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Current practice in Australia and New Zealand for defunctioning ileostomy after rectal cancer surgery with anastomosis: Analysis of the Binational Colorectal Cancer Audit

Vera E. M. Grupa^{1,2} | Hidde M. Kroon^{1,3} | Izel Ozmen^{1,2} | Sergei Bedrikovetski^{1,3} | Nagendra N. Dudi-Venkata^{1,3} | Ronald A. Hunter¹ | Tarik Sammour^{1,3}

¹Colorectal Unit, Department of Surgery, Royal Adelaide Hospital, Adelaide, South Australia, Australia

²Faculty of Medical Sciences, Leiden University, Leiden, The Netherlands

³Faculty of Health and Medical Sciences, School of Medicine, University of Adelaide, Adelaide, South Australia, Australia

Correspondence

Hidde M. Kroon, Colorectal Unit, Department of Surgery, Royal Adelaide Hospital, Port Road, Adelaide, South Australia 5000, Australia. E-mail: Hidde.Kroon@sa.gov.au

Abstract

Aim: This study aimed to investigate the use of defunctioning stomas after rectal cancer surgery in Australia and New Zealand, as current practice is unknown.

Methods: From the Binational Colorectal Cancer Audit database, data on rectal cancer patients who underwent a resection between 2007 and 2019 with the formation of an anastomosis were extracted and analysed. The primary outcome was the rate of defunctioning stoma formation. Secondary outcomes were anastomotic leakage (AL) rates and other postoperative complications, length of hospital stay (LOS), readmissions and 30-day mortality rates between stoma and no-stoma groups. Propensity score matching was performed to correct for differences in baseline characteristics between stoma and no-stoma groups.

Results: In total, 2581 (89%) received a defunctioning stoma and 319 (11%) did not. There were more male patients in the stoma group (65.5% vs. 57.7% for the no-stoma group; P = 0.006). The median age was 64 years in both groups. The stoma group underwent more ultra-low anterior resections (79.9% vs. 30.1%; P < 0.0001), included more American Joint Committee on Cancer Stage III patients (53.7% vs. 29.2%; P < 0.0001) and received more neoadjuvant therapy (66.9% vs. 16.3%; P < 0.0001). The AL rate was similar in both groups (5.1% vs. 6.0%; P = 0.52). LOS was longer in the stoma group (8 vs. 6 days; P < 0.0001) with higher 30-day readmission rates (14.9% vs. 8.3%; P = 0.003). After propensity score matching (n = 208 in both groups), AL rates remained similar (2.9% for stoma vs. 5.8% for no-stoma group; P = 0.15), but stoma patients required less reoperations (0% vs. 8%; P = 0.016). The stoma group had higher postoperative ileus rates and an increased LOS.

Conclusion: In Australia and New Zealand, most patients who underwent rectal cancer resections with the formation of an anastomosis received a defunctioning stoma. A defunctioning stoma does not prevent AL from occurring but is mostly associated with a lower reoperation rate. Patients with a defunctioning stoma experienced a higher postoperative ileus rate and had an increased LOS.

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KEYWORDS

rectal cancer surgery, anastomosis, anastomotic leakage, defunctioning stoma, postoperative complications

What does this paper add to the literature?

This paper is the first to investigate the rate of defunctioning stomas created after rectal cancer resections in Australia and New Zealand and to establish on what basis this decision is made. Moreover, a defunctioning stoma does not prevent anastomotic leakage from occurring but it does diminish its consequences.

INTRODUCTION

Colorectal cancer is the second most prevalent cancer in the Western world and, after lung cancer, is responsible for the most cancer related deaths [1–3]. In Australia, for instance, 16 398 patients were newly diagnosed with colorectal cancer in 2019, of whom approximately a third had rectal cancer [3,4].

Surgery remains the main treatment modality in rectal cancer care. After resection of the rectum, an anastomosis is formed in most patients to establish continuity of the gastrointestinal tract. Low pelvic anastomoses, however, are associated with a high risk of postoperative anastomotic leakage (AL), a complication that can lead to reoperation, formation of a permanent stoma, increased length of hospital stay (LOS), increased morbidity, loss in quality of life and mortality [5,6]. Therefore, surgeons often choose to create a defunctioning stoma to cover the anastomosis in an effort to reduce AL risk and its consequences [7-9]. However, a defunctioning stoma by itself is also associated with morbidity, such as dehydration, renal failure, reduced self-image and quality of life [10,11] Additionally, a defunctioning stoma requires a second operation to achieve closure necessitating a second hospital admission, with further risks of complications such as wound infections, AL and incisional hernias [10]. Taking the benefits and disadvantages into account, a carefully weighed decision based on risk factors for AL should be made when deciding to construct a defunctioning stoma.

