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Incidence and risk factors of delayed development for stoma site incisional hernia after ileostomy closure in patients undergoing colorectal surgery with temporary ileostomy.

--Manuscript Draft--

Full Title:	Incidence and risk factors of delayed development for stoma site incisional hernia after ileostomy closure in patients undergoing colorectal surgery with temporary ileostomy.
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Keywords:	Ileostomy; incisional hernia; risk factors; stoma reversal; colorectal surgery
Abstract:	Background: Stoma site incisional hernias after ileostomy closure are complex hernias that can be associated with abdominal pain, discomfort, and a diminished quality of life. The aim of this study was to determine the incidence of incisional hernia (IH) following temporary ileostomy reversal in patients undergoing colorectal surgery, and the risk factors associated with its development. Methods: This was an observational study of patients undergoing ileostomy reversal between January 2010 and December 2016. Comorbidities, operative characteristics and postoperative complications were analysed. Bivariable and multivariable analyses were used to assess IH incidence and risk factors. Results: A total of 202 consecutive patients were prospectively evaluated (median follow-up 46 months; range: 12 - 109). Stoma site incisional hernia occurred in 23% of patients (n=47). The reasons for the primary surgery were colorectal cancer (n= 141, 69.8%), inflammatory bowel disease (n=14, 6.9%), emergency surgery (n=35, 17.3%), and other conditions (n=12, 5.9%). Statistically significant risk factors for developing an IH were obesity (higher BMI) (OR 1.15, 95% CI (1.05 – 1.26)). Other comorbidities such as diabetes, immunosuppression, and anaemia, as well as surgical technique variables, surgical wound infection and other post-surgical complications were not predictive of hernia. Conclusions: 23% of patients developed surgical site IH, a higher BMI being the only risk factor found to be statistically significant in the development of an incisional hernia.
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Dear Editors and Reviewers:

I am pleased to submit an original research article entitled "Incidence and risk factors of delayed development for stoma site incisional hernia after ileostomy closure in patients undergoing colorectal surgery with temporary ileostomy" by Calvo Espino P., MD, López Monclús J., MD, PhD, FACS, and Sánchez Turrión V., MD, PhD, FACS, et al. for consideration for publication in the *Acta Chirurgica Belgica*

In this manuscript, we have analyzed the largest series of ileostomy closure reported in the literature, showing the incidence and risk factors for incisional hernia, and that the original surgery in which the ileostomy was performed, or midline incisional hernia had no influence in the development of IH, as well as the fact that early ileostomy closure is not a protective factor.

We believe that this manuscript is appropriate for publication by the *Acta Chirurgica Belgica* because this, analyze a surgery realized for all colorectal surgeon, that it causes an important morbidity that we need to know it and should try to avoid it for the good of our patients.

This manuscript has not been published and is not under consideration for publication elsewhere. We have no conflicts of interest to disclose and there has been no significant financial support for

this work that could have influenced its outcome. As corresponding author, I confirm that the manuscript has been seen and approved by all authors.

Thank you for your consideration!

Sincerely,

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Text: 2302 words.

Background: Stoma site incisional hernias after ileostomy closure are complex hernias that can be associated with abdominal pain, discomfort, and a diminished quality of life. The aim of this study was to determine the incidence of incisional hernia (IH) following temporary ileostomy reversal in patients undergoing colorectal surgery, and the risk factors associated with its development.

Methods: This was an observational study of patients undergoing ileostomy reversal between January 2010 and December 2016. Comorbidities, operative characteristics and postoperative complications were analysed. Bivariable and multivariable analyses were used to assess IH incidence and risk factors.

Results: A total of 202 consecutive patients were prospectively evaluated (median follow-up 46 months; range: 12 - 109). Stoma site incisional hernia occurred in 23% of patients (n=47). The reasons for the primary surgery were colorectal cancer (n= 141, 69.8%), inflammatory bowel disease (n=14, 6.9%), emergency surgery (n=35, 17.3%), and other conditions (n=12, 5.9%). Statistically significant risk factors for developing an IH were obesity (higher BMI) (OR 1.15, 95% CI (1.05 – 1.26)). Other comorbidities such as diabetes, immunosuppression, and anaemia, as well as surgical technique variables, surgical wound infection and other post-surgical complications were not predictive of hernia.

