

ORIGINAL ARTICLE



Tailored SToma policY after TME for rectal cancer: The TASTY approach

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Abstract

Aim: Diverting stomas are routinely used in restorative surgery following total mesorectal excision (TME) for rectal cancer to mitigate the clinical risks of anastomotic leakage (AL). However, routine diverting stomas are associated with their own complication profile and may not be required in all patients. A tailored approach based on personalized risk of AL and selective use of diverting stoma may be more appropriate. The aim of the Tailored SToma policY (TASTY) project was to design and pilot a standardized, tailored approach to diverting stoma in low rectal cancer.

Method: A mixed-methods approach was employed. Phase I externally validated the anastomotic failure observed risk score (AFORS). We compared the observed rate of AL in our cohort to the theoretical, predicted risk of the AFORS score. To identify the subset of patients who would benefit from early closure of the diverting stoma using C-reactive protein (CRP) we calculated the Youden index. Phase II designed the TASTY approach based on the results of Phase I. This was evaluated within a second prospective cohort study in patients undergoing TME for rectal cancer between April 2018 and April 2020.

Results: A total of 80 patients undergoing TME surgery for rectal cancer between 2016 and 2018 participated in the external validation of the AFORS score. The overall observed AL rate in this cohort of patients was 17.5% ($n = 14$). There was a positive correlation between the predicted and observed rates of AL using the AFORS score. Using ROC curves, we calculated a CRP cutoff value of 115 mg/L on postoperative day 2 for AL with a sensitivity of 86% and a negative predictive value of 96%.

The TASTY approach was designed to allocate patients with a low risk AFORS score to primary anastomosis with no diverting stoma and high risk AFORS score patients to a diverting stoma, with early closure at 8–14 days, if CRP values and postoperative CT were satisfactory. The TASTY approach was piloted in 122 patients, 48 (39%) were identified as low risk (AFORS score 0–1) and 74 (61%) were considered as high risk (AFORS score 2–6). The AL rate was 10% in the low-risk cohort of patient compared to 23% in the high-risk cohort of patients, $p = 0.078$. The grade of Clavien-Dindo morbidity was equivalent. The incidence of major LARS was lowest in the no stoma cohort at 3 months ($p = 0.014$).

Conclusion: This study demonstrates the feasibility and safety of employing a selective approach to diverting stoma in patients with a low anastomosis following TME surgery for rectal cancer.

KEYWORDS

anastomotic leak, defunctioning stoma, functional outcomes, quality of life, Rectal cancer

INTRODUCTION

The incidence of anastomotic leakage (AL) following restorative surgery for rectal cancer is reported to be between 3% and 28%. AL has a significant impact on clinical, patient-reported, and oncological outcomes. To mitigate the impact of AL a diverting stoma is routinely used to protect the distal anastomosis and facilitate anastomotic healing, with these stomas reversed once the integrity and patency of the distal anastomosis is confirmed. The use of diverting stoma is associated with reduced severity of anastomotic leaks and a lower overall re-operation rate [1–5]. However, there is a significant complication profile associated with the routine use of diverting stomas, with a meta-analysis of 764 patients, across five randomized controlled trials reporting a higher rate of postoperative morbidity, excluding AL, in patients with a diverting stoma (OR 3.337, 95% CI: 1.570–7.093, $p=0.002$) [6]. Extending beyond the immediate postoperative period, there is some emerging evidence to support the association between a diverting stoma and a higher incidence of low anterior resection syndrome (LARS) [7, 8], with a prolonged time to reversal reinforcing the negative impact on bowel function [9].

The complications of diverting stoma have been well recognized, as has the significant delay to reversal and restoration of gastrointestinal continuity. To address these key concerns, early stoma closure, between eight and 14 days, postoperatively has been explored as an alternative strategy to traditional, late stoma closure [10]. This strategy provides the “protective” effects of diversion of the distal anastomosis, whilst reducing the potential risk of complications and longer-term functional sequelae. A meta-analysis of seven randomized controlled trials consisting of 814 patients reported no difference in rates of AL between early and late stoma closure, with pooled rates of 4.2% and 4.9%, respectively (OR: 0.70; 95% CI: 0.16 to 3.06; $p=0.63$) [11]. The postoperative morbidity profile differs between early and late closure, with higher rate of wound complications associated with early closure, and a higher incidence of small bowel obstruction with late closure. However, given the logistical and practical considerations required to offer routine early closure has meant that this strategy has failed to gain international traction beyond expert centres.

Given the overall rate of AL in patients with rectal cancer, the mitigating effect of diverting stomas and the complication profile associated with early and late stoma closure, due consideration should be given to whether all patients with rectal cancer require routine diversion. Selective use of diverting stomas may be of value in a subset of patients based on their own personalized risk of AL, incorporating a range of modifiable and nonmodifiable risk factors. Tailoring surgical strategy in this manner balances benefit and risk of having a non-diverted distal anastomosis based on known risk factors for AL, whilst considering the additive benefit of diversion and provides a personalized surgical strategy. The

What does this paper add to the literature?

