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Protective ileostomy creation after anterior resection of the rectum: shared decision-making or still subjective?

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ABSTRACT

Aim: The choice to perform protective ileostomy (PI) after anterior resection (AR) is mainly guided by risk factors (RFs) responsible for anastomotic leakage (AL) development. However, clear guidelines about PI creation are still lacking in the literature and this is often decided according to the surgeon's preferences, experiences, or feelings. This qualitative study aims to investigate by an open-ended question survey, the individual surgeon's decision-making process regarding PI creation after elective AR.

Method: Fifty-four colorectal surgeons took part in an electronic survey to answer the questions and describe what usually led their decision to perform PI. A content analysis was used to code the answers. To classify answers, five dichotomous categories (In favour/Against PI, Listed/Not listed RFs, Typical/Atypical, Emotions/Non-emotions, Personal experience/No personal experience) have been developed.

Results: Overall, 76% of surgeons were in favour of PI creation and 88% considered listed RFs in the question to perform PI. Atypical answers were reported in 10% of cases. Emotions and personal experience influenced surgeons' decision-making process in 22% and 49% of cases, respectively. The most frequent considered RFs were the distance of the anastomosis from the anal verge (96%), neoadjuvant chemoradiotherapy (88%), positive intraoperative leak test (65%), blood loss (37%), and immunosuppression therapy (35%).

Conclusion: The indications to perform PI following rectal cancer surgery lack standardization and evidence-based guidelines are required to inform practice. Until then, experts' opinions can be helpful to assist the decision-making process in patients who underwent AR for adenocarcinoma.

"What does this paper add to the literature?"

The present qualitative study developed through an open-ended question survey about the surgeon's decision-making process regarding protective ileostomy creation after elective anterior resection of the rectum for adenocarcinoma, shows how the experts' opinion can be helpful to assist the decision-making process in these patients.

The importance of these findings is related to the current lack of standardization and evidence-based guidelines on this topic.

INTRODUCTION

Anastomotic leakage (AL) is one of the most dreaded complications after elective anterior resection (AR) of the rectum [1,2]. It is responsible for increased postoperative morbidity and mortality, prolonged hospital stay and additional surgical procedures [2,3]. Furthermore, AL negatively affects patients' long-term overall and cancer-specific survival such as quality of life (QoL), especially if a permanent ileostomy results from this condition [4-8].

Protective ileostomy (PI) decreases morbidity and mortality [9,10]. However, it has an impact on the patients' QoL, with a high morbidity rate, metabolic impairment, and it may lead to the development of local complications [1,2,7,8]. In addition, ileostomy reversal is itself a cause of local morbidities or life-threatening complications [1,2,7,8]. Furthermore, some of those PIs will never be closed with a significant psychological impact on the patient [1,2,7,8].

The choice to perform a PI is guided by some risk factors (RFs) responsible for AL development such as age, male gender, the distance of the anastomosis from the anal verge, high body mass index (BMI), neoadjuvant chemoradiotherapy (n-CRT), operating time, and anastomotic vascularization [11-23]. However, clear guidelines on when to create PI are still lacking in the literature and often it is still decided based on individual surgeons' preferences, experiences, or feelings.

This study aims to investigate through an open-ended question survey the surgeon's decision-making process regarding PI creation after elective AR for adenocarcinoma.

METHOD

This qualitative study was conducted according to the ethical guidelines for good research and practice published by World Health Organization [24], and to the Standards for Reporting Qualitative Research recommendations [25].

Based on their international reputation (published articles, lectures in international congresses, organizers of workshops, impact on social media, members of scientific Societies, editorial board members of indexed journals) and on the contacts of the study creators, 54 colorectal surgeons were invited by email to participate in this study. Surgeons received the first invitation on April 01st, 2021 and reminders on April 26th, 2021, May 19th, 2021, and June 02nd, 2021. The deadline was June 06th, 2021.