Internationally, patient selection and practices for creating defunctioning stomas vary widely [12,13]. For Australia and New Zealand (ANZ), current practice is unknown. Therefore, the aim of this study was to investigate the practice of constructing a defunctioning stoma after rectal cancer surgery with an anastomosis in ANZ, and to detect potential differences in postoperative outcomes between patients with or without a defunctioning stoma.

METHODS

Data were derived from the Binational Colorectal Cancer Audit (BCCA), a multi-institutional ANZ clinical quality registry in which data of colorectal cancer patients are prospectively collected. Since its introduction in 2007, the number of cases recorded in the BCCA has shown a yearly increase and since 2018 it has become mandatory for accredited training hospitals to enter data into the BCCA [14].

The study was approved by the BCCA Operations Committee and the Central Adelaide Local Health Network Human Research Ethics Committee (HREC/18/CALHN/527, CALHN R20180809). BCCA data were extracted for patients who underwent elective rectal cancer resections with curative intent by a proctocolectomy, ultra-low anterior resection (anastomosis 0-6 cm from anal verge) or low anterior resection (LAR) (anastomosis 6–10 cm from anal verge) between 2007 and 2019, with the formation of a primary anastomosis. Patients who underwent transanal local procedures, had synchronous tumours or distant metastases at the time of surgery. underwent palliative resections, or underwent emergency surgery were excluded. Patients with the following missing variables were also excluded: American Society of Anesthesiologists (ASA) score, neoadjuvant therapy, operative urgency, surgical entry (open or minimally invasive), overall American Joint Committee on Cancer (AJCC) stage [15] and pathological T stage (pT). Patients with missing clinical T (cT) or N (cN) stage but with available pT or pathological N (pN) stage were included, if they had not received neoadjuvant therapy. In these cases, missing data for cT or cN stages were matched to their pT and pN stages.

After identifying eligible patients, the study population was divided into two groups: those in whom a defunctioning stoma was formed (stoma group) and those in whom no defunctioning stoma was formed (no-stoma group). Variables such as age, gender, hospital location, AJCC stage, TNM stage, and procedure, stoma and anastomosis type, complications and pathological results were extracted and analysed for included patients. A hospital was considered 'urban' if the population it serves exceeded 100 000 inhabitants. In the BCCA, AL is defined as diagnosis of a leak based on clinical and/ or radiological findings.

The primary outcome was the rate of defunctioning stoma (either loop ileostomy or loop colostomy) formation. The secondary outcomes were AL rate and other postoperative complications, LOS, readmission and 30-day mortality rates between stoma and nostoma groups.

To investigate the defunctioning stoma rate in ANZ in relation to preoperative AL risk, the risk factors for AL as published by Matthiessen et al. were used [5].

Continuous outcomes are presented as median and range, and categorical outcomes as frequency and percentage. Univariate analyses were performed on both groups, using the Mann-Whitney *U* test or *t* test for continuous variables, the chi-squared and Fisher tests for categorical variables. To minimize the effect

of confounding influences of measured covariates on the assessed outcome between the two study groups (stoma and no stoma) propensity score matching was performed. First, a propensity score for each patient was calculated using a logistic regression model, which was fitted for stoma, using the covariates listed in Table 1. Probability scores were generated by logistic regression and were matched by one-to-one nearest neighbour without replacement and a match tolerance of 0.00. To prevent poor matches, a caliper of 0.25 multiplied by the standard deviation of the logit of the propensity score was used. Covariate balance of the matched cohort was assessed using the mean standardized differences, with differences <10% and close to 0% taken to indicate good balance. After this, groups were well matched for the covariates listed in Table 1. A statistically significant *P* value was defined as \leq 0.05.

FIGURE 1 Flowchart of included and excluded patients

Statistical analyses were conducted using IBM SPSS version 24 (SPSS Inc.) and GraphPad Prism version 8.0.2 (GraphPad Software Inc.).

RESULTS

A total of 12 251 patients recorded in the BCCA database underwent rectal cancer surgery. Of them, 5201 underwent a rectal resection with formation of an anastomosis. After exclusion as described in the Methods section, 2900 patients remained for analysis (Figure 1): 2581 patients (89%) had a defunctioning stoma formed (stoma group), and 319 (11%) had not (no-stoma group).