The Tailored SToma policy (TASTY) study demonstrates for the first time the feasibility and the safety of a preoperative standardized and selective approach to diverting stoma in patients with a low anastomosis following TME surgery for rectal cancer.

aim of the Tailored SToma policy (TASTY) after total mesorectal excision (TME) for rectal cancer project is to design and pilot a standardized, tailored approach to diverting a distal anastomosis in rectal cancer which provides a personalized risk of AL patients, tailoring the approach to the use of diverting stoma by incorporating all surgical strategies.

METHOD

A pilot study was undertaken to design the TASTY approach and to assess its feasibility and safety. The aims of Phase I were to design the TASTY approach incorporating a risk prediction model for AL. The aims of Phase II were to assess the feasibility and safety of the TASTY approach within a pilot, prospective cohort study. Institutional ethical approval was obtained for this study.

Phase I: Design of the Tailored SToma policy

Phase Ia: Anastomotic leakage risk prediction

A prospective pilot study was undertaken to design the TASTY approach in an independent cohort of all consecutive patients undergoing surgery for rectal cancer with an anastomosis within 7 cm from the anal verge and a diverting stoma between 2016 and 2018. The aim of Phase Ia was to incorporate risk stratification into our TASTY approach using existing scoring systems and routine blood tests.

The anastomotic failure observed risk score (AFORS) was developed by Penna et al. using data from the TaTME registry [12]. This score calculates the risk of AL based on five preoperative risk factors; gender, body mass index, diabetes, smoking and tumour size. The score provides a cumulative score of 0–6 which corresponds to an AL rate of 6.3%–50%. The score is easy to use and implements and provides a categorical scoring system which allows risk to be easily communicated to patients. To ensure the applicability of the AFORS score to our patient cohort we compared the observed rate of AL in our cohort to the theoretical, predicted risk of the AFORS score.



The second stage of the TASTY approach was to identify the subset of patients who would benefit from early closure of the diverting stoma using C-reactive protein (CRP). CRP was routinely measured on postoperative day (POD) 2 and 4 in all patients. The Youden index (sensitivity + specificity – 1) was calculated to determine the CRP value providing the best tradeoff between sensitivity and specificity to aid the diagnosis of AL and to identify patients who can undergo safe early reversal.

Phase 1b: The Tailored SToma policY approach design

The Tailored SToma policY incorporates selective use, early and late closure of diverting stoma based on risk stratification using the AFORS score and postoperative CRP value. We incorporated the AFORS score into the TASTY approach as part of preoperative surgical decision-making. We considered a 10% risk of anastomotic failure acceptable to avoid a stoma. Patients with an AFORS score of 0–1 were low risk (predicted AL rate of 6.3%–10% according to the TaTME registry) and would undergo primary anastomosis without diverting stoma. An upper limit of 10% was selected to be acceptable for an anastomotic leak rate based on the European Society of Coloproctology cohort study data on TME, which reported an overall leak rate of 9%, with a range of 6.7%–15.6% [13, 14]. Patients with an AFORS score of 2–6 (predicted AL rate of >17.8% according to the TaTME registry) were high risk and would be appropriately diverted. This second cohort of patients would be considered for early closure based on their postoperative clinical course, CRP trajectory and radiological findings. Postoperatively patients were monitored for clinical signs consistent with AL including fever, pain or pus in the pelvic drain coupled with biochemical monitoring using CRP trajectory monitoring on POD2 and 4. A computed tomography (CT) scan with retrograde contrast enema was performed on POD7 in patients without any clinical symptoms of AL and the appropriate CRP cutoff value (as determined by Phase 1a) with an upward trajectory. If this CT-scan with retrograde contrast enema confirmed the absence of AL, early stoma closure was performed on POD 8–10, otherwise, the diverting stoma was reversed at 2–3 months postoperatively. Early closure was achieved through a dedicated clinical pathway within our institution, with all patients preoperatively counselled regarding the TASTY protocol. There was dedicated radiology access to CT-scan with retrograde contrast enema postoperatively with reporting by a gastrointestinal radiologist. Theatre slots for early stoma closure were pre-emptively booked at the time of listing patients for their index rectal cancer resection. Agreement for the implementation of the TASTY protocol was sought from all relevant departments including radiology and theatres.

Phase II: Feasibility and safety assessment of the TASTY approach

The design of the TASTY approach was evaluated within a second prospective cohort study in consecutive patients undergoing TME

with anastomosis lower than 7 cm from the anal verge for rectal between April 2018 and April 2020. The aims of this phase were to determine the feasibility and safety of the TASTY approach on early, 30-day postoperative outcomes.

Eligibility criteria

All adult patients (>18 years old) undergoing a TME by minimally invasive approach (laparoscopic or robotic) for rectal cancer with an anastomosis performed within 7 cm of the anal verge were eligible for inclusion. Patients were excluded if an abdominoperineal resection, intersphincteric resection, local excision or permanent stoma were performed.

Endpoints

The primary endpoint was anastomotic leakage within 30 days. The International Study Group of Rectal Cancer definition was used for anastomotic leakage which defines anastomotic leakage as a defect of the intestinal wall at the anastomotic site (including suture and staple lines of neorectal reservoirs) leading to a communication between the intra- and extraluminal compartments [15].