Based on the evidence reported in the literature regarding the factors involved in AL development after AR for adenocarcinoma in elective surgery [11-23], two authors (A.B. and F.S.) designed the following open-ended question: "*The most common factors reported in literature involved in the surgeon's decision-making process to create protective ileostomy and to minimize the impact of anastomotic leakage after anterior rectal resection for adenocarcinoma are mainly: age, gender, American Society of Anaesthesiology (ASA) grade, body mass index (BMI), diabetes mellitus, preoperative serum albumin, preoperative hemoglobin, malnutrition, preoperative weight loss, cardiovascular disease, electrolyte disorders, perioperative blood transfusion, smoking, steroid, non-steroidal anti-inflammatory drugs (NSAID), and alcohol habits, preoperative oral antibiotic preparation, neoadjuvant chemoradiotherapy (n-CRT), distance of the anastomosis from the anal verge, operative approach (minimally invasive or open), number of stapler firings, anastomotic fluorescence assessment, intraoperative leak test, extensive additional resection for tumour growth, intraoperative blood loss, ghost ileostomy creation, operative time, tumour size and stage, pelvic drain and rectal tube.*

In which case would you create a protective ileostomy? Please describe briefly in which way the above-mentioned factors or other situations may influence your decision making to perform the ileostomy. Please, try not to make only a list of risk factors for which you perform the ileostomy but try to make us understand what your decision-making process is".

All factors reported in the question are summarized in Table 1. All correspondence with the surgeons was in English. To investigate about the factors involved in the decision-making process,

we proposed a neutral and objective question aiming no to influence the surgeons' answers. For this reason, the question referred only to the well-known factors involved in the AL development reported in literature [11-23] and asked the surgeons to briefly describe their criteria and factors involved in the decision-making process to perform PI without other conditions.

Surgeons were divided into two groups ">50" and "≤50" based on the number of AR performed in their career. Surgeons with experience in up to 50 cases were included to evaluate if the surgeons' expertise may influence the decision-making process. Moreover, data on gender and the country where every surgeon works were collected.

This qualitative study, developed by an open-ended question, conducted to identify the most relevant and shared factors associated with the decision-making process to create a PI, is the first part of our project. Based on the present collected data obtained from a small sample of international experts on colorectal surgery, a multiple-choice questionnaire will be developed to increase the number of participants and therefore the relevance of the study.

Data analysis

A content analysis was used to code the responses [26]. To classify each answer, five dichotomous categories have been developed (Table 2). Surgeons' answers were considered to establish which of the predefined categories were able to explain and analyse the surgeons' decision-making process. If in the surgeons' answers, feedback about the predefined categories was not found, they were readjusted or eliminated by the social psychologist (M.R.).

In category 1, a global assessment is made of whether the tendency is to favour the creation of PI and its non-creation in case of certain situations (e.g., "I would always do it except when ...") or the tendency to discourage its creation (e.g., "I would never do it unless ... ").

In category 2, we reported if the surgeon considered the risk factors listed in the open question or other not reported factors or combination of factors to decide if create PI or not.

In category 3, we have included surgeons' evaluations related to typical (e.g., "I create PI to avoid reoperation in case of leakage…") or atypical (non-ordinary) approaches that they described for the decision-making process (e.g., "I do not create PI to avoid possible postoperative complications related to stoma…").

Category 4 is dedicated to those answers that contain references to the surgeon's emotions or personal content regarding patients (e.g., "I would not do it if I were afraid that this would happen..." or "if the patient could have difficulty managing stoma at home …"). When the surgeon's answer did not include objective factors related to the literature or experience, and in our opinion the decision-making process was influence from the emotional sphere, answer was included in this category.

Eventually, in category 5, we have reported if in the answers there are references concerning the role of the surgeon's personal experience influencing the decision-making process (e.g., "based on my experience I know that ..." or "after years of interventions...").

Study participants were not informed about the data analysis process. Two surgeons (A.B. and F.S.) analysed and classified each answer in each category independently. Social psychologist (M.R.) contributed to the answers analysis and all discrepancies were solved by discussing them with her.

The results obtained between ">50" and "≤50" surgeons were separately analysed and compared.

Statistical analysis

Categorical variables are expressed as frequencies and percentages. The Fisher's exact test was used for the comparison between groups. A p-value lower than 0.05 was considered statistically significant. Statistical analysis was carried out with SPSS software 22.0 (SPSS Inc., Chicago, Illinois, USA).

RESULTS

Forty-nine surgeons were included (response rate: 91%), and their answers were analysed. Table 3 reports surgeons' characteristics.

