Can a Local Drainage Salvage a Failed Colorectal or Coloanal Anastomosis? A Prospective Cohort of 54 Patients

Alexandre Challine, Jeremie Lefèvre, Ben Creavin, Olivier Benoit, Najim Chafai, Clotilde Debove, Thibault Voron, Yann Parc

Does a local drainage can maintain a failed colo-rectal or colo-anal anastomosis? A prospective cohort of 49 patients.

Short running head: Drainage of failed low anastomosis

Alexandre Challine (MD) [1], Jeremie H. Lefevre (MD, PhD) [1], Ben Creavin (MD) [2], Olivier Benoit[1], Najim Chafai (MD) [1], Clotilde Debove (MD) [1], Thibault Voron (MD) [1], Yann Parc (MD, PhD)[1]

(1) Departments of Digestive and General Surgery, Hospital Saint-Antoine AP-HP, Sorbonne Université, Paris, France.
(2) Department of Surgery, St Vincent's University Hospital, Elm Park, Dublin 4, Ireland

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Correspondance and reprint requests:
Pr Jérémie H. Lefèvre, Department of Digestive Surgery, Hôpital Saint-Antoine, Assistance Publique Hôpitaux de Paris, Sorbonne Université, Paris VI, 184 rue du Faubourg Saint-Antoine, 75012, Paris, France
Tel: 0033 1 49 28 25 47, Fax: 0033 1 49 28 25 48
e-mail: jeremie.lefevre@aphp.fr

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STRUCTURED ABSTRACT

Background*:* Local drainages can be used to manage leakage in selected patients without peritonitis.

Objective*:* The aim of this study was to evaluate the efficacy of drainage procedures in maintaining a primary low anastomosis following anastomotic leakage.

Design*:* A retrospective observational study was performed on a prospectively maintained database.

Settings*:* The study was done between 2014 and 2017 in a tertiary referral center.

Patients: Patients undergoing rectal resections with either a colorectal or coloanal anastomosis (CR-CAA) with diverting stoma were identified. Anastomotic leakages requiring a radiological or trans-anal drainage without peritonitis were included.

Main Outcome Measures: The primary outcome was the maintenance of the primary CR-CAA after local drainage of an anastomotic leakage and stoma reversal.

Results: A low CR-CAA for rectal cancer with diverting stoma was performed in 326 patients. 77 (23.6%) anastomotic leakages occurred, of which, 11(3.4%) required abdominal surgery, 17 (5.2%) were treated conservatively (medical management) and 49 (15.0%) were managed by drainage without emergency abdominal surgery.

Surgical transanal drainage was performed in 18 patients (37%), with radiological drainage procedures in 31 patients (65%). The median interval between surgery and drainage was 15 days [9-24].

24 (49%) patients did not require any further intervention following drainage procedure with 20 patients (41%) undergoing redo anastomotic surgery. 39 patients (80%) had no stoma at the end of follow up.

Failure to maintain the primary anastomosis was associated with a drainage duration >10 days (p=0.005), the time between surgery and drainage > 15 days (p=0.03) and side to end or J-pouch anastomosis (p=0.02) and surgical trans-anal drainage (p=0.05).

Limitations*:* The small sample size of the study due to incidence of drainage is the main limit of the study.

Conclusion*:* Local drainage procedures maintained primary anastomosis in 50% of cases following an anastomotic leakage.

Keywords: coloanal anastomosis; anastomotic leakage; anastomotic drainage; outcome

INTRODUCTION

Indications for sphincter sparing rectal cancer resections have increased due to the reduction in the distal margin distance [1, 2] and the downsizing effects of neoadjuvant therapy [3].

However, the rate of anastomotic leakage still ranges around 20% [4-6]. Consequences of a leakage are severe and can lead to septic shock or death [7]. The use of a diverting ileostomy does not prevent all anastomotic leakage; however, the severity of the sepsis related morbidity can be reduced [8, 9]. Leakages can be graded by the clinical outcomes of patients [10]. The most severe leakages (Grade C) are those who need a re-laparotomy for peritonitis. In such cases, the anastomosis is often taken down and an end stoma is created. For grade B leakage, medical treatment including antibiotics and local treatments are needed to treat a pelvic abscess. Finally, asymptomatic leakage can occur (A-grade) up to 6 months after bowel continuity [11].

