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Impact of fecal diversion in Perineal Necrotizing Soft Tissue Infection on disease survival: A large retrospective study

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ABSTRACT

Introduction: Colostomy is usually proposed during the acute phase of Fournier Gangrene, nevertheless its impact on disease outcome remains still debated. We conducted a retrospective study in an academic center to determine the impact of fecal diversion on disease morbidity and specific survival.

Methods: All medical charts of Fournier Gangrene cases in the past 30-years were reviewed. Mortality rate, hospitalization duration, time to complete healing and number of excision surgeries were compared between the stoma and the non-stoma groups. Time between initial diagnosis and stoma creation, type of fecal diversion, as well as specific morbidity were analyzed.

Results: Of 89 patients included, 59 had stoma creation. Stoma group had significant higher catecholamine drugs use. Mortality, time to complete healing and number of excision surgeries did not significantly differ between both groups. Hospitalization duration was significantly higher in the stoma group. Mortality and hospitalization duration were higher when loop transverse colostomy was performed, and when colostomy was done in the first 3-days. Morbidity occurred in 41 % of patients with colostomy, with 25 % life-threatening complications. 31 % of colostomies remained definitive, while median time to intestinal recovery was 159-days.

Discussion: Consistently with current literature, disease survival was not improved by colostomy creation although skewed. Colostomy creation was associated with a higher hospitalization duration and a significant morbidity including risk of definitive stoma. To limit over-indicated stoma and improve early results, a damage control strategy using colostomy creation is advised.

Conclusion: The benefit of colostomy during the acute phase of Fournier Gangrene was uncertain, with no clear impact on mortality. In fact, colostomy was associated with increased hospitalization duration and specific morbidity. Finally, when fecal diversion is deemed necessary, we advocate for coelioscopic delayed loop left colostomy. Alternative minimally invasive treatment as bowel catheters should also be discussed.

Introduction

Perineal Necrotizing Soft Tissue Infection (p-NSTI) - also called Fournier Gangrene (FG) – is a rare life-threatening condition with an incidence of 1,6/100.000, and a reported risk of death between 3 and 45 % in recent series [1]. Disease management must be initiated in an emergency setting and requires the use of broad spectrum antibiotics as well as surgical resection of necrosis areas [2–4]. However, there is no consensus about the need for a systematic fecal diversion. Whilst colostomy is often proposed during the acute phase of FG, its impact on clinical outcomes remains debated [1,5–8]. A supporting hypothesis for stoma creation was the limitation of wounds soiling, resulting in less local and systemic inflammation, which may promote wound healing, improve survival and skin grafting outcomes. Moreover, by decreasing contamination, stoma creation is likely to reduce the need for iterative, painful and time-consuming wound dressing revisions. Futhermore,

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colostomy allows the use of vacuum devices as Vacuum Assisted Closure® which may improve local treatment [9].

On the other hand, higher mortality rates were suggested with stoma formation [1], with no benefit on hospitalization duration [10], increased morbidity [8,10,11] and additional costs [8,10]. The aim of the present study was to assess the impact of colostomy on FG management outcomes and evaluate its specific complications, in order to refine its indications based on a large retrospective cohort of patients.

Material and methods

Design and data collection

A retrospective study was conducted in a French tertiary reference center. All medical charts of adult patients and hospitalized for p-NSTI management since 1990 were reviewed. Files were selected using a local institutional software (*« Entrepôt de Données de Santé Normand »*). The following data were collected: biological sex, age, body mass index (BMI), active smoking status, diabetes, alcohol intake, cirrhosis, chronic kidney failure, chronic heart failure, chronic obstructive pulmonary disease, autoimmune disease, neuropathy, non steroidal anti inflammatory use, steroidal anti inflammatory use, catecholamine drugs use, and time from symptoms to excision surgery. The simplified-Fournier Gangrene Severity Index score (s-FGSI) was calculated based on the laboratory results at the emergency care unit, including hematocrit, potassium and creatinine serum levels [12]. Platelet to Lymphocyte ratio (PLR) and the Neutophil to Lymphocyte ratio (NLR) were calculated. Disease extent was determined upon the involvement of the following anatomical regions: posterior perineal region; anterior perineal region until pubis; anterior abdominal wall from the pubis to the umbilicus; anterior abdominal wall from the umbilicus to the thorax; thorax; gluteal region; thigh. Colostomy indications were classified as elective, i.e. justified by the rationale of limitation of soiling (e.g. proximity of the wounds from the anus, occurrence of wound dressing contamination, large perineal wound, bad septic wound evolution, and preventive stoma previous skin grafting) or imperative (e.g. required by p-NSTI aetiology as infected and occlusive colorectal cancer, colonic perforation, or suspicion of anal sphincter impairment).

