# Defunctioning stoma in anterior resection for rectal cancer does not impact anastomotic leakage: a national population-based cohort study

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## Abstract

# Purpose

Anterior resection (AR) is considered the gold standard for curative cancer treatment in the middle and upper rectum. The goal of the sphincter-preserving procedure is vulnerable to anastomotic leak (AL) complications. Defunctioning stoma (DS) became the protective measure against AL. Often a defunctioning loop-ileostomy is used, which is associated with substantial morbidity. However, not much is known if the routine use of DS reduces the overall incidence of AL.

# Methods

Elective patients subjected to AR in 2007–2009 and 2016-18 were recruited from the Swedish colorectal cancer registry (SCRCR). Patient characteristics, including DS status and occurrence of AL, were analyzed. In addition, independent risk factors for AL were investigated by multivariate regression.

# Results

The statistical increase of DS from 71.6% in 2007–2009 to 76.7% in 2016–2018 did not impact the incidence of AL (9.2% and 8.2%), respectively. DLI was constructed in more than 35% of high-located tumors ≥ 11cm from the anal verge. Multivariate analysis showed that male gender, ASA 3–4, BMI > 30 kg/m$^2$, and neoadjuvant radiation were independent risk factors for AL.

# Conclusion

The role of routine DS in decreasing overall AL after AR procedure was not evident. A selective decision algorithm for DS construction is needed to protect from AL and mitigate DS morbidities.

## Introduction

Anterior resection (AR) is considered the gold standard for curative treatment of cancer in the middle and upper rectum [1]. The widespread use of total mesorectal excision (TME) and neoadjuvant therapy have improved oncological outcomes and survival [2]. Anastomotic leakage (AL) is a dreaded complication affecting 4–20% of patients undergoing AR [2, 3]. Several risk factors for AL have been described, e.g., male gender, smoking, excess alcohol, overweight, advanced ASA class, diabetes mellitus, pulmonary, renal, vascular diseases, tumor size, neoadjuvant therapy, and anastomotic height from the anal verge [3, 4]. Randomized controlled trials have shown a decreased rate of symptomatic AL and reoperation for AL in patients with a defunctioning stoma (DS). DS is frequently fashioned as a defunctioning loop-ileostomy (DLI) and more seldom as a loop colostomy [5, 6]. Around 70–80% of AR patients are protected with DS in the UK and Holland, respectively [7, 8]. According to the Swedish colorectal cancer registry

(SCRCR), around 600 ARs are performed annually in Sweden [9]. Since most DS are fashioned as DLI, DS will hereafter be named DLI [10, 11].

DLI becomes permanent in about 25% of the cases. The local and systemic physiological changes due to DLI can vary from minor symptoms of skin irritation and leakage (59%) to significant issues like dehydration, obstruction, and parastomal hernia (25%) [12]. One-third of DLI patients risk dehydration in the first six weeks, and half of them require admission for electrolytes correction, possibly putting adjuvant chemotherapy at stake [13]. DLI also impairs health-related quality of life [14]. Delayed DLI closure has been associated with impaired bowel function and major low anterior resection syndrome (LARS) [15, 16]. In addition, about 40% of patients encounter surgical complications, most commonly small bowel obstruction and wound sepsis, during the DLI reversal procedure [12, 17].

This study aimed to evaluate whether the frequency of AL has decreased as the usage of DLI has increased and, as a secondary outcome, investigate risk factors for AL. We hypothesized that the lack of clear indications for DLI leads to increased DLI usage without reducing AL.

# Material And Methods

This study is a population-based retrospective cohort study of patients subjected to rectal cancer surgery in Sweden. The SCRCR is a nationwide registry including rectal cancer patients since 1995 in Sweden with high validity and coverage [18]. We encompassed all rectal cancer patients undergoing AR during two intervals, 2007–2009 and 2016–2018. The criteria for exclusion were age < 18-year-old, emergency surgery, microscopically non-radical resection, and unregistered DLI status. Eligible patients were divided into two groups based on the time for index surgery. We expected patients in the latter group (2016–2018) to be more exposed to DLI than the early cohort (2007–2009) since RECTODES trial results were released in August 2007.

Thus, the latter group would be more protected against AL. Each group was further divided into having DLI at the index surgery or not. To be noted, the variable DLI was firstly introduced in the registry in 2007. Patients were discussed at a multidisciplinary team conference.