After answers analysis, all predefined categories were confirmed. Table 4 shows results based on categories stratification. Overall, 76% of included surgeons were in favour of PI creation after AR in most of cases, and this data is similar in ">50" and "≤50" surgeons. Some examples of surgeons' answers that pointed to a decision in favour of PI creation were:

- "*Given the extensive use of neoadjuvant chemoradiation and more recently total neoadjuvant treatment the vast majority of my elective anterior resection will have an ileostomy.*";
- "*In our experience protective ileostomy is offered to all patients undergoing TME with a low/ultralow colorectal anastomosis, irrespective of the approach (open, laparoscopic, robotic, TATME) and in all patients who received neoadjuvant radiation therapy.*";
- "*I would create an ileostomy in any patient who has had pre-operative neoadjuvant chemoradiotherapy in whom I am performing an anastomosis </=10 cm from the dentate line*";
- "*Any time I perform an optimal or total mesorectal excision with either infraperitoneal stapled colorectal anastomosis or manual coloanal anastomosis, I make a temporary ileostomy. In summary, systematic ileostomy for all infraperitoneal anastomosis. This choice is completely independent of possible risk factors for leakage.*";
- "*The cases in which I would perform a protective stoma are usually when a Total Mesorectal Excision is performed and if neoadjuvant treatment was added to the treatment.*".

Conversely, some answers suggest being against PI creation:

- "*…whenever possible, I try to avoid an ileostomy because sometimes its presence is more detrimental than useful, causing for example dehydration and electrolyte disorders that may be difficult to be dealt with.*";

- "*My decision making on constructing a PI is influenced by my view on the harm/benefit ratio of this preventive surgical intervention… In summary, PI only reduces the need for early reintervention. But in my view, the associated morbidity is very high: ileostomy construction is associated with additional complications and prolonged hospital stay during the index admission, resulting in complications with readmissions and reinterventions during the period that it is still in place, results in complications (even mortality) after reversal, results in substantial rates of incisional hernia, interferes with adjuvant treatment, and often becomes permanent even with intact anastomosis (for example in case of treatment of metachronous metastases). This price is too high in my view, and construction of a PI is probably only justified with an estimated risk of anastomotic leakage of >50%. But then the question is whether you should make an anastomosis anyway in such a patient. The majority of patients that will not develop a leak are suffering from the "preventive" PI that is constructed for the minority of patients that will leak, and is probably more intervention for the own reassurance of the surgeon.*";
- "*Regarding the subject at hand, which is whether or not PI is performed after a low anterior resection of the rectum, I must say that my current tendency is to decrease the number of times on which I perform them, as until a while ago I was providing all my patients with an ileostomy that had neoadjuvant treatment and/or EMT.*".

To perform PI, most surgeons (88%) considered the RFs listed in the open question while others considered factors that were not listed (12%) (Tables 4 and 5). Some examples of not listed factors that were considered:

- "*…as well as patients who need intraoperative inotropic treatment, are receiving PI treatment."*;
- "*…intraoperative bowel perforation with gross faecal contamination…*";
- "*…the presence of a significant difference in calibre between the two portions of the bowel*".

An "Atypical" approach to deciding on PI creation, reported in a few cases (10%) (Table 4), was considered as follows:

- "*…we perform at most 5 LAR without ileostomy when all other risk factors are nil and the patient is highly motivated and understand the risk of refraining from a protective ileostomy.*";
- "*Age and comorbidity have some influence on me, but if the patient has multiple comorbidities or is elderly and or frail then often I don't actually make an anastomosis and give the patient a permanent end colostomy instead.*";
- "*If the patient has some kind of renal failure, and is at risk of complication due to dehydration, then I would consider not to create a protective ileostomy but a protective colostomy instead.*".

Also, emotions influenced surgeons' decision-making process in a few cases both among ">50" and "≤50" surgeons (overall 22%) (Table 4). Examples of the "Emotions" approach were:

- "*In terms of patient factors, one of the most important over and above the specific risk factors is whether I feel the patient will be able to tolerate and be salvaged from an anastomotic leak. If I feel they would not, then I would be inclined to defunction the anastomosis (if performed), irrespective of anastomotic height and any other factors.*";
- "*The stoma formation might carry an intrinsic risk of complications in addition to the discomfort for the patient, however, there are conditions that imply the need to package it based on some risk factors.*";
- "*The performance of more radical or multivisceral resections is a factor to take into account, in the same way as the subjective sensation of difficulty that the surgeon has had during the surgical procedure.*";
- "*I consider that the most important thing is to perform a procedure that is tailored as much as possible to the characteristics of each patient and not to standardize the use of a protective stoma for all patients who will undergo this type of intervention, without discriminating between some cases and others.*".

