Received: 20 April 2022 | Revised: 21 September 2022 | Accepted: 26 October 2022

DOI: 10.1111/codi.16454

ORIGINAL ARTICLE

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

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[Correction added on 21 Jan 2023, after first online publication: Affiliation numberings for authors - Isaias Alarcón, Jesus Bollo Rodriguez, Luigi Boni and Francesco Maria Carrano have been corrected in this version.]

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Abstract

Aim: The choice of whether to perform protective ileostomy (PI) after anterior resection (AR) is mainly guided by risk factors (RFs) responsible for the development of anastomotic leakage (AL). 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/Unlisted 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 of whether 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 frequently considered RFs were the distance of the anastomosis from the anal verge (96%), neoadjuvant chemoradiotherapy (88%), a 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, expert opinion can be helpful to assist the decision-making process in patients who have undergone AR for adenocarcinoma.

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KEYWORDS
Adenocarcinoma, Anterior resection of the rectum, Decision-making process, Defunctioning stoma, Protective ileostomy

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 and 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 patients' QoL, with a high morbidity rate and metabolic impairment, and may lead to the development of local complications [1, 2, 7, 8]. In addition, ileostomy reversal is itself a cause of local morbidity 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 of whether to perform PI is guided by some risk factors (RFs) responsible for development of AL, 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 a 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, surgeons' decision-making processes regarding PI creation after elective 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 creation of a protective ileostomy after elective anterior resection of the rectum for adenocarcinoma. It shows how expert opinion can 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.

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 1 April 2021 and reminders on 26 April 2021, 19 May 2021 and 2 June 2021. The deadline was 6 June 2021.

Based on the evidence reported in the literature regarding the factors involved in development of AL after AR for adenocarcinoma in elective surgery [11–23], two authors (AB and FS) 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 Anesthesiologists (ASA) grade, body mass index (BMI), diabetes mellitus, preoperative serum albumin, preoperative haemoglobin, 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 the factors involved in the decision-making process, we proposed a neutral and objective question, aiming not to influence the surgeons' answers. For this reason, the question referred only to the well-known factors involved in the development of AL reported in literature [11–23] and asked the surgeons to briefly describe their criteria and factors involved in their decision-making process on whether to perform PI without other conditions.

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

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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 were 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 (MR).

In category 1, a global assessment is made of whether the tendency is to favour the creation of a PI and its noncreation 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 unreported factors or a combination of factors to decide whether or not to create a PI.

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 (nonordinary) 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 influenced from the emotional sphere, the answer was included in this category.

Finally, 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 (AB and FS) analysed and classified each answer in each category independently. A social psychologist (MR) contributed to the analysis of the answers and all discrepancies were solved by discussing them with her.

The results obtained for the >50 and ≤50 groups of surgeons were analysed separately and compared.

TABLE 1 Factors reported in the question

Age
Gender
American Society of Anesthesiologists grade
Body mass index
Diabetes mellitus
Preoperative serum albumin
Preoperative haemoglobin
Malnutrition
Preoperative weight loss
Cardiovascular disease
Electrolyte disorders
Perioperative blood transfusion
Smoking
Steroid
Nonsteroidal anti-inflammatory drugs
Alcohol habits
Preoperative oral antibiotic preparation
Neoadjuvant chemoradiotherapy
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

Statistical analysis

Categorical variables are expressed as frequencies and percentages. 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 version 22.0 (SPSS Inc.).

RESULTS

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

TABLE 2 Dichotomous categories

Category 1: In favour of/Against creation of a protective ileostomy
Category 2: Listed risk factors/Unlisted factors
Category 3: Typical/Atypical
Category 4: Emotions/Non-emotions
Category 5: Personal experience/No personal experience

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TABLE 3 Demographics characteristics of the surgeons included on the panel

	All surgeons (*N* = 49)	>50 AR surgeons (*n* = 38; 78%)	≤50 AR surgeons (*n* = 11; 22%)
Gender ratio (women:men)	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 AR surgeons (*n* = 38; 78%)	≤50 AR 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/ Unlisted 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**

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

After analysis of the answers, all predefined categories were confirmed. Table 4 shows the results based on category stratification. Overall, 76% of included surgeons were in favour of PI creation after AR in most of cases, and these data are similar in the >50 and ≤50 groups of 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 preoperative 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 the surgeon is 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

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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 unlisted factors that were considered are the following:

- '… 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 in the >50 and ≤50 groups (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 the >50 and ≤50 groups was the 'personal experience' in favour of the >50 group ($p = 0.0019$), even if this factor influenced only 64% of the >50 surgeons. Some examples of 'surgeons' experience' answers are:

- *'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 a 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 in the decision to create a PI were the distance of the anastomosis from the anal verge (96%), n-CRT (88%), a positive intraoperative leak test (65%), intraoperative blood loss (37%), and immunosuppression therapy (35%). These data were similar between the >50 and ≤50 groups of surgeons without a statistically significant difference. On the contrary, few surgeons reported some factors that led them to avoid PI creation (Table 5). The most frequent factors that did not influence 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

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

Risk factors	All surgeons (*N* = 49)	>50 AR surgeons (*n* = 38; 78%)	≤50 AR surgeons (*n* = 11; 22%)	*p*-value
Factors in favour of protective ileostomy creation, *n* (%)				
Patient factors				
Age	10 (20)	6 (16)	4 (36)	0.0634
Gender	9 (18)	7 (18)	2 (18)	1.0000
American Society of Anesthesiologists 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 haemoglobin	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
Nonsteroidal anti-inflammatory drugs	1 (2)	1 (3)	-	1.0000
Alcohol habits	1 (2)	-	1 (9)	0.2245
Preoperative oral antibiotic preparation	-	-	-	1.0000
Tumour factors				
Neoadjuvant chemoradiotherapy	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 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
Non-influencing factors, *n* (%)				
Patient's factors				
Age	6 (12)	6 (16)	-	0.3148