### Definitions

Rectal cancer was defined as adenocarcinoma within ≤ 15 cm from the anal verge to the sigmoid colon measured with rigid sigmoidoscopy.

According to the International Study Group of Rectal Cancer (ISREC), AL after AR for rectal cancer is defined as a communication between the two cavities (intra- and extraluminal compartments) manifested as a defect in the anastomosis (anastomotic staple or suture line), the presence of a presacral pelvic abscess or a rectovaginal fistula [19].

DLI is an ileostomy that diverts bowel contents and protects the newly reconstructed colorectal anastomosis applied during the elective AR.

Ethics

**Ethical approval**

was obtained via the Swedish Ethical Review Authority (Diary number 2020 – 01082).

# Statistical analysis

Statistical analyses were made using IBM SPSS version 26. Demographic characteristics were reported as medians with first and third interquartile range (IQR) when continuous and categorical variables as numbers and percentages. Mann-Whitney U test was applied for continuous variables, Fisher's Exact or Chi-square tests for categorical variables. A two-sided p-value $< 0.05$ was considered statistically significant. Missing data were reported when exceeding 2% in a variable.

Risk factors for AL were analyzed using univariate analysis followed by multivariable analysis, including significant univariable variables and the variable DLI.

## Results

# Study cohort

A total of 3948 AR procedures for rectal cancer were performed during 2007 to 2009 and 2016 to 2018. One hundred thirty-one patients were non-radically resected, 123 patients had missing data regarding resection margins, and six with unregistered DLI status were excluded resulting in 3688 included patients in the study cohort, Fig. 1.

DLI patient characteristics and demographics are displayed in Table 1. Noteworthy, patients in the latter cohort (2016–2018) had more commonly high-located rectal tumor (≥ 11cm from the anal verge) than the earlier cohort (37% vs. 35%; $P < 0.001$), and less low-located tumor (< 5cm from the anal verge) 1.7 vs. 3.4%; $P < 0.001$. Additionally, less advanced tumor stage and less distant metastasis were found in the latter cohort.

Table 1
Comparison of patients with DLI after AR grouped according to the time (2007–2009) and (2016–2018)

| | 2007–2009<br>n = 1345 | 2016–2018<br>n = 1387 | p-value |
|---|---|---|---|
| **Age (years)** | 66 (60–73) | 67 (60–73) | 0.38[1] |
| **Gender (male)** | 854 (63.5) | 852 (61.4) | 0.27[2] |
| **ASA** | | | **0.001**[2] |
| ASA1-2 | 1128 (83.9) | 1092 (78.7) | |
| ASA3-4 | 189 (14.1) | 271 (19.5) | |
| **BMI** (kg/m$^2$) | | | **0.001**[2] |
| <30 | 1063 (79) | 1127 (81.3) | |
| ≥30 | 165 (12.3) | 244 (17.6) | |
| Missing data | 117 (8.7) | 16 (1.2) | |
| **Tumor location*** | | | **0.001**[3] |
| 11–15 cm | 474 (35.2) | 515 (37.1) | |
| 6–10 cm | 799 (59.4) | 842 (60.7) | |
| 0–5 cm | 64 (3.4) | 23 (1.7) | |
| **pTumor stage** | | | **0.001**[3] |
| T0 | 35 (2.6) | 29 (2.1) | |
| T1-2 | 479 (35.6) | 554 (39.9) | |
| T3-4 | 818 (60.8) | 803 (57.9) | |

[1]Mann-Whitney U

[2]Fisher's exact test

[3]Chi-squared test

*cm for anal verge

*ASA*, American society of anesthesiologists, *BMI*, body mass index, *pT*, pathological tumor stage, *pN*, pathological lymph node stage, *cM*, clinical metastasis, *IMA*, inferior mesenteric artery.