Conclusions: 23% of patients developed surgical site IH, a higher BMI being the only risk factor found to be statistically significant in the development of an incisional hernia.

Keywords: Ileostomy; incisional hernia; risk factors; stoma reversal; colorectal surgery

Introduction

Temporary ileostomies can be carried out when high-risk colorectal anastomosis are performed, to minimise the symptoms of a potential anastomotic leak. These ileostomies can also be performed in patients with ulcerative colitis after a panproctocolectomy to avoid sepsis related to the ileo-anal pouch, or as emergency surgery to treat actual anastomotic leaks, among other reasons [1-3].

The morbidity associated with ileostomy closure is 14% to 31% [4-7]. The possible complications include incisional hernia (IH), surgical wound infection, small bowel obstruction, and anastomotic leaks. These complications may counteract the possible benefits of a protective ileostomy.

The incidence of stoma site IH after an ileostomy closure reported in the scientific literature varies between 5% and 23.9% [8-13]. The risk factors for these complications are: a higher body mass index (BMI) [8-10,12]; high blood pressure [8,11]; a previous history of IH [8-10]; and surgical factors, such as open surgery [10].

The goal of this study is to determine the incidence of IH after an ileostomy closure related to colorectal surgery. The secondary objective is to determine the incidence of a midline IH, and to describe any risk factors associated with developing surgical site IH.

Material and Methods

This was a prospective observational study: all of the patients included underwent an

ileostomy closure between January 2010 and December 2016 in a University Hospital in Madrid, Spain. Patients who had an ileostomy in other hospitals and those who had a follow-up of less than one year were excluded.

We included demographic variables, such as age, gender, and smoking habit; the reason for the primary operation within which the ileostomy was performed, for example, for rectal cancer, inflammatory bowel disease, emergency surgery, or other reasons (familial adenomatous polyposis, oncologic gynaecological surgery, etc.); any comorbidities and the basal health status, including BMI, diabetes, immunosuppression, chronic obstructive pulmonary disease (COPD), connective tissue diseases, and anaemia. Other variables analysed were the presence/absence of previous surgeries; the ASA classification; the surgical technique and any postoperative complications, such as postoperative emergency surgery or surgical site infection, according to the Clavien Dindo classification. In patients with rectal cancer, we also included variables related to their disease, such as stage, presence of metastasis on diagnosis, and the presence of adjuvant or neoadjuvant treatment.

Definition of surgical site incisional hernia

We defined IH according to the criteria of the European Hernia Society, in other words, any abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging [14].

Surgical Technique

The ileostomy closures were performed under general anaesthesia by a colorectal surgeon or by a supervised general surgery resident. Prophylactic antibiotic was administered in

every case. The surgery was initiated with a mucocutaneous disinsertion and a circular incision, as close as possible to the edge of the ileostomy. Patients with a terminal ileostomy also required a median laparotomy. After performing adhesiolysis, stoma resection and manual or mechanical latero-lateral anastomosis followed. Fascia closure was performed using slow absorbing 0 or 1 monofilament in 96.5% of patients, and a fast absorbing multifilament in 7/202 patients (3.5%). Skin closure was performed using a purse-string suture, leaving no drainage.

Follow-up

Patient follow-up data was obtained from the evaluations carried out in the general surgery medical offices, and from the reports on additional diagnostic procedures.

From a radiology perspective, a CT scan was performed on oncology patients, such as those with rectal cancer and gynaecological tumours. The scans were ordered following the protocols at our hospital: at least two CT scans during the first two years, the first between six months and one year after surgery, and the second between the first and the second year. In non-oncological patients, if no CT scan was performed during follow-up and there were doubts in physical examination, an abdominal wall sonography during a Valsalva manoeuvre was performed to assess a possible incisional hernia.

Statistical analysis

The statistics were calculated using the Statistical Package for the Social Sciences (SPSS), v.21.0 for Windows (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp). Quantitative variables were described as means and standard deviations in normal distributions, or as medians and ranges in the

event of a non-normal distribution. Qualitative variables were expressed in percentages. The Pearson's Chi-Square test was used to compare the qualitative variables; for quantitative variables that met the necessary conditions, the Student's T-test was used; the Mann-Whitney and Wilcoxon U-test was used for non-parametric correlations. A multivariate analysis was considered with a binary logistical regression, showing the odds ratio (OR) for predictor variables.