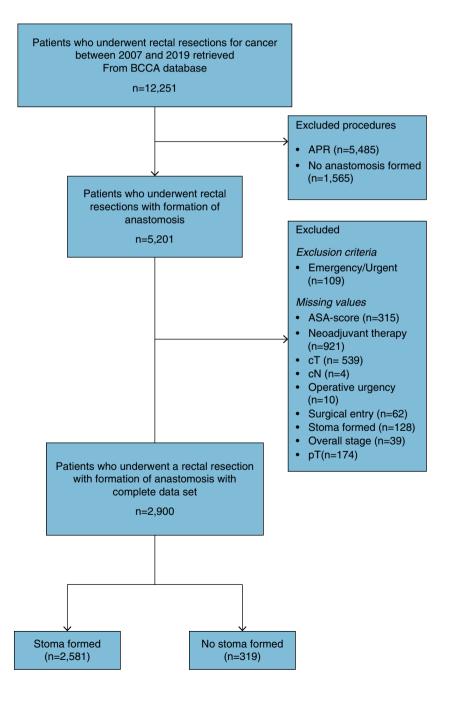


TABLE 1 Preoperative and intra-data

	Total (n = 2900)	Stoma+ (n = 2581)	Stoma- (n = 319)	P value
Gender (%)				
Male	1874 (64.6)	1690 (65.5)	184 (57.7)	0.006
Female	1026 (35.4)	891 (34.5)	135 (42.3	
Median age in years (range)	64 (23–100)	64 (23–100)	64 (23-90)	0.47
Domestic living location (%)				
Urban	2578 (88.9)	2293 (88.8)	285 (89.3)	0.79
Rural	322 (11.1)	288 (11.2)	34 (10.7)	
Tumour site (%)				
Upper rectum (>12 cm)	369 (12.7)	230 (8.9)	139 (43.6)	<0.0001
Mid rectum (8–12 cm)	1326 (45.8)	1187 (46.0)	139 (43.6)	
Lower rectum (<8 cm)	1203 (41.5)	1162 (45.1)	41 (12.8)	
Missing	2	2	0	
Clinical tumour (cT) stage (%)				
T1	136 (4.7)	105 (4.1)	31 (9.71)	<0.0001
T2	726 (25.0)	617 (23.9)	109 (34.2)	
Т3	1739 (60.0)	1605 (62.2)	134 (42.0)	
T4	186 (6.4)	176 (6.8)	10 (3.1)	
Tx ^a	113 (3.9)	78 (3.0)	35 (11.0)	
Clinical nodal (cN) stage (%)				
NO	1219 (42.0)	1029 (39.9)	190 (59.6)	<0.0001
N1	887 (30.6)	825 (32.0)	62 (19.4)	
N2	608 (21.0)	577 (22.3)	31 (9.7)	
Nx ^b	186 (6.4)	150 (5.8)	36 (11.3)	
Clinical AJCC stage (%)				
0	3 (0.1)	3 (0.1)	0	<0.0001
1	693 (23.9)	566 (21.9)	127 (39.8)	
2	614 (21.2)	550 (21.3)	64 (20.1)	
3	1480 (51.0)	1387 (53.7)	93 (29.2)	
Xc	110 (3.8)	75 (2.9)	35 (11.0)	
Neoadjuvant therapy (%)				
Yes	1778 (61.3)	1726 (66.9)	52 (16.3)	<0.0001
No	1122 (38.7)	855 (33.1)	267 (83.7)	
Neoadjuvant therapy type (%)		· ·		
Short-course RT	230 (14.4)	223 (14.5)	7 (13.5)	0.55
Long-course CRT	1328 (83.5)	1283 (83.4)	45 (86.5)	
Other	33 (2.1)	33 (2.1)	0	
Missing	187	187	0	
ASA score (%)				
	579 (20.0)	518 (20.1)	61 (19.1)	0.93
II	1577 (54.4)	1405 (54.4)	172 (53.9)	-
	705 (24.3)	623 (24.1)	82 (25.7)	
IV	39 (1.3)	35 (1.4)	4 (1.3)	
Procedure type (%)	. ,			
Proctocolectomy or colo-anal anastomosis	102 (3.5)	100 (3.9)	2 (0.6)	

TABLE 1 (Continued)



	Total (n = 2900)	Stoma+ (n = 2581)	Stoma- (n = 319)	P value
LAR ^d	640 (22.1)	419 (16.2)	221 (69.3)	<0.0001
ULAR ^e	2158 (74.4)	2062 (79.9)	96 (30.1)	
Anastomosis type (%)				
Colonic pouch	527 (26.6)	516 (27.4)	11 (11.7)	0.002
Side-to-end anastomosis	364 (18.4)	347 (18.4)	17 (18.1)	
End-to-end anastomosis	1087 (55.0)	1021 (54.2)	66 (70.2)	
Missing	922	697	225	
Stoma type (%)				
Loop ileostomy	-	2509 (99.6)	-	n/a
Loop colostomy	-	11 (0.4)	-	
Missing	-	61	-	
Surgical entry (%)				
Open	1047 (36.1)	1005 (38.9)	42 (13.2)	<0.0001
Minimally invasive ^f	1853 (63.9)	1576 (61.1)	277 (86.8)	
Conversion in case of minimally invasive (% of minimally invasive procedures)	177 (9.6)	163 (10.3)	14 (5.1)	0.01

Bold values are statistical significant values.

