD (Scale 1-10 [1 = lowest, 10 = highest])	6.1 ±2.5
Average rating of patients with VNS	4.4 ±2.3
VNS	
No need	31 (66)
Daily	12 (26)
Twice a week	4 (8)

Discussion

This study aimed to determine if a perioperative ostomy educational pathway increases the level of independence and decreases the need for VNS in new ostomates. The most important finding of this study was the significant increase in LOI and consequently the decrease in the use of VNS after discharge (67.6% vs. 15.2%) after implementation of the perioperative ostomy educational pathway. The increase in LOI might also explain the significant increase in the ability to perform alterations and to place the skin barrier or the ostomy pouch. Despite this increase in independence, not all the patients who were independent in ostomy self-care were discharged without VNS. Mostly, this was due to the patients' insecurity regarding their own ability to perform the self-care. Based on the self-care and satisfaction questionnaire, patients gave themselves an average score of 6 out of 10 regarding ostomy self-care confidence when leaving the hospital. This relatively low score may indicate the need for more guidance among new ostomates leaving the hospital. However, patient satisfaction regarding the preoperative practice session and the guidance provided by both the ostomy nurse and the surgical ward nurses was rated with a score between 7.5 and 7.9 out of 10 points, indicating adequate guidance.

The average level of confidence was strikingly lower (4 out of 10) in patients who received ostomy care at home, which was possibly due to the fact that they did not feel the need to acquire these skills since someone else would provide most of the ostomy care for them. Another reason might be that these patients had more ostomies that made self-care more challenging, due to problems such as stool leakage and skin irritations. Nonetheless, the LOI in new ostomates should be further increased, thus hopefully further decreasing the number of patients who need VNS and ensuring a higher quality of life. This further increase may be achieved with tailor-made, efficient, affordable and innovative health care solutions such as telemedicine.[16-19]

A particularly interesting outcome in the intervention group was the significantly higher number of telephone consultations with the ostomy nurse within one month after discharge. The number of outpatient clinic visits after discharge did not increase, indicating that those patients without VNS were more self-reliant, solved problems on their own and found that the remaining problems could easily be solved by telephone.

This study presented some unexpected findings. Firstly, a BMI higher than 30 was not significantly associated with an increase in the need for VNS. This is in contrast to a previous study that showed that higher BMI was related to self-care challenges.[21] Some of the overweight patients who were not able to perform ostomy care independently blamed this on their high abdominal circumference and skinfolds, which interfered with proper vision of the ostomy. The latter was, according to some patients, the reason for not being able to perform adequate placement of the skin barrier and pouch. However, our results showed that being overweight did not significantly increase the need for VNS. This is possible due to our patient population being trained in different manners of performing ostomy self-care, varying from lying down on the bed to standing in front of a mirror. These different methods ensure that patients with different body types are able to independently manage the ostomy self-care.

Secondly, it was expected that ostomy history would be associated with lower needs for VNS. However, our results showed that previous ostomies did not result in lower needs for VNS. This might be explained by the fact that patients with an ostomy history were relying on VNS before, since this was the standard method of care at that time and they were not encouraged to acquire the relevant ostomy self-care skills. This means that patients with an ostomy history mostly still needed to learn ostomy self-care in order to be independent, in the same way that new ostomates needed to learn this.

Thirdly, there was no association between the need for VNS and a permanent or temporary ostomy. It was expected that patients with a temporary ostomy would

rely more on VNS, since they would not have to perform the self-care for the rest of their lives, in most cases even only for a couple of months. However, with the right approach, these patients could also be stimulated to learn how to be independent in ostomy self-care, even when this was needed for only a short period of time.

Finally, there was no association between IC admission for more than one day and an increased need for VNS. Longer hospitalisation might ensure that patients still have enough time to acquire the necessary self-care skills when they are transferred to the general surgical ward. ICU admission may therefore result in a delay to start with ostomy self-care, but not in the inability to perform ostomy self-care at discharge.

Several significant associations were found between certain factors and the need for VNS. Our finding that patients aged 70 of older received more VNS than younger patients is in line with a previous study showing that elderly patients have a higher use of care services after discharge, especially after surgeries such as colectomies.[8] The higher needs in the elderly found in our study also confirm the findings of *Sacks et al.,* who showed that VNS was the most frequently used care service after discharge.[8] However, self-care should still be maximally stimulated in this group of patients to ensure that VNS are used only if necessary and in a cost-effective way.

Furthermore, we found that cognitive impairment was associated with increased use of VNS, indicating that the limits to which self-care is possible should probably be accepted in this subpopulation. The focus should be on the aspects of self-care that these patients can accomplish, for instance emptying the pouch. In this way, these patients are still able to achieve some LOI.

Lastly, the need for VNS was significantly reduced by attending the preoperative practice session. This is in line with a previous study showing that preoperative education results in improved skill acquisition, as well as an increase in health-

related QoL and longstanding adjustment to the ostomy.[22] However, in the present study, only 32% of the patients in the intervention group attended the preoperative practice session. It is possible that if this percentage is increased, the number of patients in need for VNS will decrease even further. The preoperative practice session should therefore be implemented in the pathway as a mandatory step. The main reason for patients to not attend the preoperative practice session was that they would have had to travel to the hospital yet again. Since Catharina Hospital Eindhoven is a tertiary referral hospital, many patients travel long distances for their treatment. Therefore, this practice session should be combined with an appointment that is needed for the surgery (e.g. an appointment with the surgeon or the anaesthesiologist) or should be scheduled on the day of admission. In multivariate analysis, emergency surgery was not associated with increased need for VNS. A possible explanation is that patients in an emergency setting were unable to attend the preoperative practice session and that the increase in VNS is due to missing this session rather than to the emergency setting itself.

The results of this study are in line with the outcomes of the study of *van Loon et al.,* on which the implemented pathway was based, namely that the implementation of the perioperative ostomy educational pathway reduced the need for VNS.[15] The present study even found a higher decrease in the need for VNS. A possible explanation for this greater decrease is that in the present study, the nurses on the surgical ward were more experienced in ostomy care and in teaching ostomy self-care skills to patients due to the high number of colorectal patients receiving ostomy surgery in this hospital. Our study included more patients and was executed in a tertiary referral hospital with more complex surgery and more ill patients. In contrast to the study of *van Loon et al.*, the present study included all patients undergoing ostomy surgery without excluding patients with an ostomy history or more severely ill patients. In this way, the population of this study provides a more accurate representation of the actual ostomy population. These results indicate that the perioperative ostomy educational pathway is not only easy to implement and execute, but also effective in both a different population and in a hospital setting.

This study had several limitations. Firstly, the pathway was implemented as a new standard of care on the surgical ward, without selection and randomisation of patients to either the control or intervention group. Instead, a historical observational control group was used for baseline measurements, without matching controls to cases. However, to limit selection bias, the same inclusion and exclusion criteria were used for selecting patients for the historical control group as for the intervention group. Secondly, a large amount of the data was collected by nurses on the surgical ward, reported in the electronic patient records. This could possibly have led to information bias, since not all nurses had equally accurate documentation. This may possibly have led to an underestimation of the effect of the educational pathway, if nurses did not report the actual first time of performing self-care steps.

Conclusion

In conclusion, this study showed that the perioperative ostomy educational pathway is an effective and feasible method for increasing the LOI and thereby significantly decreasing the need for VNS in new ostomates. However, further research is warranted to investigate the pathway's effect on QoL and its cost-effectiveness. New methods to improve guidance for new ostomates throughout the entire ostomy process and to increase their level of confidence by means of telemedicine are currently being investigated.

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Appendix 7.1

Satisfaction questionnaire

Patiëntgegevens

Hier sticker plakken

Datum: ..... - ..... - .....

Dag .... na de operatie

Naam van uw verpleegkundige:

.....

Beste meneer/mevrouw,

Wij vragen u vriendelijk om onderstaande vragen te beantwoorden. Deze vragen zijn opgesteld om een beter inzicht te krijgen in hoe patiënten het ervaren om zelfstandig de stoma te verzorgen.

Bedankt voor uw hulp!

Vragenlijst aanleren van stomazorg

De vragen worden gescoord door middel van een cijfer van 0 tot 10 of met ja/nee.
Omcirkel uw antwoord of haal door wat niet van toepassing is.

Type stoma: colostoma (dikke darm) / ileostoma (dunne darm)
Type operatie: ingeplande operatie / spoedoperatie

1. Heeft u voor uw operatie een (poliklinisch) gesprek gehad met een stomaverpleegkundige?

Ja / Nee

Indien ja, door naar vraag 2. Indien nee, door naar vraag 4.

2. Wat vond u van de informatie die u heeft gekregen over uw stoma, voorafgaand aan de operatie?

Geen Meerwaarde 1 2 3 4 5 6 7 8 9 10 Zeer waardevol

3. Heeft u het gevoel voldoende informatie te hebben ontvangen tijdens deze voorlichting voorafgaand aan de operatie?

Ja / Nee

Indien nee, kunt u in enkele woorden of zinnen omschrijven wat u gemist heeft aan informatie voorafgaand aan de operatie?

4. Wat vond u van de begeleiding bij de verzorging van uw stoma op de afdeling na de operatie?

Slechte Begeleiding 1 2 3 4 5 6 7 8 9 10 Uitstekende begeleiding

5. Wat vond u van de informatie die u kreeg over uw stoma op de afdeling na de operatie?

Geen Meerwaarde 1 2 3 4 5 6 7 8 9 10 Zeer waardevol

6. Heeft u het gevoel voldoende informatie te hebben ontvangen over uw stoma op de afdeling <u>na de operatie</u>?

Ja / Nee

Indien nee, kunt u in enkele woorden of zinnen omschrijven wat u gemist heeft aan informatie op de afdeling na de operatie?

7. Vond u dat u snel genoeg betrokken werd bij het aanleren van uw stomazorg?

Ja / Nee

8. Was het moment dat u begon met het zelfstandig verzorgen van uw stoma samen met de verpleegkundige op de afdeling voor uw gevoel

Te vroeg / precies goed / te laat

9. Zijn uw familieleden of mantelzorgers betrokken geweest bij het aanleren van de zorg voor uw stoma?

Ja / Nee

Indien nee, kunt u in enkele woorden of zinnen omschrijven wat de reden hiervoor is?

10. Had u op het moment van ontslag al de volgende handelingen geoefend op de afdeling?

Zelfstandig stomazakje legen: Ja / Nee

Zelfstandig stomazakje wisselen: Ja / Nee

Zelfstandig de stomaplaat knippen: Ja / Nee

11. Hoe zeker voelde u zich over de vaardigheden omtrent de zorg voor uw stoma die u waren aangeleerd op de afdeling?

Erg Onzeker	1	2	3	4	5	6	7	8	9	10	Erg zeker

12. Had u de behoefte aan meer begeleiding bij het leren omgaan en zorgen voor uw stoma op de afdeling?

Ja / Nee

Indien ja, kunt u in enkele woorden of zinnen verwoorden waar de begeleiding voor uw gevoel te kort geschoten is?

13. Heeft u bij thuiskomst gebruik gemaakt van thuiszorg voor uw stoma?

Dagelijks / paar keer per week / alleen in moeilijke situaties

14. Kon u voor uw gevoel laagdrempelig bij ons terecht voor eventuele vragen omtrent uw stoma?

Ja / Nee

Indien nee, kunt u in enkele woorden of zinnen omschrijven waarom en wanneer u voor uw gevoel niet bij ons terecht kon?

15. Heeft u nog opmerkingen, verbeterpunten of complimenten omtrent de informatie rondom uw stomazorg, begeleiding rondom uw stomazorg of het aanleren van de zorg voor uw stoma of stomazorg in het algemeen?

Dank u wel voor uw tijd en voor het invullen van deze vragenlijst omtrent het aanleren van stomazorg. Op de volgende pagina's vindt u de SF-36 gezondheidstoestand vragenlijst. Gelieve deze ook in te vullen en beide af te geven bij de balie van de verpleegkundigen.

Appendix 7.2

Dutch version ostomy selfcare steps after surgery

Goed voorbereid naar huis met een stoma

Na de operatie	Heeft u vragen over uw stoma? Stel ze aan uw verpleegkundige! De verpleegkundige maakt afspraken met u en uw familielid of mantelzorger over het aanleren van de stomazorg op dag 2 en 4.	
Dag na de operatie	Uw verpleegkundige geeft uitleg over uw stoma. U **ledigt** het stomazakje onder begeleiding van een verpleegkundige. Ook als het stoma nog niets heeft geproduceerd, is het de bedoeling dat u het zakje "leegt" om zo de handeling te oefenen.	
Dag 2 na de operatie	De verpleegkundige verwisselt samen met u de materialen. U **plaatst** zelf de plak onder begeleiding van de verpleegkundige. Overdag ledigt u uw stomazakje, houdt het stomazakje goed in de gaten en vraag uw verpleegkundige om advies. Uw **familielid of mantelzorger** leert uw stomazakje legen.	
Dag 3 na de operatie	U wisselt zelf uw materialen onder begeleiding van een verpleegkundige. U leert uw **stomaplaat zelf op maat te knippen** onder begeleiding van uw verpleegkundige. U (evt met familie) leegt overdag het stomazakje zelfstandig.	
Dag 4 na de operatie	U wisselt uw stomaplaat onder begeleiding van een verpleegkundige, hierbij is uw familielid of mantelzorger aanwezig. Overdag ledigt u uw stomazakje onder begeleiding. 's Avonds wisselt u de materialen zonder begeleiding.	
Dag 5 na de operatie	U heeft nu alle stappen voor goede stomazorg al eens zelf gedaan. Vanaf vandaag doet u uw **eigen stomazorg**. Bij ontslag uit het ziekenhuis wisselt u uw materialen zelf.	
U mag naar huis. Wij streven er samen met u naar dat:	U zelf uw stomazakje kunt legen. U zelf uw stomaplaat kunt knippen en geoefend heeft met het wisselen. Uw familielid of mantelzorger uw stomazakje kan legen. Uw familielid of mantelzorger een materialenwissel heeft geoefend.	

Figure S7.1 Dutch version of ostomy selfcare steps during admission.

Part III

Use of single-port laparoscopy in colostomy reversal surgery

Intermezzo

New normal

YT van Loon, SHEM Clermonts, DDE Zimmerman

Colorectal Dis 2021

New normal

Dear Sir/Madam,

We read with great interest the recent study by Mirza et al.[1]. We would like to applaud the authors for their extensive analysis of the results of 150 consecutive Hartmann's reversal (HR) procedures in two academic tertiary referral centres between 2010 and 2019. In a study group with a majority of open index cases (93.3%), laparoscopic HR (LHR) was attempted in 22% of the cases with 42% conversion rate. They conclude that HR comes with substantial risk of morbidity and that the laparoscopic approach may decrease morbidity in selected patients but have high conversion rates.

However, we would like to highlight some important nuances. There are many reports stating the positive effects of LHR with smaller morbidity and mortality rates compared to open HR with great advantages in perioperative outcomes: less blood loss, shorter length of hospital stay and fewer overall postoperative complications such as ileus or surgical site infections.[2] We believe that the use of the laparoscopic or minimally invasive approach is under-utilized in not only this but many other HR studies.

Obviously, many factors are important when assessing the effectiveness and applicability of LHR. Not only patient related factors such as gender, body mass index, American Society of Anesthesiologists score or comorbidity play an important part; but also the details of the index surgery such as surgical approach, reasons for surgery and the details of postoperative recovery. These factors have an undeniable influence in a surgeon's choice to pursue LHR but are often left unreported in the available literature.[2] Even though laparoscopy undeniably has its merits and positive effects, the technical difficulties of this approach must be acknowledged, especially after open index surgeries with peritonitis. Trocar insertion and adhesiolysis of intra-abdominal or midline adhesions can be hazardous and possibly result in surgical calamities and ultimately conversions. These factors, admittedly, make it difficult for fair and unbiased comparison. However, we still believe that in elective HR surgery a laparoscopic approach must

be attempted, even in open index cases. It is important to mention that high rates of success of LHR are reported after open surgery (78% using single-port and 100% using the laparoscopic approach).[3,4]

It is worth mentioning that increased experience in minimally invasive surgery has led to ancillary use of new surgical techniques. The application of the transanal total mesorectal excision technique resulted in transanal HR with laparoscopic assistance with favourable results.[5] The preliminary results of using the robot in HR seem to be promising, safe and feasible.[6] There will surely be more surgical innovations in efforts to improve the outcomes of HR surgery.

In conclusion, we agree that HR is not without complications or morbidity, but we would also like to emphasize the possibility and applicability of minimally invasive approaches as not only feasible and attractive alternatives but also as beneficial for HR besides the conventional open approach. We are convinced that minimally invasive surgery has become the foundation of today's surgical practice in gastrointestinal surgery and that it will develop into our new normal.

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Intermezzo

Reversal of Hartmann's procedure utilizing single-port laparoscopy: an attractive alternative to laparotomy

SHEM Clermonts, WMJ de Ruijter, YT van Loon, DK Wasowicz, J Heisterkamp, JK Maring, DDE Zimmerman

Surg Endosc 2016;30(5):1894-901

Abstract

Background

Complications after restoration of intestinal continuity (RIC) following Hartmann's procedure occur frequently and are often serious. These complications result in a reported morbidity of 4-30% and a reported mortality of 10-14%. Reducing the amount of surgical trauma accompanying abdominal access seems an attractive tool to reduce perioperative morbidity. This possibility is offered by single-port Hartmann's reversal (SPHR) through the colostomy site.

Methods

The purpose of the present prospective study was to compare outcome of SPHR to a retrospectively collected historical control group of conventional open Hartmann's reversal (OHR). All patients undergoing RIC between January 1, 2009, and January 1, 2014, were included in the present study. Operation time, morbidity and hospital stay were assessed. Postoperative surgical results of SPHR and OHR were the main outcome of the study.

Results

During the study period, 41 patients (M/F = 23:18; median age 58 (26-85) years) were included in the present study. Sixteen patients underwent OHR; 25 patients underwent SPHR. No mortality was observed in the present series. Median operation time was similar between groups [184 (29-377) vs. 153.5 (73-332) min]. Hospital stay was significantly shorter in the SPHR group [16 (4-74) vs. 4 (1-34) days, $p<0.05$]. The number of complications was significantly lower in the SPHR group (33 vs. 10, $p<0.05$); furthermore, significantly less patients had severe complications (Clavien–Dindo III or higher) in the SPHR group (7/33 vs. 1/10). Less wound related complications occurred in the SPHR group (12 vs. 5, $p<0.05$).

Conclusion

This study confirms recent findings in the literature regarding the safety and feasibility of SPHR. SPHR seems to be an attractive alternative to OHR.

Introduction

Hartmann's procedure was first described in 1921 by Henri Hartmann for resection of left-sided malignancy of the colon and sigmoid.[1,2] The procedure was initially designed to reduce mortality from anastomotic dehiscence. It is not clear whether Hartmann ever intended intestinal continuity to be restored. Nowadays, despite recent evidence that primary anastomosis can be considered in selected patients,[3,4] Hartmann's procedure (HP) is often the preferred operation for Hinchey III–IV diverticulitis. After Hartmann's procedure, patients are left with an end colostomy. Patients with stomas face many physical and psychological challenges, including leakage, skin rashes, lifestyle alterations and sexual dysfunction.[5,6] However, restoring the intestinal continuity (RIC) after Hartmann's operation is a difficult operation that is associated with a high morbidity rate, with anastomotic leakage rates range from 4 to 16% and an operative mortality reported as high as 10%.[7-10] In patients undergoing HP for complicated diverticulitis, morbidity and mortality rates can be as high as 30 and 14%, respectively.[11] The high incidence of morbidity and mortality is the main reason why surgeons are reluctant to restore intestinal continuity in approximately 40% of the patients that underwent HP.[10] In the ongoing quest to find the optimal technique for reversal of HP, several laparoscopic and hand-assisted techniques have been described.[3,12-14] More recent studies suggest advantages of single-incision laparoscopic surgery utilizing single-port access systems for reversal of the colostomy after HP.[15,16] Single-port Hartmann's reversal (SPHR) with access through the former site of the colostomy potentially reduces the incidence of injury during trocar placement, wound infection and hernia formation.

The purpose of the present prospective study was to investigate the safety and feasibility of SPHR compared to a retrospectively collected historical control group of conventional open Hartmann's reversal (OHR).

Patients and methods

Patients

All consecutive patients undergoing reversal of Hartmann's procedure (HP) between January 2009 and January 2014 were included in this study if they were eligible for restoration of intestinal continuity (RIC). The enhanced recovery after surgery (ERAS) protocol[17] was implemented in January 2009 in our center. In order to compare patients that were all treated accordingly and make both study groups as homogeneous as possible, all Hartmann reversals conducted before 2009 were therefore excluded from the current study. A total of 43 patients underwent RIC at the Elisabeth-TweeSteden Hospital Tilburg, The Netherlands (large general teaching hospital) in this time period. Before September 2013, all Hartmann's reversals were performed in an open fashion at our center, and from October 2013, all Hartmann's procedures were reversed using the single-port approach. Inclusion criteria for this analysis were patients being eligible for restoration of intestinal continuity. Exclusion criteria were concomitant incisional hernia repair at the time of the RIC. From October 2013 until January 2014, a total of 25 single-port Hartmann's reversal (SPHR) procedures were performed. The control group consisted of the last 18 open Hartmann's reversals performed in our center between January 2009 and October 2013. The two patients with concomitant incisional hernia repair at the time of the RIC were excluded from the OHR group in this analysis. A total of 41 patients undergoing RIC were included in this study (Figure 1). Patient characteristics (gender, age, weight and ASA classification), primary reason for HP (diverticulitis, carcinoma, anastomotic dehiscence), duration of surgery, complications and length of hospital stay were collected. Data from the SPHR group were collected prospectively; data of the group undergoing open Hartmann's reversal (OHR), the control group, were collected retrospectively. Approval of the institutional review board or ethics committee was not required. Informed consent was obtained from all patients who underwent SPHR.

