ORIGINAL ARTICLE



Long-term restoration of bowel continuity after rectal cancer resection and the influence of surgical technique: A nationwide cross-sectional study

Sanne-Marije J. A. Hazen^{1,2,3} | Eline G. M. van Geffen^{1,2,3} | Tania C. Sluckin^{1,2,3} | Geerard L. Beets^{4,5} | Henricus J. Belgers⁶ | Wernard A. A. Borstlap⁷ | Esther C. J. Consten^{8,9} | Jan-Willem T. Dekker¹⁰ | Roel Hompes^{2,7} | Jurriaan B. Tuynman^{1,2,3} | Henderik L. van Westreenen¹¹ | Johannes H. W. de Wilt¹² | Pieter J. Tanis^{2,3,7,13} | Miranda Kusters^{1,2,3} | on behalf of the Dutch Snapshot Research Group

¹Department of Surgery, Amsterdam UMC Location Vrije Universiteit Amsterdam, Amsterdam, The Netherlands

²Treatment and Quality of Life, Cancer Center Amsterdam, Amsterdam, The Netherlands

³Imaging and Biomarkers, Cancer Center Amsterdam, Amsterdam, The Netherlands

⁴Surgery, The Netherlands Cancer Institute, Amsterdam, The Netherlands

⁵GROW School of Oncology and Developmental Biology, University of Maastricht, Maastricht, The Netherlands

⁶Surgery, Zuyderland Medical Center, Heerlen, The Netherlands

⁷Surgery, Amsterdam UMC Location University of Amsterdam, Amsterdam, The Netherlands

⁸Surgery, Meander Medical Center, Amersfoort, The Netherlands

⁹Surgery, University Medical Centre Groningen, Groningen, The Netherlands

¹⁰Surgery, Reinier de Graaf Gasthuis, Delft, The Netherlands

¹¹Surgery, Isala Hospital, Zwolle, The Netherlands

¹²Surgery, Radboud Institute for Health Sciences, Radboud University Medical Centre, Nijmegen, The Netherlands

¹³Surgical Oncology and Gastrointestinal Surgery, Erasmus Medical Center, Rotterdam, The Netherlands

Abstract

Aim: Literature on nationwide long-term permanent stoma rates after rectal cancer resection in the minimally invasive era is scarce. The aim of this population-based study was to provide more insight into the permanent stoma rate with interhospital variability (IHV) depending on surgical technique, with pelvic sepsis, unplanned reinterventions and readmissions as secondary outcomes.

Method: Patients who underwent open or minimally invasive resection of rectal cancer (lower border below the sigmoid take-off) in 67 Dutch centres in 2016 were included in this cross-sectional cohort study.

Results: Among 2530 patients, 1470 underwent a restorative resection (58%), 356 a Hartmann's procedure (14%, IHV 0%–42%) and 704 an abdominoperineal resection (28%, IHV 3%–60%). Median follow-up was 51 months. The overall permanent stoma rate at last follow-up was 50% (IHV 13%–79%) and the unintentional permanent stoma rate, permanent stoma after a restorative procedure or an unplanned Hartmann's procedure, was 11% (IHV 0%–29%). A total of 2165 patients (86%) underwent a minimally invasive resection: 1760 conventional (81%), 170 transanal (8%) and 235 robot-assisted (11%). An anastomosis was created in 59%, 80% and 66%, with corresponding unintentional permanent stoma rates of 12%, 24% and 14% (p=0.001), respectively. When corrected for age, American Society of Anesthesiologists classification, cTNM, distance to the anorectal junction and neoadjuvant (chemo)radiotherapy, the minimally invasive technique was not associated with an unintended permanent stoma (p=0.071) after a restorative procedure. **Conclusion:** A remarkable IHV in the permanent stoma rate after rectal cancer resection was found. No beneficial influence of transanal or robot-assisted laparoscopy on the unintentional permanent stoma rate was found, although this might be caused by the

Participating members of the Dutch Snapshot Research Group members are listed in the Appendix 1.

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Correspondence

Miranda Kusters, Department of Surgery, Amsterdam University Medical Centres, Vrije Universiteit Amsterdam, De Boelelaan 1117, PO Box 7057, 1007 MB Amsterdam, the Netherlands. Email: m.kusters@amsterdamumc.nl

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INTRODUCTION

Since the local recurrence rate of rectal cancer has substantially declined [1–3] there has been an increased focus on functional outcomes and quality of life after treatment for rectal cancer. A large proportion of patients undergoing surgery for rectal cancer will end up with a stoma, and this has a significant effect on quality of life in about a quarter of the patients [4].

Stomas in rectal cancer patients might be either intentional or unintentional, with substantial variety among centres and countries [5]. Intentional stoma rates in northern European countries are relatively high. In Dutch clinical practice, approximately 30% of rectal cancer patients used to undergo abdominoperineal resection (APR) and another 20% a Hartmann's procedure (HP), although these proportions have decreased over time [6]. The unintentional stoma rate in patients undergoing restorative rectal cancer resection was as high as 19% [7].

When the tumour is in the distal rectum it becomes more challenging to achieve clear resection margins and to restore bowel continuity due to tapering of the pelvis and a short distal margin. To overcome these challenges, robot-assisted surgery and the transanal TME (TaTME) technique have been introduced [8–10]. Several studies have reported on short-term outcomes regarding the different minimally invasive rectal cancer resection techniques, but little is known about the long-term outcomes with regard to permanent stoma and complication rates [11, 12]. The aim of this population-based study was primarily to provide more insight into the permanent stoma rate with interhospital variability (IHV) depending on surgical technique, with pelvic sepsis, unplanned reinterventions and readmissions as secondary outcomes.