Statistically significant results were considered where $p<0.05$.

Results

Over the period analysed, a consecutive sample of 284 subjects were given a temporary ileostomy after colorectal surgery. However, 82 patients did not meet the inclusion criteria, meaning the final sample comprised 202 patients (**Fig. 1**). Their mean age was 61.81 years (±13 years) and 127 were male (62.9%). They had an average body mass index (BMI) of 25.7 kg/m^2 (±3.82 kg/m^2), 13.4% were smokers, and 9.9% were diabetic. The demographic variables, basal health status, comorbidities, and the statistical analysis, is shown in Table 1.

The original surgeries, which were the reason for the temporary ileostomy, were: colorectal cancer (n=141, 69.8%); emergency surgery (n=35, 17.3%); inflammatory bowel disease (n=14, 6.9%); and other surgeries (n=12, 5.9%). Open surgery was performed in 80% of cases, while a laparoscopic approach was selected in the remaining 20%. A lateral ileostomy was performed on 195 patients (96.5%), and a terminal ileostomy on 7 patients (3.5%). Early ileostomy closure (less than 21 days after the initial

surgery) was undertaken in 46% of cases, with the average being 14 days after the initial surgery. Delayed ileostomy closure was performed in the other 54% of cases, at a mean of 199 days after the initial surgery.

The median follow-up was 46 months (range: 12 – 109). The postoperative and follow-up variables, as well as the statistical analysis, are described in Table 2.

Clinical and radiological evaluation of the abdominal wall

Stoma surgical site IH after an ileostomy closure was diagnosed in 23% of patients. The IH was clinically diagnosed in 24/47 patients (51%) and radiologically diagnosed with a CT scan in 41/44 patients (93.1%). (Table 3) (**Fig. 2**)

Our series of patients, in which we also analyse the midline IH, shows an incidence of 46% (n=93), both abdominal wall defects being present in 12.8% of patients (n=26). The presence of a midline IH was not a risk factor for developing a stoma site IH (p=0.145). During follow-up, the abdominal wall was surgically repaired in 29.8% of patients with a stoma site IH.

Risk factors for developing an IH after ileostomy closure surgery

The different demographic variables, basal health status, and comorbidities were analysed. These variables included gender, age, diabetes, COPD, anaemia, smoking, ASA classification, and obesity (Table 1). The only variable identified as a risk factor, both in the bivariable and multivariable analyses, was a higher BMI.

A multivariate analysis of the predictor variables (those with a univariate p value of

<0.150; risk of suffering diabetes, age, BMI, and a midline incisional hernia) was run to determine the risk of stoma site incisional hernia. This was performed using a conditional back-step model, and only BMI was significant with an OR of 1.15 (IC95%:1.05-1.26; p=0.003).

The original surgery, during which the ileostomy was performed, had no influence on the development of IH. Thus, colorectal cancer, inflammatory bowel disease and emergency surgery were not identified as risk factors (p=0.152).

For patients with colorectal cancer, stage, neoadjuvant and adjuvant treatments were not identified as risk factors for developing IH after the stoma closure (Table 4).

Another interesting result was that surgical wound infection was present in 27% of patients (n=55), but had no statistical significance as a risk factor for IH (p=0.231).

Surgical time was also analysed. For patients who developed an IH the average surgical time was 72 minutes (± 30 minutes), while for those that did not develop an IH the average time was 70 minutes (±27). There was no statistically significant difference between the groups (p=0.66).

Lastly, neither the time lapse between the first surgery and the ileostomy closure nor the presence of postoperative complications were identified as risk factors.

Discussion

IH can be associated with abdominal pain, discomfort, a worse quality of life, and emergency surgery due to incarceration or strangulation of abdominal content [15,16]. Stoma site IH after an ileostomy closure is a complex hernia and usually associated with IH in other locations. Surgical technique is key in lowering the IH rate.