Secondary endpoints included overall stoma rates, postoperative complications, grade of complications, reoperation rate and functional outcome. Postoperative complications were classified as adverse events within 30 days of the operation and were classified according to the Clavien-Dindo (CD) classification. The CD classification consists of 5 grades; grade 0 – no complications, grades I–II – minor complications; and grades III–V – major complications. The highest-ranking complication was recorded for each patient. Reoperation rates were reported as any unplanned reoperation within 30 days of the index operation.

Postoperative functional outcomes were assessed using the LARS score, which is a well validated scoring system consisting of five questions, which was developed specifically for use in patients undergoing restorative rectal cancer surgery [16]. The score has a range of 0–42 points and stratifies patients into three categories: no (0–20), minor (21–29), or major LARS (30–42).

Statistical analysis

The data obtained were analysed using SPSS version 20.0.0 software (IBM Corporation, Chicago, IL, USA). A descriptive analysis was done of the patient characteristics using measures of central tendency and dispersion (mean and standard deviation [SD]) for continuous variables and frequency distribution for qualitative variables. A chi-squared test was used to compare categorical variables, and a non-parametric Mann-Whitney U test to compare continuous variables.

To determine the predictive capacity of the CRP in the detection of AL, ROC curves were plotted, describing the area under the curve

(AUC) with its corresponding 95% CI. The best cutoff points were determined using the Youden index, presenting the classic diagnostic test indicators: sensitivity, specificity and negative predictive value (NPV). A p -value <0.05 was considered statistically significant.

RESULTS

Phase I design of the Tailored SToma policy

A total of 80 patients undergoing TME with an anastomosis within 7 cm from the anal verge and a diverting stoma for rectal cancer between 2016 and 2018 participated in the external validation of

the AFORS score. Patient and clinical demographics are outlined in Table 1. The overall observed AL rate in this cohort of patients was 17.5% ($n = 14$). Based on the AFORS score we identified 23 low risk patients with an AFORS score of 0–1 and 57 high risk patients with an AFORS score of 2–6. There was a positive correlation between the predicted and observed rates of AL using the AFORS score (Table 2) thus suggesting this was a reliable predictive score in our cohort of patients.

ROC curves were calculated to establish a relationship between postoperative CRP values and the development of AL. We calculated a CRP cutoff value of 115 mg/L on POD2 for anastomotic leakage with a sensitivity of 86% and a negative predictive value of 96%. We obtained an AUC of 0.786 for early AL within 30 days postoperatively (Figure 1). Based on the combination of the AFORS score

TABLE 1 Phase I – Patient and clinical characteristics.

Variable	Number (%)
Male	57 (71.3)
Age (years) ^a	64 (24–87)
BMI (kg/m ²) ^a	25.3 (19.0–38.7)
BMI ≥ 30 kg/m ²	12 (15)
Diabetic	12 (15)
Smoker	22 (28)
Tumour height from anal verge (cm) ^a	7.0 (1.5–12.0)
Tumour size (mm) ^a	39 (10–80)
Tumour size >25 mm	55 (69)
AFORS	
0	5 (6)
1	18 (23)
2	32 (40)
3	17 (21)
4	4 (5)
5	4 (5)
6	0 (0)
Surgery	
Stapled colorectal anastomosis	26 (33)
Handsewn coloanal anastomosis	44 (55)
Stapled coloanal anastomosis	10 (13)
Height of anastomosis from anal verge (cm) ^a	4 (0–7)
Diverting stoma	76 (95)
Hospital stay (days)	6 (3–22)
Anastomotic leak	14 (17.5)
Early	9
Late	5
Neoadjuvant treatment	
None	20 (25)
Radiochemotherapy	39 (49)
Chemotherapy+radiochemotherapy	18 (23)
Chemotherapy alone	3 (4)
Radiotherapy alone	1 (1)

Abbreviations: AFORS, anastomotic failure observed risk score; BMI, body mass index.

^aMedian (range).

TABLE 2 Predicted and observed anastomotic leak rate.

Anastomotic failure observed risk score (AFORS)	Number of patients	Predicted risk	Actual AL rate
0	5	6.3	0 (0.0)
1	18	10.7	2 (11.1)
2	32	17.8	7 (21.9)
3	17	23.3	3 (17.6)
4	4	26.2	1 (25.0)
5	4	33.3	1 (25.0)
6	0	50.0	0 (0.0)

Abbreviations: AFORS, anastomotic failure observed risk score; AL, anastomotic leakage.