METHOD

This large collaborative research project, performed by the Dutch Snapshot Research Group, was conducted in 67 Dutch hospitals. Short-term outcomes of patients undergoing a surgical resection for colorectal cancer in the Netherlands are registered in the Dutch ColoRectal Audit (DCRA) [13]. All patients who underwent a resection of primary rectal cancer between 1 January and 31 December 2016 were selected from the DCRA. Between October 2020 and November 2021, a local collaborative team for each hospital, consisting of surgical residents or physician assistants, supervised by a

surgical learning curve. A reduction in IHV and improving preoperative counselling for decision-making for restorative procedures are required.

KEYWORDS

permanent stoma, rectal cancer, robot-assisted laparoscopy, total mesorectal excision, transanal total mesorectal excision

What does this paper add to the literature?

This nationwide cross-sectional study showed an overall permanent stoma rate of 50% and an unintentional permanent stoma rate of 11% after rectal resection for rectal cancer, with huge interhospital variability. Improvement in preoperative counselling for decision-making for restorative procedures and a reduction in interhospital variability are necessary.

surgeon, collected additional data and long-term outcomes through a secure web-based tool, resulting in a follow-up period of 4 years. A more detailed description of this study design has been published previously [14]. The MRI images were re-reviewed by collaborators who had fulfilled the online sigmoid take-off training to determine whether the tumour was located under or above the sigmoid takeoff [15].

Ethics

This study was performed and reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. The Medical Ethical Committee Vrije Universiteit Medical Centre in Amsterdam reviewed and approved the study protocol on 30 June 2020. The Dutch Medical Research Involving Human Subjects Act was not applicable. Local approval for execution of the study and the need to provide informed consent or the opportunity to opt out was obtained by the local institutional review board of each participating centre.

Patient selection

For the current analysis, patients who underwent an anterior resection with anastomosis (AR), HP or an APR for primary rectal cancer were selected from the cross-sectional cohort database. Patients with a tumour above the sigmoid take-off and patients who underwent a local excision (defined as transanal endoscopic microsurgery or transanal minimally invasive surgery), proctocolectomy or unknown procedure were excluded.

End points

The primary outcome was the permanent stoma rate, which was defined as a stoma being present at last follow-up. The permanent stoma rate was further subdivided into the intentional and unintentional permanent stoma rate. An intentional permanent stoma was defined as a stoma after an APR or planned HP (preoperatively discussed because of comorbidities, expected risk of anastomotic leakage or expected incontinence problems). An unintentional permanent stoma was defined as the presence of a stoma in patients who initially underwent a restorative resection or in patients in whom the procedure was peroperatively converted to a HP due to technical difficulties. If the reason for a HP was not clear, this was scored as reason unknown. Secondary outcomes were pelvic sepsis (anastomotic leakage or presacral abscess) at any time during follow-up, unplanned reinterventions and readmissions. Anastomotic leakage was defined as the presence of any of the following conditions: contrast extravasation on imaging studies, a presacral collection requiring surgical, radiological or endoscopic intervention, or a presacral collection that either led to delay in stoma closure or to resection of the colorectal anastomosis. Furthermore, IHV regarding the surgical approach and permanent stoma rate was evaluated. The permanent stoma rate was stratified for annual hospital volume, defined as low (<20), medium (20-50) or high (>50). Surgeon experience and the learning curve could not be assessed and were therefore not included in the analyses.

Statistical analyses

Continuous outcomes are presented as means with standard deviation (SD) for normally distributed continuous variables and as medians with interquartile range (IQR) for nonnormally distributed variables. Categorical variables are presented as numbers (n) with percentages. To compare baseline characteristics, the chi-square test was used for categorical intergroup variation and one-way analysis of variance for continuous variables. Binary logistic regression analysis with backward selection was performed to determine the independent association of the minimally invasive surgical technique for having an unintentional permanent stoma, corrected for expected relevant clinical factors, namely sex, age at resection, American Society of Anesthesiologists (ASA) classification, clinical tumour characteristics [cT-stage, cN-stage, involved mesorectal fascia (MRF) (<1mm distance), cM-stage and distance to the anorectal junction measured on MRI] and the use of neoadjuvant (chemo)radiotherapy. Analyses were performed with IBM SPSS statistics, version 27.00 (IBM Corp Armonk, NY, USA). A p-value less than 0.05 was considered statistically significant.

RESULTS

Sixty-seven of the 69 hospitals in the Netherlands that performed rectal cancer surgery in 2016 participated in this study. This resulted in the inclusion of 3107 of the 3178 potentially eligible patients (98%) in the cross-sectional cohort database. After excluding patients with a tumour above the sigmoid take-off (n=314), local excision (n=197),