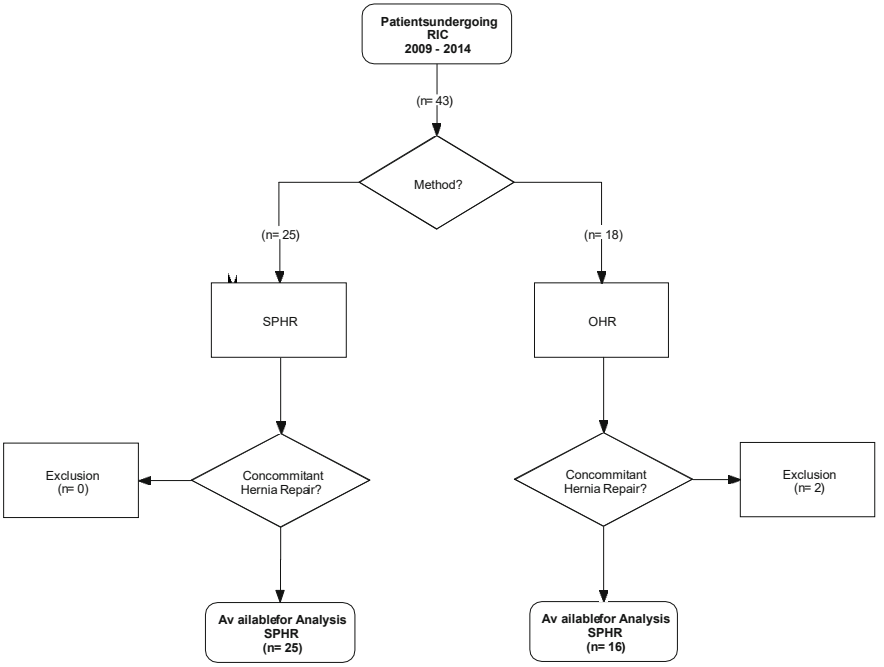

Figure 1 Flow chart of patient selection. OHR open Hartmann's reversal, SPHR single-port Hartmann's reversal through the site of the colostomy.

Statistical analysis

Descriptive statistics were expressed as median and range (minimum, maximum) for continuous variables. Differences between groups were calculated by using the Mann-Whitney test for continuous variables. The Pearson χ_2 test or the Fisher's exact tests, if appropriate, were used for categorical variables. Statistical analysis was performed using the SPSS software package version 19 (SPSS, Chicago, IL). All *p* values <0.05 were considered statistically significant.

Procedures

All OHR and SPHR procedures were performed or supervised by a certified colorectal surgeon with extensive experience with single port and minimally invasive surgery (D.D.E.Z). Prior to the operation, patients underwent either a sigmoidoscopy, barium enema or CT scan in order to evaluate the rectal stump and descending colon integrity. A single phosphate enema in the rectal remnant was administered prior to the procedure.

Operative procedure

OHR After inducing general anesthesia, the open Hartmann reversal was performed by re-opening the abdominal cavity through the initial abdominal midline incision. Subsequent dissection of the peritoneal attachments and rectal stump was achieved using either bipolar electrosurgery device or sharp dissection. Loose adhesions from small bowel loops to the rectal stump were mobilized in the pelvis. The colostomy was then mobilized down to the fascia. An anvil for the CDH29 circular stapler (Ethicon Endo-Surgery, Cincinnati, OH, USA) was placed in the lumen, either in the terminal or in the lateral position. A purse-string 3-0 Prolene suture was used to secure the anvil, or a linear stapler was used to close the end of the colostomy when a side-to-side configuration was chosen. If necessary to gain sufficient length in order to perform a tension-free anastomosis, the splenic flexure was mobilized. The rectal stump usually required some degree of mobilization prior to the introduction of a CDH29 circular stapler through the rectum but was never shortened. The anvil was secured to the stapling device. An air leak test was performed. The fascia was closed with a PDS suture, and skin closed using Monocryl (Ethicon Somerville, NJ, USA). The former colostomy site was rinsed several times with 0.9% saline solution and closed with Monocryl.
SPHR First, the colostomy was mobilized down to the fascia, and the abdominal cavity was entered through the original colostomy site. The descending colon was then exposed. An anvil for the CDH29 circular stapler (Ethicon Endo-Surgery, Cincinnati, OH, USA) was placed in the lumen, either for a side-to-end or for a side-to-side configuration. A purse-string 3-0 Prolene suture was used to secure the

anvil, or a linear stapler was used to close the end of the colostomy when a side-to-side configuration was chosen. Then, the colon was returned to the peritoneal cavity. The GelPOINT Path Access Platform (Applied Medical, Los Angeles, CA, USA) was then placed in the fascial defect at the colostomy site; a pneumoperitoneum was established. Adhesiolysis was performed. If necessary to gain sufficient length in order to perform a tension-free anastomosis, the left colon and splenic flexure were mobilized. Loose adhesions from small bowel loops to the rectal stump were mobilized in the pelvis. Adhesions to the previous midline incision were left in place. The rectal stump usually required some degree of mobilization prior to the introduction of a CDH29 circular stapler through the rectum but was never shortened. The anvil was secured to the stapling device. An air leak test was performed prior to removal of the port. The fascia was closed with a PDS suture, and skin closed using Monocryl (Ethicon Somerville, NJ, USA). The former colostomy site was rinsed several times with 0.9 % saline solution.

Postoperative procedure

Patients were treated according to the enhanced recovery after surgery (ERAS) protocol.[17] No alterations to the protocol were made throughout the entire length of the study. Patients were discharged from the hospital when they were able to tolerate normal food, pass stool, were able to mobilize at a level that was similar to preoperative levels of mobilization and had adequate control of pain with use of oral analgesia.

Results

From January 2009 to January 2014, a total of 41 RIC after HP were performed. Twenty-five patients underwent singleport Hartmann's reversal through the colostomy site. The control group consisted of 16 patients in which open Hartmann's reversal was performed. All 41 patients had leftsided colostomies. Patients baseline characteristics are summarized in Table 1. Patients in the SPHR group had a median age of 52.2 years (range 26-85); body mass index 27.8 and a

male/female ratio of 18:7. The patients in the control group had a male/female ratio of 5:11, a mean age of 63 years (range 52-73) and a mean BMI of 27.6. Of the 41 patients, 23 (56.1%) had undergone initial HP for diverticulitis. In the SPHR group, 5 (33.3%) patients had a Hinchey stage I-II and 10 (66.6%) had a Hinchey III-IV diverticulitis. In the OHR group, 3 (18.75%) patients had a Hinchey stage I-II and 5 (31.3%) had a Hinchey III-IV diverticulitis. Indications for initial HP also included sigmoid cancer in 7 patients (28.0%) in the single-port group and 5 patients (31.3%) in the laparotomy group. Three patients (12%) in the SPHR group and 3 patients (18.7%) in the OHR group had anastomotic dehiscence after primary low anterior resection for which the anastomosis was broken down and a terminal colostomy was made. Of the 41 primary Hartmann's procedures, 38 (92.7%) were performed in an open fashion, and 3 (7.3%) were performed using laparoscopy. Time intervals between initial HP and restoration of intestinal continuity did not differ between the SPHR group and the OHR group, 15.9 months (range 6.6-32.9) and 15.7 months (range 4.6-28), respectively.

Table 1 Patient characteristics

	OHR	SPHR	*p*
Patients (n)	16	25	
Sex (M/F) (%)	5:11 (31.3–68.8)	18:7 (72–28)	0.032
Age, mean ± SD (range)	63.1 ± 7.6 (52–73)	52.2 ± 13.2 (26–85)	0.275
BMI	27.6	27.8	0.509
ASA (%)			0.828
1	1 (6.3)	8 (32)	
2	11 (68.8)	15 (60)	
3	3 (18.8)	2 (8)	
4	1 (6.3)	0 (0)	
Primary indication for HP			
Diverticulitis (%)	8 (50.0)	15 (60.0)	0.264
Hinchey stage			
I–II (%)	3 (18.75)	5 (33.3)	0.461
III–IV (%)	5 (31.3)	10 (66.6)	0.282
Carcinoma (%)	5 (31.3)	7 (28.0)	0.412
Anastomotic dehiscence (%)	3 (18.7)	3 (12)	0.282
Delay between procedures, [months, mean ± SD (range)]	15.7 ± 7.1 (4.6–28)	15.9 ± 7.9 (6.6–32.9)	0.489

OHR open Hartmann's reversal, *SPHR* single-port Hartmann's reversal through the site of the colostomy.

Of the 25 single-port Hartmann's reversal procedures, additional access ports were needed in two patients (8%); two extra 5-mm trocars were placed (because of difficult adhesiolysis) in both patients. In one of the above-mentioned patients, conversion to multiport laparoscopy was not enough; therefore, conversion to laparotomy was necessary. The median operation time of the single-port procedures was 153.5 min (range 73-332); this was not significantly different compared to the laparotomy procedure in which the median operation time was 184.4 (range 29-377) (p=0.407). Postoperative hospital stay was significantly shorter for the SPHR group, median 4 days (range 1-34), and median hospital stay in the OHR group was 16 days (range 4-74) (p≤0.001). Follow-up periods were the same for both groups. The surgical results are summarized in Table 2.

Table 2 Surgical procedure.

	OHR	SPHR	*p*
Patients (n)	16	25	
Primary Hartmann's procedure			
Open (n) (%)	16 (100)	22 (88)	0.032
Laparoscopic (n) (%)	0 (0)	3 (12)	0.032
Reversal of Hartmann's			
Conversion to laparotomy (n)(%)	–	1 (4)	–
Conversion to multiport laparoscopy (n) (%)	–	2 (8)	–
Number of extra ports added (n per case)	–	2	–
Operation time, minutes, mean ± SD (range)	184.4 ± 86.1 (29–377)	153.5 ± 67.2 (73–332)	0.402
Hospital stay, days, mean ± SD (range)	16 ± 16.3 (4–74)	4 ± 6.3 (1–34)	<0.001

OHR open Hartmann's reversal, *SPHR* single-port Hartmann's reversal through the site of the colostomy.

The number of postoperative complications within 30 days after restoration of intestinal continuity differed significantly between the two groups: 10 complications in the SPHR group versus a total of 33 complications in the control group (p≤0.001). A total of 11 (68.75%) patients in the OHR group had complications compared to a total of 8 (32%) patients in the SPHR group. The severity of the complications is summarized in Table 3, using Dindo-Clavien grading scale for surgical complications.[18]

Table 3 Postoperative complications after restoration of intestinalcontinuity.

	OHR	SPHR	*p*
Patients (*n*)	16	25	
Number of complications (*n*)	33	10	<0.001
Dindo–Clavien complications	type, (*n*) (%)		
I	12 (75)	7 (28)	0.001
II	15 (93.75)	2 (8)	<0.001
III-a	1 (6.25)	–	0.151
III-b	2 (12.5)	–	0.065
IV-a	1 (6.25)	–	0.151
IV-b	2 (12.5)	1 (4)	0.271
Mortality (*n*) (%)	1 (6.25)	0	0.151
Patients readmitted (*n*) (%)	4 (25)	1 (4)	0.065

OHR open Hartmann's reversal, *SPHR* single-port Hartmann's reversal through the site of the colostomy.

Wound infections, 5 (20%) versus 12 (75%), accounted for the largest number of complications in the SPHR and OHR groups. In the OHR group, two patients (12.50%) developed sepsis secondary to anastomotic leakage for which admittance to the intensive care unit and reoperation was necessary. In one of the previously mentioned patients, the ongoing sepsis deteriorated to multiorgan failure and eventually death. This resulted in a mortality rate of 6.25% in comparison with 0% in the SPHR group. Detailed postoperative complications are summarized in Table 4.

Table 4 Detailed postoperative complications within 30 days orduring primary admission.

	OHR	SPHR	*p*
Postoperative complications	33	10	<0.001
Surgical (*n*) (%)			
Anastomotic leakage/abscess	3 (18.75)	1 (4)	0.138
Hemorrhage	1 (6.25)	1 (4)	0.500
Ileus 1 (6.25)		1 (4)	0.500
Wound infection	12 (75)	5 (20)	<0.001
Sepsis/MOF	2 (12.50)	0 (0)	0.065
Anastomotic stenosis	1 (6.25)	0 (0)	0.151
Nonsurgical, (*n*) (%)			
Pneumonia	7 (43.75)	1 (4)	<0.001
Urinary tract infection	4 (25)	1 (4)	0.010

OHR open Hartmann's reversal, *SPHR* single-port Hartmann's reversal through the site of the colostomy.

Discussion

Restoration of bowel continuity after HP remains technically challenging and is associated with high morbidity and mortality rates even despite modern surgical techniques. This is the main reason why restoration of intestinal continuity is often not attempted. Intraoperative difficulties during laparotomy or multiport laparoscopy are mainly caused by the formation of adhesions in the midline (at the laparotomy site) and lower part of the abdomen after active inflammation and/or infection and previous surgery.[19,20]

Use of the colostomy site as access to the abdominal cavity is gaining in popularity and has recently been used more often in the reversal of HP. Vermeulen et al.[12] described manual access through the stomal site in combination with a manually and blindly performed adhesiolysis. In the Netherlands, this technique was widely criticized, due to the blind nature of the dissection and the potential risk of serosa damage and risk of inadvertent enterotomies. Parkin et al.[14] were the first group that described the use of the colostomy site as an access point for the camera port. Later, several authors improved these techniques with the use of single-port access systems, combining the potential benefits of minimally invasive surgery (shorter postoperative recovery time, minimal postoperative hospital stay and lower morbidity rates) with the advantages of HP reversal through the colostomy site (total absence of new incisions and decreased necessity of midline adhesiolysis). These first series involved relatively small sample sizes without control groups[15,16] (Table 5). In this study, we performed a single-port Hartmann's reversal through the colostomy site in 25 patients. Our group was compared to a historical control group of 16 patients in whom open Hartmann's reversal was performed.

The morbidity and mortality rates in our study group correspond to those in the present literature reporting on single-port reversal of Hartmann's procedure. In our single-port group, the complication rate was exceptionally low compared to our control group.

Table 5 Summary of single-port reversal of Hartmann's procedure in the current literature.

Study	Year of publication	Number of patients	procedure	Control group (no of patients)	Morbidity (%)	Mortality (%)	Hospital stay (days)
Carus et al.	2011	8	Stoma single port	No (0)	1 (12.5)	0 (0)	4
Borowski et al.	2011	5	Stoma single port	No (0)	1 (20)	0	4.2
Joshi et al.	2013	14	Stoma glove port	No (0)	3 (21)	0 (0)	5.5
Present study	2015	25	Stoma single port	Yes (16)	8 (32)	0 (0)	4.1

Morbidity and mortality are presented in total number of cases.

However, an apposing argument can be the fact that our control group merely included open procedures and no laparoscopic procedures. This can be attributed to the implementation process of minimally invasive surgery in our institution. We chose this group of patients as an ideal group for the use of single-port surgery. The reason for this choice is that a colostomy (and therefore potential access point) is already present, and use of laparoscopy is relatively difficult due to increased incidence of intraabdominal adhesions after prior surgery and thus considered as a challenging procedure (Figure 2).[13,19,20]

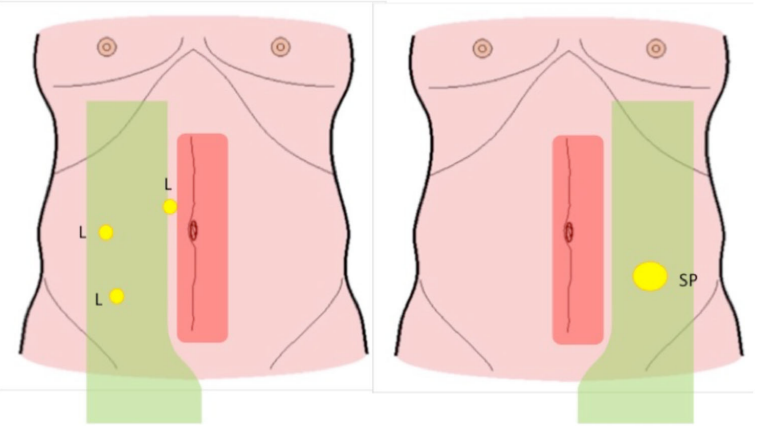

Figure 2 Preferred port positions for laparoscopic Hartmann's reversa[19] (*left*), port position for single-port Hartmann's reversal (*right*). *L* laparoscopictrocar position, *SP* single-port trocar position. *Red shaded area*: area of maximal adhesion formation after previous laparotomy. *Green shaded area*:area of range of action for different modalities.

Furthermore, in this study the control group and the intervention group are composed of an unequal amount of study subjects. This approach was chosen deliberately because only with the current study design it is possible to compare patients that all were treated according to same perioperative care program.

The reversal of gastrointestinal stomas is considered contaminated surgery and is associated with high wound infection rates. Literature shows wound infection incidence ranging from 2 to 40%.[21-23] There is considerable debate[22,24] about whether or not the colostomy site can be closed or whether it needs to be left open, in order to heal by secondary intention. In the present study, 5 patients in the SPHR group developed a superficial wound infection at the former stomal site. In the OHR group, 12 wound infections developed; in two patients, the wound infections developed at the former stomal site and at the laparotomy wound at the same time. With regard to surgical site infections, we consider the SPHR technique superior over the conventional OHR technique. In the SPHR group, wound infections not only seem to develop less frequently, they also have less serious long-term consequences in comparison with the wound infections of laparotomy wounds in the OHR group. It is standard practice to close the skin of the formal ostomy site in our hospital when Hartmann is reversed according to the above-described single-port technique. The present study shows that this regimen is justified since only a minority of our patients (20%) suffers from this complication. Moreover, the incidence of SSI in the present series compares favorably to the incidence reported in the literature.

Furthermore, previous studies already demonstrated that the open approach for restoration of bowel continuity had a significant negative impact on body image and cosmesis compared with those who underwent a laparoscopic approach.[25] We believe that there are potential cosmetic advantages in performing single-port restoration of bowel continuity in comparison with restoration via laparotomy.

We acknowledge certain limitations to the present study. A retrospectively conducted study provides the potential for inaccurate data or follow-up evaluation. We believe that this was overcome by the fact that the patients' follow-up was conducted by a single surgeon (D.D.E.Z) and the use of electronic medical records that allow for easy access of the patients data. Another limitation was the small

number of patients who underwent SPHR. Despite these limitations, we believe that the present study suggests that single-port Hartmann's reversal through the colostomy site has a low morbidity and mortality rate and is safe and potentially safer than open restoration of intestinal continuity. In our institution, SPHR is even considered the standard procedure for restoration of continuity. Currently, we are broadening the indications for performing SPHR to include the performance of ileocolostomies for patients with end ileostomies. Also, more and more patients undergo this procedure in whom open repair would not be considered due to presence of large hernias etcetera. In our opinion, there is no indication for primarily open attempts at restoration of continuity. Entry into the abdomen is always safe through the colostomy site. If dense adhesions are present, conversion to laparoscopy is easily attainable, no operative time is lost and no additional risks are taken. If a laparoscopic repair is unattainable, we believe that early conversion to laparotomy is mandated and is preferable to a lengthy laparoscopic procedure. However, in the present series conversion to laparotomy was only necessary in 1 patient.

Conclusion

Single-port Hartmann's reversal through the stoma site seems to be safe and feasible. With less severe complications due to the minimal need for adhesiolysis and shorter hospital stay, it is an attractive alternative to laparotomy and might make surgeons and patients less reluctant in their opinion about RIC. Further studies with larger patient groups are needed to confirm these findings and investigate the potential advantages in terms of cosmesis, hernia formation and postoperative pain.

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Chapter 8

Reversal of left-sided colostomy utilizing Single-Port laparoscopy; single center consolidation of a new technique

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Abstract

Background
Considerable morbidity (10-14%) and even mortality (4-30%) has been reported after reversal of intestinal continuity following Hartmann's procedure. Feasibility of and advantages in reducing peri- and postoperative morbidity by utilizing single-port techniques through the colostomy site have been suggested before in small case series. Purpose of the present prospective observational study is to evaluate the outcomes of reversal of intestinal continuity using single-port access in a relatively large consecutive cohort.

Methods
All consecutive patients undergoing single-port reversal of left-sided colostomy (SPRLC) between November 2012 and 2018 were included in the present study. Primary outcome was 30-day postoperative complication rate. Secondary outcomes were postoperative length of stay, single-port success rate and surgical details like duration and conversion rates.

Results
Of 85 procedures, 69.4% were without postoperative complications. No postoperative mortality was encountered. Superficial site infection is the most frequent complication and occurred in 22.4%, major complications classified as Clavien Dindo grade 3 or above in 9.4% and anastomotic leakage in 3.5%. Median length of stay was 3.0 days (1-69), single-port success rate was 64.7%, 15.3% was converted to an open procedure.

Conclusion
This study confirms the safety, feasibility and the advantages of SPRLC. In centers with adequate laparoscopic experienced surgeons, this technique should be considered as a serious and attractive alternative to restore intestinal continuity in patients with left-sided end-colostomy, especially in patients after open index surgery. More research must be done in a multicenter setting to evaluate the use and standardization of single-port technique in reversal of intestinal continuity procedures.