Outcome evaluation

Primary outcome was specific mortality defined as an event of death during hospitalization or after discharge if linked to treatment (including colostomy complications). Hospitalization duration was from emergency unit admission to discharge (or death). Time to complete healing was determined from first excision surgery to complete wound healing or latest plastic surgery follow-up if not mentioned. Number of excision surgeries was figured out by review of surgical reports. Specific mortality was defined as the primary outcome while all the other parameters were considered secondary outcomes.

Statistical analyses

Comparison between groups were done using Chi-square test for categorial variables, and Mann-Whitney test for continuous variables. Multivariate analyses using logistic regression analyses were performed when univariate analysis led to a significant association with outcomes with $p < 0{,}15$. Specific mortality rates in maximal bias, hospitalization duration, time to complete healing and numbers of surgical debridement were compared in both groups. Maximal bias was used as a statistical method to minimize the effect of missing data on specific mortality analyses. Descriptive analyses were used for secondary outcomes to determine colostomy indications, creation modalities and induced morbidity using Clavin-Dindo classification. The study was approved by the Institutional Ethical Committee registered N°980. All statistical analyses were conducted using R (version 3.6.3) statistical software. All P values are two-tailed, and $P < 0.05$ was considered significant.

Results

Population characteristics

Of 355 p-NSTI suspected diagnoses, 92 cases were confirmed (3 were excluded due to unexploitable charts). Eighty-nine patients were included, 59 with excision and stoma creation and 30 with excision only (Fig. 1).

No significant difference was observed between the two groups except for catecholamine drugs use, which was more prevalent in the stoma group with an OR 4,46 in multivariate analysis (Table 1). Moreover, no difference was found between time to surgery and sFGSI scores. NLR and PLR scores tended to be higher in stoma group.

There was a tendency to higher ano-rectal infection origins in the stoma group (47,5 % vs 20 %), while uro-genital origins were more represented in the non-stoma group (56,7 % vs 23,7 %).

Main outcomes

No difference was found regarding specific mortality in maximal bias (20 % in non-stoma vs 29 % in stoma, $p = 0{,}3693$), time to complete healing (mean 115 ± 69 days vs 130 ± 88 days, $p = 0.7518$) and number of excision surgeries (mean 1.8 ± 1.1 vs 2.1 ± 1, $p = 0.1747$) (Table 2).

Only hospitalization duration was significantly higher in stoma group with mean duration of 53 ± 40 days vs 37 ± 33 days in non-stoma group ($p = 0.0423$).

Secondary outcomes

Subgroup analyses were conducted in order to identify predictive factors of colostomy. Impact of stoma was determined by comparing stoma vs non-stoma groups on previous outcomes (e.g. specific mortality rate in maximal bias, hospitalization duration, time to complete healing and number of excision surgeries) in each of the following subgroups: catecholamine drug use, posterior perineal region involved, disease extent, s-FGSI score, gender, age. None of the subgroups found beneficial effect of stoma formation on these outcomes (data not shown). In contrast, specific mortality rates in maximal bias tended to higher in most of the stoma groups.

A supplementary subgroup was investigated to analyze impact of colostomy on grafting outcomes. Eighty percents of skin grafted patients had colostomy creation, with 21 % compulsory colostomies for anal sphincter injury or p-NSTI etiology, and 83 % of colostomies were

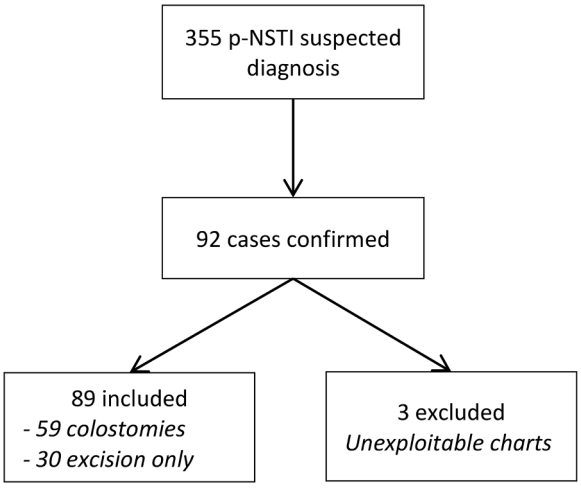

Fig. 1. Flow chart diagram.