The only statistically significant difference between ">50" and "≤50" surgeons was the "Personal experience" in favour of ">50" surgeons (p=0.0019), even if this factor influenced only 64% of ">50" surgeons. Some examples of surgeons' experience answers were:

- "*Generally for patients having a partial mesorectal excision or "high anterior resection" I do not defunction the patients unless they are perceived as being at particularly high risk – male, obese, diabetic, irradiated, poorly nourished patients being the most important factors for me. This is a clinical judgement made on an individual basis and from experience. It is not a protocolised decision.*";
- "*I rarely divert PME [partial mesorectal excision] and would selective base this upon intraoperative leak testing and visualisation by colonoscopy findings, pulsatile arterial flow at the cut colonic end. In general, my anecdotal experience is that a healthy bleeding colonic end will heal in the majority of patients.*".

To decide whether to create PI or not, two authors reported the routine use of the Colon Leakage Score [14], and one the use of the REctal Anastomotic Leak score [27].

Table 5 shows the RFs stratified based on their influence on PI creation. The RFs most frequently considered to create a PI were the distance of the anastomosis from the anal verge (96%), n-CRT (88%), positive intraoperative leak test (65%), intraoperative blood loss (37%), and immunosuppression therapy (35%). These data were similar between ">50" and "≤50" surgeons without statistically significant differences. On the contrary, few surgeons reported some factors that led them to avoid PI creation (Table 5). The most frequent factors not influencing in the decision-making process included the operative approach (16%), the presence of diabetes, NSAID therapy and pelvic drain (14%) and age, ghost ileostomy creation, operative time, and use of a rectal tube (12%). Furthermore, in this group of RFs statistically significant differences were not observed among surgeons (Table 5). Regarding the use of ghost ileostomy, four surgeons (8%) consider it to avoid PI creation, only in patients with moderate risk for AL. Two surgeons report the creation of

ghost ileostomy after a surgical procedure without adverse events and in patients with a Colon Leakage Score [14] of <14 and 8-11, respectively.

Several surgeons also considered factors not listed in the question (Table 5). The most frequently reported were comorbidities (22%), difficult dissection (18%), incomplete doughnuts (14%) and surgeon's perception (10%). Difficult dissection is reported in almost half of "≤50" surgeons and a statistically significant difference is observed in comparison to ">50" surgeons (p=0.0186).

The distance of the anastomosis from the anal verge, as a factor that influences the surgeon's decision-making process, deserves a separate mention. Although it was the most frequently reported factor, it has proven to be a very heterogeneous parameter. In fact, some surgeons provided an exact value, even if arbitrary, as the limit under which to perform a PI (for example anastomosis under "*8 cm"*; *"6 cm"*; *"<8-12 cm"*; *"<6 cm"*; *"<7 cm"*; *"10 cm with n-CRT, 5 without n-CRT"*; *"5 cm"*; *"5-6 cm"*; *"<5 cm"*; *"< 7 cm or <8 when n-CRT"*; *"≤ 10 cm from the dentate line"*). On the other hand, other surgeons provided indications for PI creation in selected cases (for example: *"below the peritoneal reflection"*; *"ultralow anastomosis"*; *"transperitoneal ultralow anastomosis"*; *"up to 12 cm from the anal verge, or 7 without n-CRT, coloanal anastomosis"*; *"below peritoneal reflection, coloanal and pouch-anal"*; *"coloanal anastomosis"*; *"mid to low rectal cancer"*; *"coloanal anastomosis, TaTME"*; *"TME, infraperitoneal stapled colorectal anastomosis, manual coloanal anastomosis"*; *"below 6 cm, coloanal anastomosis, TME, intersphincteric dissection"*; *"< 5 cm, handsewn coloanal or double pursestring stapling"*; *"<5 cm, handsewn coloanal or double pursestring stapling"*; *"very low"*).

DISCUSSION AND CONCLUSIONS

This study was conducted to describe the surgeon's decision-making process to establish whether to create PI following AR for adenocarcinoma. For this reason, as a method to conduct the present study, a Delphi panel approach was excluded, because achieving a consensus regarding the

indication to perform PI was not the objective of the study. The utility of the present analysis derives from the lack of clear guidelines or indications on this topic.

To our knowledge, currently, the recommendations to perform PI are based on the presence of patient's RFs which would probably be responsible for AL, without having any standardized or widely accepted protocol, and leaving the final decision to the surgeon [9-23]. To overcome this problem, some scores have been proposed in the literature, without however being universally adopted [14,27].

For these reasons, we believed that the analysis of the decision-making process from a panel of ">50" surgeons might be helpful in further investigating this issue. To strengthen the study, we have included "≤50" surgeons and compared the obtained data.