Recently, the endo-SPONGE® has been used to treat leakage but currently there are few studies with small sample sizes describing this procedure [12-19]. Stoma reversal rates following this procedure vary between 37-90%. This technique requires several procedures in order to change the endo-SPONGE® but can be performed in an outpatient setting and sometimes without sedation. The majority of grade B leakages are drained either by a surgical trans-anal approach or a radiological approach.

Radiologic trans-gluteal drainage is a safe with rare complications reported as hemorrhage or creation of a fistula tract [20] and effective approach with successful management of abscess without recurrence being reported around 96%[11, 20]. However, the functional outcomes of the anastomosis after radiological drainage is unknown. This too is true with regard to the trans-anal approach, with a lack of data currently in the literature. [21, 22] The need for a further drainage with this approach is reported to be 38% without abdominal surgery, however, stoma reversal rates are above 90% [22].

Definitive stoma rates following failed sphincter sparing surgery is close to 20% for all rectal cancer patients [23]. Maggiori et al. found the rate of definitive stoma increases after a non-conservative approach for grade C leakage [24]. Redo surgery to create a new anastomosis is challenging, with a high morbidity and risk of injury to the genitourinary system [25, 26].

The aim of this study was to evaluate the efficacy of drainage procedures in maintaining a primary low anastomosis following anastomotic leakage

MATERIAL AND METHODS

Study design and settings

A retrospective observational study was performed on a prospectively maintained database of patients undergoing rectal resections with either a colorectal or coloanal anastomosis (CR-CAA) with diverting stoma between 2014-2017. Patients medical records were reviewed for patient characteristics, co-morbidities, surgical and histological characteristics, date of drain, duration of drain, the need for redo coloanal anastomosis and stoma closure rates.

Population and follow-up

Patients who had an anastomotic leakage diagnosed by imaging (CT scan) or local examination under general anesthesia and requiring a radiologic or trans anal surgical drainage during their post-operative courses were analyzed. Patients were excluded if they presented with peritonitis requiring emergency surgery by abdominal approach.

Follow-up included clinical examination and C-Reactive Protein (CRP) levels at 1, 3 and 5 postoperative days [27]. In case of any deviation in the post-operative clinical course, a CT scan was performed. When a pelvic abscess occurred, 2 types of pelvic drainage were utilized: a radiologic drain (usually done under CT guidance) by a trans gluteal approach or by a trans anal approach under a general anesthetic. Drains were flushed with 10cc of sterile saline 3 times a day by a specialized nurse. Drains were removed when outputs remained low (<20cc a day)

or when a repeat CT scan showed good resolution of the collection. When patients were discharged home with a drain, outpatient consultations occurred weekly. A consultation 1 month after discharge was performed to repeat a CT scan to assess resolution of the leakage and plan the stoma closure. Before stoma closure, integrity of anastomosis was tested with radiological assessment and clinical local exam. In case of persisting leakage with chronic sepsis or stricture, a redo surgery and new CAA was performed. The follow-up was stopped on October the first 2018.

Outcome and variables

The primary outcome was maintenance of the primary CR-CAA after a local drainage and the closure of the diverting stoma. The secondary outcome was the rate of definitive stoma.

Statistical analysis

The R software was used (R Development Core Team (2005). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL: http://www.R-project.org). Descriptive analysis was performed using percentages, means, medians and proportion, with standard deviation and interquartile ranges reported. Univariate analysis was performed on the primary binary outcomes with general linear models with the *univariateTable* function of the R-Package *Publish*. A p-value lower than 0.05 was considered as significant. ~~(software version 9.3; SAS Institute Inc., Cary, NC, USA).~~ .

RESULTS

Participants and incidence of leakage

The flowchart of the study is presented in the figure 1. A total of 326 patients underwent a low anastomosis with diverting stoma for rectal cancer in the present study, of which, 77 (23.6%) anastomotic leakages occurred. 11 (3.4%) anastomotic leakages needed an emergency abdominal surgery (Grade C). Among the remaining 66 B-grade leakages, 17 (5.2%) were

treated medically with antibiotics alone and 49 (15.0%) were managed by drainage. The evolution of our practice is illustrated in figure 2. There was no difference in the rate of leakage per year (p=0.41), or number requiring drainage (p=0.30), however, abdominal re-intervention for new coloanal anastomosis rates were lower (p<0.001).