Values are shown in numbers and percentages in parentheses for categorical variables. Continuous variables are expressed as median and interquartile ranges.

| | 2007–2009<br>n = 1345 | 2016–2018<br>n = 1387 | p-value |
|---|---|---|---|
| Tx | 11 (0.8) | 0 | |
| **pN stage** | | | 0.17[3] |
| N0 | 810 (60.2) | 857 (61.8) | |
| N1-N2 | 522 (38.8) | 523 (37.7) | |
| Nx | 12 (0.9) | 5 (0.4) | |
| **cM stage** | | | **0.001[3]** |
| M0 | 1229 (91.4) | 1220 (90.7) | |
| M1 | 81 (6) | 74 (5.5) | |
| Mx | 33 (2.5) | 0 | |
| Missing data | 2 (0.1) | 93 (6.9) | |
| **Neoadjuvant chemotherapy** | 182 (13.5) | 315 (22.7) | **0.001[2]** |
| **Neoadjuvant radiotherapy** | 957 (71.2) | 867 (62.5) | **0.001[2]** |
| **Laparoscopic index AR** | 73 (5.4) | 815 (58.8) | **0.001[2]** |
| **High ligation of IMA** | 601 (44.7) | 766 (55.2) | **0.001[2]** |
| **Intraoperative perforation** | 28 (2.1) | 28 (2) | 0.953[2] |
| **Adjuvant therapy** | 398 (29.6) | 232 (16.7) | **0.001[2]** |
| Missing data | 22 (1.6) | 709 (51.1) | |
| [1]Mann-Whitney U | | | |
| [2]Fisher's exact test | | | |
| [3]Chi-squared test | | | |
| *cm for anal verge | | | |
| *ASA*, American society of anesthesiologists, *BMI*, body mass index, *pT*, pathological tumor stage, *pN*, pathological lymph node stage, *cM*, clinical metastasis, *IMA*, inferior mesenteric artery. | | | |
| Values are shown in numbers and percentages in parentheses for categorical variables. Continuous variables are expressed as median and interquartile ranges. | | | |

Table 2
Incidence of AL related to DLI over twelve year-period (2007–2009) and (2016–2018)

| | **AR 2007–2009 (n = 1879)** | **AR 2016–2018 (n = 1809)** | **P-value** |
|---|---|---|---|
| DLI | 1345 (71.6) | 1387 (76.7) | **0.001** |
| AL | 124 (9.2) | 114 (8.2) | 0.35 |
| Reoperation for AL | 58 (4.3) | 46 (3.3) | 0.17 |
| Fisher's Exact Test was used. | | | |
| *AR* anterior resection, *DLI*, defunctioning loop-ileostomy, *AL*, anastomotic leakage. | | | |

Compared to the former cohort, patients in the latter group comprised more patients with ASA 3–4 (19.5% vs. 14.1%; $p < 0.001$), and BMI > 30 (17.6% vs. 12.3%; $P < 0.001$). Concerning adjuvant therapy, the latter cohort received more neoadjuvant chemotherapy (23% vs. 14%; $P < 0.001$) but less neoadjuvant radiotherapy (62% vs. 71%; $P < 0.001$). Moreover, fewer patients in the latter group were treated with adjuvant therapy (17% compared to 39%; $P < 0.001$). Perioperatively, the latter cohort more frequently underwent minimally invasive anterior resection and high ligation of the inferior mesenteric artery.

# Defunctioning loop-ileostomy, anastomotic leakage, and risk factors

Although more than two-thirds of the patients, 71.6% (1345/1879), were diverted by DLI (2007–2009), the diversion rate increased further to 76.7% (1387/1809) ($p < 0.001$) in the latter group (2016–2018).

There was no significant reduction in AL incidence over 11 years despite the expansion in DLI usage (9.2% (124/1879) in 2007–2009 compared to 8.2% (114/1809) in 2016–2018) ($p = 0.35$). The number of reoperations for AL was unchanged (4% (58/1435) vs. 3% (46/1387), respectively).

The study cohort was divided into +/-AL, and AL risk factors were analyzed (Table 3). Patients with AL had as many DLI as patients without AL (72% compared to 74%, $p = 0.36$). AL was significantly related to the male sex, ASA class, BMI, pathological tumor stage, and neoadjuvant radiotherapy. Tumor distance from the anal verge did not play a significant role in AL.