Most surgeons are in favour of PI creation. Despite in the last decades' efforts have been made to reduce the impact of surgery on patients' postoperative course and QoL [2,28-30], PI remains a very common procedure. Therefore, notwithstanding the surgeons' expertise involved and their possibility to work in a high-volume centre for colorectal disease, prudent behaviour emerges regarding defunctioning stoma creation.

Although the recognized RFs as responsible for AL are the most relevant among surgeons, some of them take also into account other situations, such as the occurrence of intraoperative events (difficult dissection, incomplete doughnuts, lack of pulsatile arterial flow, conversion), presence of multiple comorbidities, patients' wishes, and the inability to provide medical assistance to patients 24/7. Furthermore, some surgeons also consider an atypical approach to the problem, such as the colostomy creation or avoiding PI in selected patients who are strongly motivated to reject it, after an exhaustive interview and the acquisition the informed consent.

Another aspect is that, based on this subjective analysis, the PI creation does not seem to generate emotion in most of surgeons in this sample. This is not underpinned by the emotional status of the surgeon but rather rational thinking of the potential impact of the alternative approach to not creating PI on patients' life and QoL. Finally, this study shows as experience can influence

the surgeon's choice, notwithstanding the RFs responsible for AL are well known and cleared reported in the literature. This is the only statistically significant difference between ">50" and "≤50" surgeons and in our opinion, it highlights the importance of the surgeon's decision-making process due to the lack of standardization about the indication to perform PI.

As expected, low anastomosis and n-CRT are the most frequently reported factors involved in the decision, but, from our analysis, it seems there is no consensus about the distance of the anastomosis from the anal verge (or dentate line) to establish whether to create PI or not. Hence, in our opinion, this parameter also becomes subjective and increases the confusion about when the defunctioning stoma should be created. The heterogeneity of this assessment suggests that before drawing up comprehensive guidelines on this topic, a wide consensus among colorectal surgeons should be achieved regarding the definition of anatomical landmarks (for example distance of the anastomosis from the anal verge or mid rectal anastomosis) leading to perform PI and the clinical or instrumental preoperative evaluation (by endoscopy, magnetic resonance or clinically intraoperative).

Thus, RFs play a fundamental role in the surgeons' decision-making process as well as in the emerged factors there are some related to the surgeons' familiarity with this procedure and connected to the surgeons' experience is equally important. The level of comfort experienced by surgeons concerning PI creation can play a crucial role in the decision-making process. For this reason, the analysis of the surgeons' answers proved to be a valuable tool to learn more about the decision-making processes that guide the choice to perform a PI.

From the analysis of the responses, it is clear that the RFs to develop AL and how they can interact among them, are subject to the surgeon's interpretation who compares them with the already encountered experiences, sometimes hypothesizing innovative scenarios, or reducing the probability of plausible scenarios.

This study is based on RFs for AL that can influence the surgeons' decision-making process, as reported by other authors [31,32]. However, in this analysis surgeons' personality was not

considered, so how it may influence the decision-making process is unknown. Moug *et al.* reported their results retrieving data from the investigation of surgeons' personality which can influence their decision-making process about anastomotic creation during colorectal surgery [31]. They found that the decision to perform primary anastomosis, PI or end colostomy is related to surgeons' personalities especially in complex cases when a consensus is not achieved [31]. Surgeons' personality adds further variables to this topic, which make it extremely complex and difficult to standardize.

MacDermid *et al.* in 2014 conducted an analysis similar to the present study [33]. To the participants surgeons were asked if they had created a PI in predefined anterior resection scenarios, considering, however few RFs such as anastomosis height, preoperative radiotherapy, age, ASA grade and smoking habit [33]. They found that anastomosis height, preoperative radiotherapy, and ASA grade are significant independent predictors of PI creation [33]. The same authors in 2017, confirmed the same findings with different sample of participants surgeons [34]. Also Mackay *et al.* in their study proposed some hypothetical scenarios to stomal therapy nurses, colorectal surgeons, and patients attending the colorectal outpatients' clinic [35]. They concluded that surgeons, in comparison to patients and nurses, have a higher risk-taking propensity, not creating PI, in scenario with low risk of AL [35].

Lastly, independently from the indication to create PI, it is important to underline that in the literature the real utility and advantages of a stoma are still debated [28-30,36-51].

PI is conceived to reduce the AL rate, the symptomatic dehiscence, and overall, postoperative morbidity and mortality rates [30,36,37]. However, the real impact on the reduction of AL incidence is not clear and some authors advocate that the effective utility of PI is to reduce the morbidity related to AL, not AL rate [36-38].