Characteristics of drained patients

49 patients underwent pelvic drainage, with the majority diagnosed by fever in the post-operative course. 43 patients (96%) had a CRP at post-operative day (POD) 3 or 5 >100. Patient characteristics are detailed in table 1. The mean age was 62±13 years, of which, 29 (59.2%) were male. A total of 34 patients (69%) underwent neoadjuvant therapy.

47 (96%) patients had resections for low or mid rectal tumors. All patients had a diverting ileostomy. A laparoscopic approach was the most frequent approach used (n=40, 82%). The majority of patients had a J-pouch or side to end anastomosis (n=40, 82%).

Drainage description

Characteristics of drain management are described in table 2. A surgical trans-anal approach under general anesthetic was performed for 18 (37%) patients while 31 (63%) patients underwent a radiological transgluteal approach. Surgical trans-anal drainage was more likely used for purulent flowing and radiological drainage for fever (p=0.01). The median interval between surgery and drainage was 15 days [9-24]. *Escherichia coli* was found in 19 (73%) available cases while 2 (10%) had extended spectrum Beta Lactamase. Drainage duration more than 10 days was more frequent for surgical drainage (p<0.001). 14 (28%) patients needed a second drainage to treat a recurrent abscess (median time interval between drainages of 44 days [22-66]). The length of stay (LOS) for surgery and drain management was 24±10 days. LOS was lower for radiologic drainage (22±10 *vs.* 28±10, p=0.02). 12 (26%) patients were discharged with a drain.

Follow-up

Maintenance of the anastomosis was achieved in 24 (49%) patients, with stoma reversals after a mean interval of 5.0 ± 2.7 months.

20 (41%) patients needed a new procedure to treat a chronic leakage (n=18, 90%) or a stenosis (n=2, 10%). Among those 20, 14 (70%) patients required a new coloanal or ileoanal anastomosis, 4 (20%) required a new delayed coloanal anastomosis, and 2 (10%) had an end-stoma performed.

39 on the 49 patients (80%) had no stoma at the end of follow up (22 ± 14 months) with stoma closure interval of 7 ± 4 months and 15 ± 12 months of follow-up after stoma reversal. On those 10 patients who had a definitive stoma (20%), 5 had a redo-procedure, with 2 patients who had an end stoma during the redosurgery, 3 presented a recurrence of leakage after their redo coloanal anastomosis. 5 patients had not redosurgery and no stoma reversal (1 lost of follow-up, 2 for chronic leakages, 2 for patient's refusal).

Risk factor of failure to maintain the anastomosis

In univariate analysis (table 3), a surgical drainage (p=0.05), a drainage duration> 10 days (p=0.005), the interval between surgery and drainage> 15 days (0.03), side to end or J-pouch anastomosis (p=0.02) and year of surgery were associated with failure to maintain the CR-CA anastomosis.

DISCUSSION

This study reports a single centers experience of drainage procedures following anastomotic leakage for low colorectal/coloanal anastomosis for rectal cancer. Maintenance of the anastomosis was achieved in 50% of the cohort undergoing local drainage, however, the rate of definitive end stoma was 20%. The present study found that a short drainage duration was associated with maintenance of the primary anastomosis in univariate and multivariate analysis. Furthermore, the implementation of a more conservative management (drainage) over

the years, decreased the rate of redo-surgery, increasing the likelihood of maintaining the anastomosis.

Local drainage

Only 5 patients, excluded from the analysis, needed an emergency abdominal surgery after a local drainage for peritonitis. The choice of the drainage procedure is not clear in the literature. In our study, we found a benefit to maintain for the radiological drainage in univariate analysis. A recent review reported quite the same rate of definitive stoma of 25% after vacuum-assisted therapy. [19] Bortslap et al. found also the same efficacity to heal leakage at 6 months with only the half of anastomosis healed. [17] However, utilizing a local drainage as a first approach in the management of grade B leakages is feasible based on the results reported in the present study.