Introduction

Even though recent evidence shows that laparoscopic lavage or primary anastomosis can be considered in selected patients, Hartmann's procedure (HP) remains to be frequently used as primary treatment for patients with Hinchey III-IV diverticulitis.[1-3] Patients undergoing emergency colorectal surgery because of left-sided colon malignancy also suffer from significantly higher odds of a postoperative stoma.[4,5]

Besides the known physical and psychological challenges new colostomy patients face,[6,7] they are also confronted with the risk of added morbidity: anastomotic leakage rates range from 4-16% when choosing for restoration of intestinal continuity (RIC) after convalescence time.[8-11] Perioperative mortality rates are reported as high as 14%.[8-11] These are the main reasons why many surgeons are reluctant to perform RIC surgery in approximately 40% of the patients who underwent left-sided colectomy with an end-colostomy or HP.[11]

Laparoscopic reversal of HP was introduced in 1993[12] and was shown to have considerable advantages over classic open reconstruction.[12,13] Our previous study showed that the single-port technique is feasible, also resulting in shorter hospital stays and significant reduction of postoperative complications as superficial site infections compared to classic open RIC in our center.[3]

Aim of the present study was to evaluate the results of implementing and standardizing (consolidating) the single-port reversal of left-sided colostomy (SPRLC) in a single center setting in a large cohort. We postulate that SPRLC is safe and results in advantages such as shorter hospital stay and less postoperative morbidity compared to open RIC. To our knowledge, the present study is the largest cohort of SPRLC in the available literature to date.

Materials and methods

All consecutive patients undergoing SPRLC between November 2012 and November 2018 were included in the present study. During this period all RIC procedures of end colostomies were performed utilizing the single-port technique. Single-port reversal of right-sided (ascending) colostomy or ileostomy procedures and laparoscopic multiport procedures were excluded from this analysis. All procedures are performed or supervised by experienced colorectal surgeons or consultants with extensive skills in laparoscopy and minimally invasive surgery.

The operative procedure of the SPRLC has been described in detail previously.[3] In short, the colostomy was mobilized down to the fascia and the anvil for the CDH29 circular stapler (Ethicon Endo-Surgery, Cincinnati, OH, USA) was placed in the descending colon before returning it to the abdominal cavity through the original colostomy site. A pneumoperitoneum was established after placement of the GelPOINT Path Access Platform (Applied Medical, Los Angeles, CA, USA). Where necessary, the splenic flexure or transverse colon was mobilized and adhesiolysis was performed under direct vision. Continuity was restored after adhesiolysis and proper visualization of the rectal stump with the use of the CDH 29 circular stapler.[3] All wounds were closed by either by intracutaneous or transcutaneous sutures.

All patients were treated within an established Enhanced Recovery After Surgery (ERAS) protocol.[14] Patients were discharged from the hospital when they were able to tolerate normal food, pass stool, were able to mobilize at a level that was similar to preoperative levels of mobilization and had adequate control of pain with use of oral analgesia. Minimum follow up period consisted of 30 days postoperatively.

Patient (sex, age, length and weight) and index surgery characteristics (reason for surgery and postoperative complications) were collected using the electronic patient database. Surgical details such as time interval between index surgery and SPRLC, duration of SPRLC, conversion to multiport laparoscopy or laparotomy and ostomy site closure method were collected using the electronic patient database.

Primary outcome was 30-days postoperative complication rate classified using the Clavien-Dindo score. Clavien-Dindo grade 3 or higher complications were considered major complications in this analysis.
Secondary outcomes were postoperative length of stay, single-port success rate, other surgical details of the procedure such as duration, conversion to multiport laparoscopy or open and overall success rate of the RIC procedure. Single-port success rate is defined as successful RIC procedure solely using the single-port technique without placement of additional laparoscopic trocars or conversion to open surgery. Placement of additional trocars besides the GelPOINT Path Access Platform is considered conversion to multiport laparoscopy.

Approval of the institutional review board or ethics committee was not required because of the observational character of this study. This report was prepared in concordance with the STROBE guidelines (http://www.equator-network.org/reporting-guidelines/strobe/).

Statistical analysis

An intention-to-treat analysis was performed. Descriptive statistics were expressed as median and range (minimum, maximum) for continuous variables. The Pearson Chi square test or the Fisher exact tests, if appropriate, were used for categorical variables. Statistical analysis was performed using the SPSS software package version 22 (SPSS, Chicago, IL). All p-values <0.05 were considered statistically significant.

Results

A total of 85 SPRLC have been performed in Elisabeth-TweeSteden Hospital, Tilburg, the Netherlands. All included patients are depicted in Figure 8.1.

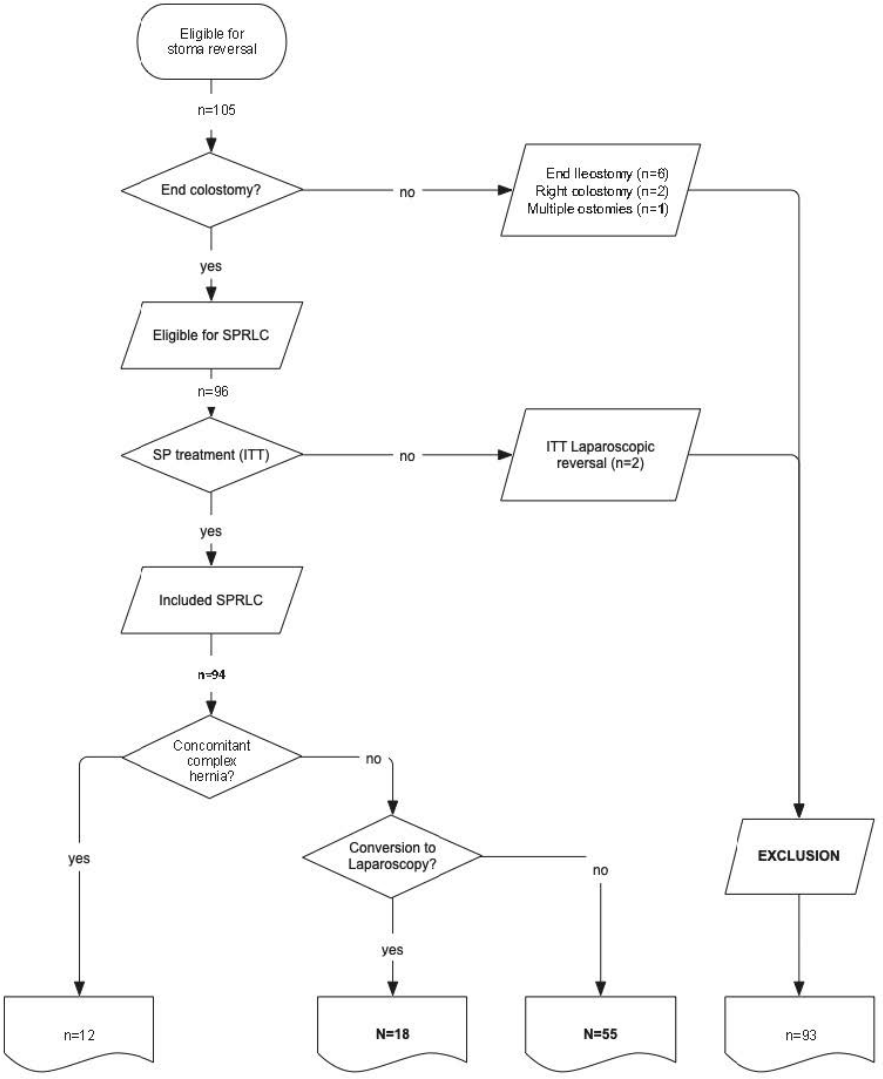

Figure 8.1 Flow chart of patient selection. RIC restoration of intestinal continuity, SPRLC single-port reversal of left-sided colostomy, SP singleport, ITT intention to treat.

The majority of the patients were male (m:f = 56:29) with a mean age of 60.5 (range 25.5-85.0) years. Most common indications for index surgery were complicated diverticulitis, malignancy and anastomotic leakage. Of the included patients, 8 of them had concomitant complex abdominal hernia as a result of the index and subsequent surgeries. The average time between the index surgery and SPLRC is approximately one year, median time is 8 months. Overview of patient specific characteristics can be found in Table 8.1.

Table 8.1 Patient characteristics.

Total included patients	85
Male / female (%)	56 (65.9) / 29 (34.1)
Age in years, mean ± SD (range)	60.8 ± 12.6 (25.5 – 85.0)
BMI in kg/m^2, mean ± SD (range)	27.9 ± 59.7 (18.3 – 61.1)
Primary surgery indication, n (%)	
Diverticulitis	54 (63.5)
Malignancy	14 (16.5)
Anastomotic leakage	8 (9.4)
After colonoscopy	2 (2.4)
After trauma	3 (3.5)
After aortic aneurysm surgery	2 (2.4)
Other	2 (2.4)
Primary mode of index surgery	
Laparoscopy	34 (40.0)
Open	51 (60.0)
Delay between procedures in days, mean (range)	368 (80 – 2966)

Postoperative results

No 30-day postoperative mortality was encountered in the present series. Majority of the patients (n=59; 69.4%) encountered no postoperative complications whatsoever within 30 days after surgery, 30.6% of the patients (n=26) encountered at least one postoperative complication. Overview of all the postoperative complications can be found in Table 8.2. Major complications of Clavien Dindo grade 3 and 4 occurred in 8 patients (9.4%). A total of 4 patients were admitted to the intensive care unit. Five patients (5.9%) underwent reoperation, 1 underwent reoperation because of a suspicion of postoperative hemorrhage from the

laparotomy wound which was not found and 1 needed transrectal sonography guided drainage of an intra-abdominal abscess. This patient had an abscess without receiving successful RIC and needed postoperative intensive care observation due to cardiac dysrhythmia. Three patients underwent reoperation because of anastomotic leakage (3.5%), two of them needed postoperative intensive care treatment. Two patients (2.4%) encountered staple-line hemorrhage for which they were treated with re-interventions by the gastroenterologist. One patient with COPD suffered from a severe pneumonia postoperatively and needed intensive care observation. None of these complications were deemed specific to the new technique that was used, but are to be considered inherent to RIC procedures.

Table 8.2 Postoperative results and complications.

	Overall (n=85)	SPLRC (n=55)	Multiport laparoscopy (n=17)	Open (n=13)
Length of hospital stay in days, median (range)	4.0 (1-69)	3.0 (1-34)	3.0 (2-12)	5.0 (3-69)
Any postoperative complication, n (%)	26 (30.6)	16 (29.1)	5 (29.4)	5 (38.5)
Anastomotic leakage	3 (3.5)	2 (3.6)	0	1 (7.7)
Superficial Site Infection, n (%)	19 (22.4)	11 (20.0)	4 (23.5)	4 (30.8)
Intra-abdominal abscess (%)	3 (3.5)	2 (3.6)	0	1 (7.7)
Reintervention, n (%)	7 (8.2)	5 (9.1)	0	2 (15.4)
Reoperation	5 (5.9)	3 (5.5)	0	2 (15.4)
Sigmoidoscopy	2 (2.4)	2 (3.6)	0	0
Postoperative ileus, n (%)	5 (5.9)	5 (9.1)	0	0
Urinary retention, n (%)	2 (2.4)	2 (3.6)	0	0
Clavien-Dindo complication type, n (%)				
I	16 (18.8)	9 (16.4)	4 (23.5)	3 (23.0)
II	2 (2.4)	2 (3.6)	0	0
III	4 (3.5)	3 (5.5)	0	1 (7.7)
IV	4 (4.7)	2 (3.6)	1 (5.9)	1 (7.7)
Mortality, n (%)	0 (0)	0	0	0
Readmission within 30 days after discharge, n (%)	1 (1.2)	1 (1.8)	0	0

Intra-abdominal abscesses occurred in 3 patients (3.5%), 2 of them after anastomotic leakage with reoperation and 1 after unsuccessful RIC with a false route during placement of the stapler. Two patients were treated with

percutaneous drainage. Postoperative ileus occurred in 5.9% (n=5), all of them resolved after conservative therapy. Two of these patients had an ileus after they were re-operated due to an anastomotic leakage. One patient was discharged without any postoperative complication, was readmitted within 30 days after discharge, because of an ileus that resolved with conservative measures.
Superficial site infection (SSI) was the most frequent complication and occurred in 22.4%. Four of the 19 patients with SSI developed this after re-operation (21.1%). Regarding the SSI rate in SPRLC, 8 patients suffered from SSI of the old ostomy incision and 3 patients suffered from SSI of the laparotomy wound after reoperation. One patient suffered from SSI after re-operation after an open RIC procedure due to an anastomotic leakage.
Overall median length of hospital stay was 4.0 days (range 1-69 days). Patients after conversion to open RIC had a significant longer hospital stay compared to those after SPRLC or multiport laparoscopy, median of 5.0 days compared to 3.0 days respectively. This difference was statistically significant, p=0.013.

Operative technique

Of the 85 procedures, 64.7% (n=55) were technically successful by solely using SP approach. Twenty-eight of the 85 procedures were performed by surgery residents in training under supervision of a colorectal surgeon or consultant. Minimally invasive approach which is defined as SPRLC or conversion to multiport laparoscopy was successful (without conversion to laparotomy) in 84.7% of the cases (n=72). Conversions to multiport laparoscopy was performed in 17 patients (20.0%) by insertion of one, two or three extra 5 mm trocar ports. Reasons for placement of extra trocars are mainly due to the necessity for extensive adhesiolysis and for over sewing the anastomosis after positive air leak testing. Conversion to laparotomy was necessary in 13 cases (15.3%) and was significantly higher in patients who had an open index surgery compared to those who had a laparoscopic approach, 84.6% (11/13) conversions occurred in patients with open index surgery (p=0.049). Still, SPRLC and multiport laparoscopy was feasible in 78.4% (40/51) of the patients who underwent open index surgery.

Overall median duration of operation was 127 minutes (range 40-332). Single-port and multiport laparoscopy procedures were significantly shorter compared to operations where conversion to laparotomy was necessary, respectively 110 minutes (range 54-274) and 116 minutes (range 74-234) versus 208 minutes (range 114-332), *p*=0.003. Duration of surgery in patients with laparoscopic index surgery was significantly shorter compared to those who had open index surgery, 102 minutes (range 44-279) versus 144 minutes (range 90-332), *p*=0.007.
Two procedures (2.2%) were technically not successful in restoring intestinal continuity. One case due to a false route when placing the stapler device in the rectal stump and one case due to a frozen pelvis combined with a non-vital rectal stump with leakage during perioperative rectoscopy, so RIC was abandoned in both procedures. One other patient had persisting positive air leak test, even after several additional sutures, so loop colostomy proximal to this anastomosis was placed. This stoma was reversed after 42 days, this reversal was uneventful. Overview of surgical details can be found in Table 8.3.

Table 8.3 Surgical details of RIC procedures.

Successful reversal of intestinal continuity, n (%)	83 (97.6)
Duration in minutes, median (range)	127 (40-332)
Single-port technique, n (%)	55 (64.7)
Conversion	30 (35.3)
Laparotomy	13 (15.3)
Multiport laparoscopy, addition of one 5 mm trocar	12 (14.1)
Multiport laparoscopy, addition of two 5 mm trocars	4 (4.7)
Multiport laparoscopy, addition of three 5 mm trocars	1 (1.2)
Deviating ostomy, n (%)	1 (1.2)

Discussion

The feasibility and safety of the laparoscopic and single-port approach in restoring intestinal continuity (RIC) after a Hartmann's procedure (HP) has been reported in smaller case series before.[3,12,13,15] The present series is, to our knowledge, to date the largest series of single-port reversal of left-sided colostomy (SPRLC).

There are considerable technical difficulties in laparoscopic RIC, especially after initial open resection in fecal or purulent peritonitis. Intra-abdominal adhesions can cause serious difficulty to safe entry of the first trocar into the abdominal cavity during laparoscopic reversal after HP. Furthermore, adhesiolysis of the midline is often necessary, can be cumbersome and harbors the risk of advertent or inadvertent enterotomies.[12,13] Using the colostomy site as single incision or port for the RIC procedure with a hand-assisted technique has been introduced in 2008 by Vermeulen et.al.[16] was to overcome the before mentioned problems and was shown in small case-series to have advantages compared to the classic open technique.[3,17,18] In our earlier study we have shown that the single-port technique yields superior results to open Hartmann's reversal in our center, the technique that was considered to be standard of care in our center until that moment.[3] Since then, we have extended the single-port technique as our standard of care for restoring patients' intestinal continuity. In fact, after going through the initial learning curve, this study shows that SPRLC has become a procedure which is also performed by residents in training under direct supervision of a colorectal surgeon or consultant in almost a third of the procedures. This proves that the single-port technique requires some laparoscopic skill, but is not necessarily deemed as an expert level procedure. It's not just our primary approach to reverse a left-sided end colostomy, but for all types of terminal ileo- and colostomies.

This study shows that SPRLC leads to short postoperative hospitalization with an overall median of 4.0 days, an acceptable overall complication rate of 30.6% and high success rates of the procedure of 97.6%. There was only one readmission within 30 days after discharge. An overall SSI rate of 22.4%, conversion rate of 15.3% and overall anastomotic leakage rate of 3.5% were noted. Our overall postoperative length of stay maintained a median of 4.0 days after implementing and standardizing the single-port technique, which is an obvious progress compared to our previous reported 16 days when open RIC was still our standard of care.[3] All of our results are in line with or compare favorably to the rates which can be found in the literature for laparoscopic or single-port reversal of HP.[12,13,19] A striking observation from the present study is that the postoperative morbidity

after SPRLC is comparable to morbidity and mortality rates RIC of ileostomies reported in literature.[20] These results might possibly shed a new light on the different approaches and treatments of left-sided colonic surgical pathology, where it is often advocated to perform anastomoses protected by loop ileostomies rather than performing Hartmann.

When appraising the surgical aspects of the single-port technique for RIC, we find some major advantages. Our mean operation time of the SPRLC certainly was not notably different when compared to the single incision reversal by Vermeulen et.al.,[16] conventional open RIC or laparoscopic RIC; 127 vs. 172 vs. 150 minutes respectively.[15] As a matter of fact, compared to our initial single-port procedures and after our learning curve, our center has managed to reduce our median operation time from 154 minutes to 127 minutes. The present data show that median operation time is significantly lower in laparoscopic index surgeries compared to open index procedures. We believe that the differences in results lie in the necessity of adhesiolysis of the abundant adhesions after open surgery.

Avoiding adhesiolysis of the midline, especially in those patients with a laparostomy, multiple laparotomies, severe wound infection or complex abdominal wall defects in their medical history is also considered one of the merits of this technique.[3] SPRLC can be used as a step-up approach by restoring the intestinal continuity with low morbidity rates and avoiding a laparotomy or extensive adhesiolysis in those patients with complex abdominal wall defects to minimize their contamination before their subsequent (complex) hernia repair. We believe that SPRLC should be used as first approach in all the patients who are eligible for RIC, despite the type of index surgery or concomitant comorbidity due to the ease in which the procedure could be converted into a multiport laparoscopy or open laparotomy when needed. A possible contraindication could be insufficient laparoscopic experience by the performing colorectal surgeon.

The introduction and growing expertise of minimally invasive surgery has led to the growing use of laparoscopy for abdominal emergencies as ileus, peritonitis and

post traumatic damage control. This will, in our opinion, result in lesser incisional hernias, lesser wound problems and also less intra-abdominal adhesions. It is our expectation that with this shift of technique and skill will also lead to a different point of view for the need for primary anastomosis (with protective ileostomies) during emergency surgery such as in complicated perforated diverticulitis or necessary left-sided colectomy due to stenotic malignancies. After all, our results show that SPRLC after a laparoscopic HP or left-sided colectomy can be compared to the postoperative morbidity after loop ileostomy reversal. The possibility to perform an emergency laparoscopic HP or left-sided colectomy with end colostomy should be incorporated in a colorectal surgeons' palette as surgical treatment. Especially since single-port or multiport laparoscopic reversal of left-sided end colostomy do not longer harbor the high postoperative morbidity and mortality rates of conventional open surgery. RIC in patients with left-sided colostomies should therefore be taken into reconsideration. SPRLC is not only a safe and feasible procedure, it also leads to equal or even better results with some major advantages compared to conventional open RIC procedures.

This study confirms the safety, feasibility and the advantages of low postoperative morbidity, mortality and short length of stay of SPRLC. In centers with adequate laparoscopically experienced colorectal surgeons, this technique should be considered as a serious and attractive alternative to restore intestinal continuity in patients with left-sided end- colostomy. The single-port approach could be especially beneficial in patients with end left-sided colostomy after open abdominal surgery, severe wound infections or with complex abdominal wall defects or complex ventral hernias. Further research should be done to evaluate the results of SPRLC in a multicenter setting and to evaluate the applicability of this technique for the reversal of other types of stomas.

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Chapter 9

Reversal of left-sided colostomy utilizing single-port laparoscopy a multicenter European audit and overview of the literature

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Abstract

Background

Stoma reversal surgery can result in considerable morbidity and even mortality. Feasibility of utilizing single-port laparoscopy through the stoma fenestration have been shown before. Aim of the present observational study is to evaluate multicenter experiences of single-port reversal of left-sided colostomy (SPRLC) throughout Europe and to provide an overview of available literature on this topic.

Methods

All patients undergoing SPRLC in four different teaching hospitals throughout Europe are included. Primary outcome was 30-day postoperative complication rate. Secondary outcomes were postoperative length of stay (LOS), single-port success rate and conversion rates. Appraisal of the available literature in PubMed was performed.