Abbreviations: AJCC, American Joint Committee against Cancer; ASA, American Society of Anesthesiologists; CRT, chemoradiotherapy; n/a, not applicable; RT, radiotherapy.

^aClinical tumour stage could not be assessed.

^bClinical nodal stage could not be assessed.

^cClinical AJCC stage could not be assessed.

^dLow anterior resection: anastomosis at 6.1–10 cm from anal verge.

^eUltra-low anterior resection: anastomosis at 0–6 cm from anal verge.

^fLaparoscopic/transanal total mesorectal excision/robotic/hybrid.

The stoma group consisted of more men compared to the nostoma group (65.6% vs. 57.7%; P = 0.006; Table 1). The stoma group patients had a tumour located in the lower rectum more often (45.1% vs. 12.8%; P < 0.0001) and had higher cT stages, cN and pretreatment AJCC stages (P < 0.0001). Patients in the stoma group received more neoadjuvant therapy (66.9%), compared to 16.3% in the no-stoma group (P < 0.0001). Most stoma group patients underwent an ultra-low anterior resection (79.9%), while a LAR was the most frequently performed procedure in the no-stoma group (69.3%; P < 0.0001). Most patients in both groups underwent minimally invasive surgery, but more open procedures were performed in the stoma group (38.9% vs. 13.2%; P < 0.0001). The conversion rate from laparoscopic to open surgery was higher in the stoma group (10.3% vs. 5.1%; P = 0.01).

Overall, surgical complications occurred more frequently in stoma group patients (27.4% vs. 19.4% for no-stoma group patients; P = 0.002; Table 2). The AL rate was similar in both groups (5.1% vs. 6.0% for stoma and no-stoma group, respectively; P = 0.52), but stoma group patients with AL were treated conservatively with antibiotics more frequently compared to no-stoma group patients (40% vs. 12.5%), while more patients in the no-stoma group underwent a re-intervention to treat AL (87.5% vs. 60% for the stoma group; P < 0.0001). Thirteen patients in the no-stoma group with AL (81.2%)

underwent a reoperation while this was 17 patients (16.2%) in the stoma group (P < 0.0001). Stoma group patients experienced more often a postoperative ileus (11.2% vs. 6.0% for the no-stoma group; P = 0.004) and had more medical complications (13.0% vs. 9.1% for the no-stoma group; P = 0.48). Median LOS was prolonged in the stoma group (8.0 vs. 6.0 days for the no-stoma group; P < 0.0001) and they were more frequently readmitted within 30 days (12.2% vs. 7.5% for the no-stoma group; P = 0.014). The 30-day mortality rate was similar between both groups (1.1% vs. 1.3% for stoma group and no-stoma group, respectively; P = 0.79). Postoperative histopathology showed that the no-stoma group had more advanced disease with higher pT stages (P < 0.0001), pN stages (P = 0.04) and AJCC stages (P = 0.002).

Table 3 shows the number of patients in both groups according to the preoperative risk factors for AL. The rate of constructed defunctioning stomas increased from 63.0% in the case of no risk factors to 97.8% in the case of three risk factors (P < 0.0001). In the stoma group, higher rates of AL were seen in patients with more AL risk factors compared to the no-stoma group (P < 0.0001; Table 4).

Propensity score matching yielded 208 patients in each group. After matching, preoperative and intra-operative data were similar between groups: age, domestic living location, neoadjuvant therapy

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TABLE 2 Postoperative and histopathological outcomes