Table 1
Population characteristics.

	Non-stoma group ($n = 30$)	Stoma group ($n = 59$)	p-value
Sex ratio (M:F)	4	6.6	0.5718
Age (years), mean ± SD (n)	63.3 ± 14.6 (30)	58.6 ± 13.2 (59)	0.1456
BMI, mean ± SD (n)	32.8 ± 9.6 (22)	28.3 ± 5.9 (37)	/
Active smoking, n (%)	7 (29)	20 (37)	0.5001
Type 2 diabet, n (%)	9 (32)	21 (37)	/
Chronic alcoholism, n (%)	5 (19)	15 (37)	0.4585
Cirrhosis, n (%)	1 (4)	4 (7)	/
Chronic kidney failure, n (%)	2 (7)	3 (5)	1
Chronic heart failure, n (%)	4 (14)	7 (12)	0.7433
Chronic Obstructive Pulmonary Disease, n (%)	2 (7)	4 (7)	/
Auto-immune disease, n (%)	1 (4)	3 (5)	/
Neuropathy, n (%)	2 (7)	5 (9)	1
Non Steroïdal anti-inflammatory use, n (%)	4 (19)	8 (20)	/
Steroïdal anti-inflammatory use, n (%)	2 (14)	8 (20)	/
sFGSI, mean ± SD (n)	1.7 ± 1.6 (22)	1.6 ± 2.1 (47)	/
PLR, median [Q1; Q3] (n)	260.8 [129.4; 357.9] (21)	312.9 [229.5; 498] (39)	/
NLR, median [Q1; Q3] (n)	14.1 [11.7; 23.9] (21)	22.9 [10.4; 30.9] (39)	/
Catecholamine drugs use, n (%)	7 (29)	34 (61)	0.0097*
Disease extent, mean ± SD (n)	2.1 ± 0.8 (28)	2.6 ± 1.2 (59)	0.09
Time to surgery (days), mean ± SD (n)	4 ± 2.8 (25)	4.2 ± 4.4 (49)	/

*$p < 0,05$ with Chi^2 test
°$p < 0,05$ with Mann-Whitney test

BMI : Body mass index ; sFGSI : simplified Fournier Gangrene Severity Index ; PLR : Platlet to Lymphocyte ratio ; NRL : Neutrophile to Lymphocyte ratio.

Table 2
Main outcomes.

	Non-stoma group ($n = 30$)	Stoma group ($n = 59$)	p-value
Specific mortality in maximal bias, n (%)	6 (20)	17 (29)	0.3693
Hospitalization duration (days), mean ± SD (n)	36.5 ± 33.1 (26)	52.5 ± 40.0 (56)	0.0423°
Time to complete healing (days), mean ± SD (n)	114.9 ± 69.2 (19)	130.1 ± 87.9 (36)	0.7518
Number of excision surgeries, mean ± SD (n)	1.8 ± 1.1 (28)	2.1 ± 1 (55)	0.1747

* $p < 0,05$ with Chi^2 test
° $p < 0,05$ with Mann-Whitney test

created in the first 3-days. Mean time to first skin grafting seemed similar with 35 ± 16 days in the non-stoma group vs 39 ± 17 days in the stoma group, as well as mean time to complete healing with 139 ± 92 days vs 145 ± 100 days respectively.

Colostomy results

Specific mortality rate seemed to be higher when loop transverse colostomy was performed versus loop left colostomy (respectively 31% vs 24 %; Table 3). Same tendency was observed for hospitalization duration, with 59 ± 50 days for loop transverse colostomy vs 50 ± 36 days for loop left colostomy. When differed colostomy was considered, specific mortality rate and hospitalization duration tended to higher values when colostomy was performed in the first 3-days than later (Table 3).

Among the 59 patients with stoma procedure, 42 patients survived and follow-up data were available for 39 patients. 41 % of these patients

Table 3
Outcomes depending on type and colostomy creation delay.