In our data set, 23% of patients who underwent an ileostomy closure after colorectal surgery developed a surgical site IH; similar results are found in the literature, with an incidence ranging between 5% and 23.9% [8-13]. Unlike in other studies, we did not include IH secondary to colostomy closures, since we do not consider the two groups to be comparable. For example, the incidence of IH is described as being much higher in the latter, up to 48% [17,18]. One reason for this disparity could be the need for a larger fascial defect when performing the initial colostomy.

The bivariable and multivariable analyses identified only one variable as a statistically significant risk factor for developing a surgical site IH: a higher BMI. In a literature review, studies analysing the risk factors for surgical site IH after an ileostomy closure describe the risk factors as being a higher BMI [8,10-12], high blood pressure [8,11] and a previous history of IH [8,10]; surgical factors have also been identified as risk factors, such as open surgery when the ileostomy was performed, being younger, and delayed ileostomy closure [10].

In our series there were no statistically significant differences in the rate of surgical site IH when comparing open and laparoscopic surgery. Keersmaecker et al. [13] reached the same conclusion, although the study performed by Mishra et al. [19] showed a higher rate of IH with laparoscopic surgery. Since in many studies surgical wound infection has been

described as a risk factor for IH, various skin closure techniques have also been analysed [20]. Our group performs a purse-string closure, which showed a 27% incidence of surgical wound infection and did not significantly impact the incidence of IH (p=0.231).

One factor that we included has never before been analysed, which was our hypothesis for supporting early ileostomy closure: the time lapse between performing the ileostomy and its closure. We hypothesised that a longer time would lead to a higher incidence of IH due to more altered dynamics of the abdominal wall forces. However, our study revealed that this duration is not a risk factor in developing an IH; the comparison of early (<21 days) and delayed (>21 days) ileostomy closures did not significantly influence the development of an IH (p=0.90). The same result was seen when a stratified analysis was made over several time periods (p=0.52).

We consider that many studies underdiagnose their IH rate, for both the midline and ileostomy closure, since they do not include imaging techniques in their follow-up. In our case, 51% patients with IH were diagnosed clinically, whereas when a CT scan was included in the follow-up, the diagnosis rose to 93.1% of patients. This latter percentage could have been even higher if the imaging had included a dynamic sequence, with the patient making a Valsalva manoeuvre. In addition, performing an abdominal ultrasound during a physical exploration could increase sensitivity for diagnosing an IH [21].

As we have already mentioned, IH can be symptomatic and may develop complications. For this reason, surgical treatment may be indicated to repair this defect, a procedure which might be necessary in up to 64% of patients [22]. In our series, approximately one in three patients (29.8%) required an eventroplasty. Our favoured technique involved

placing a mesh in the retromuscular space.

It is interesting to note that, in our series, no stoma site IH after ileostomy closure occurred in patients with inflammatory bowel disease. Our explanation for this is that these patients underwent scheduled non-emergency surgeries, and that the patients were younger and had a lower BMI than the other patients.

There is still no consensus on the use of a prophylactic mesh during ileostomy closure to lower the prevalence of IH, and only a few studies describe its use. Liu et al. [23] presented a case-control study with 83 patients. They placed a preaponeurotic polypropylene mesh and had a lower incidence of IH, dropping from 36.1% to 6.4% (OR 8.29, p=0.001), with no significant statistical differences in surgical wound infection between the two groups. Warren et al. [24] made a retrospective review of their patients with a polypropylene preperitoneal mesh; they do not describe any IH in ileostomy closure patients, but with no statistical significance, and there were also no differences in infection rate. Maggiori et al. [25] presented a blind prospective case-control study, in which a prophylactic porcine biological mesh was placed in the retromuscular space after ileostomy closure in 30 patients. No short-term statistically significant differences were found, including infection rates; although, a long-term CT-scan control during follow-up found significantly lower rates of IH (3% versus 19%, p=0.043).

Although these are very satisfactory results, more studies are needed to support the use of the mesh, as well as a consensus on the material used and where to place this.

The limitations of our study are those inherent to any descriptive study. The moment of

IH diagnosis is not recorded, so this work is not useful for determining how long it takes an IH to develop. Another limitation is the lack of a CT control scan for some patients.

In conclusion, in our series, 23% of patients developed a surgical site IH, a higher BMI being the only risk factor that was found to be statistically significant in the development of an incisional hernia.