(Continues)

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TABLE 5 (Continued)

Risk factors	All surgeons ($N = 49$)	>50 AR surgeons ($n = 38$; 78%)	≤50 AR surgeons ($n = 11$; 22%)	*p*-value
Gender	5 (10)	5 (13)	-	0.5742
American Society of Anesthesiologists 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 haemoglobin	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
Nonsteroidal anti-inflammatory drugs	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
Unlisted factors, *n* (%)				
Patient factors				
Comorbidities	11 (22)	8 (21)	3 (27)	0.6923
Advanced kidney diseases (dialysis)	2 (4)	2 (5)	-	1.0000
Patient refusal	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 (anaesthetic, cardiorespiratory, haemodynamic)	3 (6)	3 (8)	-	1.0000
Partial mesorectal excision	3 (6)	3 (8)	-	1.0000

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TABLE 5 (Continued)

Risk factors	All surgeons ($N = 49$)	>50 AR surgeons ($n = 38$; 78%)	≤50 AR surgeons ($n = 11$; 22%)	p-value
Different bowel calibre	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 h of care available	1 (2)	1 (3)	-	1.0000

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

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 by almost half of the ≤50 surgeon group and a statistically significant difference is observed in comparison to the >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 proved to be a very heterogeneous parameter. In fact, some surgeons provided an exact value, even if arbitrary, as the limit under which to perform PI (e.g. 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 (e.g. *'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 surgeons' decision-making processes to establish whether to create a PI following AR for adenocarcinoma. For this reason, a Delphi panel approach was excluded as a method to conduct the present study because achieving a consensus regarding the indication to perform PI was not our objective. The utility of the present analysis derives from the lack of clear guidelines or indications on this topic.

To our knowledge, the current recommendations to perform PI are based on the presence of patient 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, but these have not been universally adopted [14, 27].

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

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

Although the RFs recognized as responsible for AL are the most relevant for the 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), the 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 colostomy creation or avoiding a 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, PI creation does not seem to generate emotion in most surgeons in this

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sample. This is not underpinned by the emotional status of the surgeon but rather rational thinking about the potential impact of the alternative approach (not creating a PI) on a patient's life and QoL. Finally, this study shows that experience can influence a surgeon's choice, notwithstanding the RFs responsible for AL being well known and clearly reported in the literature. This is the only statistically significant difference between the >50 and ≤50 groups of surgeons and, in our opinion, it highlights the importance of the surgeon's decision-making process due to the lack of standardization about the indications 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 a PI or not. Hence, in our opinion, this parameter also becomes subjective and increases the confusion about when a 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 (e.g. distance of the anastomosis from the anal verge or mid rectal anastomosis) leading to performance of PI and the preoperative clinical or instrumental evaluation (by endoscopy, magnetic resonance or clinically intraoperative).

Thus, RFs play a fundamental role in surgeons' decision-making processes, but factors related to surgeons' familiarity with this procedure and connected to their experience can be 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 for learning more about the decision-making processes that guide the choice of whether or not to perform PI.

From the analysis of the responses, it is clear that the RFs for developing AL and how they can interact are subject to the interpretation of the surgeon, who compares them with 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 surgeons' decision-making processes, as reported by other authors [31, 32]. However, in this analysis the personality of the surgeon was not considered, so how this may influence the decision-making process is unknown. In their investigation, Moug et al. [31] reported data on the influence of surgeons' personalities on the decision-making process about anastomotic creation during colorectal surgery. 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 has not been achieved [31]. The personality of the surgeon adds further variables to this topic, making it extremely complex and difficult to standardize.

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

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

A PI is conceived to reduce the rate of AL, symptomatic dehiscence and the overall postoperative morbidity and mortality rates [30, 36, 37]. However, the real impact on the reduction of incidence of AL is not clear, and some authors advocate that the effective utility of PI is to reduce the morbidity related to AL, not the 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 the 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 that the prolonged presence of a PI increases the morbidity after its closure; on the contrary others report a high rate of postoperative complications in the 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].

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

Finally, about 28% of PIs 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 to study this condition [28–30, 36–52].

To be able to salvage patients without a PI who develop sepsis from AL, some authors have 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 surgeons located in Europe, and consequently the lack of surgeons' points of view worldwide, and the arbitrary nonevidence-based distinction between the >50 and ≤50 groups of surgeons. Moreover, the answers to an open question are subjective. Experts' opinions have a low level of evidence, but they may be of

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interest in informing the future direction of guidelines. Furthermore, as the results were obtained from surgeons who operate in different hospital settings the analysis is generalizable, adding an interesting contribution to this topic.

However, the second part of this project will be developed based on the present study, with the aim of overcoming the current limitations. Hence it will include a greater number of surgeons from all over the world and the surgeon expertise will be 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 in the present study and to describe clinical practice worldwide. The ultimate goal of the study is not to develop guidelines or consensus but to provide useful information for surgeons waiting for a shared and standardized approach.

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

In conclusion, indications whether or not 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, expert opinion can help to assist in the decision-making process in these patients.

CONFLICT OF INTEREST

All authors declare that there is no conflict of interest.

FUNDING INFORMATION

None.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Balla A, Saraceno F, Rullo M, Morales-Conde S, Targarona Soler EM, Di Saverio S, et al. Protective ileostomy creation after anterior resection of the rectum: Shared decision-making or still subjective? Colorectal Dis. 2022;00:1–13. https://doi.org/10.1111/codi.16454

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