	Type of loop colostomy		Colostomy creation delay (days)		
	Left ($n = 41$)	Transverse ($n = 16$)	0–3 ($n = 44$)	4–7 ($n = 8$)	> 7 ($n = 5$)
Specific mortality in maximal bias, n (%)	10 (24)	5 (31)	13 (30)	1 (13)	1 (20)
Hospitalization duration (days), median [Q1; Q3] (n)	43 [28 ; 69] (39)	50 [28 ; 90] (16)	52 [28 ; 78] (42)	43 [29 ; 51] (7)	32 [22 ; 46] (5)

had complications, mainly severe since most of them were Clavien-Dindo grade IIIb or higher (Table 4). Hospitalization in intensive care unit was required for life-threatening complications (Clavien-Dindo IV-V) in 25 % of cases. Anastomotic leakage with peritonitis after stoma closure occurred in 15 % of patients, with one death reported. Thirty-one percent of colostomies remained definitive related to anal sphincter injury (42 %), concomitant diagnosis of colorectal cancer (33 %) or patient comorbidities (25 %), while median [IQR] time to closure was 159-days [116 ; 269].

Discussion

p-NSTI is a life-threatening condition, but its management remains highly debated and based on limited evidence. Immediate introduction of antibiotics is consensual, as well as surgical excision of necrotic tissues and medical support through intensive care but the indication of systematic fecal diversion is debated in the literature. Indeed, some reports have shown a negative impact of colostomy due to increased mortality [1]. In addition, colostomy has reported to have no benefit on the initial hospitalization duration at the acute phase [1], but increased hospital stay due to intestinal recovery [10]. Other studies report a similar number of excision surgeries [1,6], but additional procedures for stoma closure [10].

Timing of colostomy is also a matter of debate. One study reported lower mortality when colostomy creation was proposed at the initial surgery rather than later [6], whereas other series suggested systematic postponement to second surgery because transit was reported scarce during the first 48-hours of management resulting in limited soiling [7], and could be promoted by parenteral nutrition or “easily absorbable diet” [13]. Delaying stoma also seemed to improve physiological status using early resuscitation management, to allow a better evaluation of anal sphincter injury limiting over-indicated fecal diversion, and favored coelioscopic stoma creation approach [7,8].

Some studies have also investigated the technical issues of colostomy. We found no study comparing outcomes between loop left and loop transverse colostomy, while Hartmann procedure was associated with a high risk of definitive stoma [14,15]. Stapling of the distal loop segment or use of stoma cutaneous stick support had been reported, with better prevention of soiling and low morbidity [16], while coelioscopic colostomy creation method had been associated with faster transit

Table 4
Colostomy complication types.

Complication type	n
Parastomal hernia	4
Peristomal cellulitis	1
Stomal prolapse	1
Following intestinal recovery	
Parietal abcese	7
Anastomotic leakage and peritonitis	6
Instestinal obstruction by fecaloma	1
Severe metabolic disorders	1
Ulcerea with digestive hemorrhage	1

recovery, food intake and lower consecutive pain out of p-NSTI context [17]. At least, colostomy creation was associated with significant morbidity up to 21,1 % [8,10,11].

To our knowledge, the present study was the largest dataset investigating stoma creation in p-NSTI management. In line with some previous reports, we found that benefit of fecal diversion was uncertain, with no clear improvement on mortality, although skewed by more severe diseases in the stoma group with higher use of catecholamine drugs. However, creating a stoma induced a significantly longer hospitalization duration in our experience associated with a specific morbidity, including life-threatening complications and risk of definitive stoma. As suggested by Sarofim and al, mortality may be increased by stoma creation because of prolonged operative time during initial surgery [1]. In the same approach of damage control surgery, mortality may be directly associated with resuscitation delay. Some consensual indications for damage control surgery were defined such as acidosis (pH < 7,2), hypothermia (<34 °C) and low systolic blood pressure (< 90 mmHg), based on the acute circulation insufficiency pathophysiology and the hemorrhagic chock related coagulopathy. Sepsis ongoing in p-NSTI presented similarities to these prognostic parameters, with acute circulation insufficiency, coagulopathy and finally organ failure. Our data underlined that early stoma creation was associated with major mortality by increased inflammation. Therefore, when colostomy was necessary, delaying its creation to the second surgery with coelioscopic approach was better. Besides mortality, we observed in our study a significant difference in initial hospitalization duration. This finding may be due to disease severity bias, but specific stoma morbidity can also explain such data. The lack of difference on the number of excision surgeries observed is consistent in the literature. To our knowledge, time to complete healing was not investigated. While fecal diversion was supposed to improve wound healing, this was not evidenced in our study. No obvious difference was observed when skin grafted patients were considered. Only 21 % of colostomies were deemed compulsory, including 83 % created in the first 3-days, which might be justified by uncontrolled sepsis. Avoidance of the remaining 17 % colostomy should be discussed since sepsis must be overcome. Colostomy creation should not be justified by the limited soiling rational alone, as time to complete healing was not improved, and considering the morbidity observed.