1155 i Coso proctocolectomy (n=14) and unknown procedure (n=2), 2530 patients with an AR, HP or APR for primary rectal cancer performed by any surgical approach were included, as shown in Figure 1. The variety in distribution of the different surgical techniques for each hospital is shown in Figure 2A. The TaTME procedure was performed in 27 hospitals, of which 15 performed between one and three TaTME procedures in this cohort (median 2, range 1-41). A total of 12 hospitals used robot-assisted laparoscopy (R-TME), of which four performed between one and three R-TMEs (median 13, range 1-79). IHV in permanent stoma rate The distribution of patients with either a functional anastomosis or a permanent stoma for each participating hospital is shown in Figure 2B. The median follow-up was 51 months (IQR 43-55 months). The overall permanent stoma rate at the end of follow-up was 50%, with an IHV ranging between 13% and 79%. The variability in performing an APR procedure was between 3% and 59% (median 25%). The variability in performing an HP was between 0% and 42% (me-

dian 10%). A planned HP varied between 0% and 42% (median 8%) and an unplanned HP (peroperatively converted) varied between 0% and 15% (median 2%). The permanent stoma rate was not influenced by the hospital volume (41% vs. 51% vs. 50% for 0–20, 21–50 and >50 resections annually, respectively; p=0.127). The unintentional permanent stoma rate (a permanent stoma after an initial restorative resection or an unplanned HP) was 11%, with variability between 0% and 29%. The hospital volume did not influence the unintentional permanent stoma rate (6% vs. 12% vs. 11% for 0–20, 21–50 and >50 resections annually, respectively: p=0.119).

Use of a minimally invasive approach

After excluding patients who underwent resection by a primary open or unknown approach (Figure 1), there were 2165 patients who had an initial minimally invasive approach. A total of 1760 patients (81%) underwent a conventional laparoscopic approach (L-TME), 170 patients (8%) a TaTME approach and 235 patients (11%) an R-TME. Baseline characteristics are displayed in Table 1. Patients with a TaTME were more often male and had more distal tumours (4cm vs. 5 cm for both L-TME and R-TME; p = 0.027). There were no significant differences in cTNM stage or the use of neoadjuvant (chemo) radiotherapy. An anastomosis was created in 1041 (59%) patients with L-TME, in 136 (80%) with TaTME and in 154 (66%) with R-TME. Specific characteristics and complications after TaTME and R-TME can be found in the Appendix 0.

Minimally invasive restorative procedures

Of 1331 patients who underwent a minimally invasive resection with anastomosis, the surgical approach was L-TME in 1041 patients (78%), TaTME in 136 patients (10%) and R-TME in 154 patients (12%)



(Figure 1, Table 2). A diverting stoma was constructed in 703 patients (53%). Patients with a TaTME approach had more advanced and distally located tumours and more often received neoadjuvant treatment. The long-term outcomes regarding pelvic sepsis, permanent stoma and reinterventions and readmissions are displayed in Table 3. Of the 246 patients with anastomotic leakage, 105 had a permanent stoma at the end of follow-up (43%). Anastomotic leakage occurred more often in the TaTME group (27%, p=0.042). A total of 32 patients (24%) had a stoma at the end of follow-up in the TaTME group, and this was significantly higher than the L-TME group (n=121, 12%) and R-TME group (n=22, 14%) (p=0.001). The type of permanent stoma and the reason for the permanent stoma were no different between the groups. Of the 175 permanent stomas, 54 (31%) were created before or during the rectal resection, 55 (31%) were created within the first year after the rectal resection and 54 (31%) were created more than 1 year after the rectal resection [for 12 stomas (7%) this was unknown]. Patients in the TaTME group more often had an unplanned reintervention (n = 53, 39%; p = 0.001) and unplanned readmission (n = 54, 40%; p < 0.001).

When determining the independent association of the type of minimally invasive approach on permanent stoma rate corrected for ASA classification, distance to the anorectal junction measured on

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FIGURE 1 Flowchart for study inclusion (APR, abdominoperineal resection; AR, anterior resection; DCRA, Dutch ColoRectal Audit; HP, Hartmann's procedure; Wait-and-See).





Planned Hartmann Procedure

Abdominoperineal resection

HOSPITAL VARIATION PERMANENT STOMA RATE



Unplanned Hartmann Procedure

Unknown

Hartmann Procedure, reason unknown

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 TABLE 1
 Baseline characteristics per type of minimal invasive surgical technique for all total mesorectal excision (TME) procedures.

Clinical value	Conventional laparoscopy (N = 1760), n (%)	Transanal TME (N = 170), n (%)	Robot-assisted laparoscopy (N = 235) n (%)	p-value
Male	1124 (64)	131 (77)	156 (66)	0.002
Age at resection (years), mean (SD)	67 (10)	66 (11)	67 (10)	0.128
Previous bowel segment resection	20 (1)	1 (1)	3 (1)	0.780
ASA III/IV	290 (17)	22 (19)	31 (13)	0.262
Distance from the ARJ (cm), mean (SD)	5 (3)	4 (2)	5 (3)	0.027
cT-stage				
cT1/T2	555 (33)	46 (28)	72 (31)	0.383
cT3	1012 (60)	106 (64)	135 (59)	
cT4	97 (6)	14 (8)	20 (9)	
сТх	19 (1)	1 (1)	2 (1)	
MRF+	456 (28)	53 (33)	54 (25)	0.273
cN-stage				
cN0	742 (44)	79 (47)	108 (47)	0.872
cN1	543 (32)	55 (33)	73 (32)	
cN2	391 (23)	32 (19)	47 (21)	
cNx	7 (0)	1 (1)	1 (0)	
cM1	108 (6)	11 (7)	10 (4)	0.497
Neoadjuvant radiotherapy				
None	747 (42)	670 (41)	95 (40)	0.713
5×5 short interval	321 (18)	24 (14)	45 (19)	
5×5 long interval	164 (9)	21 (12)	23 (9)	
Chemoradiation	528 (30)	55 (32)	73 (31)	
Type of resection				
Anterior resection with anastomosis	1041 (59)	136 (80)	154 (66)	<0.001
Hartmann procedure	237 (14)	10 (6)	14 (6)	
Abdominoperineal resection, intersphincteric	110 (6)	20 (12)	11 (5)	
Abdominoperineal resection, conventional or extralevator	356 (20)	3 (2)	55 (23)	
Abdominoperineal resection, type unknown	16 (1)	1 (1)	1 (0)	
Reason for Hartmann procedure				
Planned	171 (72)	5 (50)	9 (64)	0.484
Unplanned	50 (21)	4 (40)	3 (21)	
Unknown reason	16 (7)	1 (10)	2 (14)	
Multivisceral resection	69 (4)	4 (2)	9 (4)	0.593
Conversion to open surgery	86 (5)	3 (2)	4 (2)	0.069
Involved resection margin	76 (4)	10 (6)	22 (9)	0.003