Results

Of 156 SPRLC procedures, 98.7% of them were technically successful and 71.8% were without postoperative complications. No postoperative mortality was encountered. Superficial site infection occurred in 14.7%, anastomotic leakage in 3.9% and major complications in 8.3%. Median LOS was 4.0 days (1-69), single-port success rate was 64.7%, 12.8% and 21.2% (33/154) were converted to an open and multiport laparoscopic procedure respectively. Literature shows equally favorable results in 131 patients divided over 5 cohorts with morbidity ranging from 0-30.4% and mortality from 0-2.2% and median LOS of 4-8 days.

Conclusion

This study confirms the safety, feasibility and favorable results of the use of single-port approach in the reversal of left-sided colostomy in different centers in Europe with laparoscopic experienced colorectal surgeons. The available literature on this topic support and show equally favorable results using single-port laparoscopy for left-sided colostomy reversal surgery.

Introduction

Stomas are not only used in emergency colorectal surgery for benign disorders such as diverticulitis after a Hartmann's Procedure (HP);[1-3] they are also widely accepted and propagated in colorectal cancer surgery. Up to 35% of the Dutch elderly patients still receive an ostomy after colorectal cancer surgery and patients undergoing emergency colorectal surgery because of left-sided colon malignancy still suffer from significantly higher odds of a colostomy.[4-6]

Pursuing stoma reversal surgery is not without risks; anastomotic leakage rates range from 4-16%, perioperative mortality and morbidity rates are reported as high as 14% and 40% respectively.[7-10] These are the main reasons why many surgeons are reluctant to perform stoma reversal surgery; in up to 40% of the patients, stoma reversal will never be performed.[8-10]

In 1993 laparoscopic reversal of HP was introduced in an effort to reduce morbidity and mortality.[11] It was shown to have considerable advantages over classic open reversal of HP.[11,12] Further evolution of minimal invasive abdominal surgery introduced the use of single-port laparoscopy, this approach has also been used for stoma reversal surgery, first described by Smith and Bettinger.[13] The necessity of difficult trocar placement and laborious midline adhesiolysis are obvious advantages of the single port approach over the conventional laparoscopic approach.[14,15] Previous studies show that single-port reversal of a left-sided colostomy (SPRLC) is feasible, safe and also results in significant shorter length of stay and reduction of postoperative complications as superficial site infections compared to classic open stoma reversal surgery.[3,15] Adoption of this approach has led to an increasing body of literature on SPRLC since its introduction in 2011.

Aim of the present study was to evaluate the results of single-port reversal of left-sided colostomy (SPRLC) in a multicenter setting across different countries in Europe and to give a comprehensive overview of the literature on the use of the single-port (SP) approach in the reversal of a left-sided colostomy. We postulate

that SPRLC is feasible and safe with a shorter hospital stay and less postoperative morbidity compared to an open approach.

Materials and methods

This is a retrospective observational study, all patients undergoing SPRLC in four different teaching hospitals throughout Europe were included in present analysis. The four different hospitals are Churchill Hospital in the United Kingdom (CH), Humanitas Research Hospital (HRH) in Italy, Elisabeth-TweeSteden Hospital (ETH) and Zuyderland Medical Center (ZMC) both in the Netherlands. Approval of the institutional review board or ethics committee was not required because of the retrospective and observational character of this study. This report was prepared in concordance with the STROBE guidelines.[16]

Patient characteristics (sex, age, length and weight), index surgery characteristics (reason for surgery and postoperative complications), surgical details (time interval between index surgery and SPRLC, duration of SPRLC, conversion to multiport laparoscopy or laparotomy, colostomy site closure methods) and postoperative outcomes (length of stay, complications, readmissions) were collected in electronic case report forms by local investigators using the electronic patient records. All procedures were performed or supervised by experienced colorectal surgeons or consultants with extensive skills in laparoscopy and minimally invasive surgery. Patients undergoing stoma reversal of a loop or right-sided colostomy or ileostomy or via open procedure were excluded. This study included cases previously published by authors from our current collaborative group from Clermonts and van Loon (ETH) and Joshi (CH).[3,15,19] In CH and ETH all consecutive patients eligible for HP reversal were included, without additional patient selection or exclusion in the enrollment period from 2010-2019 and 2012-2020 respectively. Patients included from HRH (2008-2019) and ZMC (2015-2018) were selected by their operating surgeon by the surgeon's preference, in these hospitals all procedures were performed by one (supervising) surgeon. In HRH patients included in this study

comprised almost half of all the patients who underwent stoma reversal surgery. Single-port laparoscopy is the preferred approach of choice in CH and ETH when performing stoma reversal surgery for left-sided colostomies. SPRLC became the preferred approach of choice towards the second half of the study period. The preferred approach for stoma reversal surgery in ZMC is surgeon dependent.

Surgical technique

All patients were placed in modified lithotomy position and given metronidazole 500mg and cefuroxime 1500mg intravenously. The operative procedure of the SPRLC has been described in detail previously.[3,13-15,17-19] In short, the colostomy was mobilized down to the fascia and the anvil for a circular stapler was placed in the descending colon before returning it to the abdominal cavity through the original colostomy site. Pneumoperitoneum was established after placement of a single-port device or surgical glove port. Where necessary, the splenic flexure or transverse colon was mobilized and adhesiolysis was performed under direct vision. Continuity was restored after adhesiolysis and proper visualization of the rectal stump with the use of a circular stapler. An air leak test was performed before port removal. Fascia and skin at colostomy site were closed as deemed appropriate. See Table 9.1 for a detailed description of the materials and techniques used during SPRLC.

All patients were treated within an established Enhanced Recovery After Surgery (ERAS) protocol.[20] Important components of the ERAS protocol applied similarly in all centers are antimicrobial prophylaxis with skin preparation, perioperative near-zero fluid balance, no use of pelvic, peritoneal or nasogastric drains or tubes, multimodal analgesia without use of NSAIDs, early postoperative mobilization and oral diet. Patients were discharged from the hospital when they were able to tolerate normal food, pass stool, were able to mobilize at a level that was similar to preoperative levels of mobilization and had adequate control of pain with use of oral analgesia. Minimum follow up period consisted of 30 days postoperatively.

Table 9.1 Overview of materials used during single port reversal of left-sided colostomy.

Center, Country	Type of stapler	Type of single port access	Closure of fascia	Closure of skin
Humanitas, Italy	EEA28™ EEA31™	GelPOINT™	Interrupted stitches, Vicryl	Sutures and staples
Churchill, United Kingdom	CDH29A	Surgical glove-port	Running suture, PDS	Skin glue, staples and sutures, Monocryl
Zuyderland, Netherlands	CDH29A	OCTO™Port, surgical glove-port	Running suture, PDS	Intracutaneous purse-string suture, Vicryl
Elisabeth-TweeSteden, Netherlands	CDH29A, EEA™,!	GelPOINT™	Running suture, PDS	Intracutaneous, purse-string sutures, Monocryl

! This hospital switched to the EEA™ stapler from 2017. EEA™ circular stapler, Medtronic CDH29A, Ethicon J&J. GelPOINT™, Applied Medical. OCTO™Port, Dalim SurgNet, Frankenman. Vicryl: polyglactin suture, Ethicon J&J. PDS: polydioxanone suture, Ethicon J&J. Monocryl: polyglactin suture, Ethicon J&J.

Outcomes

Primary outcome was 30-days postoperative complication defined as infections (surgical site, intra-abdominal abscess), urogenital complications (urinary tract infection, urine retention), ileus or gastroparesis, pulmonary complications (pneumonia, exacerbation) and blood-related complications (rectal blood loss, thrombosis or hematoma in wound or anastomosis) was classified using the Clavien-Dindo score. Clavien-Dindo grade 3 or higher were considered major complications in this analysis.

Secondary outcomes were postoperative length of stay (LOS), technical and single-port success rate, other surgical details of the procedure such as duration, conversion to multiport laparoscopy or open and overall success rate of SPRLC. Technical success rate is defined as successful stoma reversal with creation of an anastomosis. Single-port success rate is defined as successful stoma reversal solely using the single-port technique without placement of additional laparoscopic trocars or conversion to open surgery. Placement of additional trocars besides the OCTO™ Port, GelPOINT Path Access Platform or single-site glove port is considered conversion to multiport laparoscopy.

Statistical analysis

Descriptive statistics were expressed as median and range (minimum, maximum) for continuous variables. The Pearson Chi square test or the Fisher exact tests, if appropriate, were used for categorical variables. Mann-Whitney U and Kruskal-Wallis test was used for continuous variables. Statistical analysis was performed using the SPSS software package version 26 (SPSS, Chicago, IL). All *p*-values <0.05 were considered statistically significant.

Appraisal of the literature

A literature search for relevant literature from 2011 (the introduction of single-port reversal of HP) on was performed using PubMed. Articles were screened using title and abstract. When multiple articles from a single study group with matching authors was found, only most recent was used in an effort to reduce duplication bias. Previous published articles on this topic from our current collaborative group of authors were excluded.

Results

A total of 156 patients were included from four different surgical departments throughout Europe: 30 patients from CH, 13 patients from HRH in Italy, 9 patients from ZMC and 104 patients from ETH.
The majority of the patients are male (m:f = 99:57), ASA 2 or 3 (40.4% and 34.6% respectively) with a median age of 61.0 years (range 17.7-92.6). Majority of the index surgeries were via conventional open approach (64.7%), most common indications for index surgery were diverticulitis (58%) or colorectal cancer (23.7%). The median time between the index surgery and SPRLC is approximately 9 months (284 days). An overview of patient specific characteristics at baseline can be found in Table 9.2.

Table 9.2 Patient characteristics at baseline per center.

Center, country	Number	Sex M : F	Median age (range)	Median BMI (range)	ASA n (%)		Reason for stoma n (%)		Primary open approach n (%)
					1	1 (7.7)	Diverticulitis	4 (30.8)	
Humanitas,	13	9 : 4	64.5	24.4	2	9 (69.2)	Malignancy	4 (30.8)	
Italy			(21.2 - 92.6)	(18.2-34.7)	3	3 (23.1)	Perforation or trauma	3 (23.1)	10 (76.9)
					4	-	Inflammatory Bowel Disease	1 (1.8)	
							Clostridium	1 (1.8)	
							Diverticulitis	17 (56.7)	
					1	1 (3.3)	Malignancy	5 (16.7)	
Churchill,			60.0	26.0	2	7 (23.3)	Perforation or trauma	3 (10.0)	
United Kingdom	30	16 : 14	(17.7 - 80.1)	(19.0-45.2)	3	18 (60.0)	Anastomotic leakage	2 (6.7)	25 (83.3)
					4	4 (13.3)	Ischemia	1 (3.3)	
							Volvulus	1 (3.3)	
							Stoma retraction	1 (3.3)	
					1	2 (22.2)	Diverticulitis	4 (44.4)	
Zuyderland,			56.1	25.6	2	4 (44.4)	Malignancy	2 (22.2)	
the Netherlands	9	6 : 3	(37.5 - 67.2)	(21.1-33.6)	3	3 (33.3)	Volvulus	1 (11.1)	6 (66.7)
					4	-	Ischemia	1 (11.1)	
							Perforation or trauma	1 (11.1)	
							Diverticulitis	66 (63.5)	
					1	25 (24.0)	Malignancy	26 (25.0)	
Elisabeth-			61.0	26.4	2	43 (41.3)	Perforation or trauma	6 (5.7)	
TweeSteden,	104	68 : 36	(25.5 - 85.0)	(18.3-61.1)	3	30 (28.8)	Ischemia	2 (1.9)	60 (57.7)
the Netherlands					4	6 (5.8)	Volvulus	2 (1.9)	
							Inflammatory Bowel Disease	1 (1.0)	
							Perianal abscesses	1 (1.0)	
							Diverticulitis	91 (58.3)	
							Malignancy	37 (23.7)	
					1	29 (18.6)	Perforation or trauma	13 (8.3)	
Cumulative	156	99 : 57	61.0	26.3	2	63 (40.4)	Ischemia	4 (2.6)	101 (64.7)
			(17.7-92.6)	(18.2 - 61.1)	3	54 (34.6)	Volvulus	4 (2.6)	
					4	10 (6.4)	Inflammatory Bowel Disease	2 (1.3)	
							Anastomotic leakage	2 (1.3)	
							Other	3 (1.9)	

Postoperative results

No 30-day postoperative mortality was encountered in the present series. Majority (112/156, 71.8%) of the patients encountered no 30-day postoperative complications whatsoever, 28.2% of the patients encountered at least one postoperative complication. Major complications were encountered in 8.3%, Clavien Dindo grade 3 occurred in 5.7% (n=9) and grade 4 in 2.6% (n=4) of the patients. Anastomotic leakage rate was 3.9% (n=6). Five of the patients with anastomotic leakage underwent reintervention under general anesthesia, two of them had their anastomosis disconnected into colostomies.

The anastomosis of the other three patients could be salvaged by additional sutures at the staple line in one patient, additional stapling of the leaking rectal stump in one patient and drainage of the abscess and deviating ileostomy in one patient. One patient with anastomotic leakage presented with an intra-abdominal abscess which didn't require a re-intervention. Surgical site infection (SSI) was the most frequent complications and occurred in 14.7% (n=23). Six of the 23 patients with SSI developed this after conversion to open surgery, additional four of the 23 patients developed this after reoperation, these patients all had SSI of the laparotomy wound. The other 13 patients suffered from SSI of the old ostomy incision. Overall median LOS was 4.0 days (range 1-69 days).

Four patients needed ICU admission, two were after anastomotic leakages, one patient with COPD suffered from a severe postoperative pneumonia and one patient needed rhythm observation due to severe tachycardia as a result of intra-abdominal abscess. None of these complications were deemed specific to the technique that was used, but are to be considered inherent to restoration of intestinal continuity procedures. Detailed overview of overall postoperative complications and complications per hospital can be found in Table 9.3.

Table 9.3 30-day postoperative outcome.

30-day postoperative outcome	Humanitas Italy (n=13)	Churchill United Kingdom (n=30)	Zuyderland Netherlands (n=9)	Elisabeth-TweeSteden Netherlands (n=104)	Cumulative (n=156)
Median length of stay, days (range)	6 (3-19)	5 (2-35)	3 (1-11)	4 (1-69)	4 (1-69)
Any postoperative complication, n (%)	4 (30.8)	4 (13.3)	1 (11.1)	35 (33.7)	44 (28.2)
Anastomotic leakage, n (%)	1 (7.7)	-	1 (11.1)	4 (3.8)	6 (3.9)[#]
Surgical site infection, n (%)	-	1 (3.3)	1 (11.1)	21 (20.2)	23 (14.7)
Intra-abdominal abscess, n (%)	1 (7.7)	2 (6.7)	1 (11.1)	4 (3.8)	8 (5.1)
Urogenital complication[!], n (%)	-	1 (3.3)	-	2 (1.9)	3 (1.9)
Postoperative ileus, n (%)	1 (7.7)	-	-	5 (4.8)	6 (3.9)
Pulmonary complication, n (%)	-	1 (3.3)	-	2 (1.9)	3 (1.9)
Bleeding-related complication*, n (%)	1 (7.7)	2 (6.7)	-	2 (1.9)	5 (3.2)
Clavien-Dindo Classification, n (%)					
I	1 (7.7)	-	-	23 (22.1)	24 (15.4)
II	1 (7.7)	2 (6.7)	-	4 (3.8)	7 (4.5)
III	2 (15.4)	2 (6.7)	1 (11.1)	4 (3.8)	9 (5.7)
IV	-	-	-	4 (3.8)	4 (2.6)
Mortality, n (%)	-	-	-	-	-

[!] Urogenital complication: urine retention, urinary tract infection; *Bleeding-related: rectal blood loss, haematoma in wound or anastomosis; [#] Calculated over the number of patients who had successful reversal of left-sided colostomy, see Table 9.4.

Operative technique

Of the 156 procedures, two procedures (1.3%) were not technically successful in restoring intestinal continuity, resulting in a surgical success rate of 98.7%. Of the remaining 154 procedures, deviating stoma was needed in 2.6% of the procedures. SP approach was technically successful in 64.7% (101/156) of the procedures. Overall median operating time was 128 minutes (range 44-332). Conversion to multiport laparoscopy and open surgery was needed in 21.2% (n=33) and 12.8%

(n=20) respectively. Additional ports were mostly needed for (extensive) adhesiolysis, oversewing the anastomosis after positive air leak testing or mobilizing the splenic flexure. Conversion to open surgery was significantly higher in patients who had an open index surgery compared to those who had a laparoscopic approach, 85.0% (17/20) of the conversions occurred in patients with open index surgery (p=0.03), albeit single-port and multiport laparoscopy was feasible in 80.2% (81/101) of the patients who underwent open index surgery. Overview of the overall surgical details and outcomes and per hospital can be found in Table 9.4. Overview of the encountered intra-operative complications and reasons for conversion in ETH can be found in Appendix 9.1.

Table 9.4 Surgical details and outcomes.

Surgical outcome	Humanitas Italy (n=13)	Churchill United Kingdom (n=30)	Zuyderland Netherlands (n=9)	Elisabeth-TweeSteden Netherlands (n=104)	Cumulative (n=156)
Surgical success rate, n (%)	13 (100)	30 (100)	9 (100)	102 (98.1)	154 (98.7)
Deviating stoma, n (%)	-	1 (3.3)	1 (11.1)	2 (2.0)	4 (2.6)*
Single port success rate, n (%)	13 (100)	12 (40.0)	9 (100)	67 (65.7)	101 (64.7)
Conversion	-	18 (60.0)	-	35 (34.3)	53 (34.0)
Multiport laparoscopy	-	12 (40.0)	-	21	33 (21.2)
Open	-	6 (20.0)	-	14	20 (12.8)
Median operation time (range)	160 (75-322)	165 (75-310)	88 (68-232)	128 (40-332)	128 [40-332]

Appraisal of the literature

The specific details of the literature search in PubMed can be found in Appendix 9.2. The flow diagram of inclusion of the studies can be found in Figure 9.1. A total of 86 studies were excluded for solely discussing laparoscopy (n=15), comparing results of laparoscopic reversal versus open reversal of left-sided colostomy (n=11), treatment of diverticulitis (n=25), video vignettes (n=4), using other novel techniques of stoma reversal (n=5), case reports on stoma problems (n=3) and other articles unrelated to single-port stoma reversal surgery (n=23).

Three previous published articles on this topic from our current collaborative group of authors were excluded,[3,15,19] one article was excluded due to inclusion of their more recent manuscript,[21] one meta-analysis on this topic was excluded since it had no additional new studies,[22] leaving 5 included original articles.[13,14,18,23,24]

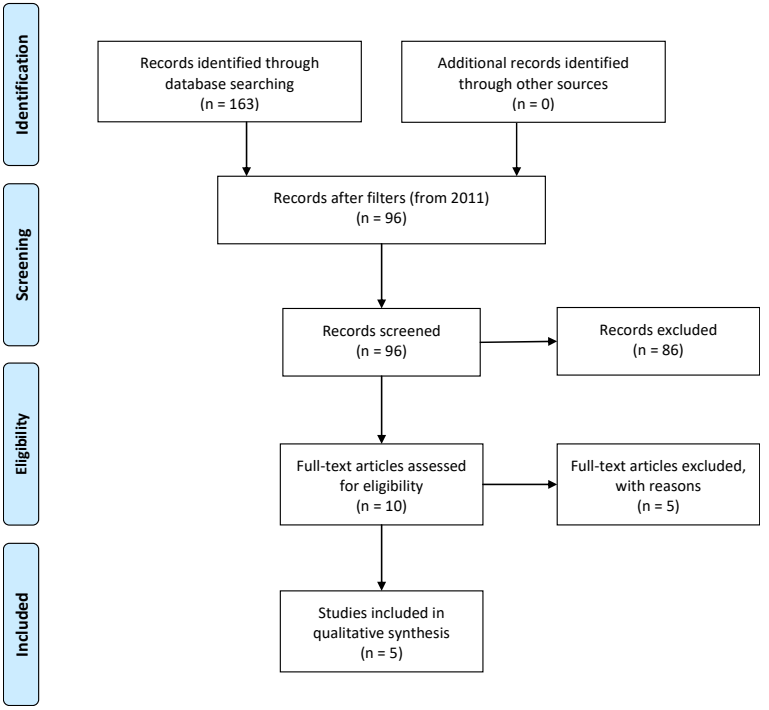

Figure 9.1 PRISMA flow diagram of included studies.

This appraisal shows that since the introduction of the single-port approach in Hartmann's reversal in 2011 by Smith and Bettinger,[13] additional case series have been published on this topic. At this moment no randomized controlled trials between the different approaches (open, laparoscopic or single-port) were published. Literature shows that patient selection for SPRLC is mainly in patients

after laparoscopic index surgery 53.4% overall, figures ranging from 34%-72.7%. It also shows that SP approach is safe and feasible with high success rates, morbidity and mortality rates ranging from 12.5%-30.4% and 1.8%-2.2% respectively. Major complication rate is also low, varying from 0%-8.9% and median length of stay between 4 and 8 days. Details and an overview can be found in Table 9.5.

Discussion

The merits of the single-port reversal of left-sided colostomy compared to the open approach have been shown before.[3,11-15,18-21] The present series is, to our knowledge, the only and largest European multicenter cohort to date. This study shows that SPRLC is an attractive technique and with favorable postoperative outcomes across different hospitals in Europe. Acceptable rates of postoperative morbidity (28%) and low rates of major complication (8%) combined with a short postoperative hospitalization (median 3 to 6 days) after SPRLC could result in lowering a surgeons' threshold to restore intestinal continuity.