No indication for colostomy was recommended to date. Subgroup failed to define specific indications. However, in subgroups based on catecholamine drugs use, stoma increased mortality. These findings underlined the impact of colostomy on mortality regardless of disease severity. To our opinion, colostomy remained sometimes compulsory according to p-NSTI aetiology – infected colorectal cancer, colonic perforation - or to its consequence as anal sphincter injury, which lead to fecal incontinence with permanent soiling. Increased mortality observed in the first 3-days of colostomy creation group must be balanced with higher prevalence of severe diseases and with the damage control rational. Mortality according to colostomy creation at first versus second surgery was not investigated. In order to preserve colonic function, performing distal left colostomy seems better than transverse colostomy. However, according to p-NSTI aetiology or abdominal infection extent, transverse colostomy is sometimes mandatory with worst prognosis. As figured out in literature, we confirmed that loop colostomy by coelioscopic creation method should be favored.

One lesson of our retrospective study was the fully described induced morbidity, with 41 % among the 39 followed-up patients with colostomy. By including all complications from stoma creation until its closure, our data confirmed expected induced morbidity by colostomy creation in p-NSTI. Anastomotic leakage after stoma closure was higher compared to colorectal cancer surgery literature (15 % versus 2–4 % ; [18]), but can be explained by p-NSTI context associated with poor nutritional status, comorbidity, prolonged bed rest and hospital stay. The high rate of definitive colostomies of 31 %, still lower than Hartmann stoma strategy [14,15], were mainly due to compulsory indications as anal sphincter injury, p-NSTI aetiology and previous patient comorbidities. When anal sphincter injury was suspected at baseline management, 25 % of patients died from p-NSTI, 50 % had definitive colostomy and 25 % had stoma closure success. Median time to closure was 159-days in our series with a great variability related to prolonged perineal cicatrization. Only Eray and al reported a mean time to closure of 128-days [10]. These data enlighten the long-term impact of colostomy formation in p-NSTI and suggest that indication must be well balanced. Indeed, colostomy altered long term quality of life as recently reported with deteriorated genito-urinary functions sequelae [19]. An interesting alternative to achieve fecal diversion in the setting of p-NSTI is represented by bowel management catheters [20]. Devices previously used were not dedicated to fecal diversion, and complications must be updated. These systems are inserted under local anesthesia during a maximum of 29 days and maintained with a 40 mL-inflated balloon. To prevent system occlusion, the catheter was designed for rectal irrigations, performed everyday with 100–300 mL of warm water. Few studies with limited samples have focused on this subject [21,22]. Keshava and al have reported 20 cases of perineal trauma or perineal lesions improved by a bowel management system. Bordes and al have reported avoidance of 5 colostomies among 8 perineal brunt patients by using this device, with skin grafting successes. In these two studies, duration of use was often higher than recommended, with a maximum duration of 70 days. In p-NSTI context, only one study have compared the use of bowel management systems and colostomy [10]. Complication rate was higher with 15,6 % in the colostomy group while no complication occurred in the catheter group. Finally, bowel management catheter should be considered and more evaluated in future in p-NSTI fecal diversion strategies as proposed in our decision-making algorithm (Fig. 2).

Conclusion

The benefit of fecal diversion during the acute phase of p-NSTI remained uncertain, with no clear impact on mortality. In fact, colostomy was associated with increased hospitalization duration and specific morbidity, including life-threatening complications and risk of definitive stoma. When fecal diversion was necessary, our data suggested a delayed loop left colostomy using coelioscopic approach during the second look surgery. Alternative minimally invasive options as bowel management catheters should also be considered. Contribution of a prospective multicenter trial would be of interest to identify the best fecal diversion strategy.