	Total (n = 2900)	Stoma+ (n = 2581)	Stoma-(n = 319)	P value
Anastomotic leakage (%)				
No	2749 (94.8)	2449 (94.9)	300 (94.0)	0.52
Yes	151 (5.2)	132 (5.1)	19 (6.0)	
Anastomotic leakage treatment (% of leaks)				
Conservative with antibiotics	44 (36.4)	42 (40.0)	2 (12.5)	<0.0001
Transanal/percutaneous drainage	47 (38.8)	46 (43.8)	1 (6.3)	
Reoperation	30 (24.8)	17 (16.2)	13 (81.2)	
Missing	30	27	3	
Return to theatre (%)				
No	2710 (93.4)	2418 (93.7)	292 (91.5)	0.14
Yes	190 (6.6)	163 (6.3)	27 (8.5)	
Overall surgical complications (%)				
No	2131 (73.5)	1874 (72.6)	257 (80.6)	0.002
Yes	769 (26.5)	707 (27.4)	62 (19.4)	
Surgical complications specified (%)				
Pelvic collection	131 (4.5)	118 (4.6)	13 (4.1)	0.69
Superficial wound dehiscence	26 (0.9)	25 (1.0)	1 (0.3)	0.24
Deep wound dehiscence	6 (0.2)	5 (0.2)	1 (0.3)	0.66
Wound infection	82 (2.8)	74 (2.9)	8 (2.5)	0.72
Sepsis	66 (2.3)	60 (2.3)	6 (1.9)	0.62
Postoperative ileus	309 (10.7)	290 (11.2)	19 (6.0)	0.004
Small bowel obstruction	45 (1.6)	44 (1.7)	1 (0.3)	0.06
Urinary retention	116 (4.0)	108 (4.2)	8 (2.5)	0.15
Ureteric injury	16 (0.6)	15 (0.6)	1 (0.3)	0.54
Postoperative haemorrhage	20 (0.7)	19 (0.7)	1 (0.3)	0.39
Other surgical complications	149 (5.1)	136 (5.3)	13 (4.1)	0.36
Overall medical complications (%)				
No	2536 (87.4)	2246 (87.0)	290 (90.9)	0.48
Yes	364 (12.6)	335 (13.0)	29 (9.1)	
Medical complications specified (%)				
DVT/PE ^a	17 (0.6)	15 (0.6)	2 (0.6)	0.92
Chest infection	79 (2.7)	74 (2.9)	5 (1.6)	0.18
Cardiac	97 (3.3)	84 (3.3)	13 (4.1)	0.44
Other medical complications	229 (7.9)	215 (8.3)	14 (4.4)	0.01
Median LOS in days (range)	8.0 (2-502)	8.0 (2-502)	6.0 (3-43)	<0.0001
30-day mortality (%)				
No	2868 (98.9)	2553 (98.9)	315 (98.7)	0.79
Yes	32 (1.3)	28 (1.1)	4 (1.3)	
30-day readmission (%)				
No	2561 (88.3)	2266 (87.8)	295 (92.5)	0.014
Yes	339 (11.7)	315 (12.2)	24 (7.5)	
Pathological tumour (pT) stage (%)				
ТО	258 (8.9)	245 (9.5)	13 (4.1)	<0.0001
Tis	23 (0.8)	20 (0.8)	3 (0.9)	
T1	399 (15.5)	340 (13.2)	59 (18.5)	
T2	756 (26.1)	688 (26.7)	68 (21.3)	

TABLE 2 (Continued)



	Total (n = 2900)	Stoma+ (n = 2581)	Stoma-(n = 319)	P value
Т3	1292 (44.6)	1137 (44.1)	155 (48.6)	
T4	114 (3.9)	95 (3.7)	19 (6.0)	
Tx ^b	58 (2.0)	56 (2.2)	2 (0.6)	
Pathological nodal (pN) stage (%)				
NO	1887 (65.1)	1701 (65.9)	186 (58.3)	0.04
N1	734 (25.3)	639 (24.8)	95 (29.8)	
N2	275 (9.5)	237 (9.2)	38 (11.9)	
Nx ^c	4 (0.1)	4 (0.1)	0	
Pathological metastatic (pM) stage (%)				
M0	2328 (80.3)	2071 (80.3)	257 (80.6)	0.67
M1	204 (7.0)	185 (7.2)	19 (6.0)	
Mx ^d	367 (12.7)	324 (12.5)	43 (13.5)	
Missing	1	1	0	
Pathological AJCC stage (%)				
0	292 (10.1)	278 (10.8)	14 (4.4)	0.002
1	894 (30.8)	797 (30.9)	97 (30.4)	
2	636 (21.9)	563 (21.8)	73 (22.9)	
3	874 (30.1)	758 (29.4)	116 (36.4)	
4	204 (7.0)	185 (7.2)	19 (6.0)	
Circumferential resection margins (%)				
Negative	2659 (96.8)	2362 (96.6)	297 (97.7)	0.56
Positive	89 (3.2)	82 (3.4)	7 (2.3)	
Missing	152	137	15	
Mucosal margins (%)				
Negative	2669 (99.5)	2357 (99.5)	312 (99.7)	0.60
Positive	14 (0.5)	13 (0.5)	1 (0.3)	
Missing	217	211	6	

Bold values are statistical significant values.

Abbreviations: AJCC, American Joint Committee on Cancer; LOS, length of stay; Tis, tumour in situ.

^aDeep vein thrombosis/pulmonary embolism.

^bPathological tumour stage could not be assessed.

^cPathological nodal stage could not be assessed.

^dPathological metastases not assessed.

TABLE 3Number of patientsaccording to preoperative risk factors foranastomotic leakage [5]	No. of risk factors ^a	Total n = 2900 (%)	Stoma+ n = 2581 (%)	Stoma- n = 319 (%)	Stoma rate (%)	P value
	0	292 (10.1)	184 (7.1)	108 (33.9)	63.0	<0.0001
	1	944 (32.6)	786 (30.5)	158 (49.5)	83.3	
	2	1083 (37.3)	1043 (40.4)	40 (12.5)	96.3	
	3	581 (20.0)	568 (22.0)	13 (4.1)	97.8	

Bold values are statistical significant values.