Moreover, PI creation is itself responsible for morbidity, including intestinal atrophy, leakage from the stoma appliance, skin irritation, bowel obstruction, enterocutaneous fistula, high

output stoma, renal impairment, parastomal hernia or prolapse, and hospital readmission, so in case of patients without AL, its utility should be balanced with its complications [36,39-42].

Another aspect of PI is the timing of its closure [36,43-47]. The timing of the closure is not clearly defined, and some authors report as the prolonged PI presence increases the morbidity after its closure on the contrary others reports a high rate of postoperative complications in case of early closure [36,43-46]. Moreover, PI closure depends on several factors such as the patient's condition, anastomotic stricture, the presence of chronic fistula, and oncological disease progression [36,47,48].

Then, PI closure can be the source of postoperative complications itself, achieving up to 20% overall postoperative complications rate, including AL, surgical site infection, postoperative ileus, and even death [36,49,50].

Finally, about 28% of PI become permanent due to anastomotic complications, the need for adjuvant chemotherapy or oncological disease progression [36,39,51,52]. For these reasons, many efforts have been made the study of this condition [28-30,36-52].

To be able to salvage patients without PI who develop sepsis from AL, some authors proposed management algorithms including PI creation only in selected cases, availability of endoscopic vacuum-assisted drainage, reliable access to emergency theatre and 24/7 specialist colorectal surgeon emergency cover [53,54].

The limitations of the present study are the small number of surgeons involved, which makes the value of the statistical analysis low, the predominance of European extractions and consequently the lack of surgeons' point of view worldwide, and the arbitrary non-evidence-based distinction between ">50" and "≤50" surgeons. Moreover, the answers to an open question are subjective such as the analysis. Experts' opinions have a low level of evidence, however, they may be of interest in informing future guidelines direction. Furthermore, as the results are referred from surgeons who operate in different hospital settings all around the world, the analysis is generalizable, adding an interesting contribution to this topic.

However, the second part of this project will be develop based on the present study, with the aim to overcome the current limitations, hence including a greater number of surgeons from all over the world and selecting the surgeon's expertise based on more than one parameter. The primary aim of our future project will be to confirm or not the results obtained from the expert surgeons of the present study, and to describe the clinical practice worldwide. The ultimate goal of the study is not to develop guidelines or consensus, but only to provide useful information for surgeons, waiting to finally have shared and standardized guidelines.

Based on the present collected data obtained from a small sample of international experts on colorectal surgery, a multiple-choice questionnaire will be developed to increase the number of participants and therefore the relevance of the study.

In conclusion, the indications to perform PI after AR for adenocarcinoma lack standardization and evidence-based guidelines, probably informed by large registries, are required to draw definitive conclusions about this topic and to guide practice. Until then, experts' opinion can be helpful to assist in the decision-making process in these patients.

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Table 1. Factors reported in the question.

Age
Gender
American Society of Anaesthesiology (ASA) grade
Body mass index (BMI)
Diabetes mellitus
Preoperative serum albumin
Preoperative hemoglobin
Malnutrition
Preoperative weight loss
Cardiovascular disease
Electrolyte disorders
Perioperative blood transfusion
Smoking
Steroid
Non-steroidal anti-inflammatory drugs (NSAID)
Alcohol habits
Preoperative oral antibiotic preparation

Neoadjuvant chemoradiotherapy (n-CRT)
Distance of the anastomosis from the anal verge
Operative approach (minimally invasive or open)
Number of stapler firings
Anastomotic fluorescence assessment
Intraoperative leak test
Extensive additional resection for tumour growth
Intraoperative blood loss
Ghost ileostomy creation
Operative time
Tumour size
Tumour stage
Pelvic drain
Rectal tube

Table 2. Dichotomous categories.

Category 1: in favour of / against to create a protective ileostomy
Category 2: Listed risk factors / Not listed factors
Category 3: Typical / Atypical
Category 4: Emotions / Non-emotions
Category 5: Personal experience / No personal experience

Table 3. Demographics characteristics of the included surgeons panel.

	All surgeons N = 49	**">50" surgeons n = 38 (78%)**	**"≤50" surgeons n = 11 (22%)**
Gender ratio, Women (n) : Men (n)	5 : 44	3 : 35	2 : 9
Country, n (%)			
- Italy	19 (40)	12 (32)	7 (64)
- Spain	15 (30)	12 (32)	3 (27)
- United Kingdom	6 (12)	6 (16)	-
- Unites States of America	4 (8)	4 (11)	-
- Switzerland	2 (4)	2 (5)	-
- Netherlands	1 (2)	1 (3)	-
- France	1 (2)	1 (3)	-
- Egypt	1 (2)	-	1 (9)

Table 4. Results based on categories.