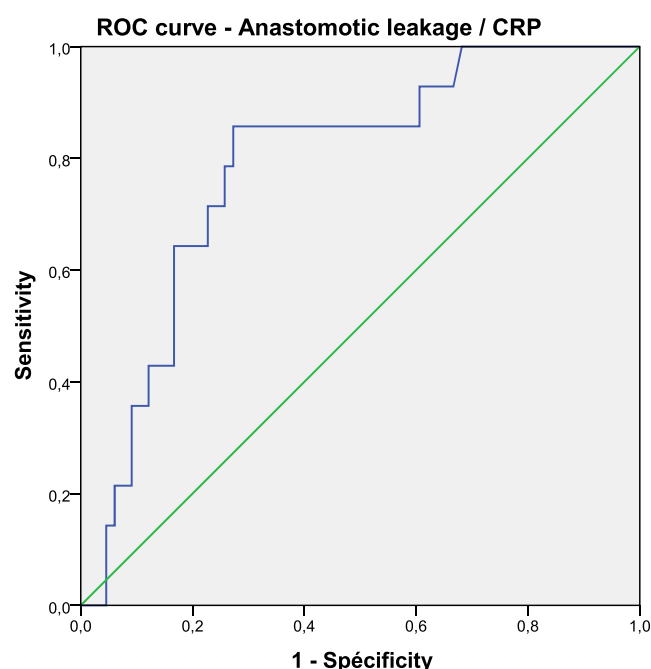


FIGURE 1 Receiver operating characteristic (ROC) curve for day 2 C-reactive protein (CRP).

and a POD2 CRP cutoff value of 115 mg/L, we designed the TASTY approach, which is outlined in Figure 2.

Phase II feasibility and safety assessment of the TASTY approach

The TASTY approach was piloted in 122 patients undergoing a TME with the formation of an anastomosis within 7 cm of the anal verge between 2018 and 2020. A total of 84 (69%) male patients, with a median age of 65 years (range 32–85) were included. Patient and clinical characteristics are outlined in Table 3. All patients underwent preoperative risk stratification with the AFORS score, with 48 (39%) patients considered to be low risk with an AFORS score of 0–1 and 74 (61%) patients considered to high risk with an AFORS score of 2–6. The treatment pathway of all patients is highlighted in Figure 3.

Patients with low risk of AL: Recommendation of no diverting stoma

Of the 48 patients considered to be low risk, 38 patients underwent a stapled low colorectal anastomosis, nine patients underwent a handsewn coloanal anastomosis and one patient underwent a delayed coloanal anastomosis. Of the 47 patients with a primary anastomosis, five patients required a diverting stoma due to significant pre-existing cardiac comorbidity in one patient, intraoperative haemorrhage in two patients, and surgical risk factors for AL in three patients. Of this small cohort of five patients, two patients were suitable for early closure based on clinical, biochemical and radiological assessment.

The overall rate of AL in the low-risk patient cohort was 10% ($n=5$), with early relook laparoscopy leading to early identification of AL, pelvic washout and the formation of diverting stoma.