Table 3
Univariate and multivariate analysis for anastomotic leakage risk factors.

| | Univariate analysis | | | Multivariate Analysis | | |
|---|---|---|---|---|---|---|
| | OR | 95% CI | p-value | OR | 95% CI | p-value |
| Male sex | 1.4 | 1.09–1.75 | **0.008**[1] | 1.5 | 1.13–1.88 | **0.004** |
| ASA 3–4[2] | 1.4 | 1.05–1.82 | **0.023**[1] | 1.4 | 1.05–1.85 | **0.023** |
| BMI (> 30kg/$m^2$) | 1.5 | 1.097–1.966 | **0.013**[1] | 1.5 | 1.12–2.04 | **0.007** |
| Tumor location | | | 0.426[2] | | | 0.484 |
| 11–15 cm | 1545 (46) | 158 (47.7) | | 0.6 | 0.27–1.51 | 0.311 |
| 6–10 cm | 1691 (50.4) | 160 (48.3) | | 0.9 | 0.69–1.16 | 0.409 |
| 0–5 cm (ref) | 98 (2.9) | 6 (1.8) | | | | |
| pTumor stage 3–4 | 1.3 | 1.024–1.646 | **0.034**[1] | 1.7 | 0.61–4.75 | 0.307 |
| Defunctioning loop-ileostomy | 0.9 | 0.688–1.139 | 0.357[1] | 0.9 | 0.63–1.15 | 0.301 |
| Neoadjuvant Radiotherapy | 1.3 | 1.024–1.632 | **0.031**[1] | 1.5 | 1.13–1.95 | **0.004** |

[1] Fisher's Exact test

[2] Chi-squared test

*ASA*, American society of anesthesiologists, *BMI*, body mass index, *pT*, pathological tumor stage

The binary logistic regression model for multivariate analysis showed similar results to the univariate analysis, but the pathological tumor stage was not identified as an independent risk factor. There was no clear association between DLI and AL (Table 3). Male gender, ASA class 3–4, BMI ≥ 30, and neoadjuvant radiotherapy remained risk factors for AL.

# Discussion

This study demonstrated a five percent increase in DLI construction between 2007–2009 and 2016–2018. Surprisingly, a high number of DLI (71.6%) was registered from 2007 to 2009, although RECTODES-trial was not reported until 2007 [6]. The increased usage of DLI did not reduce AL incidence nor reoperations due to AL. More than one-third of the DLI-patients in both periods had tumors located ≥ 11cm from the anal verge.

AL is deemed one of the most feared surgical complications after sphincter-preserving surgery. Significant efforts to preclude its occurrence are conducted by minimizing modifiable risk factors and implementing protective measures, including DS. There are inconsistent results on how DS affect AL rates despite well-conducted randomized controlled trials, prospective multicentre studies, and meta-analyses [20, 21]. The present national study indicates that too many AR patients receive a DLI without a beneficial effect on AL, suggesting that the selection process is too blunt. Similarly, a comparison of the Dutch TME-trial in 1996–1999 to the Dutch Surgical Colorectal Audit in 2010 demonstrated significantly increased defunctioning rates from 57–70%, albeit AL remained stable (12% vs. 11%)[7].

Additionally, a Swedish regional study identified increase of DS construction from 15% (2002–2006) to 91% (2007–2011), the latter group probably influenced by RECTODES trial results, while AL lingered around 10% [22]. This shift reflects the early adoption of the routine use of DLI in Sweden. There is no causal effect of DLI on AL, but our study could not detect a reduced rate of reoperations either. However, we may speculate that there might be a shift towards a lesser need for laparotomy and emergency procedures, although SCRCR data cannot prove this.

The interpretation of the results from RCTs advocating the protective role of DS must consider the circumstances that entail DS construction. In the case of the RECTODES-trial, several detrimental factors were considered. More than two-thirds of AR patients were not accepted for randomization. The most critical exclusion criterion, in our opinion, was anastomosis level > 7 cm above the anal verge or resection with a PME procedure. However, in Sweden, a high proportion (25%) of AR patients have high-located tumors (≥ 11cm from the anal verge), and about 34% subjected to PME were diverted with DLI in Sweden. This high proportion of PME is consistent with our findings which detected a diverting rate of 35% (2007–2009) and 37% (2016–2018) [22, 23]. Furthermore, the most frequent exclusion factor was intraoperative technical difficulties or intraoperative adverse events, which would create a selection bias and, consequently, decrease the external validity.

The short- and long-term stoma-related morbidities for a DS are not negligible. The few weeks after hospital discharge carry a high risk of readmission (17%) due to dehydration by high-output stoma [24]. Moreover, the risk for chronic kidney injury (CKD) accompanying DLI is also time-related, as the incidence of severe CKD injury is higher during the first six months [25]. Stoma reversal is another eventful step that conveys a high rate of 18–40% complications which might require reoperation in 3–8% [26, 27]. Two Swedish population-based cohort studies have investigated the permanent stoma rate, and up to 26% of AR patients would have a permanent stoma. Although AL is one of the most prominent risk factors for the permanent stoma, constructing a defunctioning stoma has no more than negligible effect on maintaining a permanent one [23, 28].