Categories	All surgeons N = 49	">50" surgeons n = 38 (78%)	"≤50" surgeons n = 11 (22%)	p value
1: In favour of / Against of protective ileostomy, n (%)	37 (76) / 12 (24)	29 (76) / 9 (24)	8 (73) / 3 (27)	1.0000
2: Listed risk factors / Not listed factors, n (%)	43 (88) / 6 (12)	33 (87) / 5 (13)	10 (90) / 1 (10)	1.0000
3: Typical / Atypical, n (%)	44 (90) / 5 (10)	35 (92) / 3 (8)	9 (82) / 2 (18)	0.3110
4: Emotions / Non-emotions, n (%)	11 (22) / 38 (78)	9 (24) / 29 (76)	2 (18) / 9 (82)	1.0000
5: Personal experience / No personal experience, n (%)	25 (51) / 24 (49)	24 (63) / 14 (37)	1 (10) / 10 (90)	**0.0019**

Statistically significant differences in bold. Fisher's exact test was used for the comparison between groups. A p-value lower than 0.05 was considered statistically significant.

Table 5. Risk factors stratified based on their influence on protective ileostomy creation.

Risk factors	All surgeons N = 49	">50" surgeons n = 38 (78%)	"≤50" surgeons n = 11 (22%)	p value
Factors in favour of protective ileostomy creation, n (%)				
Patient's factors:				
- Age	10 (20)	6 (16)	4 (36)	0.0634
- Gender	9 (18)	7 (18)	2 (18)	1.0000
- American Society of Anesthesiology (ASA) grade	10 (20)	6 (16)	4 (36)	0.0634
- Body mass index	7 (14)	4 (11)	3 (27)	0.1782
- Diabetes mellitus	7 (14)	4 (11)	3 (27)	0.1782
- Preoperative serum albumin	9 (18)	6 (16)	3 (27)	0.4003
- Preoperative hemoglobin	1 (2)	1 (3)	-	1.0000
- Malnutrition	14 (29)	10 (26)	4 (36)	0.7060
- Preoperative weight loss	3 (6)	3 (8)	-	1.0000
- Cardiovascular disease	1 (2)	-	1 (9)	0.2245
- Electrolytes disorders	-	-	-	1.0000
- Perioperative blood transfusions	4 (8)	3 (8)	1 (9)	1.0000
- Smoking	7 (14)	6 (16)	1 (9)	1.0000
- Steroid (or immunosuppression) therapy	17 (35)	15 (40)	2 (18)	0.2871
- Non-steroidal anti-inflammatory drugs (NSAID)	1 (2)	1 (3)	-	1.0000
- Alcohol habits	1 (2)	-	1 (9)	0.2245
- Preoperative oral antibiotic preparation	-	-	-	1.0000
Tumour factors:				
- Neoadjuvant chemoradiotherapy (n-CRT)	43 (88)	34 (90)	9 (81)	0.6052
- Distance of the anastomosis from the anal verge	47 (96)	36 (95)	11 (100)	1.0000
- Tumour size	3 (6)	3 (8)	-	1.0000
- Tumour stage	3 (6)	3 (8)	-	1.0000
Intraoperative factors:				
- Operative approach (minimally invasive or open)	1 (2)	-	1 (9)	0.2245
- Number of stapler firings	12 (25)	10 (26)	2 (18)	0.7085
- Anastomotic fluorescence assessment	15 (31)	11 (30)	4 (36)	0.7165
- Intraoperative leak test	32 (65)	25 (66)	7 (64)	1.0000
- Extensive additional resection for tumour growth	9 (18)	8 (21)	1 (9)	0.6621
- Intraoperative blood loss	18 (37)	15 (40)	3 (27)	0.7238
- Ghost ileostomy creation	-	-	-	1.0000