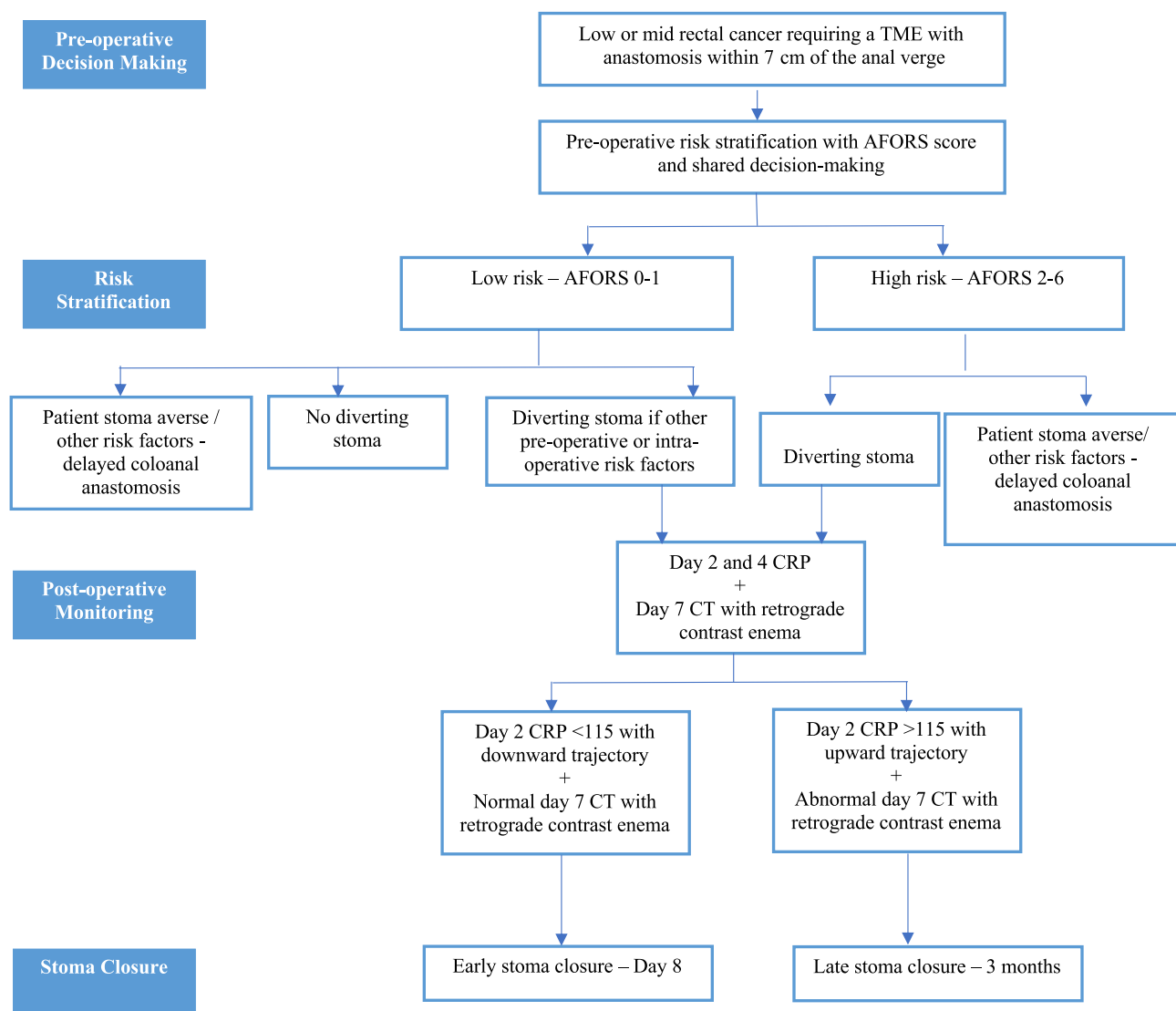


FIGURE 2 Outline of the Tailored SToma policy (TASTY) approach to selective diverting stoma.

Patients with high risk of AL: Recommendation of diverting stoma

Of the 74 patients considered high risk for AL, all patients were recommended to have a diverting stoma to mitigate the risk of AL. A total of 10 (14%) patients declined the option of a diverting stoma and were appropriately counselled to have a delayed coloanal anastomosis. The remaining 64 patients underwent a primary anastomosis, 31 handsewn coloanal anastomosis and 34 stapled colorectal anastomoses, with diverting ileostomy. Early stoma closure was performed in 21 patients, with the remaining 43 patients undergoing stoma closure with 3 months postoperatively. The overall rate of AL in the high-risk cohort of patients was 23% ($n = 17$).

TABLE 3 Phase II – overall patient and clinical characteristics.

Variable	Number	%
Gender		
Female	38	31%
Male	84	69%
Age (years) ^a	65 (32–85)	
BMI (kg/m ²) ^a	24.6 (15.1–38.2)	
Diabetes	20	16%
Smoker		
Current	24	20%
Ex-smoker	12	10%
None smoker	86	70%
Tumour height from anal verge (cm)	7.5 (2.0–12.0)	
AFORS		
0	12	9.8%
1	36	29.5%
2	47	38.5%
3	14	11.5%
4	11	9.0%
5	2	1.6%
Neoadjuvant treatment	81	66%
Surgical approach		
Open	8	7%
Laparoscopy	94	77%
Robot	20	16%
Anastomosis		
Handsewn	50	41%
Stapled	72	59%
Diverting stoma		
No	53	43%
Early closure	23	19%
Late closure	46	38%

Abbreviations: AFORS, anastomotic failure observed risk score; BMI, body mass index.

^aMedian (range).

Low-risk versus high-risk patients

Patients in the high-risk cohort were more likely to be male ($p < 0.001$), with a high BMI ($p = 0.004$), have a low rectal tumour ($p = 0.006$) and receive neoadjuvant treatment ($p = 0.002$) – Table 4. There were several operative differences between the two groups, with a higher proportion of patients in the high-risk cohort undergoing coloanal anastomosis compared to the low-risk cohort, with rates of 45% and 19%, $p = 0.001$, respectively. Patients in the high-risk cohort were more likely to undergo a hand-sewn anastomosis compared to the low-risk cohort, 41% and 9%, $p < 0.001$, respectively.

The AL rate was 10% in the low-risk cohort of patient compared to 23% in the high-risk cohort of patients with no significant difference between groups, $p = 0.078$. The grade of Clavien-Dindo morbidity was equivalent between the two groups for the 30day reintervention rate in the high risk cohort compared to the low risk cohort, with respective rates of 12% and 6%, $p = 0.362$. Low-risk patients had a lower stoma rate at 30days compared to high-risk patients, with rates of 11% and 61%, $p < 0.001$, respectively. There were no differences observed in the rate of AL in patients in the high-risk cohort who underwent early and late stoma closure and patients who had no stoma in the low-risk cohort, with observed AL rates of 9%, 28% and 13% respectively, $p = 0.06$.

Functional outcomes

Based on the TASTY approach a total of 42 patients underwent primary anastomosis alone, 23 patients underwent early closure of stoma within 8–14 days, 11 patients underwent a delayed coloanal anastomosis and 46 patients underwent routine closure of stoma within 3 months. Functional outcomes using the LARS score were available in 113 (92%) patients (Table 5). The lowest incidence of LARS at 30days was in the no stoma cohort compared to the early closure, delayed coloanal anastomosis and late closure group, with respective rates of 27%, 62%, 64% and 50%, $p = 0.02$. This difference prevailed at 3 months postoperatively, with the lowest incidence of major LARS in the no stoma cohort ($p = 0.014$). At 6 months, similar observations were seen, with less LARS syndrome in the no stoma cohort ($p = 0.026$).