Disclosure of interest

The authors report no conflict of interest

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Figure Legends

Table 1. Demographic variables, basal health status and comorbidities.

Table 2. Patient operative & follow-up data.

Table 3. Patients with incisional hernia.

Table 4. Risk factors for incisional hernia in colorectal cancer surgery.

Fig. 1. Flow diagram of patient inclusion.

Fig. 2. Abdominal computerized axial tomography showing a stoma site incisional hernia after an ileostomy closure.

Table 1. Demographic variables, basal health status and comorbidities.

	Hernia (N=47)	**No hernia (N=155)**	***p***
Age, mean(sd)	64.5 (9.95)	60.3 (13.8)	0.054
Gender			
Male, n (%)	29 (61.7)	98 (63.2)	0.85
Female, n (%)	18 (38.3)	57 (36.8)	
Initial surgery			
Rectal cancer, n (%)	35 (74.5)	106 (68.4)	0.152
IBD, n (%)	0 (0.0)	14 (9.0)	
Emergency surgery, n (%)	10 (21.3)	25 (16.1)	
Others, n (%)	2 (4.3)	10 (6.5)	
Diabetes	8 (17.0)	14 (9.0)	0.124
Immunosuppresion	1 (2.1)	2 (1.3)	0.678
COPD	3 (6.4)	7 (4.5)	0.605
ACE inhibitor	10 (21.3)	33 (21.3)	0.998
Conectivopathy	0 (0.0)	2 (1.3)	0.434
Previous laparotomy	11 (23.4)	37 (23.9)	0.678
Smoking habit	4 (8.5)	23 (14.8)	0.365
Hemoglobin, mean (sd)	13.0 (1.96)	13.2 (1.99)	0.574
Anemia (Hb < 12 g/dl)	15 (31.9)	43 (27.7)	0.580
BMI, mean (sd)	27.23 (4.13)	25.28 (3.61)	0.002
ASA classification			
I, n (%)	2 (4.3)	9 (5.8)	0.590

II, n (%)	27 (57.4)	95 (61.3)
III, n (%)	16 (34.0)	49 (31.6)
IV, n (%)	2 (4.3)	2 (1.3)

*Statistical significance ($p<0.05$)

COPD: chronic obstructive pulmonary disease; ACE: angiotensin-converting-enzyme; Hb: Haemoglobin; BMI: Body Mass Index; ASA American Society of Anaesthesiologists.

Table 2. Patient operative & follow-up data

	Hernia (N=47)	**No hernia (N=155)**	***P***
Follow-up			
1-2 years, n (%)	9 (19.1)	25 (16.1)	0.488
2-3 years, n (%)	6 (12.8)	33 (25.3)	
3-4 years, n (%)	11 (23.4)	26 (16.8)	
>4 years, n (%)	21 (44.7)	71 (45.8)	
Ileostomy closure			
Early, n (%)	22 (46.8)	71 (45.8)	0.904
Delayed, n (%)	25 (53.2)	84 (54.2)	
Days to ileostomy closure			
<20 days, n (%)	22 (44.4)	71 (45.8)	0.480
20-50 days, n (%)	0 (0.0)	2 (1.3)	
51-100 days, n (%)	4 (8.5)	6 (3.9)	
101-200 days, n (%)	9 (19.1)	42 (27.1)	
>200 days, n (%)	12 (25.5)	35 (22.6)	
Surgical technique			
Laparotomy, n (%)	38 (80.9)	124 (80.0)	0.898
Laparoscopy, n (%)	9 (19.1)	31 (20.0)	
Resurgery	4 (8.5)	5 (3.2)	0.124
Midline incisional hernia	26 (55.3)	67 (43.2)	0.145
Abdominal wall repair surgery	14 (29.8)	20 (12.3)	0.007
Stoma closure infection	16 (34.0)	39 (25.2)	0.231
Post-operative complication			0.173

No, n (%)	38 (80.9)	139 (89.7)	
Paralytic ileus, n (%)	5 (10.6)	10 (6.5)	
Anstomotic leak, n (%)	3 (6.4)	6 (3.9)	
Bowel perforation, n (%)	1 (2.1)	0 (0.9)	
Clavien Dindo Classification			
I, n (%)	20 (42.6)	79 (51.0)	
II, n (%)	22 (46.8)	70 (45.2)	0.235
IIIA, n (%)	1 (2.1)	0 (0.0)	
IIIB, n (%)	3 (6.4)	5 (3.2)	
IVA, n (%)	1 (2.1)	1 (0.6)	