Abbreviations: ARJ, anorectal junction; ASA, American Society of Anesthesiologists; MRF, mesorectal fascia.

MRI, cM-stage and the use of neoadjuvant (chemo)radiotherapy, the type of minimally invasive approach was no longer associated with the presence of a permanent stoma (Table 4, p=0.094). Sex, cT-stage and MRF involvement were also not significantly associated with the presence of a permanent stoma in the multivariable analysis. Patients treated with neoadjuvant (chemo)radiotherapy had an unintentional permanent stoma significantly more often (117/702, 17%) than patients with upfront TME (60/635, 9%) (p < 0.001).

DISCUSSION

This nationwide cross-sectional study of 2530 patients who underwent a resection for primary rectal cancer in the Netherlands in 2016 gives an overview on long-term permanent stoma rates for the different minimally invasive approaches for TME-surgery. The results revealed a 50% permanent stoma rate with substantial IHV. The chance of undergoing a restorative resection differed among

TABLE 2 Baseline characteristics per type of minimally invasive surgical technique for anterior resection with anastomosis.

Clinical value	Conventional laparoscopy (N=1041), n (%)	Transanal TME (N = 136), n (%)	Robot-assisted laparoscopy (N = 154), n (%)	p-value
Male	661 (64)	101 (74)	102 (66)	0.044
Age at resection (years), mean (SD)	66 (10)	63 (11)	65 (9)	0.041
Previous bowel segment resection	7 (1)	1 (1)	1 (1)	0.996
ASA III/IV	131 (13)	21 (16)	10 (7)	0.044
Distance from the ARJ (cm), mean (SD)	6 (3)	4 (2)	6 (2)	<0.001
cT-stage				
cT1/T2	351 (34)	37 (27)	53 (34)	0.002
cT3	590 (57)	85 (63)	90 (58)	
cT4	26 (3)	11 (8)	6 (4)	
сТх	74 (7)	3 (2)	5 (3)	
MRF+	186 (2)	38 (30)	25 (18)	0.023
cN-stage				
cN0	456 (44)	64 (47)	75 (49)	0.193
cN1	318 (31)	44 (32)	51 (33)	
cN2	201 (19)	25 (18)	24 (16)	
cNx	66 (6)	3 (2)	4 (3)	
cM1	54 (5)	9 (7)	6 (4)	0.580
Neoadjuvant treatment				
None	500 (48)	59 (43)	73 (47)	0.028
5×5 short interval	218 (21)	16 (12)	33 (21)	
5×5 long interval	70 (7)	16 (12)	13 (8)	
Chemoradiation	253 (24)	45 (33)	35 (23)	
Multivisceral resection	21 (2)	4 (3)	5 (3)	0.537
Diverting stoma	511 (49)	88 (65)	104 (68)	<0.001
Conversion to open surgery	49 (5)	1 (1)	3 (2)	0.115
Involved resection margin	21 (2)	5 (4)	9 (6)	0.016
CRM+	14 (67)	4 (80)	6 (67)	0.602
DRM+	6 (29)	O (O)	2 (22)	
CRM and DRM +	1 (5)	1 (20)	1 (11)	

Abbreviations: ARJ, anorectal junction; ASA, American Society of Anesthesiologists; CRM, circumferential resection margin; DRM, distal resection margin; MRF, mesorectal fascia; TME, total mesorectal excision.

the minimally invasive surgical techniques, with the highest proportion for transanal procedures, although this is probably biased by patient selection. Univariable analysis showed that TaTME resulted in a higher rate of unintentional permanent stoma after a restorative procedure compared with L-TME and R-TME. However, the TaTME approach was used for more advanced and distally located tumours. After correcting for confounders, the type of minimally invasive approach was not significantly associated with having a permanent stoma.

TaTME and R-TME are increasingly used for rectal cancer surgery, but high-quality evidence on the short- and long-term outcomes is limited [16–18]. Several studies have shown favourable outcomes regarding sphincter preservation and bowel continuity for TaTME and R-TME compared with L-TME [11, 12]. An analysis of data from the Dutch Colorectal Audit of cohorts between 2015 and 2018, including patients with a tumour located within 5 cm of the anus, showed that the TaTME approach resulted in more restorative procedures (66% vs. 28% for L-TME and 40% for R-TME) and also remained independently associated with performing a restorative procedure in the multivariable analysis [12]. Another study by Hol et al., which included patients from Dutch expert centres between 2015 and 2017, showed more anastomoses after TaTME (62%) and R-TME (62%) compared with L-TME (39%) [11]. These results are in line with the results from the current study.