This observational study is strengthened by a large sample representing the national population of this patient group and thus enhances its generalizability and external validity. It was unbiased in selecting all consecutive patients from two periods. The study is limited by some unavailable variables, such as type of reoperation for AL, type of DS, and no follow-up of AL after 30-day, thus only reflecting the early AL rate.

Although our findings indicate that routine DLI construction is inefficient in diminishing the risk of AL in routine AR use, the role of selective DLI in mitigating AL consequences in low anastomoses should be emphasized. Other preventive measures include ghost ileostomies, an AL-check list, and scheduled postoperative AL surveillance, including sigmoidoscopy, labs, and rectography [29–31].

Thus, an urge for a decision algorithm regarding selective criteria for DLI is called for to spare DLI usage in this complex patient group with multiple risk factors for AL. Noteworthy, there is a significant shift from open to laparoscopic approach in TME-procedure. Therefore, new studies should explore the protective role of DLI specifically in the current surgical practice of laparoscopic and trans-anal TME procedures.

# Declarations

**Competing Interests:**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper

**Funding Declaration:**

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**Authors contribution:**

This original research is a part of doctoral studies for Dr. Eihab Munshi, who wrote the main manuscript with the figure and tables. The project is supervised and guided by Dr. Pamela Buchwald (supervisor) and Dr. Marie-Louise Lydrup (Co-supervisor), who contributed to designing the project, then reviewing and editing the manuscript.

**Ethical approval:**

This study obtained an ethical approval via the Swedish Ethical Review Authority (Diary number 2020-01082).

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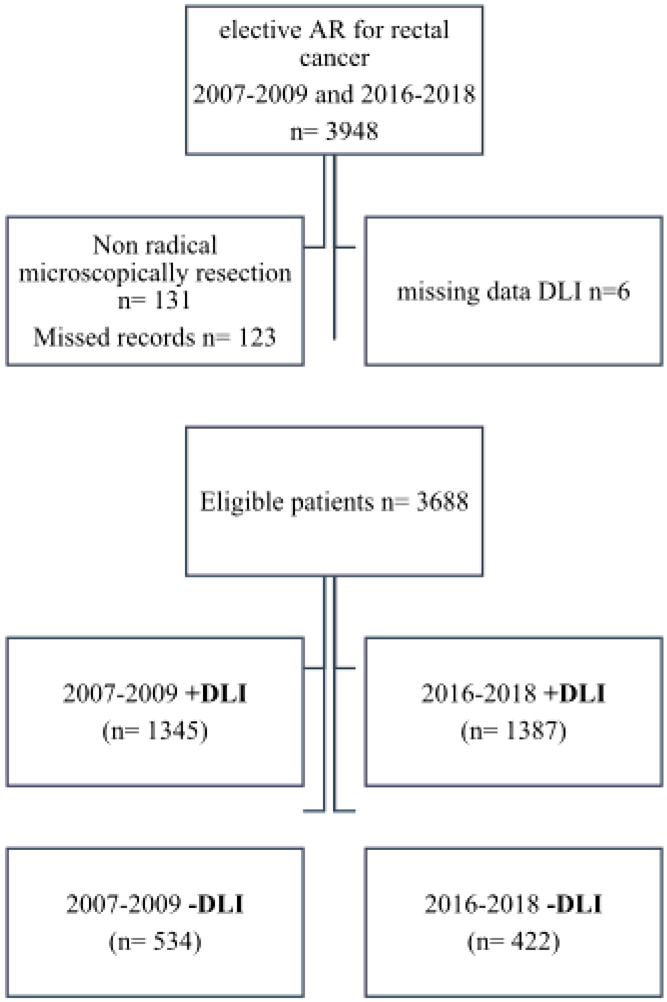
# Figures




## Figure 1

Retrieved patients from the Swedish Colorectal Cancer Registry (SCRCR). Rectal cancer patients undergoing anterior resection (*AR*) (2007-09) and (2016-2018) were divided into two groups *+DLI* and *-DLI*.