Definitive stoma rate and leakage rate

The end-stoma rate in this study is in line with previous reported literature (>20%) [4, 23] although, the results in the present study are based on grade B leakages with longer follow up. Overall symptomatic leakage rate was 24% with 3% classified as grade C leakage and 20% as grade B. These rates are in accordance with previous reported studies, with rates varying between 8-28% [4, 5, 28]. Our rate of leakage is high, but the inclusion of patient is highly selective with 96% of patients had a low or a mid tumors and consequently had a total mesorectal excision. [29] Near 70% of patients had neoadjuvant therapy. Even if neoadjuvant irradiation did not seem increase the rate of leakage, literature is not clear about the outcome of a leakage occurring after radiotherapy. [30, 31] It could increase the rate of definitive stoma. At least, rate of leakage varies based on definition of leakage[32], and our definition of leakage included all pelvic collection and peritonitis.

Risk factors

The present study reported that an early and short duration drainage was associated with maintenance of the anastomosis. However, this should be interpreted with caution and could be

influenced by leakage and drainage characteristics. For example, a leakage with high output is associated with worse outcomes and may require a longer drainage period especially if there is a longer interval between surgery and drainage. Previous studies report similar result with improved stoma reversal rates after an early drainage [13, 15]. As showed in several studies on the vacuum therapy, leakages with an early drainage have a better prognostic than others. [13, 17] It is probably explained by the fibrosis which is more frequent after a chronic leakage found during the redo-surgery. Influenced by previous reports in the literature, the management of anastomotic leakage in our center has evolved, which has resulted in a reduction in the number of re-do surgeries [6, 24, 33]. This evolution was significantly associated with maintaining the anastomosis on univariate and multivariate analysis. Furthermore, and end-to-end anastomosis was associated with maintenance of the anastomosis compared to a side-to-end or J-pouch anastomosis. We did not have the details of the leakage location in patients with side-to end of J pouch. Interestingly, Hain et al. found no difference in terms of definitive stoma rates based on the location of leakage in side to end or J-pouch anastomosis [34]. The functional outcome is significantly better when an alternative anastomosis to an end to end is used. We believe that an end-to-end should be not systematically performed in regards of our results to improve the functional results and quality of life. However, it may be of interest in high-risk patient as recent randomized control trials have questioned this finding [35]. Finally, after comparison of type of local drainage, radiological drainage was associated with the success to maintain the primary anastomosis.

Limitations

Firstly, the retrospective design of the present study does not allow the authors to standardize the indication for drainage. The majority of drainages in this study were performed for sepsis, however, some drainages were performed for asymptomatic leakage, elevated CRP levels and following radiological assessment. Surgical trans-anal drainage was commonly

utilized for purulent leakage. There was no significant difference regarding the maintenance of anastomosis, but all 6 patients drained for purulent flowing did not kept their initial anastomosis. Characteristics of each drainage influenced the length of stay and the feasibility of outpatient management for the drain. The use of CT scans to diagnose anastomotic leakage has increased over the years, mainly due to the improved access to scanners and imaging quality. Bias in this study was minimized by adjusting for time on multivariate analysis. However, data collection on drain output, microbiology and length of drainage was limited due to the retrospective nature of the study.

Furthermore, the small size of patients undergoing drainage was small, limiting the results of the study and the strength of the association interpretation. However, to the authors knowledge, this is the first and largest study to assess risk factor for failing to maintain a colorectal anastomosis.

Conclusion

Local drainage avoided re-do anastomosis in 50% of patients who had a grade B leakage for low colorectal/coloanal anastomosis for rectal cancer. An end-to-end anastomosis, a shorter length of drainage and radiological drainage were associated with maintenance of the primary anastomosis.

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Figure Legend:

Figure 1. Flow chart of the study

Figure 2. Representation of the evolution of the rates of conservation, leakage, drainage and new anastomosis by years.

Table 1. Characteristics of patient treated by local drainage.