It remains difficult to reliably compare the three minimally invasive techniques due to allocation bias and the preference of the surgeon for a surgical technique. When correcting for tumour characteristics and the use of neoadjuvant treatment, the type of minimally invasive technique was not associated with an unintentional permanent stoma after the initial creation of an anastomosis.

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 TABLE 3
 Long-term outcomes per type of minimally invasive surgical technique for anterior resection with anastomosis.

Clinical value	Conventional laparoscopy (N = 1041), n (%)	Transanal TME (N = 136), n (%)	Robot-assisted laparoscopy (N = 154), n (%)	p-value
Anastomotic leakage	182 (18)	36 (27)	28 (18)	0.040
ISREC classification B/C ^a	151 (83)	30 (83)	25 (89)	0.699
Permanent stoma	121 (12)	32 (24)	22 (14)	0.001
Type of permanent stoma				
Stoma created before resection	4 (3)	0 (0)	2 (9)	0.262
Diverting stoma created during resection	32 (26)	10 (31)	5 (23)	
Secondary diverting ileostomy	12 (10)	1 (3)	5 (23)	
Secondary diverting colostomy	12 (10)	1 (3)	1 (5)	
Secondary end ileostomy	6 (5)	2 (6)	O (O)	
Secondary end colostomy	55 (46)	18 (56)	9 (41)	
Reason for permanent stoma				
Nonhealed anastomotic leakage/presacral abscess	37 (31)	5 (16)	6 (27)	0.076
Patient not fit for surgery	18 (15)	8 (25)	4 (18)	
Primary choice	8 (7)	2 (6)	1 (5)	
Resection for locoregional recurrence	4 (3)	5 (16)	1 (5)	
Palliative stoma for locoregional recurrence	7 (6)	0 (0)	O (O)	
Low anterior resection syndrome	6 (5)	3 (9)	O (O)	
Patient's wish	10 (8)	3 (9)	0 (0)	
Stenosis anastomosis	O (O)	1 (3)	0 (0)	
Necrotic colon	4 (3)	0 (0)	0 (0)	
Patient has died before planned stoma closure	7 (6)	2 (6)	2 (9)	
Other	12 (10)	1 (3)	3 (14)	
Unknown	8 (7)	2 (6)	5 (23)	
Patients with at least one unplanned reintervention	263 (25)	53 (39)	50 (33)	0.001
Type of reintervention				
Adhesiolysis	10 (1)	3 (2)	4 (3)	0.143
Surgical drainage intraabdominal abscess	8 (1)	4 (3)	4 (3)	0.022
Surgical drainage presacral abscess	38 (4)	9 (7)	10 (7)	0.097
Dilatation anastomosis	12 (1)	5 (4)	2 (1)	0.065
Segment resection small bowel	4 (0)	O (O)	2 (1)	0.203
EndoSponge	32 (3)	6 (4)	6 (4)	0.649
Correction hernia cicatricalis	32 (3)	6 (4)	7 (5)	0.501
Reconstruction anastomosis	9 (1)	4 (3)	3 (2)	0.075
Nefrodrain	1 (0)	0 (0)	2 (1)	0.011
Radiological drainage intraabdominal abscess	6 (1)	2 (2)	0 (0)	0.264
Radiological drainage presacral abscess	26 (2)	3 (2)	3 (2)	0.936
Reintervention for bleeding	5 (1)	1 (1)	0 (0)	0.618
Transanal drainage abscess	8 (1)	1 (1)	0 (0)	0.552
Transanal closure defect anastomosis	7 (1)	1 (1)	0 (0)	0.588
Ureter reconstruction	1 (0)	0 (0)	0 (0)	0.870
Wound toilet or VAC under narcosis	3 (0)	1 (1)	O (O)	0.515
Resection rectal stump	5 (1)	4 (3)	0 (0)	0.002
Correction parastomal hernia	8 (1)	2 (2)	O (O)	0.348
Stoma revision	13 (1)	4 (3)	1 (1)	0.199
Unplanned construction stoma	158 (15)	31 (23)	28 (18)	0.062

TABLE 3 (Continued)



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Clinical value	Conventional laparoscopy (N = 1041), n (%)	Transanal TME (N = 136), n (%)	Robot-assisted laparoscopy (N = 154), n (%)	p-value
Other	36 (4)	7 (5)	8 (5)	0.405
Patients with at least ine unplanned readmission	256 (25)	54 (40)	52 (34)	<0.001
Cause of readmission				
Wound problem	10 (1)	1 (1)	1 (1)	0.908
Dehydration	19 (2)	8 (6)	5 (3)	0.011
lleus	37 (4)	7 (5)	12 (8)	0.043
Hernia cicatricalis	23 (2)	6 (4)	5 (3)	0.262
Abscess/fistula intra-abdominal or presacral	61 (6)	10 (7)	14 (9)	0.275
Anastomotic leakage	32 (3)	7 (5)	4 (3)	0.391
Stoma related complication	16 (2)	2 (2)	4 (3)	0.619
Unplanned construction stoma	132 (13)	30 (22)	26 (17)	0.007
Other	34 (3)	8 (6)	4 (3)	0.240

Abbreviation: VAC, Vacuum Assisted Closure.

^aISREC (International Study Group of Rectal Cancer): Grade B, anastomotic leakage requiring active therapeutic intervention, but manageable without relaparotomy; Grade C, anastomotic leakage requiring relaparotomy.