Our review and appraisal of the literature shows that type of single-port platform does not influence the favorable results after SPRLC. It appears that the postoperative results found in the literature are slightly better compared to the results found in our multicenter cohort. One reason might be that the majority of patients in this cohort have had open index surgery compared to the patients in the different cohorts in the literature (101/156 versus 61/131, p=0.003). Another reason might be a possible publication or selection bias of those smaller case series in the literature. It seems reasonable and sensible to perform a certain patient selection (ASA 1-2 patients with low BMI and swift uncomplicated recovery after a laparoscopic procedure) when one is still adapting to a new technique.[14] Our cohort, on the other hand, contains mostly ASA 2-3 patients with a tendency towards being overweight. As time progressed and sufficient exposure was gained, SPRLC evolved from a novel technique, to the preferred approach which was applied to all left-sided colostomy reversal surgeries in ETH, CH and HRH.

Table 9.5 Summary of single-port reversal of left-sided colostomy in the current literature.

Study	Country	Year of publication	Number of patients	Type of single port access	Open index surgery	Conversion to laparoscopy	Conversion to open	Morbidity	Mortality	Median LOS (range)
Smith et al.	USA	2011	1	SSLAS	1 (100)	-	-	-	-	5*
Carus et al.	Germany	2011	8	SILS^{TM} port	3 (37.5)	-	-	1 (12.5)	-	6.4 (4-8)
Choi et al.	Korea	2015	22	Surgical glove port, OCTO^{TM} Port	6 (27.3)	-	-	4 (18.2)	-	8 (4-31)
Thambi et al.	UK	2019	56	GelPOINT^{TM}, SILS port, OCTO^{TM} Port	37 (66.1)	1 (1.8)	5 (8.9)	17 (30.4)	1 (1.8)	4 (2-44)
D'Alessandro et al.	France	2020	44	GelPOINT^{TM}	14 (31.8)	6 (13.6)	-	7 (15.9)	1 (2.2)	4.8$^{\&}$
Cumulative			131		61 (46.6)	7 (5.3)	5 (3.8)	29 (22.1)	2 (1.5)	4-8

LOS = length of stay. * No range. $^{\&}$ No range could be found in the results or discussion section of this article. $^{\#}$ 3 patients had a single incision Hartmann's procedure. SSLAS (Single-Site laparoscopic access system), Ethicon. SILS^{TM}Port, Covidien. GelPOINT^{TM}, Applied Medical. OCTO^{TM}Port, Dalim SurgNet, Frankenman.

This might have resulted in an increase in conversions to multiport laparoscopy in the ETH cohort due to the inclusion of increasingly complex patients. Moreover, it needs to be stressed that the majority of these conversions consist of addition of one single 5 mm port, below the old laparotomy scar, not necessitating conversion to open laparotomy. Noteworthy is that CH cohort has an exceptionally high number of primary open approach in their mostly ASA 3 patients compared to others, which could be an explanation for their higher conversion rate during SPRLC.

Midline adhesiolysis or adhesiolysis in order to place trocars have become unnecessary when using the stoma fenestration as port, since the reversal of a left-sided colostomy takes place the left side of the abdomen alone. This advantage has been confirmed before.[3,13,15,23,24] Another advantage of SP is that it obviates the need to treat a concomitant complex abdominal wall defect or incisional hernia, this entire area can be left alone when using the stoma fenestration as access.[15] The use of a single-port with availability of multiple instruments through the stoma-fenestration can be beneficial compared to conventional multiport laparoscopy, especially in patients after open surgery with extensive intra-abdominal adhesions. If needed, direct adhesiolysis can be safely performed first with those instruments through the single-port to ensure safe additional trocar placement elsewhere. This adhesiolysis to clear space for additional trocar placement is not always easy or feasible when using the conventional multiport laparoscopy.

SP surgery also has its down sides, it takes some adjustment from surgeons and surgical team to adapt to the off-centered vision and limited space to 'triangulate' the laparoscopic instruments. Despite this, we have shown before that experienced residents are able to perform this procedure under supervision, especially in centers with adequate experience and exposure in minimally invasive laparoscopic surgery.[15]

This study is limited by the retrospective observational character; no randomization or case-matched comparisons have been carried out in this cohort. Another limitation of a retrospective observational study is the inability to include variables if they are not a part of the standard electronic patient records or operation reports, such as blood loss. Other factors such as enhanced recovery after surgery programs, low opioid anesthesia and analgesia or increasingly subspecialization of colorectal surgery with increasing laparoscopic index surgery could all have a part in the favorable results of SPRLC. Especially patient selection at surgeons' preference (such as in the ZMC cohort) might result in exceptionally favorable results. It would be an interesting avenue of further research to evaluate if a standardized way of using the a single-port in the stoma fenestration with adding one or two additional ports from the start of the procedure would result in better peri- and post-operative results with possibly increased uptake of this technique.

This study confirms the safety, feasibility and favorable results of the use of single-port approach in the reversal of left-sided colostomy in different centers in Europe with laparoscopic experienced colorectal surgeons. The available literature on this topic support and show equally favorable results using single-port laparoscopy for left-sided colostomy reversal surgery.

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Appendix 9.1

Overview of conversions and accompanying intra-operative complications or difficulties in SPRLC procedures in Elisabeth-TweeSteden Hospital

Conversion	Multiport or Open	Intra-operative complication or difficulties
Yes	Multiport	ischemia of colon
Yes	Open	not enough length for anastomosis
Yes	Multiport	flexure mobilisation
Yes	Open	extensive adhesiolysis, positive air leak test
Yes	Open	rectal stump stapeler induced injury
Yes	Open	extensive adhesiolysis, serosal injury
Yes	Multiport	not enough length for anastomosis formation
Yes	Open	small bowel injury during port placement
Yes	Multiport	flexure mobilisation, adhesiolysis
Yes	Multiport	extensive adhesiolysis
Yes	Open	extensive adhesiolysis, inadvertant enterotomy
Yes	Multiport	positive air leak test
Yes	Open	positive air leak test
Yes	Open	extensive adhesiolysis, serosal injury
Yes	Multiport	positive air leak test
Yes	Open	frozen pelvis
Yes	Multiport	extensive adhesiolysis
Yes	Open	positive air leak test
Yes	Multiport	extensive adhesiolysis, positive air leak test
Yes	Multiport	extensive adhesiolysis
Yes	Open	positive air leak test
Yes	Open	extensive adhesiolysis
Yes	Multiport	extensive adhesiolysis, serosal injury
Yes	Open	extensive adhesiolysis, inadvertant enterotomy
Yes	Multiport	positive air leak test
Yes	Open	frozen pelvis
Yes	Multiport	extensive adhesiolysis, rectal stump stapeler induced injury

Appendix 9.2

Advanced search details

Search performed on pubmed.ncbi.nlm.nih.gov on 29-06-2020 for the last time

((((((single-port) OR (single-incision)) OR (laparoscopy)) OR (trephine)) OR (stoma-site)) AND (((reversal) OR (colostomy take down)) OR (restoration))) AND (((hartmann) OR (hartmann procedure)) OR (hartmann's procedure)),,,"(((((""single-port""[All Fields] OR ""single-incision""[All Fields]) OR (((""laparoscopie""[All Fields] OR ""laparoscopy""[MeSH Terms]) OR ""laparoscopy""[All Fields]) OR ""laparoscopies""[All Fields])) OR (((((((""trephinated""[All Fields] OR ""trephinations""[All Fields]) OR ""trephine""[All Fields]) OR ""trephined""[All Fields]) OR ""trephines""[All Fields]) OR ""trephining""[MeSH Terms]) OR ""trephining""[All Fields]) OR ""trephination""[All Fields])) OR ((((""surgical stomas""[MeSH Terms] OR (""surgical""[All Fields] AND ""stomas""[All Fields])) OR ""surgical stomas""[All Fields]) OR (""stoma""[All Fields] AND ""site""[All Fields])) OR ""stoma site""[All Fields])) AND ((((((((((((""reversal""[All Fields] OR ""reversals""[All Fields]) OR ""reverse""[All Fields]) OR ""reversed""[All Fields]) OR ""reversely""[All Fields]) OR ""reverses""[All Fields]) OR ""reversibilities""[All Fields]) OR ""reversibility""[All Fields]) OR ""reversible""[All Fields]) OR ""reversing""[All Fields]) OR ""reversion""[All Fields]) OR ""reversions""[All Fields]) OR (((""colostomy""[MeSH Terms] OR ""colostomy""[All Fields]) OR ""colostomies""[All Fields]) AND ""take""[All Fields] AND ""down""[All Fields])) OR ((((((((((""restorability""[All Fields] OR ""restorable""[All Fields]) OR ""restorated""[All Fields]) OR ""restoration""[All Fields]) OR ""restoration s""[All Fields]) OR ""restorations""[All Fields]) OR ""restorative""[All Fields]) OR ""restoratives""[All Fields]) OR ""restore""[All Fields]) OR ""restored""[All Fields]) OR ""restores""[All Fields]) OR ""restoring""[All Fields]))) AND ((((""hartmann""[All Fields] OR ""hartmann s""[All Fields]) OR ""hartmanns""[All Fields]) OR (((""hartmann""[All Fields] OR ""hartmann s""[All Fields]) OR ""hartmanns""[All Fields]) AND (((((((""methods""[MeSH Terms] OR ""methods""[All Fields]) OR ""procedure""[All Fields]) OR ""methods""[MeSH Subheading]) OR ""procedures""[All Fields]) OR ""procedural""[All Fields]) OR ""procedurally""[All Fields]) OR ""procedure s""[All Fields])))) OR (((""hartmann""[All Fields] OR ""hartmann s""[All Fields]) OR ""hartmanns""[All Fields]) AND (((((((""methods""[MeSH Terms] OR ""methods""[All Fields]) OR ""procedure""[All Fields]) OR ""methods""[MeSH

Subheading]) OR ""procedures""[All Fields]) OR ""procedural""[All Fields]) OR ""procedurally""[All Fields]) OR ""procedure s""[All Fields])))"
Results: 163

Filters: from 2011-2020
Results: 96

Chapter 10

Feasibility of single-port reversal of left-sided colostomy in the presence of incisional hernia; promising results

YT van Loon, SHEM Clermonts, DK Wasowicz, J Heisterkamp, DDE Zimmerman

Turk J Colorectal Dis 2021;31:149-155

Abstract

Aim

Stoma reversal in patients with concomitant abdominal wall defects can be cumbersome with the risk of many postoperative complications. Present study was conducted to evaluate feasibility and safety of single port restoration of left-sided colostomy in patients with concomitant incisional hernia.

Method

All patients with concomitant incisional hernia undergoing single-port reversal of left-sided colostomy between 2012 and 2020 were included. Primary outcomes were surgical success rate and 30-day postoperative complication rate. Secondary outcome was subsequent hernia repair after successful stoma reversal.

Results

Twelve patients were included for analysis. Single-port reversal was possible in five patients, conversion to open surgery was needed in one patient and conversion to multiport laparoscopy in six patients. There was no postoperative mortality, reoperations or anastomotic leakages. Seven patients (58%) encountered no postoperative complications, superficial surgical site infection occurred in four patients, pneumonia in one patient. Median postoperative stay was 4 (range 3-12) days. Two patients pursued hernia repair after successful stoma reversal.

Conclusions

Single-port reversal of left-sided colostomy is feasible and can be considered as an attractive alternative to open approach in patients with a colostomy and concomitant incisional hernia. It can be considered as a step-wise approach for future abdominal wall repair.

Introduction

Hartmann's procedure is often used for surgical emergencies of colorectal, gynecological or vascular nature.[1] Feared and common complications are superficial or deep site infections, wound dehiscence with subsequent laparostomy or incisional hernia, all resulting in significant morbidity and impaired quality of life. Repair of these hernias results in higher risk of postoperative complications due to the possibility of bacterial contamination.[2,3] Classic or laparoscopic stoma reversal in patients with incisional hernias cannot be performed without extensive adhesiolysis, which can be cumbersome and harbors the risk of advertent or inadvertent enterotomies, potentially resulting in enterocutaneous fistulas.[4,5] Moreover, possible contamination of prosthetic devices or dissection planes in case of mesh placement or component separation, makes simultaneous abdominal wall reconstruction unattractive due to increased infectious risks. A combined procedure with stoma reversal and complex hernia repair can result in a higher risk of anastomotic leakage.[6] These considerations result in a high threshold for stoma reversal in those patients.

Recently, a novel application of the single-port laparoscopy access system was described. By inserting this device in the abdominal fenestration of the colostomy, stoma reversal can be performed minimally invasive in a safe and controlled manner with favorable results.[7,8] By utilizing this technique, adhesiolysis of the midline is unnecessary, therefore the stoma can be reversed without extensive mobilization or adhesiolysis and moreover, without the necessity of performing simultaneous repair of the ventral hernia. The present study was conducted to assess feasibility and safety of single port reversal of left-sided colostomy (SPRLC) in patients with concomitant incisional hernia. We postulate that SPRLC is feasible and safe in patients with a left-sided colostomy combined with a moderate to complex hernia.

Materials and methods

All consecutive patients undergoing SPRLC between November 2012 and March 2020 were assessed for inclusion in the present study. During this period all stoma procedures of end colostomies were performed utilizing the single-port technique. All procedures were performed or supervised by experienced colorectal surgeons or consultants with extensive skills in laparoscopy and minimally invasive surgery.

Inclusion criteria for this study were patients with a left-sided colostomy and concomitant incisional abdominal wall hernia undergoing SPRLC. Exclusion criteria were single-port reversal of right-sided (ascending) colostomy or ileostomy procedures.

The operative procedure of the SPRLC has been described in detail previously.[7] In short, the colostomy was mobilized beyond the fascia into the abdomen and the anvil for the CDH29 circular stapler (Ethicon Endo-Surgery, Cincinnati, OH, USA) was placed in the descending colon before returning it to the abdominal cavity through the original colostomy site. A pneumoperitoneum was established after placement of the GelPOINT Path Access Platform (Applied Medical, Los Angeles, CA, USA). Where necessary, the splenic flexure or transverse colon was mobilized and adhesiolysis was performed under direct vision. Continuity was restored after adhesiolysis and proper visualization of the rectal stump with the use of the CDH 29 circular stapler. All wounds were closed intracutaneously.

All patients were treated within an established Enhanced Recovery After Surgery (ERAS) protocol. Patients were discharged from the hospital when they were able to tolerate normal food, pass stool, were able to mobilize at a level that was similar to preoperative levels of mobilization and had adequate control of pain with use of oral analgesia. Minimum follow up period consisted of 30 days postoperatively.

Patient characteristics (sex, age, body mass index), index surgery characteristics (reason for surgery and initial postoperative complications), surgical details (time

interval between index surgery and SPRLC, duration of SPRLC and conversion) were collected using the electronic patient database.

Primary outcomes were surgical success rate defined as technical success rate of single-port approach for stoma reversal and 30-days postoperative complication rate. Postoperative complication was defined as infections (surgical site, intra-abdominal abscess), urogenital complications (urinary tract infection, urine retention), ileus or gastroparesis, pulmonary complications (pneumonia, exacerbation of COPD) and blood-related complications (rectal blood loss, thrombosis or hematoma in wound or anastomosis). Anastomotic leakage, reinterventions under local or general anesthesia and intensive care unit (ICU) admission were considered major complications in this analysis. Secondary outcome was subsequent hernia repair after SPRLC.

All patients gave informed consent during outpatient clinic counseling for SPRLC. Approval of the institutional review board or ethics committee was not required because of the observational character of this study. This report was prepared in concordance with the STROBE guidelines (http://www.equator-network.org/reporting-guidelines/strobe/).

Results

A total of the 105 patients underwent single-port reversal of continuity in Elisabeth-TweeSteden Hospital, Tilburg, the Netherlands. Of them, 93 patients did not meet the inclusion criteria, for more details see Figure 10.1. Twelve patients were included in the present study; 7 men and 5 women with a median age of 60.9 years (range 27.6-76.9), median body mass index of 29.0 kg/m^2 (range 22.7-61.1) and median and mean abdominal wall defect of 120 cm^2 and 173.6 cm^2 (range 49-450) respectively. Most common indications for index surgery were complicated diverticulitis and malignancy. The mean time between the index surgery and SPRLC is approximately two years, median time was 536 (range 190-2384) days. Overview of patient characteristics and surgical and postoperative outcomes can be found in Table 10.1 and 10.2.

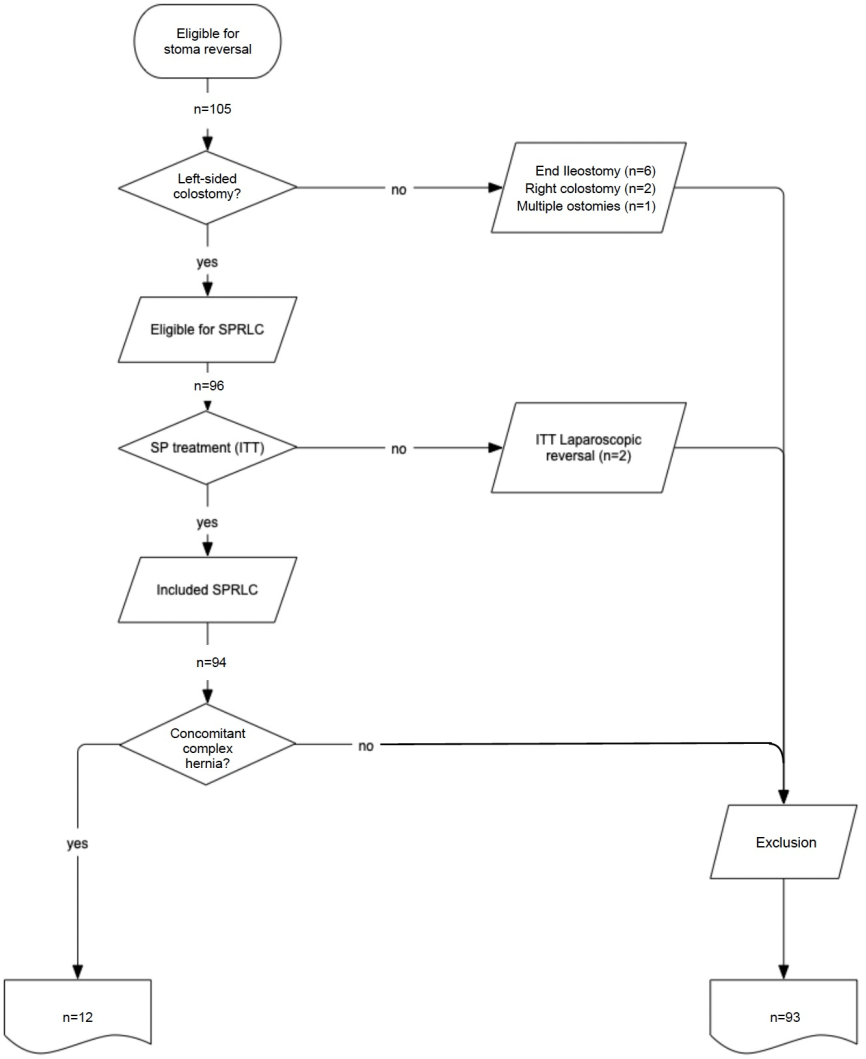

Figure 10.1 Flow chart of patient inclusion. SPRLC = Single-Port Reversal of Left-sided Colostomy, SP = Single-Port, ITT = Intention To Treat.

Table 10.1 Patient characteristics.

Number	Sex (M/F)	BMI (kg/m^2)	Age* (years)	ASA class	Indication and type of index surgery	Year index surgery	Adverse events in initial postoperative course	Dimensions abdominal wall defect[@]
1	F	26.3	66.0	3	Malignancy, open left hemicolectomy	2012	Relaparotomy for anastomotic leakage	7 x 7 cm[#]
2	F	61.1	47.3	3	Complicated diverticulitis, open sigmoidectomy	2012	Relaparotomy for anastomotic leakage, superficial and deep SSI	30 x 15 cm[@]
3	F	25.1	61.1	3	Complicated diverticulitis, open sigmoidectomy	2013	Multiple relaparotomies for wound dehiscence	18 x 13 cm[#]
4	M	24.8	65.6	1	Sigmoidvolvulus, converted sigmoidectomy	2015	Relaparotomy for anastomotic leakage, superficial and deep SSI	15 x 8 cm[#]
5	M	30.2	61.8	3	Complicated diverticulitis, open Hartmann's Procedure	2015	Superficial SSI	10 x 10 cm[#]
6	M	22.7	76.9	2	Complicated diverticulitis, open sigmoidectomy	2013	Relaparotomy for anastomotic leakage, superficial and deep SSI	8 x 15 cm[#]
7	M	32.9	59.3	3	Endovascular Aorta Aneurysm Repair	2015	Laparotomy for sigmoid ischemia, superficial SSI	20 x 17 cm[@]
8	F	30.5	72.4	2	Complicated diverticulitis, laparoscopic sigmoidectomy	2018	Laparotomy for anastomotic leakage, superficial and deep SSI	18 x 15 cm[@]
9	M	31.5	56.3	2	Malignancy, converted left hemicolectomy with stoma	2013	Superficial SSI	11 x 10 cm[@]
10	F	27.8	60.8	2	Malignancy, open left hemicolecomy with stoma	2016	Relaparotomy for stoma revision	7 x 7 cm[@]
11	M	32.1	27.6	1	Complicated diverticulitis, laparoscopic lavage	2014	Relaparotomy for Hartmann's procedure	7 x 7 cm[@]
12	M	27.8	62.2	1	Open iliac aneurysm repair	2012	Relaparotomies for trombectomy and sigmoid ischemia, superficial SSI	16 x 12 cm[@]

*Age at time of the single-port left-sided colostomy reversal. [@]Defect measured using CAT-scans. [#] Defect measured during physical examination. BMI = Body Mass Index, ASA class = American Society of Anesthesiologists Classification, SSI = Surgical Site Infection.