^aRisk factors included: Male gender; neoadjuvant therapy; tumour in lower rectum (<8 cm from anal verge).



TABLE 4 Anastomotic leakage and anastomotic leakage rate by preoperative risk factors [5]

No. of risk factors ^a	Total n = 151 (%); AL%	Stoma+ n = 132 (%); AL%	Stoma– n = 19 (%); AL%	P value
0	8 (6); 2.7	4 (3); 2.2	4 (21); 3.7	<0.0001
1	43 (28); 4.6	32 (24); 4.1	11 (58); 6.9	
2	57 (38); 5.3	54 (41); 5.2	3 (16); 7.4	
3	43 (28); 7.4	42 (32); 7.4	1 (5); 7.7	

Bold values are statistical significant values.

Abbreviation: AL, anastomotic leakage.

^aRisk factors included: Male gender; neoadjuvant therapy; tumour in lower rectum (<8 cm from anal verge).

type and ASA score remained equally distributed, while gender, tumour site, clinical disease stage, neoadjuvant therapy, procedure and anastomosis type, surgical entry and conversion rates were no longer significantly different (Table 5).

Overall surgical complication rates were similar between groups (21.6% vs. 22.1%; P = 0.90). In the stoma group, six (2.9%) patients suffered AL, compared to 12 (5.8%) patients suffering AL in the nostoma group (P = 0.15; Table 6). Of those with AL, eight no-stoma group patients required a reoperation, while none of the stoma group did (P = 0.016). More stoma group patients experienced a postoperative ileus (12.5% vs. 6.7%, respectively; P = 0.046). Median LOS remained longer in the stoma group (8.0 vs. 7.0 days, respectively; P = 0.001). Postoperative histopathology was similar between the two matched cohorts.

TABLE 5 Preoperative and intra-operative data of propensity score matched cohort

	Stoma+ (n = 208)	Stoma- (n = 208)	P value
Gender (%)			
Male	131 (63.0)	131 (63.0)	>0.99
Female	77 (37.0)	77 (37.0)	
Median age in years (range)	66 (26-92)	64 (23-90)	0.07
Domestic living location (%)			
Urban	186 (89.4)	183 (88.0)	0.64
Rural	22 (10.6)	25 (12.0)	
Гumour site (%)			
Upper rectum (>12 cm)	59 (28.3)	59 (28.3)	
Mid rectum (8-12 cm)	114 (54.8)	114 (54.8)	>0.99
Lower rectum (<8 cm)	35 (16.8)	35 (16.8)	
Missing	0	0	
Clinical tumour (cT) stage (%)			
T1	19 (9.1)	25 (12.0)	0.78
Τ2	83 (39.9)	72 (34.6)	
Т3	86 (41.3)	91 (43.8)	
T4	6 (2.9)	6 (2.9)	
Tx ^a	14 (6.7)	14(6.7)	
Clinical nodal (cN) stage (%)			
NO	120 (57.7)	134 (64.4)	0.22
N1	38 (18.3)	35 (16.8)	
N2	19 (9.1)	21 (10.1)	
Nx ^b	31 (14.9)	18 (8.7)	
Clinical AJCC stage (%)			
0	0	0	>0.99
1	93 (44.7)	93 (44.7)	
2	45 (21.6)	45 (21.6)	
3	56 (26.9)	56 (26.9)	
X ^c	14 (6.7)	14 (6.7)	
Neoadjuvant therapy (%)			
Yes	45 (21.6)	45 (21.6)	>0.99

TABLE 5 (Continued)



	Stoma+ (n = 208)	Stoma- (n = 208)	P value
No	163 (78.4)	163 (78.4)	
Neoadjuvant therapy type (%)			
Short-course RT	6 (19.6)	6 (14.3)	0.93
Long-course CRT	37 (76.1)	39 (85.7)	
Other	0	0	
Missing	2	0	
ASA score (%)			
I	37 (17.8)	46 (22.1)	0.20
II	109 (52.4)	116 (55.8)	
111	56 (26.9)	44 (21.2)	
IV	6 (2.9)	2 (1.0)	
Procedure type (%)			
Proctocolectomy or colo-anal anastomosis	0	0	>0.99
LAR ^d	119 (57.2)	119 (57.2)	
ULAR ^e	89 (42.8)	89 (42.8)	
Anastomosis type (%)			
Colonic pouch	11 (13.3)	10 (11.5)	0.27
Side-to-end anastomosis	25 (30.1)	16 (18.4)	
End-to-end anastomosis	47 (56.6)	61 (70.1)	
Missing	125	121	
Surgical entry (%)			
Open	35 (16.8)	35 (16.8)	>0.99
Minimally invasive ^f	173 (83.2)	173(83.2)	
Conversion in case of minimally invasive (% of minimally invasive procedures)	10 (5.8)	10 (5.8)	>0.99

Abbreviations: AJCC, American Joint Committee against Cancer; ASA, American Society of Anesthesiologists; CRT, chemoradiotherapy; RT, radiotherapy.