The increased permanent stoma rate in the TaTME group during follow-up might be caused by the higher complication rate in the TaTME group, especially the higher anastomotic leakage rate. The anastomotic leakage rate of 25% in the TaTME group in this study is also higher than previously reported in other studies (16%–18%) [11, 19]. A recently published study which specifically included centres with experienced surgeons (those who performed at least 40 procedures with the specific technique) did show a lower permanent stoma rate in the TaTME (15%) and R-TME (11%) groups [20]. While the use of R-TME was centralized in a few hospitals, TaTME was performed in 27 of the 67 hospitals (40%) without proper training; 15 hospitals performed only one to three TaTME procedures in this cohort. The learning curve is likely to have influenced these poor outcomes in the TaTME group. Since 2016, a large proportion of these hospitals have stopped performing TaTME [21, 22]. Prospective studies such as the COLOR III trial [23] and the VANTAGE trial [24] are being performed to prospectively evaluate the outcomes of the different minimally invasive techniques in a quality-controlled setting.

Another noticeable difference between the three techniques was the higher positive surgical resection margin rate in the R-TME group (9% for all TME procedures and 6% for the restorative procedures). There were no differences in tumour stage or height of the tumour in the R-TME group compared with L-TME and TaTME that could have explained this increased rate. This increased risk has not been reported in other studies [11, 12] but does require attention.

The permanent stoma rate after a rectal resection is still very high at 50%. This is slightly less than in 2011 (57%) [14, 25]. An important difference compared with the 2011 cohort and other studies is that the definition of sigmoid take-off was used in the

current study, probably resulting in a higher proportion of distal tumours. Overall, the proportions of APR and HP procedures slightly decreased in 2016 compared with 2011 [14]. In the 2016 cohort, 28% of the TME procedures were APRs and 13% were HPs. This was 31% and 19%, respectively, in 2011. The use of a diverting stoma decreased from 74% in 2011 to 53% in 2016 but remains high. The proportion of HPs in the 2016 cohort is comparable with results from population-based studies from Denmark (14%) [26] and Sweden (12%) [27], but is still high compared with recent randomized controlled trials (4%–6%) [28, 29].

There remains a large IHV in the permanent stoma rate in the current study. This can be explained by centralization of the difficult tumours, often located more distally in the rectum and therefore more often requiring a nonrestorative procedure. However, surgeon preference is likely to be an important factor. Furthermore, the large proportion of patients with an unintentional permanent stoma after an initial restorative procedure (even 24% in the TaTME group) accentuates the need for improvement in preoperative risk-assessment for complications and functional outcomes [25, 30–32].

Limitations

Due to the retrospective design of this study the results should be interpreted with caution. Firstly, due to the 4-year oncological follow-up period, the patients included in this study received their resection in 2016. Meanwhile, surgeons might now be better trained in the minimally invasive techniques and implementation has become stricter due to the first results of the TaTME technique [21]. Therefore, results might be more favourable in a

		Permanent stoma					
		Univariable analysis			Multiva	riable analy	sis
Variable	n	OR	95% CI	p-value	OR	95% CI	p-value
Sex							
Male	868	1		0.007			
Female	469	0.612	0.428-0.874				
Age	1337	1.011	0.994-1.028	0.214			
ASA score							
1/11	1161	1		0.041	1		0.004
III/IV	163	1.568	1.1018-2.417		1.992	1.250- 3.174	
Distance to the ARJ	1202	0.836	0.781-0.895	<0.001	0.834	0.778- 0.895	<0.001
cT-stage							
cT1/cT2	444	1		0.005			
cT3	768	1.755	1.208-2.549				
cT4	43	2.534	1.138-5.642				
Distance to the M	IRF						
MRF >1 mm	906	1		0.012			
MRF ≤1mm	244	1.609	1.108-2.337				
cN-stage							
cN0	598	1		0.108			
cN1	416	1.267	0.873-1.839				
cN2	250	1.548	1.021-2.346				
cM-stage							
cM0	1267	1		0.006	1		0.018
cM1	70	2.219	2.254-3.928		2.083	1.132- 3.831	
Neoadjuvant radiotherapy							
No	635	1		<0.001	1		0.016
Yes	702	1.917	1.375-2.671		1.545	1.083- 2.204	
Approach							
Laparoscopic	1041	1		<0.001			
TaTME	136	2.339	1.508-3.630				
Robotic	154	1.267	0.777-2.068				

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TABLE 4 Univariable and multivariable
 binary logistic regression for presence of permanent stoma.

Abbreviations: ARJ, anorectal junction; ASA, American Society of Anesthesiologists; MRF, mesorectal fascia; OR, odds ratio; TaTME, transanal mesorectal excision. CONCLUSION new cohort. However, besides the previously extensive attention

to local recurrence rates, the results of this study should also be used to critically evaluate the different techniques and further improve outcomes. Secondly, complications and other details might not have been consequently documented in the patient files and might therefore have been missed during data collection. Lastly, the study design did not allow us to collect patientreported outcomes, meaning that quality of life and low anterior resection syndrome scores are unfortunately unknown, although these would be essential during further investigation to aid clinical decision-making.