Table 10.2 Surgical and postoperative outcomes.

Number	Sex (M/F)	Age at SPRLC	Year SPRLC	Days until SPRLC	Surgical time (min)	Extra 5mm trocar	Reason for extra trocar placement	LOS (days)	Postoperative complication	Calvien Dindo	Hernia repair after SPRLC
1	F	66.0	2014	760	85	1	Mobilisation splenic flexure	12	Pneumonia	4	No
2	F	47.3	2015	1193	91	1	Extensive adhesiolysis	4	Superficial SSI (stoma wound)	1	Yes
3	F	61.1	2017	1294	133	1	Extensive adhesiolysis, anastomosis suture reinforcement	5	No	-	No
4	M	65.6	2016	481	128	0	-	3	Superficial SSI (stoma wound)	1	No
5	M	61.8	2015	246	128	0	-	2	No	-	No
6	M	76.9	2014	255	-	0	-	5	No	-	No
7	M	59.3	2017	706	115	1	Extensive adhesiolysis, aiding visibility small pelvis	4	No	-	No
8	F	72.4	2019	359	163	1	Extensive adhesiolysis	3	No	-	No
9	M	56.3	2015	591	174	*	-	5	Superficial SSI (both wounds)	1	No
10	F	60.9	2017	331	197	0		3	No	-	No
11	M	27.6	2015	190	149	0		3	Superficial SSI (stoma wound)	1	No
12	M	56.9	2014	508	148	2	Extensive adhesiolysis	3	No	-	Yes

* Conversion to open, SSI = Surgical Site Infection.

Surgical details

Of the 12 procedures, 42% (n=5) were technically successful by solely using the single port approach. Six patients needed additional placement of one or two 5mm trocar. Reasons for the extra trocar placement were needed for extensive laparoscopic adhesiolysis (n=5), mobilization of the splenic flexure (n=1) or for suture reinforcement of the anastomosis after positive air leak testing (n=1). Conversion to open midline laparotomy was needed in one patient due to iatrogenic injury to adhesive small bowel during placement of the single port device. All procedures were technically successful in restoring intestinal continuity. Mean duration of operation was 137 minutes (range 85-197), duration of operation was not recorded in one patient. See Figure 10.2 for photos of abdomen before and after SPRLC.

A B

Figure 10.2 A*:* picture of a patient with a left-sided colostomy and complex hernia before SPRLC, B: picture of the same patient after SPRLC.

Postoperative results

No 30-day postoperative mortality, reoperations or anastomotic leakage was encountered in these patients. Seven patients (58.3%) encountered no postoperative complications whatsoever within 30 days after surgery, five patients encountered one postoperative complication. Four patients (33.3%) developed a surgical site infection (SSI), all were treated conservatively by removing the sutures and regular wound dressings. One patient suffered from a major complication and needed ICU observation due to postoperative pneumonia and recovered without other postoperative adverse events. Median postoperative stay was 4.0 (range 2-16) days.

Hernia repair

Two patients pursued abdominal wall reconstruction due to persisting symptoms of their incisional hernias and underwent abdominal wall repair after recovery from SPRLC. One patient died due to peritoneal metastases while considering hernia repair. Most of the other patients (n=7) reported to be satisfied with their abdomen and life after SPRLC. Two patients expressed their wish to pursue abdominal wall repair for purely cosmetic reasons without symptoms of their hernia, and therefore withheld from surgery. They declined abdominal wall reconstruction after counseling and shared decision making.

Discussion

This study shows that SPRLC is a feasible, safe and effective technique for stoma reversal in patients with a left-sided colostomy and a concomitant incisional hernia. Median length of stay is short with 4.0 days (range 2-16 days), there was no anastomotic leakage or need for reoperations or reinterventions. Postoperative complication rate was acceptable. Postoperative pneumonia was the only major complication in this study, which is considered inherent to intra-abdominal operations and not specifically linked to the use of the single-port approach. We

believe that the minimally invasive character of these procedures resulted in the short postoperative length of stay and low postoperative morbidity. To the best of our knowledge, this is the first study evaluating the single-port approach reversing left-sided colostomy in patients with concomitant incisional hernia.

Upon reviewing available literature, reported postoperative complication rates of reversal of left-sided colostomies vary between 3–50%,[4,9,10] most common complication is SSI in over 25% of the patients.[11] Although no differences are found in postoperative mortality after laparoscopic or open reversal of left-sided colostomy (which can be up to 5%), laparoscopic approach results in lower postoperative minor and major complications such as SSI, cardiopulmonary complications, anastomotic leakage and need for reoperations.[11] Furthermore, it is important to appreciate the difference in severity of SSI of the former stoma fenestration, which is relatively small compared to SSI of a laparotomy wound. Moreover, SSI of laparotomy wound in the presence of prosthetic devices or after component separation can have catastrophic results.

Complex hernias have great impact on perceived quality of life[12] No investigations are available that show whether the presence of a hernia, the presence of a stoma, or the combination of the two are most bothersome. Many patients pursue repair, however, because of the high rates of postoperative morbidity, most surgeons are hesitant to offer restorative surgery. We found a surprising low rate of subsequent hernia repair after SPRLC in merely two patients so far. This may suggest that patients suffer more from the presence of the colostomy (albeit combined with the hernia) than from the hernia per se. This may be an interesting avenue for further research.

Complex hernias are challenging and difficult to repair – the optimal reconstructive strategy remains unclear.[13] Some studies have shown that concomitant stoma reversal with hernia repair can result in unacceptable high rates of postoperative morbidity and increased length of hospital stay compared to patients without stoma reversal.[6,13] Either mesh infection or refraining from mesh enhancement

might lead to higher recurrence rates and postoperative complications compared to two separate procedures. After successful stoma reversal, the abdominal wall can be restored with optimal mesh reinforcement without the possible risk of contamination. Therefore single-staged reversal of the complex hernia and stoma reversal might not be advised as primary choice of treatment.

We postulate that by using the single-port approach, stoma reversal is possible without dissection of the midline and therefore without the necessity to repair the incisional hernia during the same procedure. SPRLC results in lesser adhesiolysis, shorter duration of the procedures and thus reducing the patients' surgical trauma. All these factors result in lower rates of postoperative morbidity compared to conventional open procedures.[7,8] After successful restoration of continuity, the patient can subsequently choose whether or not additional reconstruction of the abdominal wall is desirable, without the additional risk of the presence of the stoma or stoma reversal.

The small number of patients in this study is a major limitation. Neither were we able to compare our results to open stoma reversal procedures in patients with incisional hernia, also due to the very specific character of this small subgroup of patients. In our opinion, open stoma reversal with or without hernia repair is not desirable and is not our primary approach. Our experience with open stoma reversal with concomitant repair of incisional hernia is therefore limited.

The results of this new technique show favorable results in postoperative complication rate and length of stay, thus lowering our threshold to offer this approach in our patients with a stoma combined with abdominal wall defects. We believe that the single-port approach is a feasible and effective solution for stoma reversal in patients with left-sided end colostomy with a complex hernia. SPRLC could be part of the staged treatment for patients with incisional hernia and colostomy and could be safely offered and performed by (colorectal) surgeons with sufficient laparoscopic experience. Further research should be done to evaluate the

results in a larger cohort and to evaluate the applicability of this technique for the reversal of other types of stomas.

Conclusion

Single-port reversal of left-sided colostomy is feasible and can be considered as a serious and attractive alternative to an open approach in patients with a left-sided end colostomy in the presence of concomitant incisional hernia. It shows promising results in postoperative complication rate and length of stay and can be safely offered and performed by surgeons with sufficient laparoscopic experience.

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Chapter 11

General discussion and summary

General discussion and summary

There are about 32.000 patients with a permanent stoma in the Netherlands (0.2% of the population) and approximately 7000 stomas are placed each year.[1] These new stoma patients face significant physical, psychological and body image adaptation with loss of personal physical function.[2] Besides these adaptations, new stoma patients also have to face the burden of the considerable stoma related morbidity which can occur in up to 80% of the stoma patients.[3]

Worldwide, there is a growing awareness for innovation (e.g. single-port surgery), quality of life (QOL, e.g. increasing patients autonomy or independence), reducing morbidity (e.g. complications or readmissions) and health care costs (e.g. home care nursing services, length of stay) in all aspects of health care including colorectal surgery.[4] The scope of this thesis was to investigate these challenges and clinical aspects in the context of stoma use and stoma-related morbidity in colorectal surgery.

Part I focusses on postoperative results in stoma patients after colorectal surgery for benign and malignant causes.
Our views and treatment for perforated or complicated diverticulitis have changed over time. Even though advancing technologies and insights have introduced different treatments such as intra-abdominal lavage and definitive treatment with a primary anastomosis as feasible therapeutic options,[5] a Hartmann's procedure (HP, a (recto)sigmoid resection with formation of an end colostomy) continues to be a valuable procedure in the management of complicated diverticulitis to this day.[6] In **Chapter 2** we evaluated over a decade-long single center experience of emergency surgical treatments in complicated diverticulitis. Between 2007 and 2018, we studied 106 patients who underwent emergency sigmoidectomy (HP or sigmoidectomy with primary anastomosis with or without deviating ileostomy at the surgeon's preference), who were categorized in 3 time-groups: 2007-2010, 2011-2014 and 2015-2018. The majority of the patients underwent an emergency HP, overall mortality rate was 4.8%, complication rate 66.3% and median length of

stay 9.0 days. A significant rise in laparoscopic sigmoidectomy procedures was seen, resulting in 92.5% intended laparoscopic procedures from 2015 on as compared to 0% in 2007-2010 and 50.0% in 2011-2014 (p<0.001). Over time significant decrease was seen in postoperative morbidity (from 68% to 55%, p=0.01), in surgical site infections (SSI, from 32% to 15%, p=0.001) and in length of stay (LOS, from median 16.0 days to 8.0 days, p<0.001). A trend towards higher odds of intra-abdominal abscess was seen (from 12% to 18%), even though this was not statistically significant and one can argue it's clinical importance. Important to note is that reinterventions did not show an increase (20% to 13%) over time. Of HP patients, 72% underwent stoma reversal surgery, which is in line with the available literature on this subject. This is a single center evaluation of surgical outcome after emergency sigmoidectomy for perforated diverticulitis. Even though it is a retrospective observational study, which is an obvious limitation, we report real-world data in a field where randomized controlled trials are often ended prematurely due to the difficulties in enrolling patients in the emergent setting. Other limitations are present. One is the relatively small number of patients. Another is the fact that certain bias exists since the choice for HP or anastomosis was left at the surgeon's discretion. Time influence may be present as the study was performed over a longer period with increasing laparoscopic expertise and ERAS adherence over time. Also, the fact may play a role that the center is one with a dedicated colorectal surgical ward with surgeons with a preference for HP due to favorable results of single port Hartmann's reversal (intermezzo and chapter 8). These factors mean that the results should be interpreted with caution as should the extrapolation to other hospitals.

Stomas are not only used in emergency colorectal surgery for benign disorders; they are also widely accepted and propagated in elective colorectal cancer (CRC) surgery. As mentioned before, up to 35% of the Dutch elderly patients still receive an ostomy after colorectal cancer surgery.[1] The retrospective Dutch Total Mesorectal Excision trial showed a mortality rate of 57% in elderly patients compared to 8.2% in younger patients once there is an anastomotic leakage (AL).[7] Eliminating the risk of AL, its related morbidity and mortality could be important

motives for both patients and surgeons to choose for a stoma in the elderly. Nevertheless, according to the ACS NSQIP (American College of Surgeons National Surgical Quality Improvement Program) Surgical Risk calculator, this population benefits from less postoperative morbidity and mortality after a primary anastomosis (PA) compared to an end-ostomy (EO).[8] Unfortunately, there is no Dutch or European equivalent of this risk calculator available for CRC surgery. More information, therefore, on the use and effect of stomas can be useful in preoperative patient counseling and shared-decision-making. **Chapter 3** focusses on the postoperative results and survival after CRC surgery in the elderly patient, comparing the outcomes of patients with PA compared to those with EO. Data from the Netherlands Cancer Registry (NCR) were used. Patients aged ≥75 years with stage I-III left-sided colon cancer or proximal rectal cancer, diagnosed in 2015-2017 and who underwent surgical resection of the tumor (n=3286) were included and categorized in PA and EO groups. A subsample was created using propensity score matching (PSM), to reduce treatment assignment bias and create comparable groups. The propensity score represented the probability that a patient would receive an EO. Patients with higher age, ASA score and tumor stage, a perforation, ileus or a tumor located in the proximal rectum and that underwent open or converted surgery were more likely to receive EO. Postoperative LOS was longer (7.0 versus 6.0 days, $p<0.0001$) and more often prolonged (19% versus 13%, $p=0.03$) in EO patients. Sixty-day mortality (2.9% versus 6.4%, $p<0.0001$), 90-day mortality (3.4% versus 7.7%, $p<0.0001$) and crude 3-year survival (81.2% versus 58.7%, $p<0.0001$) were significantly different in disadvantage of EO patients, remaining significant after univariable, multivariable and PSM analyses. Even though the impact of an ostomy on QOL in the elderly patients has been reported before,[1,9] little is known about the impact of an ostomy on the survival of elderly patients after CRC surgery. Possible stoma related complications or reoperations, worsened QOL or mental status and social isolation, could be detrimental for the elderly patient and possibly a cause for the significantly higher 60- and 90-day postoperative mortality that we found in the elderly EO patients. Various factors, that may or may not be obvious, possibly detected at the initial out-patient assessment, might have led to the surgeons' choice for an EO instead of an

anastomosis, which could have led to a certain bias. This study is also limited due to its retrospective, observational character and by the fact that occurrence of complications (other than anastomotic leakage and abscess) and causes of death are not registered in the NCR. Relative survival was used in an effort to match cancer-specific survival as an estimation. This unfortunate shortcoming in the NCR data leaves several unknowns in our search for the exact causes of the survival differences in our elderly patients.
The downside of using PSM analysis is that the exclusion of patients from this analysis leads to loss of power. Despite the limitations of this study, one of its strengths is that it is based on the most comprehensive nationwide cancer registry with survival information we have in the Netherlands. It shows real life data and is a representation of our national elderly population with CRC. Since there is significant difference in short-term mortality and overall and relative survival between patients with PA or EO, one might advocate that it is advisable to try to avoid the use of EO in elderly patients with left sided colon and proximal rectal cancer, regardless of the comorbidities, age or tumor stage. However, more research should be done to explore if and how surgeons assess frailty, the role frailty has in surgical decision-making, the occurrence of postoperative complications and their relation to (disease free) survival in the elderly.

Another well-known entity is the deviating stoma (DS) in elective rectal cancer surgery. An ileostomy is advised and considered beneficial in an effort to prevent or attenuate the possible postoperative morbidity and mortality of a distal anastomotic leakage and reduce its re-operation rates.[10-15] A benchmark analysis of the results in new ileostomy patients in our hospital showed unacceptably high rates of postoperative morbidity and complications.[16] Also, a remarkable large variation from 0-100% use of DS between Dutch hospitals was shown, suggesting that the use of DS is not believed to necessarily lead to better outcomes and therefore, rightfully questioning if we should be 'chickens' (routine diversion) or 'cowboys' (highly selective diversion).[17] This, in combination with a growing body of literature about the disadvantages of ileostomies, have led to a paradigm shift in use of DS in our daily practice which is evaluated in **chapter 4**. All patients surgically

treated for rectal cancer with a rectal resection with PA at our hospital between 2012 and 2019 were included and analyzed. Patients were categorized in two different time periods from 2012-2015 (group A, diversion per protocol) and 2016-2019 (group B, highly selective diversion). A total of 247 patients (m:f 154:93, median age 65.3 years [34.1-83.0], median BMI 25.7 [16.2-44.1]) were included (group A n=116, B n=131), a total of 94 patients received DS (66% vs 13%, p<0.001). Notable reduction was seen in complications (43% vs. 26%, p=0.005) and median LOS (6 vs. 4 days, p<0.001) in favor of group B. No differences in AL (12.1%), mortality (0.8%) and reoperation rates (13.4%) were seen between the groups. One year stoma free survival was better in group B compared to group A (95.4% vs. 87.1%, p=0.022). Complication rate after stoma reversal surgery was 19.2% with 1.0% mortality. Discontinuing the standard use of DS was a major significant surgical change in the evaluated timespan. Other important factors which influenced surgical decision-making and quite possibly our postoperative results, are the increased skills of the colorectal surgeons in minimally invasive rectal surgery and the change in the Dutch colorectal treatment guideline in 2014, advocating a more restrictive use of neoadjuvant radiation therapy in rectal cancer patients.[18] These factors could all be considered as beneficiary contributions in the observed decrease in surgical and postoperative complications and therefore as possible confounders. Its observational character without case matching, the impossibility to decipher the reasons for DS in the highly selective diversion group are major limitations in this study. Ultimately, this analysis has evaluated the use of DS and its results in rectal cancer surgery in a single center, where a demonstrable paradigm shift has occurred in the use of DS. This change did not result in adverse effects in postoperative complications in patients without DS in the age of laparoscopic surgery and restricted neoadjuvant radiation therapy. This suggests that in the present era creating a DS is not a conditio sine qua non in case after rectal cancer surgery with anastomosis. However, these results should be verified in other centers where highly selective deviation is also applied, possibly using nationwide data. These insights could be of help for surgeons to re-evaluate the presumed benefits of using DS in rectal cancer surgery in the current practice.

An important factor to keep in mind is that new stoma patients, especially ileostomy patients, face the chance of significant morbidity. This includes dehydration, electrolyte abnormalities, and high rates of readmission, leading to an increased utilization of resources and a decrease in patient satisfaction.[19-22] Besides frequent readmissions, patients also encounter difficulties with stoma management, a loss in QOL, lower physical and social functioning, lower global health status, and a worsened body image.[9,23] The patients' inability to independent self-management of stoma care (SC), their need for information, emotional support, and continuous nursing assistance in their SC, make them very dependent on ostomy nurses and allied health personnel.[24,25] All of this results in a significant social and financial burden for patients and society.[26] **Part II** of this thesis explores easily implementable changes in our daily practice in the form of pathways and their effectiveness in reducing some of the well-known stoma-related problems. The care of patients with stoma can be perceived both as an art and a science, as many of the commonly accepted interventions in stoma management are based on empirical evidence supported by little or no objective data.[24] However, merits of clinical pathways have been reported before and are widely accepted. Pathways are designed and capable to improve the quality of care, patient satisfaction and optimal efficiency in the use of resources.[27,28]

In **chapter 5** we evaluate the efficacy and durability of an ileostomy pathway in an effort to reduce readmission rates for dehydration in new ileostomy patients. Dehydration continues to be one of the main issues that new ileostomy patients are facing.[21] The Beth Israel Deaconess Medical Center (BIDMC) Ileostomy Pathway was introduced in an effort to decrease the high rates of readmissions for dehydration in new ileostomy patients.[29] A total of 393 patients (male n=195, female n=198, median age 52 [18-87] years) in whom a new ileostomy was created between January 2007 and January 2015 were included. The patients were divided into 2 groups: 161 pre-pathway (January 1, 2007 until February 28, 2011) and 232 on-pathway (March 1, 2011 until January 31, 2015). Overall, 30-day post-discharge readmission rates decreased from 35.4% to 25.9% (p=0.04). Readmissions due to high output and/or dehydration dropped from 15.5% to 3.9% (p<0.001).

Readmissions due to small bowel obstructions dropped from 9.9% to 4.3%, (p=0.03). This study has shown that the ileostomy pathway continues to be effective and successful in reducing readmission rates in general, as well as the readmission rates for dehydration. Although the pathophysiology of high output ileostomy may vary, dehydration and subsequent readmission may be managed and prevented by this simple pathway. Proactive intervention and education may reduce the rates of complications for new ileostomy patients. Moreover, the lack of postoperative ostomy education might be an independent risk factor for readmission in new ileostomy patients.[30] Structured patient education aimed at their individual needs has been shown to have a positive effect on the QOL, the LOS and on health care costs.[31] It might be worthwhile to consider introducing this pathway in other clinics, where problems with readmissions due to dehydration exist.

Chapter 6 focusses on new stoma patients' inability to demonstrate independent SC, which leaves them dependent on the assistance of nursing staff and home nursing care services (HNCS) after discharge. An easily executable 4-day in-hospital educational stoma pathway was developed and implemented in an effort to increase their level of independence (LOI) and need for HNCS. All new stoma patients on the gastrointestinal surgery ward, physically and psychologically capable to perform independent SC, were enrolled in this pathway. They were compared to a retrospective control group of new stoma patients before the onset of the stoma pathway. Patients requiring daily HNCS for SC decreased from 80% to 50% ($p<0.001$), patients discharged without HNCS for SC increased from 5% to 27%. Patients' independence in SC at discharge increased from 8% to 68% ($p<0.001$). This study shows that a clinical 4-day in-hospital educational stoma pathway is feasible and effective in increasing the LOI in SC of new stoma patients and significantly reducing their need for HNCS. This in-hospital educational stoma pathway is not only easily implementable, the impressive beneficiary effects are also reproducible in other Dutch hospitals, as is described in **chapter 7**. A prospective longitudinal study was conducted between July 2018 and February 2020 at a tertiary referral hospital. Patients following this perioperative stoma

educational pathway were compared to a historical control group. After discharge, 67.6% of the patients in the intervention group (n=244) were able to independently perform SC and were therefore not relying on HNCS, compared to 15.2% of the patients in the control group (n=33) ($p<0.001$). These results indicate that the perioperative stoma educational pathway is not only easy to implement and execute, but also effective in both a different patient population and in a different hospital setting. However, additional research is needed to further substantiate the advantages of this educational pathway, focusing on the impact on cost-effectiveness and improved QoL of new stoma patients.