DISCUSSION

TASTY utilizes a personalized approach to the use of diverting stoma, by incorporating the principles of shared decision-making and risk stratification at the time of diagnosis, whilst ensuring all potential surgical strategies are incorporated into the pathway. This study demonstrates the feasibility and safety of employing a selective approach to diverting stoma in patients with a low anastomosis following TME surgery for rectal cancer utilizing the TASTY approach. Through the incorporation of appropriate preoperative risk stratification and careful postoperative surveillance a selective stoma

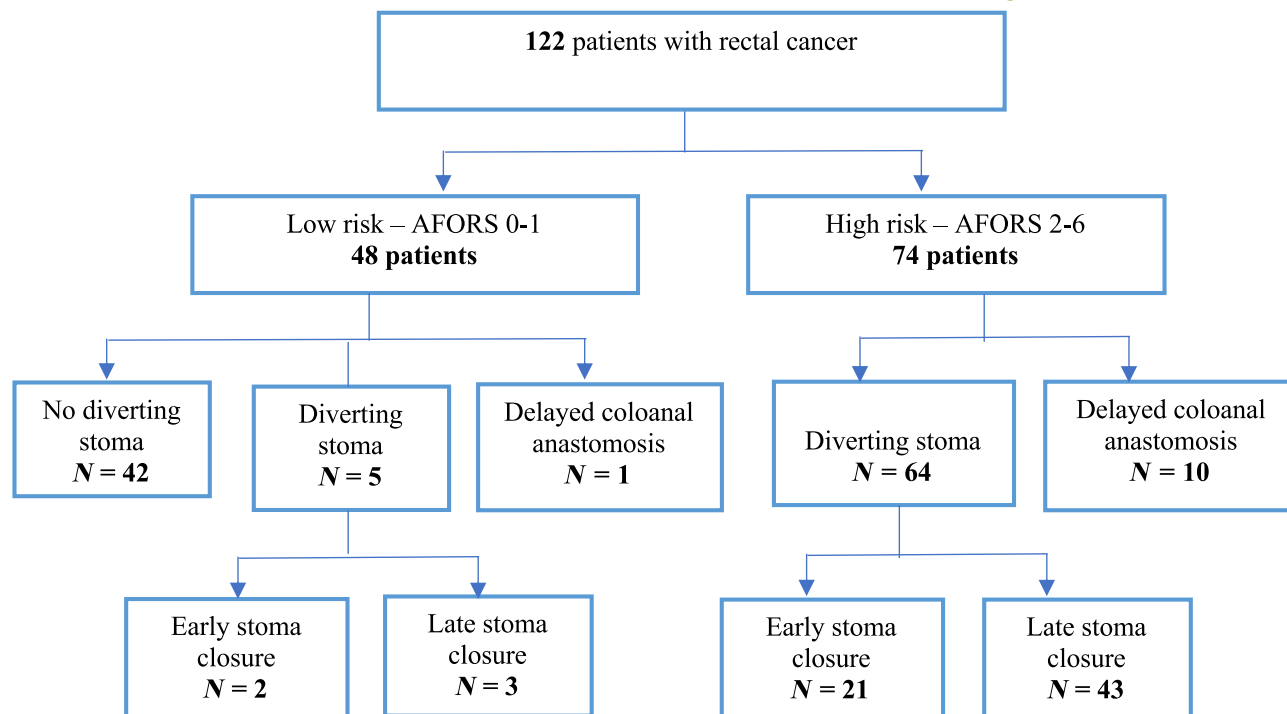


FIGURE 3 Treatment outcomes of patients enrolled into Phase II.

strategy is associated with good clinical and functional outcomes. Using this approach, we identified a low-risk AL cohort of 48 patients, of which 42 patients were suitable for primary anastomosis, with an observed AL rate of 10%, a Clavien-Dindo grade III severity rate of 6%, a 30-day reintervention rate of 6% and an overall major LARS rate of 10% at 6 months.

Although routine diversion of a low rectal anastomosis is common practice internationally, our study contributes to the growing number of centres adopting a selective diverting stoma approach. Blok et al. reported the Dutch experience of using a selective diverting stoma strategy in 40 patients compared to 50 patients undergoing routine diversion [17]. They reported a reduced overall length of stay in the selective stoma group, with equivalent anastomotic leak rates, complication rates, reintervention and readmission rates. The overall one-year stoma free rate was higher in the selective cohort compared to the routine cohort, with rates of 95% and 88%, $p=0.29$, respectively. Similarly, Rouanet et al. reported their French experience in a cohort of 433 patients, with 249 patients with no diverting stoma and 184 with a diverting stoma [18]. This group reported equivalent AL rates of 14.6% and 12.2%, $p=0.57$, respectively, with lower rate of overall morbidity and length of stay in the no diverting stoma. However, they did observe a statistically higher reoperation rate within the first 60 days in the no diverting stoma group compared to the diverting stoma group, with rates of 12.2% versus 2.4%, $p=0.003$. Our study supports these findings, reporting equivalent early postoperative outcomes, with regards to AL rates and postoperative morbidity, whilst demonstrating good long-term functional outcomes, with lower rates of LARS symptoms in patients undergoing a no diverting stoma strategy.