This cross-sectional study revealed a nationwide permanent stoma rate of 50%. No beneficial effect was observed for TaTME or R-TME on the permanent stoma rate after a restorative procedure, although this might be due to the surgical learning curve which was still ongoing in this cohort. There was huge IHV for the type of rectal cancer resection in 2016 in the Netherlands and consequently the permanent stoma rate. Better insight in long-term quality of life is needed to guide physicians and patients with rectal cancer towards decision-making on restorative procedures.

AUTHOR CONTRIBUTIONS

Miranda Kusters: Methodology; supervision; project administration; writing - review and editing; funding acquisition; investigation; conceptualization. Sanne-Marije J. A. Hazen: Conceptualization; investigation; methodology; data curation; writing - original draft; formal analysis; project administration. Eline G. M. van Geffen: Investigation; writing - review and editing; project administration. Tania C. Sluckin: Conceptualization; investigation; methodology; writing - review and editing; project administration. Geerard L. Beets: Investigation; writing - review and editing. Henricus J. Belgers: Investigation; writing - review and editing. Wernard A. A. Borstlap: Investigation; writing - review and editing; conceptualization; methodology. Esther C. J. Consten: Investigation; writing - review and editing. Jan-Willem T. Dekker: Investigation; writing - review and editing. Roel Hompes: Investigation; writing - review and editing. Jurriaan B. Tuynman: Investigation; writing - review and editing. Henderik L. van Westreenen: Investigation; writing - review and editing. Johannes H. W. de Wilt: Investigation; writing - review and editing. Pieter J. Tanis: Conceptualization; methodology; writing - review and editing; supervision: investigation.

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CONFLICT OF INTEREST STATEMENT None.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The Medical Ethical Committee Vrije Universiteit Medical Centre in Amsterdam reviewed and approved the study protocol on 30 June 2020.

PATIENT CONSENT STATEMENT

The Dutch Medical Research Involving Human Subjects Act was not applicable. Local approval for execution of the study and the need to provide informed consent or the opportunity to opt-out was obtained by the local institutional review board of each participating centre.

CLINICAL TRIAL REGISTRATION

Not applicable.

ORCID

Sanne-Marije J. A. Hazen 匝 https://orcid.

org/0000-0001-8372-1986

Geerard L. Beets D https://orcid.org/0000-0002-1671-9912 Jurriaan B. Tuynman D https://orcid.org/0000-0001-5952-8000 Pieter J. Tanis D https://orcid.org/0000-0002-3146-3310 Miranda Kusters D https://orcid.org/0000-0002-2468-9186

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APPENDIX

INTRAOPERATIVE TECHNIQUE AND COMPLICATIONS FOR TRANSANAL TME (A) AND THE ROBOTIC APPROACH (B)

(A) Clinical value	Transanal TME (N = 170), n (%)
AirSeal usage	124/166 (81)
Intraoperative complications	23/166 (14)
Bleeding presacral venous plexus	6 (4)
CO ₂ embolism	2 (1)
Incomplete doughnut	9 (5)
Incomplete anastomosis	5 (3)
Perforation rectum	2 (1)
Purse-string failure	1 (1)
Spill of faeces	1 (1)
Spill of mucus	0 (0)
Urethra damage	4 (2)
Vaginal perforation	0 (0)
Other	1 (1)
(B) Clinical value	Robot-assisted resection (N=235), n (%)
Type of robot	
Si	139 (62)
Xi	81 (36)
х	3 (1)
Unknown	12
Is the entire surgery performed with the re	obot?
Yes	160 (71)

(B) Clinical value	Robot-assisted resection (<i>N</i> = 235), <i>n</i> (%)
No, conventional laparoscopy for flexure mobilization	4 (2)
No, conventional laparoscopy for pelvic dissection	6 (3)
No, stapling through Pfannenstiel or conventional laparoscopy	41 (18)
Unknown	24
Fluorescence	65 (28)

COLLABORATORS OF THE DUTCH SNAPSHOT RESEARCH GROUP

Arend G. J. Aalbers, Susanna M. van Aalten, Femke J. Amelung, Marjolein Ankersmit, Imogeen E. Antonisse, Jesse F. Ashruf, Tjeerd S. Aukema, Henk Avenarius, Renu R. Bahadoer, Frans C. H. Bakers, Ilsalien S. Bakker, Fleur Bangert, Renée M. Barendse, Heleen M. D. Beekhuis, Geerard L. Beets, Willem A. Bemelman, Maaike Berbée, Shira H. de Bie, Robert H. C. Bisschops, Liselotte W. van Bockel, Anniek H. Boer, Frank C. den Boer, Evert-Jan G. Boerma, Leonora S. F. Boogerd, Jaap Borstlap, Wernard A. A. Borstlap, Robin D. Blok, Johanna E. Bouwman, Sicco J. Braak, Manon N. G. J. A. Braat, Jennifer Bradshaw, Amarins T. A. Brandsma, Vivian van Breest Smallenburg, Wim T. van den Broek, Sjirk W. van der Burg, Jacobus W. A. Burger, Thijs A. Burghgraef, David W. G. ten Cate, Heleen M. Ceha, Jeltsje S. Cnossen, Robert J. Coebergh van den Braak, Esther C. J. Consten, Maaike Corver, Rogier M. P. H. Crolla, Sam Curutchet, Alette W. Daniëls-Gooszen, Paul H. P. Davids, Emmelie N. Dekker, Jan Willem T. Dekker, Ahmet Demirkiran, Tyche Derksen, Arien L. Diederik, Anne M. Dinaux, Kemal Dogan, Ilse M. van Dop, Kitty E. Droogh-de Greve, Hanneke Duijsens, Michalda S. Dunker, Johan Duyck, Eino B. van Duyn, Laurentine S. E. van Egdom, Bram Eijlers, Youssef El-Massoudi, Saskia van Elderen, Anouk M. L. H. Emmen, Marc Engelbrecht, Anne C. van Erp, Jeroen A. van Essen, Hans F. J. Fabry, Thomas Fassaert, Eline A. Feitsma, Shirin S. Feshtali, Bas Frietman, Edgar J. B. Furnée, Anne van Geel, Elisabeth D. Geijsen, Nanette van Geloven, Michael F. Gerhards, Hugo Gielkens, Renza van Gils, Lucas Goense, Marc J. P. M. Govaert, Wilhelmina M. U. van Grevenstein, Elisabeth J. de Groof, Irene de Groot, Robbert J. de Haas, Nadia A. G. Hakkenbrak, Mariska D. den Hartogh, Vera Heesink, Joost T. Heikens, Ellen M. Hendriksen, Sjoerd van den Hoek, Erik J. R. J. van der Hoeven, Christiaan Hoff, Anna Hogewoning, Cornelis R. C. Hogewoning, Stefan Hoogendoorn, Francois van Hoorn, René L. van der Hul,