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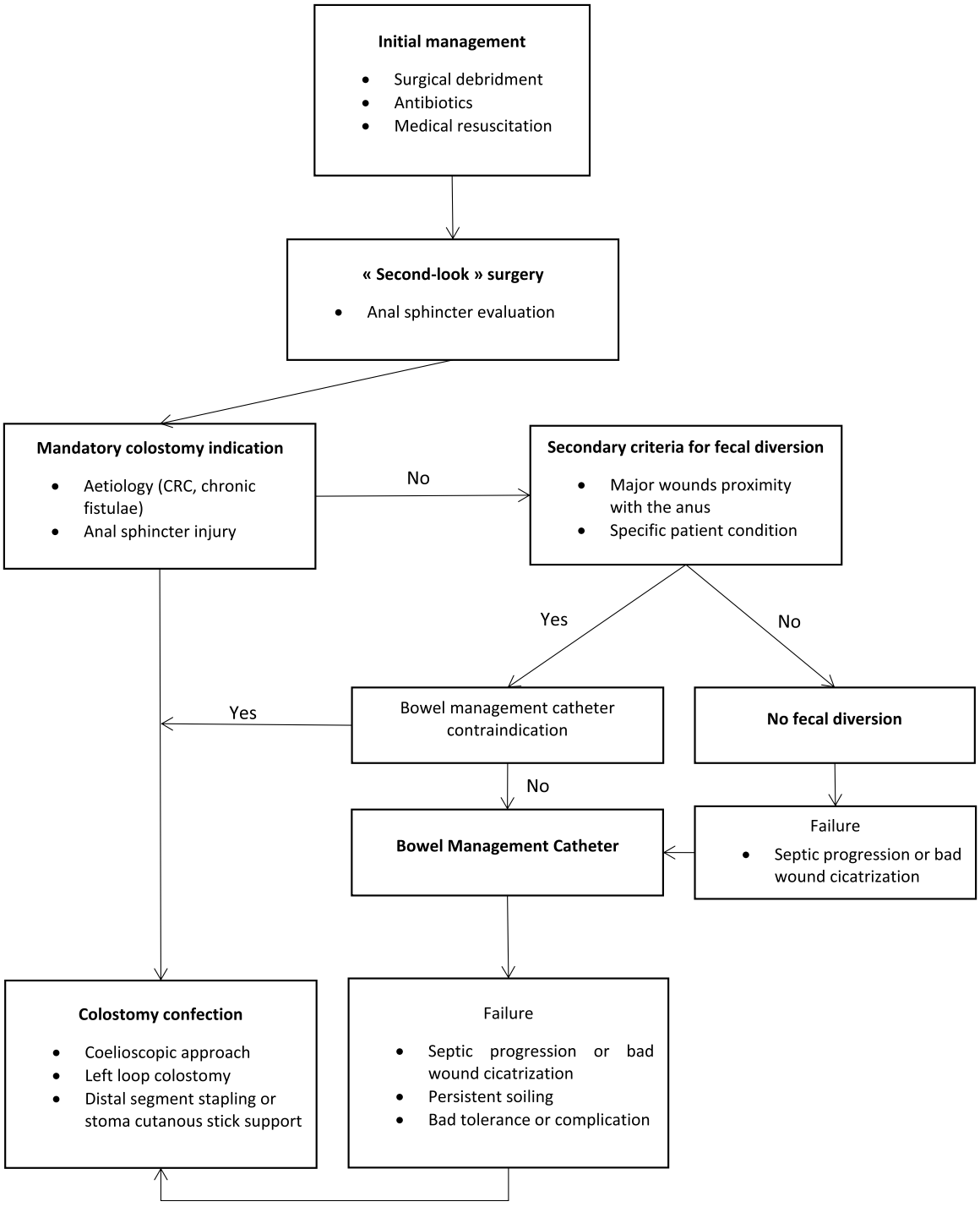

Fig. 2. Decision making algorithm for fecal diversion.

Validation, Visualization, Writing – original draft, Writing – review & editing.

Declaration of Competing Interest

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.

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