Previous studies assessing the safety and feasibility of primary anastomosis in low rectal cancer without diverting stoma have selected patients for this strategy based on the operating surgeons' preference [17, 18]. Our study uses the AFORS score to risk stratify patients based on several preoperative risk factors. The AFORS score has been developed from a cohort of 1549 patients undergoing transanal TME for rectal cancer [12]. To ensure its reliability and applicability in our patient population, which includes a range of operative approaches, including open, laparoscopic and robotic, we externally validated the AFORS score, demonstrating good overall correlation between the two populations. This provides a robust and evidence-based approach to selecting patients preoperatively based on their risk for anastomotic leak, whilst limiting selection bias. It also allows for the risk to be appropriately communicated to the patient and thus promotes the principles of shared decision-making. Appropriate risk stratification and minimization is an essential component of ensuring the safety of a no diverting stoma approach and in ensuring no unnecessary additional risk is conferred by the patient. The use of risk stratification scores, such as the AFORS score, can help aid surgical decision-making by providing data metrics based on objective variables, when deciding to defunction a patient pre- and intraoperatively, and may lead to a smaller number of patients being defunctioned overall. Implementation of the AFORS score led to a reduction in the number of formed defunctioning stomas from 95% in Phase I to 43% in Phase II in our unit. However, it is important that the AFORS score is interpreted within the clinical context and to accept protocol crossovers or violations as deemed clinically appropriate. In our Phase II, we defunctioned 10.6% of our low risk patients and performed a delayed coloanal anastomosis in 14% of high risk

TABLE 4 Low- versus high-risk AL risk patients.

	Low risk 0–1 AFORS 0–1 (N = 48) n (%)	High risk 2–6 AFORS 2–6 (N = 74) n (%)	p
Gender			
Male	19 (40)	65 (88)	<0.001
Female	29 (60)	9 (12)	
Age (years) ^a	65 (32–85)	66 (35–83)	0.731
BMI (kg/m ²) ^b	23.5 (15.1–37.5)	25.6 (17.0–38.2)	0.004
Tumour height from anal verge (mm)	80 (30–110)	63 (20–120)	0.006
Neoadjuvant treatment			
Yes	24 (50)	57 (77)	0.002
No	24 (50)	17 (23)	
Anastomosis type			
Coloanal	9 (19)	33 (45)	<0.001
Delayed coloanal	1 (2)	10 (14)	
Colorectal	38 (79)	31 (42)	
Anastomosis technique			
Handsewn	9 (19)	41 (55)	<0.001
Stapled	39 (81)	33 (44)	
Surgical approach			
Open	4 (8)	4 (5)	0.141
Laparoscopy	40 (83)	54 (73)	
Robot	4 (8)	16 (22)	
Diverting stoma			
Yes	5 (10)	64 (87)	<0.001
Delayed CAA	1 (2)	10 (14)	
No	42 (88)	0 (0)	
Anastomotic leak			
Yes	5 (10)	17 (23)	0.078
No	43 (90)	57 (77)	
Clavien-Dindo grade			
0	30 (63)	47 (64)	0.568
1	9 (19)	8 (11)	
2	6 (13)	9 (12)	
3	2 (4)	8 (10)	
4	1 (2)	2 (3)	
5	0 (0)	0 (0)	
30 day reintervention rate	3 (6)	9 (12)	0.362
Strategy for stoma closure			
No primary stoma	42 (88)	0	<0.001
Delayed CAA	1 (2)	10 (14)	
Early closure	2 (4)	21 (28)	
Late closure	3 (6)	43 (58)	
Stoma at 30 days postoperatively			
Yes	5 (10)	45 (61)	<0.001
No	43 (90)	29 (39)	

Abbreviations: AFORS, anastomotic failure observed risk score; AL, anastomotic leakage; BMI, body mass index; CAA, coloanal anastomosis.

^aMedian (range).

^bMissing data.

A *p*-value <0.05 was considered statistically significant.

patients, based on intraoperative clinical decision-making and/or patient priorities/preferences.

Risk minimization is incorporated into the postoperative surveillance of the TASTY programme using biochemical and radiological surveillance. CRP is a well-recognized and utilized biomarker for the detection of AL [16, 19]. A range of CRP values have been suggested within the literature, with varying specificity and sensitivity, to aid the detection of AL in colorectal surgery [20, 21]. During the design of TASTY we validated our own institutional experience of postoperative CRP using ROC curve analysis, to ensure a cutoff value was relevant to our patient population. We identified a POD2 CRP value of 115 mg/L to be sensitive and specific for an early anastomotic leak. However, the utility as a single predictive entity for AL is limited [22] and therefore this has been appropriately combined with early radiological assessment using a CT with retrograde contrast enema to identify early AL and suitable patients for early stoma closure. This approach enables appropriate selection of patients who will benefit from early stoma closure, whilst simultaneously facilitating proactive detection and management of AL. We observed no difference between anastomotic leak rates following early and late closure of stoma and no diverting stoma (*p*=0.06), thus supporting this is a safe and effective manner of early restoration of gastrointestinal continuity in a select cohort of high-risk patients.

Patient priorities in rectal cancer centre around cure, avoidance of a permanent stoma and the avoidance of complications [23]. The avoidance of complications is not limited to short-term consequences such as AL alone, but also extends to longer-term consequences of rectal cancer surgery, including, low anterior resection syndrome.