- Operative time	9 (18)	7 (18)	2 (18)	1.0000
- Pelvic drain	1 (2)	-	1 (9)	0.2245
- Rectal tube	1 (2)	-	1 (9)	0.2245
Factors against protective ileostomy creation, n (%)				
Patient's factors:				
- High body mass index	2 (4)	2 (5)	-	1.0000
- Preexisting electrolyte disorder	1 (2)	1 (3)	-	1.0000
Intraoperative factors:				
- Anastomotic fluorescence assessment	1 (2)	1 (3)	-	1.0000
- Ghost ileostomy creation	4 (8)	3 (8)	1 (9)	1.0000
Not influencing factors, n (%)				
Patient's factors:				
- Age	6 (12)	6 (16)	-	0.3148
- Gender	5 (10)	5 (13)	-	0.5742
- American Society of Anesthesiology (ASA) grade	4 (8)	4 (11)	-	0.5620
- Body mass index	5 (10)	5 (13)	-	0.5742
- Diabetes mellitus	7 (14)	7 (18)	-	0.3251
- Preoperative serum albumin	2 (4)	2 (5)	-	1.0000
- Preoperative hemoglobin	3 (6)	3 (8)	-	1.0000
- Malnutrition	2 (4)	2 (5)	-	1.0000
- Preoperative weight loss	2 (4)	2 (5)	-	1.0000
- Cardiovascular disease	3 (6)	3 (8)	-	1.0000
- Electrolytes disorders	5 (10)	5 (13)	-	0.5742
- Perioperative blood transfusions	2 (4)	2 (5)	-	1.0000
- Smoking	4 (8)	4 (11)	-	0.5620
- Non-steroidal anti-inflammatory drugs (NSAID)	7 (14)	6 (16)	1 (9)	1.0000
- Alcohol habits	4 (8)	4 (11)	-	0.5620
- Preoperative oral antibiotic preparation	5 (10)	5 (13)	-	0.5742
Tumour factors:				
- Tumour size	4 (8)	4 (11)	-	0.5620
- Tumour stage	3 (6)	3 (8)	-	1.0000
Intraoperative factors:				
- Operative approach (minimally invasive or open)	8 (16)	8 (21)	-	0.1718
- Number of stapler firings	3 (6)	3 (8)	-	1.0000
- Anastomotic fluorescence assessment	5 (10)	3 (8)	2 (18)	1.0000
- Intraoperative leak test	2 (4)	2 (5)	-	1.0000
- Extensive additional resection for tumour growth	1 (2)	1 (3)	-	1.0000
- Ghost ileostomy creation	6 (12)	4 (11)	2 (18)	0.5620
- Operative time	6 (12)	6 (16)	-	1.0000
- Pelvic drain	7 (14)	6 (16)	1 (9)	1.0000
- Rectal tube	6 (12)	5 (13)	1 (9)	0.5742
Not listed factors, n (%)				
Patient's factors:				
- Comorbidities	11 (22)	8 (21)	3 (27)	0.6923
- Advanced kidney diseases (dialysis)	2 (4)	2 (5)	-	1.0000
- Patients refusing	1 (2)	1 (3)	-	1.0000
- Chronic liver disease	1 (2)	1 (3)	-	1.0000
- Respiratory diseases	1 (2)	1 (3)	-	1.0000
- Abscess	1 (2)	1 (3)	-	1.0000
Intraoperative factors:				
- Difficult dissection	9 (18)	4 (11)	5 (46)	**0.0186**
- Incomplete doughnuts	7 (14)	7 (18)	-	0.3251
- Surgeons' perception	5 (10)	4 (11)	1 (9)	0.5620
- Endoscopy evaluation	4 (8)	3 (8)	1 (9)	1.0000
- Anastomotic tension	4 (8)	4 (11)	-	0.5620
- Intraoperative events (anesthetic, cardiorespiratory, hemodynamic)	3 (6)	3 (8)	-	1.0000
- Partial Mesorectal Excision	3 (6)	3 (8)	-	1.0000
- Different bowel caliber	2 (4)	1 (3)	1 (9)	0.4022
- Pulsatile arterial flow	2 (4)	2 (5)	-	1.0000
- Pull-through coloanal anastomosis	2 (4)	2 (5)	-	1.0000
- Narrow pelvis	1 (2)	1 (3)	-	1.0000

- Transanal Total Mesorectal Excision	1 (2)	1 (3)	-	1.0000
- Mechanical bowel preparation	1 (2)	1 (3)	-	1.0000
- Mechanical anastomosis	1 (2)	1 (3)	-	1.0000
- Conversion to open surgery	1 (2)	1 (3)	-	1.0000
- Intraoperative bowel perforation	1 (2)	1 (3)	-	1.0000
- Intraoperative inotropic treatment	1 (2)	1 (3)	-	1.0000
Other factors:	1 (2)	1 (3)	-	1.0000
- 24 hours of care available	1 (2)	1 (3)	-	1.0000

Statistically significant differences in bold. Fisher's exact test was used for the comparison between groups. A p-value lower than 0.05 was considered statistically significant.