Despite the introduction of modern surgical techniques, HP reversal surgery after convalescence time is still challenging. It Is related with high rates of morbidity and even mortality, which are the main reasons why many surgeons are reluctant to perform stoma reversal surgery.[32-35] **Part III** explores the challenges and difficulties in stoma reversal surgery and especially how the use of the single-port (SP) approach can be beneficial compared to already existing techniques. In the ongoing quest to find the optimal technique for reversal of HP, several laparoscopic, hand assisted and SP techniques have been described.[36] Laparoscopic reversal of HP was introduced in 1993 and was shown to have advantages over classic open reconstruction.[37,38] Even though laparoscopy has its merits and positive effects, technical difficulties of this approach must be acknowledged, especially after open index surgeries with peritonitis. Trocar insertion, adhesiolysis of intra-abdominal or midline adhesions can be hazardous and possibly result in surgical calamities and ultimately conversions. SP approach makes it possible to avoid midline adhesiolysis, especially advantageous in patients with a laparostomy, multiple laparotomies or severe wound infection in their medical history and is considered one of the merits of this technique.[39] Our previous study showed that the SP technique is feasible, also resulting in shorter hospital stays and significant reduction of postoperative complications as compared to classic open HP reversal.[39]

SP reversal of a left-sided colostomy (SPRLC) can be used as a step-up approach by restoring the intestinal continuity with low morbidity rates and avoiding a

laparotomy or extensive adhesiolysis in those patients with complex abdominal wall defects to minimize their contamination before their subsequent (complex) hernia repair. **Chapter 8** evaluates the results of implementing and standardizing (consolidating) SPRLC in a single center setting in 85 patients. The majority of the patients was male (m:f = 56:29) with a mean age of 60.5 (range 25.5-85.0) years, 70% were without postoperative complications, and no postoperative mortality was encountered. Most frequent complication was SSI (22%). Median LOS was 3.0 days, SP reversal success rate was 65%. Minimally invasive approach without conversion to laparotomy was successful in 85% of the cases; it was feasible in 78% of the patients who underwent open index surgery.

Chapter 9 explores the experiences of using SPRLC in four different hospitals across different countries in Europe and gives a comprehensive overview of the literature on the use of the SP approach in the reversal of a left-sided colostomy. Of 156 SPRLC procedures, 99% received an anastomosis and 72% were without postoperative complications. No postoperative mortality was encountered. SSI occurred in 14.7%, anastomotic leakage in 3.9% and reinterventions in 7.7% of the patients. Median LOS was 4.0 days [range 1-69], single-port success rate was 64.7%. 12.8% and 21.2% respectively were converted to an open and multiport laparoscopic procedure. At this moment no randomized controlled trials between the different approaches (open, laparoscopic or SP) are published. Literature shows that patients selected for SPRLC concern mainly patients after laparoscopic index surgery 53.4% [range 34-72.2]). It also shows that SP approach seems safe and feasible with high success rates, low morbidity (12.5%-30.4%) and mortality (1.8%-2.2%). Major complication rate is also low, varying from 0% - 8.9%, and median LOS is between 4 and 8 days. SPRLC not only seems to be a safe and feasible procedure, it also leads to equal or even better results with some major advantages compared to conventional open or laparoscopic stoma reversal procedures. In centers with adequate laparoscopic experienced (colorectal) surgeons, this technique could be considered as a serious and attractive alternative to restore intestinal continuity in patients with left-sided EO, especially in patients after open index surgery. This study is limited by the differences in number of

patients in the different groups and a certain selection bias is possible. The included centers are known for their dedicated colorectal units with surgeons trained in minimally invasive surgery. The results from this study can therefore not be extrapolated to any stoma patient after HP or to hospitals without adequate laparoscopically experienced colorectal surgeons.
Randomized studies would seem a logical further step to identify relevant differences between the SP technique and other minimally invasive techniques. Depending on the primary endpoint that would be chosen, possibly a high number of patients would be needed. This, but also the surgeon's preference will hamper this research design. Obtaining real-world data from a prospective observational study may be preferable and more obtainable. Such design also overcomes the major problem of RCT's that many of the eligible patients are not included, severely hampering the generalizability of results. Focus points of other additional research could be the implementation in specialized centers and evaluation of training and learning curve effects of the single-port approach.

Chapter 10 explores the feasibility and results of using the SPRLC in 12 patients with concomitant complex abdominal wall defects. This study shows that SPRLC is possible without midline adhesiolysis and therefore without the necessity to repair the incisional hernia during the same procedure with favorable results in postoperative complication rate (no mortality, reoperations or AL) and LOS (median 4 days). This lowers our threshold to offer this approach to patients with a stoma combined with abdominal wall defects. This technique might prove to be a valuable step-up approach in those patients when pursuing hernia repair, in an effort to reduce their possible postoperative morbidity by eliminating contamination due to their stoma out of the equation. The limitations of this study are its retrospective observational character and the very limited sample size. This makes it difficult to draw definitive conclusions whether the SPRLC approach is feasible in all stoma patients with concomitant abdominal wall defects and its role in the work-up or treatment for stoma patients pursuing hernia repair.

This thesis consists of retrospective observational and mostly single-center data analyses. These studies are known for their disadvantages such as an inferior level of evidence compared with prospective studies, certain selection or misclassification bias, confounding and difficulty to determine certain conclusions or causation. Even though this makes it difficult to draw definitive conclusions that are applicable in every surgical practice, findings from a large specialized center should not be casually disregarded. Real-world-data play a major role in current decision making and modern coloproctology should incorporate assessment of achieved clinical results; preferably within PDCA-oriented improvement programs. Moreover, some chapters contain analyses in data over a longer period of time in which a potential effect of time on the results cannot be denied. The benefits of prolonged assessment of clinical results, as well as the detection of time trends are however imperative in adequate patient information and further development of clinical care as well as hypothesis forming for further research.

Future perspectives

Colorectal surgery is ever-changing and evolving, with rapidly expanding technical innovations. Despite many innovations in the surgical world in the past decades, temporary and permanent stomas are still commonly used in elective and emergency gastrointestinal surgery. The future should focus on the critical appraisal of the use of stomas, while taking into account their presumed benefits compared to the known stoma related morbidity.

1. The first step in decreasing stoma-related morbidity is by decreasing the number of unnecessary stoma patients.

The pace of population ageing is much faster than in the past; elderly and frail patients are rapidly becoming the new challenges in colorectal surgery. In contrary to popular belief, those elderly patients might not necessarily benefit from a stoma. Our nationwide observational analysis in chapter 3 shows that they suffer from a worsened short-term and long-term survival, even after correcting for the available confounders. These findings should be further confirmed and analyzed in a prospective, multicenter setting in dedicated colorectal units with experience in minimally invasive surgery and in treating the geriatric patient population. More information is needed regarding how frailty combined with a stoma impacts postoperative outcomes, possible complications and survival. Our hopes are vested in the development of a surgical prediction model for colorectal surgery for the elderly patient, focusing on which patients would benefit from surgery and which patients would benefit from a stoma. Collaboration and connection between the data of the Netherlands Cancer Registry and the Dutch ColoRectal Audit would certainly aid further research on this subject. This is important in the clinical practice, will change our surgical decision making and reduce the number of unnecessary elderly stoma patients.

The paradigm shift in the use of deviating ileostomy in rectal cancer surgery described in chapter 4 could also result in reducing unnecessary stoma patients.

The next step would be to evaluate possible differences in hospital policies across the country and between countries, especially in this time and age where laparoscopy, organ sparing treatments and restrictive neoadjuvant radiotherapy are the new golden standards in rectal cancer surgery. One can imagine that many hospitals are still routinely using deviating stomas in rectal cancer surgery, holding on to policies based on evidence and practices from a different timeframe and different surgical treatments, without challenging or questioning these dogmas. Preparations for these nationwide analyses and evaluations are in progress by our research group. The results of these analyses will help colorectal surgeons substantiate and better understand the value of a deviating stoma in rectal cancer surgery.

2. Decreasing the incidence of anastomotic leakages will also decrease the number of stoma patients and therefore decrease the burden of stoma related morbidity.

Anastomotic leakage (AL) rates after rectal cancer surgery in the Netherlands are as high as 20% and have not decreased over the past few decades.[40] A multitude of registration and intervention studies and innovative surgical techniques are trying to understand the risk factors and etiology of AL, and to reduce the total incidence of this terrible sequel. The multiple treatment strategies for an encountered leak and the different ways and time frames in which AL can become symptomatic, only adds to the range of complexity of this problem. New technical innovations have been introduced these past years in an effort to eliminate the incidence and the sequelae of AL.[41] Some of these promising innovations are the implementation of the transanal TME technique, integrating the transanal technique with a single stapled anastomosis[42], the use of intraoperative fluorescence imaging[43] and the use of a ghost or virtual ileostomy after rectal cancer surgery.[44] Besides these, current studies such as the TENTACLE-Rectum[45] and IMARI[46] will surely be important steps forward in providing the evidence-base for recommendations of the treatments of AL. It is our hope that these continued endeavors will substantially reduce the burden of AL and AL-related problems in rectal cancer surgery.

3. Results from randomized controlled trials are not enough; we need other types of research such as real-world data to fill the gap between trial results and current clinical practice.

The growing awareness of the negative impact surgery can have on our patients has led to a steady increase of the use of minimally invasive surgery and even withholding surgery altogether. Treatments for complicated diverticulitis evolved further from open emergency surgery to laparoscopy to the use of percutaneous drainage, to even conservative treatment with antibiotics and careful close observation in a specific subset of patients.[47] Many efforts have been made the past decades to find the most optimal treatment strategy for diverticulitis in randomized controlled trials, which unfortunately are often prematurely ended due to treatment calamities or the inability to enroll enough patients.[48-50] This sheds light on the complexity of including the intended patient population and therefore on reporting on important clinical outcomes in the eligible patients and validating our (surgical) treatments. This is not only true for complicated diverticulitis, but for a variety of surgical problems such as the treatment of acute left colonic obstruction, recurrent hemorrhoidal disease, complex peri-anal fistulas, use of preoperative mechanical or oral bowel preparation and many more. Our "golden standard" randomized controlled trials (RCT) are expensive, difficult to carry out in terms of patient inclusion, (double) blinding or placebo and often the victim of selective patient inclusion. The results are therefore often hard to reproduce and the conclusions can lack generalizability to the real-world clinical practice due to the strict patient inclusion criteria which differs from the patients we see and treat in our daily practice. Many important clinical questions regarding the surgical treatment of complicated diverticulitis remain therefore unanswered.[51]

The growing awareness of the shortcomings of the RCT in surgery is not new, and has been pointed out two decades ago.[52] The difficulties of RCT's have led to an increase in the use of observational, cross-sectional (snapshot) studies with real-world data (RWD) and real-world evidence.[53] For now, RWD offer crucial insights of already known or widespread treatment modalities, their applicability and results.

Only time will tell if our conception regarding “high level” evidence will remain and if RWD is able to fill the evidentiary gaps or the unanswered clinical questions that RCT’s have left behindOur hopes are vested in the stepped wedge cluster design approach, which might possibly be a suitable type of research to help us answer these important clinical questions

4. It is our duty to provide education and guidance for new stoma patients with easily implementable stoma pathways that reduce stoma-related morbidity.

A little goes a long way, big results can come from seemingly small changes in every day practice. This is specifically true for easily implementable pathways for stoma patients and has been shown in chapters 4 -7.
It is our hope that these stoma pathways will be adopted throughout the Netherlands and -in our opinion- should be considered as an integral part of the Enhanced Recovery After (Stoma-)Surgery protocols. These pathways are easily adjusted to local protocols and habits and they have shown to be successful over time and in different hospitals. A possible cost reduction of 12 million euros per year was calculated as a result of the decrease of home care nursing services, if all new stoma patients in the Netherlands were enrolled in an educational stoma pathway.[54] Transparency of health care costs and collaboration with health care insurance companies would be huge steps forward in the process of improving our care for (new) stoma patients.

Internet and social media platforms have made significant impact in connecting surgeons (and patients) worldwide, gaining more insight and knowledge, improving education and patient care.[55] This combined with new applications of technology such as smartphone applications[56], teleconsultation or telemedicine[57], will only continue to influence how patients use our health care system, undergo treatments and show new ways to provide guidance for our (stoma) patients.

5. When pursuing stoma reversal surgery, the surgeon should choose the approach with the least morbidity and (if possible) use the single-port approach.

When discussing stoma-related morbidity, it is necessary to include the risks and complications that stoma reversal surgery harbors. It is well known that these types of surgeries are not without complications or morbidity. Our research group has reported the feasibility, the safety and the merits of the single port reversal of left-sided colostomy compared to the conventional open approach (intermezzo and chapter 8). It has favorable postoperative results and is also applicable in patients with concomitant abdominal wall defects (chapter 10). These advantages are important considerations for a surgeon when offering and discussing stoma reversal surgery with their patients. A surgeon with adequate laparoscopic experience should always attempt to use minimally invasive surgery when performing stoma reversal surgery and preferably the single-port approach. It is our hope that the single-port approach will be considered the new "golden standard" or primary approach of choice within the colorectal surgical society.

It is also worth mentioning that increased experience in minimally invasive surgery has led to ancillary use of new surgical techniques. The application of the TaTME technique resulted in transanal colostomy reversal with laparoscopic assistance with favorable results.[58] The preliminary results of using the robot in stoma reversal seems to be safe and feasible with promising results.[59] There will surely be more surgical innovations in efforts to improve the outcomes of stoma reversal surgery. We are convinced that minimally invasive surgery has become the foundation of today's surgical practice in gastrointestinal surgery and that it will further develop into our new normal.

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Dutch summary

Dutch summary

Er zijn in Nederland ongeveer 32.000 patiënten met een permanent stoma (0,2% van de bevolking) en er worden jaarlijks ongeveer 7000 stoma's geplaatst. Deze nieuwe stomapatiënten worden geconfronteerd met aanzienlijke aanpassingen van hun lichaam en psychologische toestand. Naast deze aanpassingen, worden nieuwe stomapatiënten ook geconfronteerd met de aanzienlijke stoma-gerelateerde morbiditeit die in tot 80% van de stomapatiënten kan voorkomen.

Wereldwijd is er een groeiend bewustzijn voor innovatie (bijv. single-port operaties), kwaliteit van leven (QOL, bijv. door vergroting van de autonomie of onafhankelijkheid van patiënten), vermindering van morbiditeit (bijv. complicaties of heropnames) en zorgkosten (bijv. verblijfsduur en gebruik van zorg) in alle aspecten van de gezondheidszorg, zo ook de colorectale chirurgie. Doel van dit proefschrift was om deze uitdagingen en klinische aspecten te onderzoeken in de context van stoma's en stomagerelateerde morbiditeit bij colorectale chirurgie.

Deel I richt zich op postoperatieve resultaten bij stomapatiënten na colorectale chirurgie voor benigne en maligne oorzaken. De Hartmann-procedure (HP, een (recto) sigmoidresectie met eindstandig colostoma) blijft tot op de dag van vandaag een belangrijke en veel toegepaste procedure bij de behandeling van gecompliceerde diverticulitis. In **hoofdstuk 2** hebben we de resultaten van spoedoperaties bij gecompliceerde diverticulitis van een centrum geëvalueerd. Tussen 2007 en 2018 waren er 106 patiënten die een sigmoïdresectie ondergingen (HP of sigmoïdresectie met primaire anastomose met of zonder ileostoma, afhankelijk van de chirurg), verdeeld over 3 tijdsgroepen: 2007-2010, 2011-2014 en 2015-2018. De meerderheid van de patiënten onderging een spoed-HP, totale sterftecijfer was 4,8%, complicatiepercentage 66,3% en de mediane opnameduur 9,0 dagen. Er was een significante stijging van het aantal laparoscopische procedures: 92,5% vanaf 2015, vergeleken met 0% in 2007-2010 ($p<0,001$). Na verloop van tijd werd een significante afname gezien in postoperatieve morbiditeit

(van 68% tot 55%, p=0,01), in postoperatieve wondinfecties (SSI, van 32% tot 15%, p=0,001) en in opnameduur (LOS, vanaf mediaan 16,0 dagen tot 8,0 dagen, p<0,001). Een trend naar toegenomen intra-abdominaal abcessen was zichtbaar (van 12% tot 18%, p=ns). Belangrijk om op te merken is dat er geen toename van re-interventies was in de loop van de tijd (van 20% tot 13%). Van de HP-patiënten onderging 72% een stoma hersteloperatie, dit komt overeen met de beschikbare literatuur over dit onderwerp. Hoewel het een retrospectief observationeel onderzoek is, rapporteren we “real world data”, waar gerandomiseerde onderzoeken op dit onderwerp vaak voortijdig worden beëindigd vanwege de moeilijkheden bij de inclusie van patiënten of vanwege complicaties.

Stoma's worden ook gepropageerd bij electieve colorectale kankerchirurgie (CRC). Zoals eerder vermeld, krijgt tot 35% van de Nederlandse oudere patiënt nog steeds een stoma na CRC-chirurgie. Uit retrospectieve Nederlandse studies bleek een sterftecijfer van 57% bij oudere patiënten vergeleken met 8,2% bij jongere patiënten zodra er een naadlekkage was na rectumresecties. Het wegnemen van het risico op naadlekkage en de daarmee samenhangende morbiditeit en mortaliteit kunnen belangrijke redenen zijn voor zowel patiënten als chirurgen om te kiezen voor een stoma bij ouderen. Desalniettemin profiteert deze groep volgens de ACS NSQIP (American College of Surgeons National Surgical Quality Improvement Program) risicocalculator van verminderde postoperatieve morbiditeit en mortaliteit na een primaire anastomose (PA) in vergelijking met een eindstandig stoma (EO). Helaas is er geen Nederlands of Europees equivalent van deze risicocalculator beschikbaar. Meer informatie over het gebruik en het effect van stoma's kan daarom nuttig zijn bij preoperatieve patiëntbegeleiding en gedeelde besluitvorming. **Hoofdstuk 3** richt zich op de resultaten en overleving na CRC-chirurgie bij oudere patiënten, waarbij de uitkomsten van PA-patiënten worden vergeleken met EO-patiënten. Er is gebruik gemaakt van gegevens uit de Nederlandse Kankerregistratie. Patiënten van ≥75 jaar met stadium I-III linkszijdig coloncarcinoom of proximaal rectumcarcinoom, gediagnosticeerd in 2015-2017 en die een operatie ondergingen (n=3286), werden geïncludeerd en ingedeeld in PA- en EO-groepen. Er is gecorrigeerd met behulp van propensity score matching

(PSM), met als doel eventuele vertekeningen door de behandeling te verminderen en vergelijkbare groepen te creëren. De propensity score vertegenwoordigde de kans dat een patiënt een EO zou krijgen. Patiënten met een hogere leeftijd, ASA-score en tumorstadium, een perforatie, ileus of een tumor in het proximale rectum en die een open of geconverteerde operatie ondergingen, hadden meer kans op EO. Opnameduur was langer (7,0 vs. 6,0 dagen, p<0,0001) en vaker verlengd (19% vs. 13%, p=0,03) bij EO-patiënten. Zestig-dagen mortaliteit (2,9% vs. 6,4%, p<0,0001), 90-dagen mortaliteit (3,4% vs. 7,7%, p<0,0001) en 3-jaars overleving (81,2% vs. 58,7%, p<0,0001) waren significant verschillend in het nadeel van EO-patiënten, en bleven significant na univariabele, multivariabele en PSM-analyses. Hoewel de impact van een stoma op QOL bij oudere patiënten al eerder is gerapporteerd, is er weinig bekend over de impact van een stoma op de overleving van oudere patiënten na CRC-chirurgie. Stoma-gerelateerde complicaties of heroperaties, verslechterde kwaliteit van leven of mentale status en sociaal isolement, zouden mogelijk nadelig kunnen zijn voor de oudere patiënt en mogelijk een oorzaak kunnen zijn voor de significant hogere postoperatieve mortaliteit na 60 en 90 dagen die we vonden bij oudere EO-patiënten. Verschillende factoren, die al dan niet voor de hand liggend zijn, die wellicht zijn geobserveerd bij de poliklinische intake, hebben mogelijk geleid tot de keuze van de chirurgen voor een EO in plaats van een PA. Ondanks de beperkingen van dit onderzoek, is het gebaseerd op de meest uitgebreide landelijke kankerregistratiedata die we in Nederland hebben. Het toont een reële weergave van onze landelijke populatie van ouderen met CRC. Aangezien er een significant verschil is in mortaliteit op korte termijn en algehele en relatieve overleving tussen patiënten met PA of EO, zou men kunnen pleiten dat het raadzaam is om het gebruik van EO te vermijden, ongeacht de comorbiditeit, leeftijd of tumorstadium.