There is a clearly a complex interplay between mitigating the risks of AL using diverting stoma, time to stoma closure and LARS. There is emerging evidence which recognizes the association between an ileostomy and the development of LARS, with the prolonged time to closure of ileostomy reinforcing the adverse impact on subsequent bowel function [9]. To circumvent the issue of poor postoperative bowel function due to prolonged stoma closure the TASTY approach incorporates the concept of both no diverting stoma in low-risk patients and early stoma closure at day eight postoperatively in high-risk patients with no clinical or radiological evidence of AL. Early stoma closure has been demonstrated to be safe and feasible, with no additional AL risk conferred, compared to standard or delayed closure [10, 24]. There is some limited evidence available that this approach is associated with improved bowel function; however, has little impact on overall LARS [25]. The TASTY approach prioritizes anastomotic healing, a reduction in anastomotic leak rate and long-term bowel function. Our results support this by demonstrating comparable anastomotic leak rates in the no diverting stoma and diverting stoma groups, whilst preserving bowel function in patients without a stoma or early closure of stoma, with a higher rate of no LARS at 6 months postoperatively in both these cohorts of patients compared to late closure at 3 months (*p*=0.05). Our results demonstrate an improving trend across all cohorts, including no stoma, early and late closure, over a 6-month period;

TABLE 5 Incidence of low anterior resection syndrome.

	No stoma <i>n</i> (%)	Early closure <i>n</i> (%)	Delayed CAA <i>n</i> (%)	Late closure <i>n</i> (%)	<i>p</i>
30 days					
No LARS	24/41 (59)	6/21 (29)	1/11 (9)	12/40 (30)	0.004
Major LARS	11/41 (27)	13/21 (62)	7/11 (64)	20/40 (50)	0.020
3 months					
No LARS	29/37 (78)	13/19 (68)	5/11 (46)	21/38 (55)	0.093
Major LARS	4/37 (11)	4/19 (21)	5/11 (46)	14/38 (37)	0.014
6 months					
No LARS	32/39 (82)	14/19 (74)	5/11 (46)	22/37 (60)	0.026
Major LARS	4/39 (10)	3/19 (16)	2/11 (18)	11/37 (30)	0.182

Abbreviations: CAA, coloanal anastomosis. LARS, low anterior resection syndrome.

A *p*-value <0.05 was considered statistically significant.

however, it is important to interpret this in the context that our late closure of stoma was at 3 months and therefore is likely to render improved outcomes compared to stoma closure beyond 3 months. Furthermore, our results only reflect short-term outcomes with regards to bowel function.

The key strength of the TASTY protocol is the personalized approach it takes towards a diverting stoma in patients with low rectal cancer. It employs a multistep process incorporating all potential surgical options and appropriately risk stratifying patients. Through external validation of the AFORS score and internal validation of our institutional CRP we have created a comprehensive algorithm which is relevant, applicable and generalizable to our patient cohort. It is important to note that we employed a convenience sampling strategy to design the TASTY procedure by recruiting an internal pool of patients within Phase I. This sampling strategy ensures high internal validity due to recruiting from within a homogenous patient pool, however, has low external validity due to sampling bias. This may potentially limit its wider generalizability to other institutions and may require further validation prior to widespread dissemination and adoption. The TASTY approach incorporates all available options to diverting a distal rectal anastomosis, thus reflecting the complexity of modern management of rectal cancer. It is important to note that a small proportion of our high-risk patient cohort underwent a delayed coloanal anastomosis as an alternative to a diverting stoma, thus leading to a diversion from the TASTY protocol. We did not incorporate the delayed coloanal anastomotic technique into the TASTY protocol given that this a highly specialized technique, usually reserved for low coloanal anastomosis in high-risk patients or as a salvage procedure following a previous anastomotic leak [26]. Delayed coloanal anastomosis is associated with significant postoperative morbidity and an impact on postoperative functional outcomes [27], it requires careful counselling, within specialized units, with appropriate postoperative bowel rehabilitation [28], and should be used in highly selective patients. As a result, we have not incorporated delayed coloanal anastomosis within the TASTY protocol. A key limitation of our work is that

we focus on early AL detection alone, with a 30-day cutoff for assessing postoperative clinical outcomes. There is a recognized late anastomotic failure rate, which includes anastomotic strictures and chronic sinuses. Further work needs to be done on whether TASTY is applicable and generalizable, and whether it can be implemented on a wider scale.

CONCLUSION

The TASTY approach provides a structured and evidence-based approach to diverting stoma in low rectal cancer, balancing risk of anastomotic leak with preserving postoperative functional outcomes.

AUTHOR CONTRIBUTIONS

Lara Boissieras: Data curation; writing – original draft. **Deena Harji:** Conceptualization; writing – original draft; methodology; writing – review and editing; formal analysis. **Bertrand Celerier:** Data curation; resources. **Eric Rullier:** Conceptualization; writing – review and editing; supervision. **Quentin Denost:** Supervision; conceptualization; investigation; writing – review and editing; methodology; formal analysis.

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CONFLICT OF INTEREST STATEMENT

None.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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