^aClinical tumour stage could not be assessed.

^bClinical nodal stage could not be assessed.

^cClinical AJCC stage could not be assessed.

^dLow anterior resection: anastomosis at 6.1–10 cm from anal verge.

 $^{\rm e}$ Ultra-low anterior resection: an astomosis at 0–6 cm from anal verge.

^tLaparoscopic/transanal total mesorectal excision/robotic/hybrid.

DISCUSSION AND CONCLUSIONS

This analysis of the BCCA demonstrates that 89% of the patients in ANZ undergoing a rectal resection for cancer with the formation of an anastomosis receive a defunctioning stoma with low AL rates. Propensity score matched analysis shows that AL rates in patients with a defunctioning stoma did not differ from those without a stoma; however, a defunctioning stoma is associated with lower reoperation rates.

Similar analysis of other national audits reported lower defunctioning stoma rates. Snijders et al. for instance used the Dutch Colorectal Audit and reported a defunctioning stoma rate of 67%, but with large variation between hospitals [12]. Postoperative complications, LOS and mortality were not reported, making it difficult to compare outcomes to the current study. Kuryba et al. found that out of all patients in the UK who underwent a LAR 66% received a defunctioning stoma, while a German study by Gastinger et al. reported a defunctioning stoma rate of 32.3% after LAR [15,16].

Although the defunctioning stoma rates in these European studies were lower, overall AL rates were similar to the current study [12,15,16]. Interestingly, these studies did not report a difference in AL rate between stoma and no-stoma groups either, and similar to our propensity score matched outcome Frouws et al. reported that it is less probable for patients with a defunctioning stoma to suffer a severe AL requiring reoperation [8].

The fact that the defunctioning stoma rate increased significantly with more AL risk factors present (Table 3) suggests that the ANZ surgeons are well aware of these risk factors and are more likely to create a defunctioning stoma when increasing AL risk factors are present [5,12] ESCP

TABLE 6 Postoperative and histopathological outcomes of propensity score matched cohort

	Stoma+ (n = 208)	Stoma- (n = 208)	P value
Anastomotic leakage (%)			
No	202 (97.1)	196 (94.2)	0.15
Yes	6 (2.9)	12 (5.8)	
Anastomotic leakage treatment (% of leaks)			
Conservative with antibiotics	4 (66.7)	2 (18.2)	0.016
Transanal/percutaneous drainage	2 (33.3)	1 (9.1)	
Reoperation	0	8 (72.7)	
Missing	0	1	
Return to theatre (%)			
No	200 (96.2)	192 (92.3)	0.09
Yes	8 (3.8)	16 (7.7)	
Overall surgical complications (%)			
No	163 (78.4)	162 (77.9)	0.90
Yes	45 (21.6)	46 (22.1)	
Surgical complications specified (%)			
Pelvic collection	5 (2.4)	10 (4.8)	0.19
Superficial wound dehiscence	0	1 (0.5)	0.32
Deep wound dehiscence	0	1 (0.5)	0.32
Wound infection	2 (1.0)	7 (3.4)	0.09
Sepsis	7 (3.4)	5 (2.4)	0.56
Postoperative ileus	26 (12.5)	14 (6.7)	0.046
Small bowel obstruction	3 (1.4)	1 (0.5)	0.32
Urinary retention	8 (3.8)	5 (2.4)	0.40
Ureteric injury	0	1 (0.5)	0.32
Postoperative haemorrhage	1 (0.5)	1 (0.5)	>0.99
Other surgical complications	7 (3.4)	10 (4.8)	0.46
Overall medical complications (%)			
No	193 (92.8)	190 (91.3)	0.59
Yes	15 (7.2)	18 (8.7)	
Medical complications specified (%)			
DVT/PE ^a	1 (0.5)	0	0.32
Chest infection	2 (1.0)	4 (1.9)	0.41
Cardiac	5 (2.4)	8 (3.8)	0.40
Other medical complications	9 (4.3)	9 (4.3)	>0.99
Median LOS in days (range)	8.0 (3-72)	7.0 (3–36)	0.001
30-day mortality (%)			
No	206 (99.0)	204 (98.1)	0.64
Yes	2 (1.0)	4 (1.9)	
30-day readmission (%)			
No	184 (88.5)	187 (89.9)	0.64
Yes	24 (11.5)	21 (10.1)	
Pathological tumour (pT) stage (%)			
то	7 (3.4)	12 (5.8)	0.39
Tis	3 (1.4)	1 (0.5)	