Rieke van Hulst, Farshad Imani, Bas Inberg, Martijn P. W. Intven, Pedro Janssen, Chris E. J. de Jong, Jacoline Jonkers, Daniela Jou-Valencia, Bas Keizers, Stijn H. J. Ketelaers, Eva Knöps, Sebastiaan van Koeverden, Sylvia Kok, Stephanie E. M. Kolderman, Fleur I. de Korte, Robert T. J. Kortekaas, Julie C. Korving, Ingrid M. Koster, Jasenko Krdzalic, Pepijn Krielen, Leonard F. Kroese, Eveline Krul, Derk Lahuis, Bas Lamme, An A. G. van Landeghem, Jeroen W. A. Leijtens, Mathilde M. Leseman-Hoogenboom, Manou de Lijster, Martijn S. Marsman, Milou. H. Martens, Ilse Masselink, Wout van der Meij, Philip Meijnen, Jarno Melenhorst, Dietrich J. L. de Mey, Julia Moelker-Galuzina, Linda Morsink, Erik J. Mulder, Karin Muller, Gijsbert D. Musters, Joost Nederend, Peter A. Neijenhuis, Lindsey C. F. de Nes, M. Nielen, Jan B. J. van den Nieuwboer, Jonanne F. Nieuwenhuis, Joost Nonner, Bo J. Noordman, Stefi Nordkamp, Pim B. Olthof, Steven J. Oosterling, Daan Ootes, Vera Oppedijk, Pieter Ott, Ida Paulusma, Koen C. M. J. Peeters, Ilona T. A. Pereboom, Jan Peringa, Zoë Pironet, Joost D. J. Plate, Fatih Polat, Ingrid G. M. Poodt, Lisanne A. E. Posma, Jeroen F. Prette, Bareld B. Pultrum, Seyed M. Qaderi, Jan M. van Rees, Rutger-Jan Renger, Anouk J. M. Rombouts, Lodewijk Roosen, Ellen A. Roskott-ten Brinke, Joost Rothbarth, Dennis B. Rouw, Tom Rozema, Heidi Rutten, Harm J. T. Rutten, Marit E. van der Sande, Boudewijn E. Schaafsma, Renske A. Schasfoort, Merel M. Scheurkogel, Arjan P. Schouten van der Velden, Wilhelmina H. Schreurs, Puck M. E. Schuivens, Colin Sietses, Petra C. G. Simons, Marjan J. Slob, Gerrit D. Slooter, Martsje van der Sluis, Bo P. Smalbroek, Anke B. Smits, Ernst J. Spillenaar-Bilgen, Patty H. Spruit, Tanja C. Stam, Jaap Stoker, Aaldert K. Talsma, Sofieke Temmink, G. Y. Mireille The, Jeroen A. W. Tielbeek, Aukje A. J. M. van Tilborg, Fiek van Tilborg, Dorothée van Trier, Jurriaan B. Tuynman, Maxime J. M. van der Valk, Inge J. S. Vanhooymissen, G. Boudewijn C. Vasbinder, Cornelis J. Veeken, Laura A. Velema, Anthony W. H. van de Ven, Emiel G. G. Verdaasdonk, Wouter M. Verduin, Tim Verhagen, Paul M. Verheijen, Maarten Vermaas, An-Sofie E. Verrijssen, Anna Vera D. Verschuur, Harmke Verwoerdvan Schaik, Roy F. A. Vliegen, Sophie Voets, F. Jeroen Vogelaar, Clementine L. A. Vogelij, Hanneke A. Vos-Westerman, Marianne de Vries, Joy C. Vroemen, Bas S. T. van Vugt, Johannes A. Wegdam, Bob J. van Wely, Marinke Westerterp, Paul P. van Westerveld, Henderik L. van Westreenen, Allard G. Wijma, Johannes H. W. de Wilt, Bart W. K. de Wit, Fennie Wit, Karlijn Woensdregt, Victor van Woerden, Floor S. W. van der Wolf, Sander van der Wolk, Johannes M. Wybenga, Edwin S. van der Zaag, Bobby Zamaray, Herman J. A. Zandvoort, Dennis van der Zee, Annette Zeilstra, Kang J. Zheng, David D. E. Zimmerman, Marcel Zorgdrager.