*Statistical significance ($p<0.05$)

Table 3. Patients with incisional hernia

	Physical examination (N =202)	**CT Scan (N=183)**	**Total Hernias**
Stoma site incisional hernia	24/47 (51.1%)	41/44 (93.1%)	47/202 (23%)
Midline incisional hernia	48/93 (51.6%)	89/90 (98.8%)	93/202 (46%)

Table 4. Risk factors for incisional hernia in colorectal cancer surgery

	Hernia (N =35)	**No hernia (N=106)**	***p***
Stage**			
I, n (%)	11 (37.9)	25 (30.9)	
II, n (%)	6 (20.7)	21 (25.9)	0.212
III, n (%)	7 (24.1)	30 (37.0)	
IV, n (%)	5 (17.2)	5 (6.2)	
Diagnosed metastasis**	5 (14.3)	5 (4.7)	0.056
Neoadjuvant treatment**	25 (71.4)	79 (74.5)	0.718
Chemotherapy**	15 (42.9)	38 (35.8)	0.458

*Statistical significance ($p<0.05$)

Figure 1. Flow diagram of patient inclusion

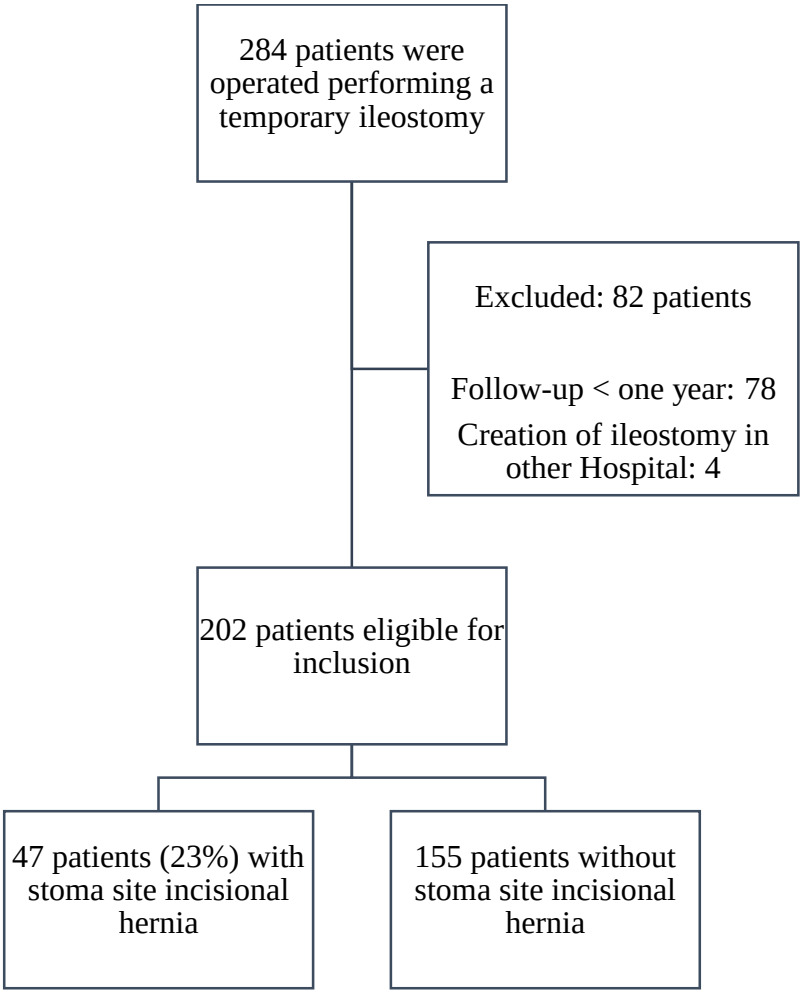
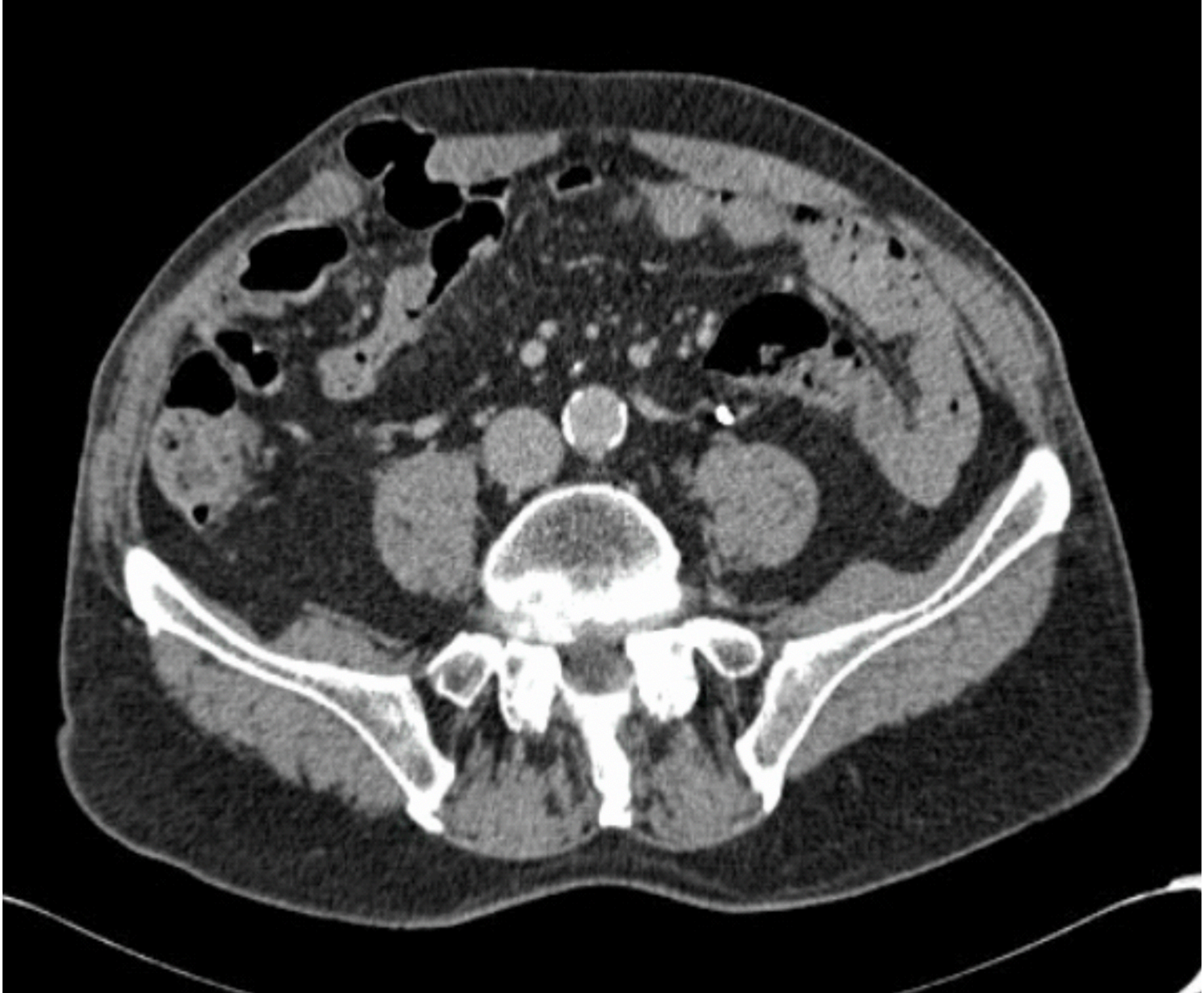


Figure (High



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

	Item No.	Recommendation	Page No.
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4,5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5,6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	5,6
Study size	10	Explain how the study size was arrived at	4,5

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6,7
		(*b*) Describe any methods used to examine subgroups and interactions	6,7
		(*c*) Explain how missing data were addressed	6,7
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	6,7
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	Fig 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7,8
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	8
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7,8,9
		(*b*) Report category boundaries when continuous variables were categorized	
		© If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8,9
Discussion			
Key results	18	Summarise key results with reference to study objectives	10,11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12,13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10,11,12,13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12,13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

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

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