Type		n = 49
Comorbidity of patient	Age in year (mean±sd)	62.1 ± 13.1
	BMI in kg/m^2 (mean±sd)	24.9 ± 4.1
	Male	29 (59.2)
	ASA score	
	1	19 (38.8)
	2	28 (57.1)
	3	2 (4.1)
	Use of anticoagulant	3 (6.1)
	Diabetes	4 (8.2)
	Cardiovascular disease	6 (12.2)
Tumor characteristics	Local excision before surgery	5 (10.2)
	Neoadjuvant treatment	34 (69.4)
	Location of tumor	
	High	2 (4.1)
	Mid	23 (46.9)
	Low	24 (49.0)
Surgical characteristics	Laparoscopy	40 (81.6)
	Mechanical anastomosis	23 (47.9)
	Type of anastomosis	
	J-pouch	17 (34.7)
	Side to end	23 (46.9)
	End to end	9 (18.4)
	Pelvic drainage	32 (65.3)
	Additional procedure	10 (20.4)
Histological characteristics	T stage	
	0	5 (10.2)
	1	5 (10.2)
	2	9 (18.4)
	3	24 (49.0)
	4	6 (12.2)
	N stage	
	0	29 (59.2)
	1	14 (28.6)
	2	6 (12.2)
	M stage 1	3 (6.1)
	R1 resection	5 (10.2)

Table 2. Characteristics of drainage

		Total (n=49)
Clinical diagnostic	**Fever**	28 (57.1)
	Purulent discharge	6 (12.2)
	Pelvic pain	5 (10.2)
	Clinical assessment	6 (12.2)
	Others	4 (8.2)
C reactive protein	**POD 3**	237.5 ± 130.7
	POD 5	212.3 ± 128.2
	before drainage	188.5 ± 115.2
Type of drainage	**Radiological**	31 (63.3)
	Surgical	18 (36.7)
Time between surgery and drainage >15 days		25 (51.0)
Duration of drainage > 10 days		19 (38.8)
Output per day		90.8 ± 72.3
Need for second drainage		14 (28.6)
Type of second drainage	**Radiological**	35.7 (n=5)
	Surgical	64.3 (n=9)
Time between first and second drainage in days		44.5 [22.2 66.0]
LOS in days		24.1 ± 10.1
Imaging Prior to Drain removal		26 (54.2)
Discharged with drain		12 (26.1)

Table 3. univariate analysis**: r**isk factors of a failure to maintain the CR-ACA anastomosis

Variable		Success (n=24)	Failure (n=25)	p value
Age		59.1 ± 13.4	65.0 ± 12.5	0.11
BMI		25.1 ± 4.4	24.8 ± 3.8	0.82
% of male		17 (70.8)	12 (48.0)	0.18
ASA score	**1**	10 (41.7)	9 (36.0)	0.92
	2	13 (54.2)	15 (60.0)	
	3	1 (4.2)	1 (4.0)	
Local resection before LARS		3 (12.5)	2 (8.0)	0.96
Neoadjuvant Teatment		14 (58.3)	20 (80.0)	0.18
Length between anal sphincter and tumor	**1-3 cm**	13 (54.2)	11 (44.0)	0.2
	3-8 cm	9 (37.5)	14 (56.0)	
	8-13 cm	2 (8.3)	0 (0.0)	
Laparoscopy		20 (83.3)	20 (80.0)	1
Mechanical anastomosis		13 (56.5)	10 (40.0)	0.39
Type of anastomosis	**End to end**	8 (33.3)	1 (4.0)	0.02
	Others	16 (66.7)	24 (96.0)	
Pelvic drainage		12 (50.0)	20 (80.0)	0.06
T	**0-2**	11 (45.8)	8 (32.0)	0.48
	3-4	13 (54.2)	17 (68.0)	
N	**0**	17 (70.8)	12 (48.0)	0.18
	+	7 (29.2)	13 (52.0)	
M	**1**	1 (4.2)	2 (8.0)	1
R	**1**	1 (4.2)	4 (16.0)	0.37
Adjuvant treatment		6 (25.0)	13 (54.2)	0.08
Septic leakage		16 (66.7)	12 (48.0)	0.3
Type of drain	**Surgical**	5 (20.8)	13 (52.0)	0.05
	Radiological	19 (79.2)	12 (48.0)	
Time between surgery and drainage > 15 days		8 (33.3)	17 (68.0)	0.03
Duration of drainage > 10 days		4 (16.7)	15 (60.0)	0.005
Need for 2nd drainage		4 (16.7)	10 (40.0)	0.14
Year of surgery	**2014-2015**	7 (29.2)	19 (76.0)	0.003
	2016-2017	17 (70.8)	6 (24.0)	