Een andere bekende entiteit is de deviërende stoma (DS) bij electieve rectumchirurgie. Een ileostoma wordt geadviseerd om de mogelijke postoperatieve morbiditeit, mortaliteit en de kans op heroperaties te verminderen. Er is een opmerkelijk grote variatie van 0-100% DS-gebruik in Nederlandse ziekenhuizen, wat suggereert dat het gebruik van DS niet noodzakelijkerwijs tot betere resultaten

leidt. Dit, in combinatie met groeiend bewijs over de nadelen van ileostoma's, heeft geleid tot een paradigmaverschuiving in het gebruik van DS in de dagelijkse praktijk in een centrum. Dit wordt geëvalueerd in **hoofdstuk 4**. Alle patiënten met een rectumresectie met PA in ons ziekenhuis tussen 2012 en 2019 werden geanalyseerd en verdeeld in twee tijdsperioden van 2012-2015 (groep A, DS volgens protocol) en 2016-2019 (groep B, selectieve DS). In totaal werden 247 patiënten geïncludeerd (A n=116, B n=131), waarvan 94 patiënten een DS kregen (A: 66% vs. B: 13%, p<0,001). Een vermindering werd gezien in complicaties (43% vs. 26%, p=0,005) en mediane opnameduur (6 vs 4 dagen, p<0,001) ten gunste van groep B. Er werden geen verschillen in naadlekkages (12,1%), mortaliteit (0,8%) en heroperaties (13,4%) gezien tussen de groepen. Het selectieve en verminderde gebruik van DS bij electieve rectumchirurgie leidde in dit centrum niet tot nadelige effecten op het gebied van postoperatieve complicaties bij patiënten zonder DS.

Nieuwe stomapatiënten, met name ileostomapatiënten, hebben kans op aanzienlijke morbiditeit. Dit bestaat onder andere uit uitdroging, elektrolytafwijkingen en vooral frequente heropnames, wat leidt tot een toename van zorgkosten en een afname van de patiënttevredenheid. Daarnaast ondervinden patiënten ook problemen met hun stomamanagement, een verlies van kwaliteit van leven, een verminderd lichamelijk en sociaal functioneren, een lagere algemene gezondheidstoestand en een verslechterd lichaamsbeeld. Wanneer patiënten niet zelfstandig hun stomazorg (SC) uit kunnen voeren, zijn ze erg afhankelijk van (stoma)verpleegkundigen en paramedisch personeel. Dit alles resulteert in een aanzienlijke sociale en financiële last voor patiënten en de samenleving. Deel II van dit proefschrift onderzoekt eenvoudig te implementeren veranderingen in onze dagelijkse praktijk in de vorm van zorgpaden en hun effectiviteit bij het verminderen van een paar bekende stomagerelateerde problemen.

In **hoofdstuk 5** evalueren we de effectiviteit en duurzaamheid van het ileostoma zorgpad van Beth Israel Deaconess Medical Center (BIDMC) in een poging om het aantal heropnames voor uitdroging bij nieuwe ileostomapatiënten te verminderen.

In totaal werden 393 patiënten (man n=195, vrouw n=198, mediane leeftijd 52 jaar) geïncludeerd die tussen januari 2007 en januari 2015 een nieuwe ileostoma kregen. De patiënten werden verdeeld in 2 groepen: 161 pre-zorgpad en 232 op-zorgpad. Over het algemeen daalde het percentage heropnames na 30 dagen (35,4% naar 25,9%, p=0,04), heropnames als gevolg van hoge output en/of uitdroging (15,5% naar 3,9%, p<0,001) en heropnames als gevolg van ileus (9,9% naar 4,3%, p=0,03). Deze studie heeft aangetoond dat het ileostoma zorgpad effectief en succesvol blijft in het terugdringen van het aantal heropnames in het algemeen, evenals het aantal heropnames wegens uitdroging. Hoewel de pathofysiologie van ileostoma met hoge output kan variëren, kunnen uitdroging en daaropvolgende heropname worden voorkomen door deze eenvoudige aanpassingen. Proactieve interventie en educatie kunnen de kans op complicaties bij nieuwe ileostomapatiënten verminderen. Bovendien zou het gebrek aan postoperatieve stoma-educatie een onafhankelijke risicofactor kunnen zijn voor heropnames bij nieuwe ileostomapatiënten. Het is aangetoond dat gestructureerde patiënten educatie gericht op hun individuele behoeften een positief effect heeft op de QOL, de opnameduur en op de zorgkosten. Het zou de moeite waard kunnen zijn om dit zorgpad in andere klinieken in te voeren, waar er problemen met heropnames als gevolg van uitdroging bij ileostoma patiënten bestaan.

Hoofdstuk 6 richt zich op het onvermogen van nieuwe stomapatiënten om onafhankelijke SC uit te voeren, waardoor ze na ontslag afhankelijk zijn van de thuiszorg. Er werd een eenvoudig uitvoerbaar, op educatie gericht stoma zorgpad van 4 dagen ontwikkeld en geïmplementeerd in een poging om het niveau van onafhankelijkheid (LOI) te vergroten en thuiszorg te verlagen. Alle nieuwe stomapatiënten op de gastro-intestinale chirurgie afdeling, fysiek en mentaal in staat om SC uit te voeren, volgden dit stoma zorgpad. Ze werden vergeleken met een retrospectieve controlegroep van nieuwe stomapatiënten vóór het begin van het stoma zorgpad. Patiënten die dagelijks thuiszorg nodig hadden voor SC daalde van 80% naar 50% (p<0,001), patiënten die werden ontslagen zonder thuiszorg voor SC nam toe van 5% naar 27%. De onafhankelijkheid van patiënten in SC bij ontslag nam toe van 8% naar 68% (p<0,001). Deze studie toont aan dat een klinische 4-daagse educatieve klinische stoma zorgpad haalbaar en effectief is om

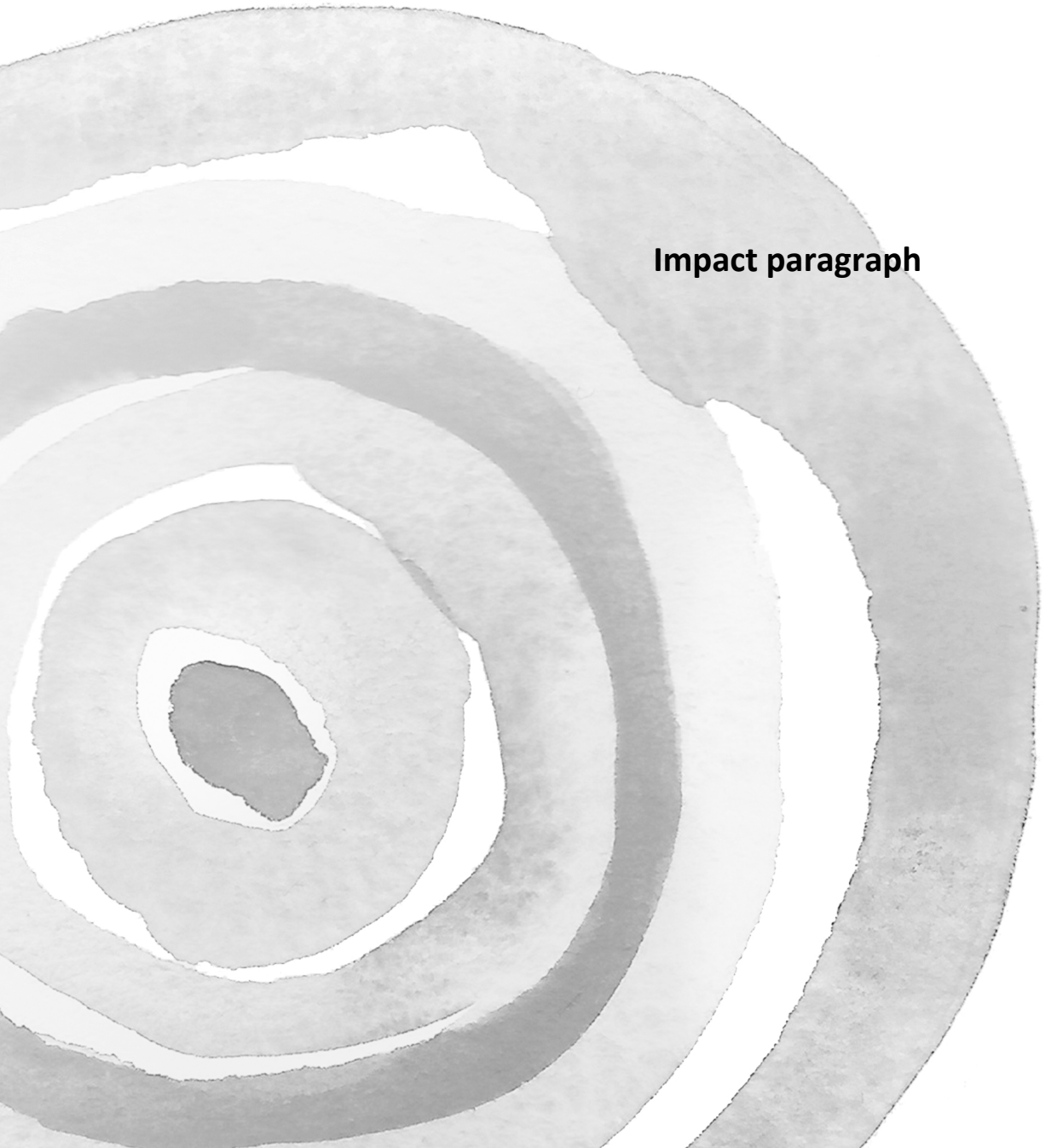
de LOI in SC van nieuwe stomapatiënten te verhogen en hun behoefte aan thuiszorg aanzienlijk te verminderen. Het is niet alleen eenvoudig te implementeren, de indrukwekkende gunstige effecten zijn ook reproduceerbaar in andere Nederlandse ziekenhuizen, zoals beschreven in **hoofdstuk 7**. Een prospectieve longitudinale studie werd uitgevoerd tussen juli 2018 en februari 2020 in een tertiair verwijzingsziekenhuis. Patiënten die dit stoma zorgpad volgden, werden vergeleken met een historische controlegroep. Na ontslag was 67,6% van de patiënten in de interventiegroep (n=244) in staat om zelfstandig SC uit te voeren zonder thuiszorg, vergeleken met 15,2% van de patiënten in de controlegroep (n=33) ($p<0,001$). Deze resultaten geven aan dat het stoma zorgpad niet alleen gemakkelijk te implementeren en uit te voeren is, maar ook effectief is bij zowel een andere patiëntenpopulatie als in een andere ziekenhuisomgeving.

Ondanks de introductie van moderne chirurgische technieken, is continuiteits-herstel na HP nog steeds een uitdaging. Het gaat gepaard met hoge morbiditeits- en mortaliteitscijfers, wat de belangrijkste redenen zijn waarom veel chirurgen terughoudend zijn een colostoma op te heffen. Deel III onderzoekt de uitdagingen en moeilijkheden bij continuiteitsherstel na HP en vooral hoe het gebruik van de single-port (SP) -benadering gunstig kan zijn in vergelijking met reeds bestaande technieken. In de voortdurende zoektocht naar de optimale techniek voor het omkeren van HP, zijn verschillende laparoscopische, “hand-assisted” en SP-technieken beschreven. Laparoscopische opheffen van HP werd geïntroduceerd in 1993 en bleek aanzienlijke voordelen te hebben ten opzichte van klassieke open reconstructie. Hoewel de voordelen van laparoscopie duidelijk zijn, moeten de technische problemen van deze benadering ook worden erkend, vooral bij patienten na open-indexoperaties met peritonitis. Het inbrengen van een trocar, adhesiolyse van intra-abdominale adhesies of adhesies ter plaatse van laparotomie litteken kan gevaarlijk zijn en mogelijk leiden tot chirurgische calamiteiten en uiteindelijk tot conversies. De SP-benadering maakt het mogelijk om adhesiolyse in de oude laparotomie wond te vermijden, dit is vooral voordelig bij patiënten met een laparostomie, multiple laparotomieën of ernstige wondinfectie in hun medische geschiedenis, en wordt beschouwd als een van de voordelen van deze

techniek. Onze eerdere studie toonde aan dat de SP-techniek haalbaar is, wat ook resulteert in kortere ziekenhuisopnames en een significante vermindering van postoperatieve complicaties in vergelijking met klassieke open continuiteitsherstel na HP.

SP opheffen van een linkszijdige colostoma (SPRLC) kan worden gebruikt als een stapsgewijze benadering door de intestinale continuïteit te herstellen met lage morbiditeitscijfers. **Hoofdstuk 8** evalueert de resultaten van het implementeren en standaardiseren (consolideren) van SPRLC in een centrum bij 85 patiënten. De meerderheid van de patiënten was man (man:vrouw = 56:29) met een gemiddelde leeftijd van 60,5 jaar. 70% had geen postoperatieve complicaties en er werd geen postoperatieve mortaliteit waargenomen. De meest voorkomende complicatie was wondinfectie (22%). De mediane opnameduur was 3,0 dagen, het succespercentage van SP-omkering was 65%. Minimaal invasieve benadering zonder conversie naar laparotomie was succesvol in 85% van de gevallen; dit was haalbaar bij 78% van de patiënten die een open-indexoperatie ondergingen. **Hoofdstuk 9** onderzoekt de ervaringen met het gebruik van SPRLC in vier verschillende ziekenhuizen in verschillende landen in Europa en geeft een uitgebreid overzicht van de literatuur over het gebruik van de SP-benadering bij het opheffen van een linkszijdig colostoma. Van de 156 SPRLC-procedures was 99% technisch succesvol en 72% had geen postoperatieve complicaties. Er werd geen postoperatieve mortaliteit geconstateerd. Wondinfectie trad op bij 14,7%, naadlekkage bij 3,9% en herinterventies bij 7,7% van de patiënten. De mediane opnameduur was 4 dagen, SP- succespercentage was 64,7%, 12,8% en 21,2% werden respectievelijk omgezet in een open en conventionele laparoscopische procedure. Op dit moment zijn er geen gerandomiseerde gecontroleerde studies tussen de verschillende benaderingen (open, laparoscopisch of SP) gepubliceerd. Literatuur laat zien dat patiënten geselecteerd voor SPRLC voornamelijk patiënten betreffen na laparoscopische indexchirurgie (53,4%). Het laat ook zien dat SP-aanpak veilig en haalbaar lijkt met hoge slagingspercentages, lage morbiditeit (12,5%-30,4%) en mortaliteit (1,8%-2,2%). Het aantal ernstige complicaties is ook laag, variërend van 0% - 8,9% met een mediane opnameduur tussen de 4 en

8 dagen. SPRLC lijkt niet alleen een veilige en haalbare procedure te zijn, het leidt ook tot gelijke of zelfs betere resultaten met enkele grote voordelen in vergelijking met conventionele open of laparoscopische stoma ophef procedures. In centra met laparoscopisch ervaren (colorectale) chirurgen, moet deze techniek worden beschouwd als een serieus en aantrekkelijk alternatief om de darmcontinuïteit te herstellen bij patiënten met linkszijdige EO, vooral bij patiënten na open-indexchirurgie. **Hoofdstuk 10** onderzoekt de haalbaarheid en resultaten van het gebruik van de SPRLC bij 12 patiënten met dergelijke bijkomende complexe buikwanddefecten. Deze studie toont aan dat SPRLC mogelijk is zonder midlijn adhesiolyse en dus zonder de noodzaak om de littekenbreuk tijdens dezelfde procedure te herstellen met gunstige resultaten in postoperatieve complicaties (geen mortaliteit, heroperaties of naadlekkage) en opnameduur (mediaan 4 dagen). Dit verlaagt onze drempel om deze aanpak aan te bieden bij onze patiënten met een stoma in combinatie met littekenbreuken. Deze benadering zou een waardevolle techniek kunnen zijn bij die patiënten die een hernia-operatie wensen. Hun mogelijke postoperatieve morbiditeit kan worden verminderd door de contaminatie als gevolg van een stoma te elimineren.



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Introduction

Despite ever-changing and evolving techniques and innovations within the surgical world, temporary and permanent stomas are still commonly used in elective and emergency gastrointestinal surgery. Approximately 7000 stomas are placed each year in the Netherlands with a total of 32.000 permanent stoma patients.[1] New stoma patients face significant physical, psychological and body image adaptation with loss of personal physical function.[2] They also face the burden of the considerable stoma related morbidity which can be found in up to 80% of the stoma patients.[3] This thesis aims to contribute in reducing unnecessary new stoma patients, stoma-related morbidity and stoma reversal related morbidity.

Scientific relevance of this thesis

From population-based data, it is shown that elderly patients after colorectal surgery with a stoma suffer from a worsened survival compared to those with a primary anastomosis. Single center observations have shown that highly selective use of deviating stomas in rectal cancer surgery actually resulted in better outcomes in terms of complications, length of stay and stoma free survival. These results indicate that the use of a permanent or deviating stoma in colorectal cancer surgery, might not always be beneficial. A careful consideration of the harm-benefit balance associated with the use of stomas in colorectal surgery continues to be a matter of debate. This thesis provides a contribution to this debate; it creates awareness, offers scientific arguments and emphasizes the scope and complexity of stoma-related problems. It is our hope that these real-world results will help clinicians, surgeons and patients in their considerations when assessing the necessity for a stoma or anastomosis in colorectal surgery. Moreover, this thesis provides additional information for the consolidation of the single port technique in stoma reversal surgery and its potential to reduce morbidity and its applicability in complex patients. This thesis provides data that shows colorectal surgeons and

their patients the benefits of the single port approach, enabling them to choose this approach, if possible, as the most appropriate minimally invasive technique for their stoma reversal.

Societal and economic relevance of this thesis

Seemingly small changes in every day practice can result in big results. Home care nursing services in new stoma patients cost around €2.200 per patient.[4] The cost of a readmission is reported in the literature to be approximately €5800.[5] Reduction of readmissions and need for home care nursing services is therefore not only of clinical but also of financial importance. This thesis proves the effectiveness of easily implementable stoma pathways in reducing readmissions and need for home care nursing services after discharge in new stoma patients. Nationwide implementation of these pathways might lead to significant reduction in health care costs of possible millions of euros.[4]

Target audience

This thesis targets a broad audience, as it contains valuable information for all clinicians who are involved in colorectal cancer care and for patients who have stomas. Not only surgeons, but also gastroenterologists, geriatricians, stoma care nurses, staff nurses, house officers and physician-assistants are all essential for a patient undergoing colorectal surgery. This thesis attempts to contribute to pre-, peri- and postoperative decision making; by showing real-world data of stoma patients and showing ways to implement pathways to take care of the patients when they have a stoma, in an effort to reduce their readmissions and increase their level of independency. These stoma pathways may also be interesting for stoma patient associations, health insurance companies and managers or policymakers of surgical departments with colorectal patients. Most importantly, our hope is that the stoma patients (with or without complex abdominal wall defect) will benefit most from this thesis. We hope to contribute to a reduction of unnecessary new stoma patients, to an increase of independency and insight in

their own situation in new stoma patients and to reduced readmissions and need for home care nursing services. Presentations at regional and national meetings for surgeons and patients have already spread awareness on the different topics of this thesis. Transparency of health care costs and collaboration with health care insurance companies would be huge steps forward in the process of improving our care for (new) stoma patients.

Innovation and future

Future research should focus on the critical appraisal of the application of diverting stomas, it would be worthwhile to investigate which patient category that has to undergo colorectal surgery would really benefit from a stoma.

The discussed pathways have been proven to be easily implementable and reproducible in large teaching hospitals. One can assume that these pathways could be introduced and implemented nationwide. New technology such as smartphone applications, teleconsultation or telemedicine offer new ways to provide guidance for our (stoma) patients and will continue to influence how patients use our health care system and undergo treatments. It is our duty and responsibility as clinicians to try to incorporate and implement such innovations in our everyday practice. We are excited to see how these innovations can help us to improve our health care system without burdening our patients and society with higher health care costs. These improvements are facilitated through the combination of the results of the present thesis and the technological implementation developments.

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List of publications

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Curriculum vitae

Curriculum vitae

Yu-Ting (Tina) van Loon was born on the 20th of September 1989 in Taoyuan City in Taiwan and emigrated to the Netherlands in 1995. She grew up in Vlijmen with her parents and younger sister. After graduating from Stedelijk Gymnasium in 's-Hertogenbosch in 2007, she started medical school at Maastricht University. As a medical student, Tina joined SKVM Kinran, a student karate club as a member and board-member. She competed during the European Competitions in Turin in 2010 after gaining her first dan (black belt) and has been rediscovering her passion for karate since 2020.

Tina started her job as a surgical resident at the surgery department of the Elisabeth TweeSteden Hospital in Tilburg in 2014. Her passion for improving patient care has led to different grants supporting an observership and research collaboration with dr. D Nagle at Beth Israel Deaconess Medical Center, a teaching hospital of Harvard Medical School, in Boston in 2015. This has been the foundation of many research and improvement projects under the supervision of dr. DDE Zimmerman, ultimately resulting in this thesis. She started her surgical training at the Elisabeth TweeSteden Hospital in Tilburg under supervision of dr. PWHE Vriens and dr. MS Ibelings and at the Radboud University Medical Center in Nijmegen under supervision of dr. BH Verhoeven in 2016. The last part of her surgical training will focus on robotic colorectal surgery, under supervision of prof. dr. ECJ Consten at Meander Medisch Centrum in Amersfoort.

Her enthusiasm for coloproctology resulted in joining as board member in the Werkgroep Coloproctologie and as education committee member of the European Society of Coloproctology (ESCP) in 2017. She is an active Young-ESCP member, co-organizer of the EBSQ Coloproctology exam and avid supporter of #womeninsurgery.

Tina lives together with her fiancé Hein and together they enjoy fine dining, travelling, skiing, bouldering and she is looking forward to planning her wedding now that her thesis is finished.