TABLE 6 (Continued)



	Stoma+ (n = 208)	Stoma- (n = 208)	P value
T2	57 (27.4)	50 (24.0)	
Т3	88 (42.3)	94 (45.2)	
T4	12 (5.8)	7 (3.4)	
Tx ^b	0	2 (1.0)	
Pathological nodal (pN) stage (%)			
NO	146 (70.2)	129 (62.0)	0.15
N1	43 (20.7)	60 (28.8)	
N2	19 (9.1)	19 (9.1)	
Nx ^c	0	0	
Pathological metastatic (pM) stage (%)			
MO	178 (85.6)	173 (83.2)	0.75
M1	5 (2.4)	7 (3.4)	
Mx ^d	25 (12.0)	28 (13.5)	
Pathological AJCC stage (%)			
0	10 (4.8)	11 (5.3)	0.60
1	79 (38.0)	68 (32.7)	
2	55 (26.4)	50 (24.0)	
3	59 (28.4)	72 (34.6)	
4	5 (2.4)	7 (3.4)	
Circumferential resection margins (%)			
Negative	191 (97.0)	196 (98.0)	0.51
Positive	6 (3.0)	4 (2.0)	
Missing	11	8	
Mucosal margins (%)			
Negative	205 (100.0)	204 (100.0)	>0.99
Positive	0	0	
Missing	3	4	

Bold values are statistical significant values.

Abbreviations: AJCC, American Joint Committee on Cancer; LOS, length of stay; Tis, tumour in situ.

^aDeep vein thrombosis/pulmonary embolism.

^bPathological tumour stage could not be assessed.

^cPathological nodal stage could not be assessed.

^dPathological metastases not assessed.

More surgical complications, in particular postoperative ileus, and more medical complications were observed in the stoma group. These patients also had a prolonged LOS and were more frequently readmitted. Previous studies found similar results and also reported more postoperative morbidity and a longer LOS, probably due to stoma education, in patients who received a defunctioning stoma, although a meta-analysis found no difference in complications between patients with or without a defunctioning stoma [7,16,17]. In addition, complications of stoma closure, and whether closure was achieved, could not be presented in the current study as these data are not recorded in the BCCA.

In the complete cohort, pTs were higher in no-stoma group patients, who also had a higher postoperative AJCC stage compared to their preoperative staging. This in contrast to stoma patients, whose postoperative AJCC stages were lower than the preoperative staging. This difference between the two groups can be explained by the higher rate of neoadjuvant therapy administered to the stoma patients, resulting in down-staging of the tumour in this group [16,18,19]. This difference was no longer observed in the matched analysis.

Some limitations of the current study have to be addressed. First, since the BCCA dataset was not complete, patients with essential missing data points had to be excluded. Furthermore, follow-up is not captured reliably in the BCCA, making it impossible to perform analyses on timing of reversal of the defunctioning stoma. In addition, the BCCA does not record stoma related complications, which limits the ability to distinguish stoma related complications from non-stoma related complications. Also, data entry into the BCCA was voluntary until 2018, which may result in a selection bias towards certain areas and institutions [14]. Despite these limitations, however, the BCCA is a large binational audit capturing current practice of colorectal surgery in ANZ and is therefore the most reliable dataset to analyse outcomes on a binational level. In the future, an increasing number of rectal cancer patients will be treated by 'watch and wait' after a complete response to neoadjuvant therapy [20]. Since the majority of these patients will not undergo surgery, this will result in a lower number of patients requiring a defunctioning stoma. Also, the accuracy of the data collected and the number of patients collected in the BCCA will increase further due to the mandatory data entry, aiding future analyses.

In ANZ, most patients who underwent rectal cancer resections with the formation of an anastomosis received a defunctioning stoma. A defunctioning stoma does not prevent AL from occurring but is mostly associated with a lower reoperation rate. Patients with a defunctioning stoma experienced a higher postoperative ileus rate and had an increased LOS.

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CONFLICT OF INTEREST

No conflict of interest.

AUTHOR CONTRIBUTIONS

All authors, VEMG, HMK, IO, SB, NNDV, RAH, TS, contributed substantially to the conception and design of the work, acquisition, analysis, interpretation of data, drafting and critically revision of the manuscript, approved the final version of the manuscript and agree to be accountable for all aspects of the work.

ETHICAL APPROVAL

The study was approved by the BCCA Operations Committee and the Central Adelaide Local Health Network Human Research Ethics Committee (HREC/18/CALHN/527, CALHN R20180809).

PATIENT CONSENT

No patient consent possible: only de-identified data were made available to the study team

DATA AVAILABILITY STATEMENT

Data are available upon request from the BCCA.

ORCID

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