Figure 1

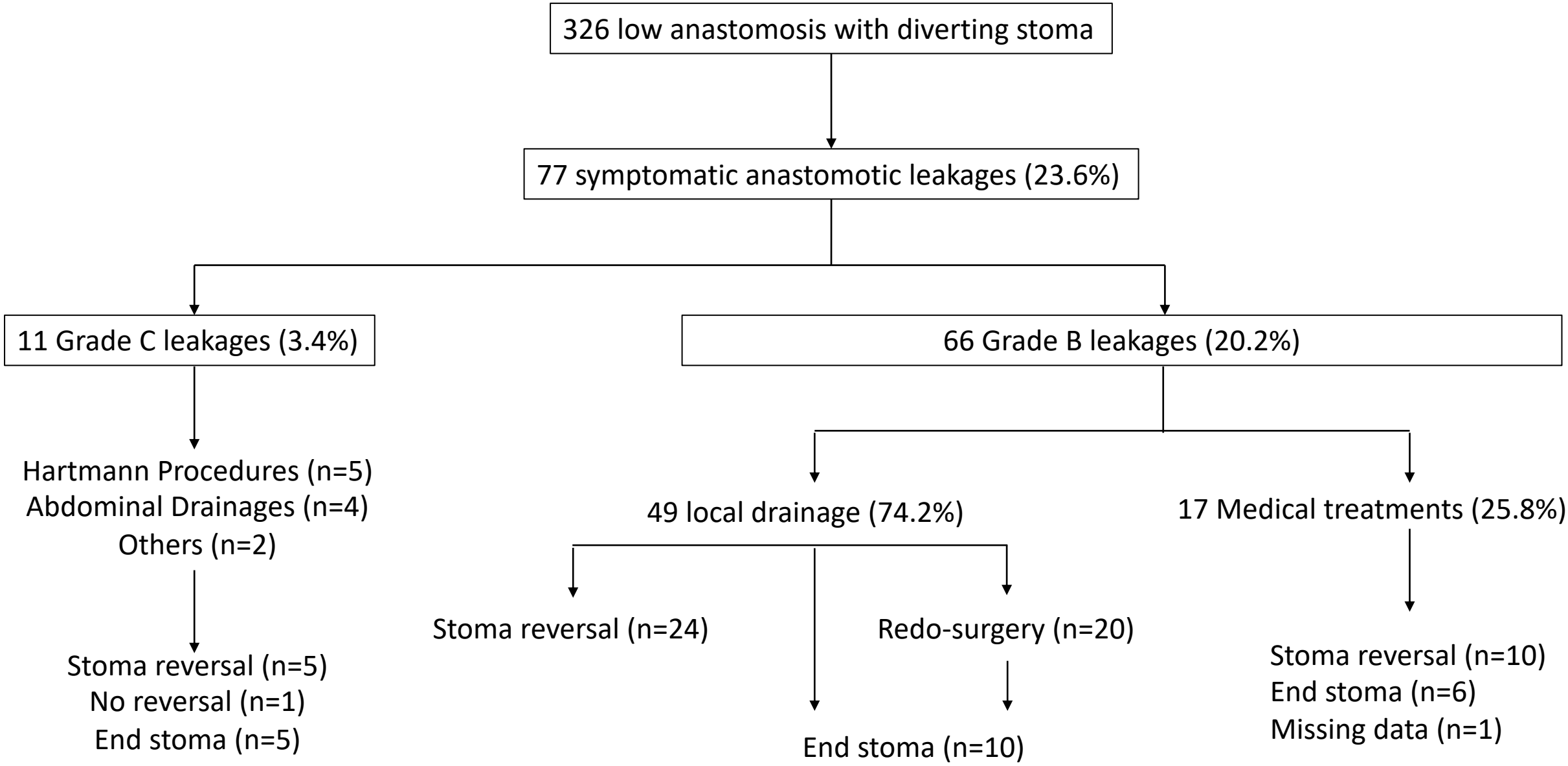
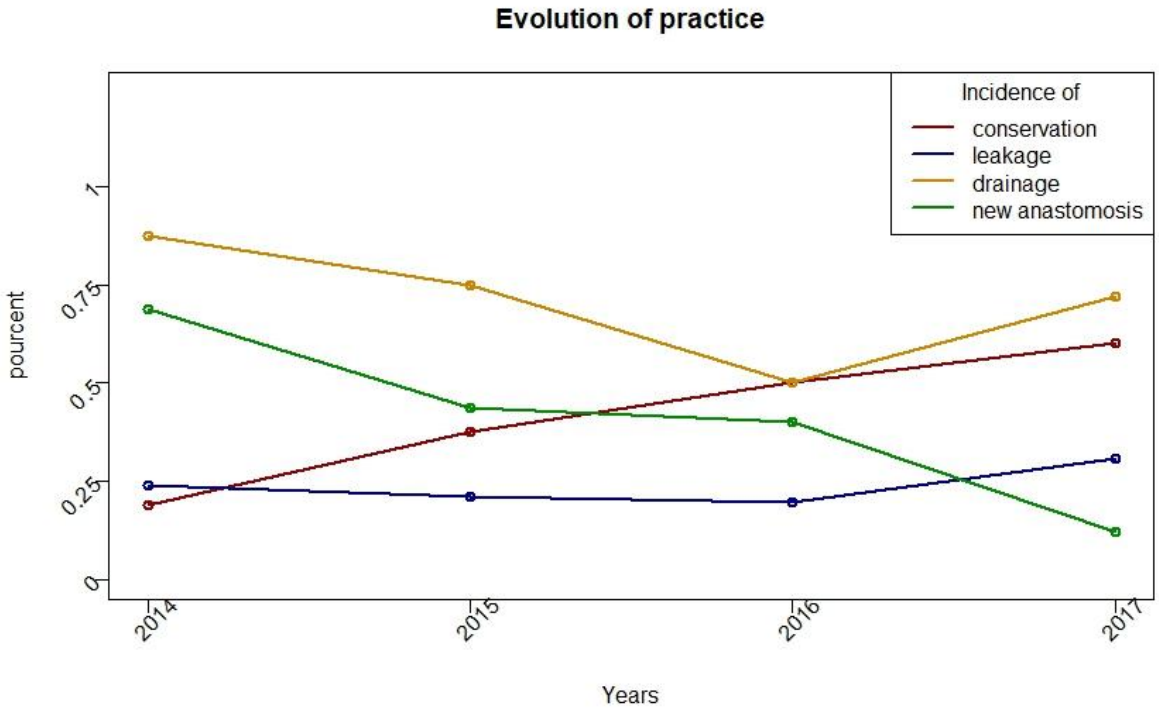

326 low anastomosis with diverting stoma
77 symptomatic anastomotic leakages (23.6%)
11 Grade C leakages (3.4%)
66 Grade B leakages (20.2%)
Hartmann Procedures (n=5)
Abdominal Drainages (n=4)
Others (n=2)
Stoma reversal (n=5)
No reversal (n=1)
End stoma (n=5)
49 local drainage (74.2%)
17 Medical treatments (25.8%)
Stoma reversal (n=24)
Redo-surgery (n=20)
End stoma (n=10)
Stoma reversal (n=10)
End stoma (n=6)
Missing data (n=1)

Figure 2. Representation of the evolution of the rates of conservation, leakage, drainage and new anastomosis by years.



STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **page 1**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **page 2**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **page 3**
Objectives	3	State specific objectives, including any prespecified hypotheses **page 4**
Methods		
Study design	4	Present key elements of study design early in the paper **page 4**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **pages 4-5**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up **page 4**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **page 5**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **page 5**
Bias	9	Describe any efforts to address potential sources of bias **page 5**
Study size	10	Explain how the study size was arrived at **page 5**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **page 5**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **page 5**
		(*b*) Describe any methods used to examine subgroups and interactions **page 5**
		(*c*) Explain how missing data were addressed **NA**
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed **NA** *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses **page 5**

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed **page 5**
		(b) Give reasons for non-participation at each stage **NA**
		(c) Consider use of a flow diagram **NA**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders **pages 5-6**
		(b) Indicate number of participants with missing data for each variable of interest **NA**
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) **page 6**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time **page 5-6**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure **NA**
		Cross-sectional study—Report numbers of outcome events or summary measures **NA**
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included **pages 6-7**
		(*b*) Report category boundaries when continuous variables were categorized **pages 6-7**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **NA**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **page 7**
Discussion		
Key results	18	Summarise key results with reference to study objectives **page 7**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **page 8-9**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **page 7-8**
Generalisability	21	Discuss the generalisability (external validity) of the study results **pages 8-9**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **page 1**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.