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Is ileostomy mandatory for ileal pouch-anal anastomosis? A propensity matched analysis of 388 procedures.

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Keywords: Familial adenomatous polyposis; Ileal pouch-anal anastomosis; Ulcerative colitis; ileostomy.

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Running head: ileo-anal anastomosis without stoma.
ABSTRACT:

Objective: Study the value of diverting stoma for ileal-pouch-anal anastomosis.

Background: Restorative proctocolectomy (RPC) with ileal-pouch-anal anastomosis (IPAA) is the standard treatment for patients with ulcerative colitis (UC) or familial adenomatous polyposis (FAP). This procedure has undergone many changes and varies in 1, 2 or 3 stages. A diverting ileostomy can be created with the aim of reducing the consequence of an anastomotic leakage, however its use is still unknown.

Method: The value of defunctioning ileostomy was studied in a population of 388 patients undergoing RPC with IPAA between 2005 and 2017. Leakage rate and post-operative morbidity were assessed. Patients were matched on a propensity score using the following criteria: ASA score, body mass index, diagnosis, surgical approach and year.

Results: 203 IPAA for UC and 185 for FAP were performed representing 165 one-stage (61.6%), 79 classic two-stage, 74 modified two-stage and 70 three-stage procedures. Regardless of the surgical strategy adopted, there were no significant difference in post-operative morbidity (p=0.416), leakage rate (p=0.369) and reoperation (p=0.237) whether a diverting ileostomy was performed or not. After propensity score matching, there was no significant difference in post-operative morbidity (p=0.363), leakage rate (p=0.247) or reoperation (p=0.243). The rate of persistent ileostomy at one year was higher in cases of classic two-stage or three stage procedures (p=0.036).

Conclusions: After propensity score matching, defunctioning ileostomy for IPAA does not reduce leakage rate or post-operative morbidity, independent of the surgical strategy. Systematic ileostomy for IPAA is probably not justified and its place should be redefined in a randomized trial.
INTRODUCTION

Patients with ulcerative colitis (UC) or familial adenomatous polyposis (FAP) often require a restorative proctocolectomy (RPC) with ileal-pouch-anal anastomosis (IPAA). This intervention, first described in 1978 by Parks et al.\(^1\), is considered as a standard procedure in these two pathologies and has changed both technically and in surgical strategy over the years.\(^2\) In order to prevent septic complications, a temporary defunctioning ileostomy is frequently performed.\(^3-5\) Metcalf et al. showed in 1986 the feasibility of IPAA without ileostomy\(^6\) which was later followed up by Grobler et al. who demonstrated in a randomized trial that avoiding a loop ileostomy reduced the rate of complications.\(^7\) Moreover, a diverting ileostomy has its own morbidity which can have a significant impact on patient outcomes.\(^8, 9\)

Complications including high output resulting in dehydration and acute renal failure, prolapse, skin excoriation and parastomal hernia are common. Furthermore, stoma closure is not without its own morbidity.\(^10\)

The choice to divert an IPAA varies and depends on multiple factors including patient characteristics (medical history, medications…) and surgical factors (tension on the anastomosis, intraoperative haemorrhage, tough dissection and fragile tissues…). One stage IPAA is usually reserved for young fit patients with limited co morbidities and no intraoperative complications.\(^11\) The classic two stage, modified two stage or three stage approaches are usually performed in the remainder of patients.\(^12, 13\)

While a defunctioning ileostomy is recommended for low rectal cancer resections, there still is no consensus for IPAA surgery.\(^14\) Currently a defunctioning ileostomy is fashioned during RPC with IPAA. Over the last few years a number of studies have looked at the use of diverting ileostomies in IPAA, particularly in ulcerative colitis patients.\(^12, 13, 15-18\) The rate of defunctioning ileostomy is high in the literature with the largest series by Fazio et al. reporting an 88.2% defunctioning stoma rate in IPAA surgery.\(^19\) However, current literature is
lacking regarding definitive stoma rates in UC and FAP patients and it also lacks comparative studies on patients with and without defunctioning stomas.

Therefore, the aim of this study was to compare the morbidity and rate of anastomotic leakage in IPAA with or without a diverting stoma in patients with UC or FAP using a propensity matched score.

**PATIENTS and METHODS**

All patients undergoing an IPAA between January 2005 and December 2017 were included in the study. The RPC was carried out according to different surgical strategies according to the clinical situation and surgeon’s choice: one-stage (RPC with IPAA without ileostomy), classic two-stage (RPC with IPAA and diverting ileostomy followed by stoma closure), modified two-stage (subtotal colectomy followed by proctectomy with IPAA without ileostomy) or three-stage (subtotal colectomy followed by proctectomy with IPAA and ileostomy then stoma closure). Surgical details have already been described. \(^{11, 20, 21}\)

Diverting ileostomy closure was performed six to eight weeks following IPAA surgery. Anastomotic integrity was examined by a digital pouch exam and a CT-scan with enema five weeks after IPAA surgery. In case of an anastomotic leakage, closure was postponed, with anastomotic integrity assessed at a later date.

All patients with UC or FAP were included in the present study. Patients were excluded if they were operated on for another pathology.

Demographic and social characteristics (age, sex, height, weight, body mass index (BMI), smoking status, ASA score), pre-operative data (medical and surgical history, corticosteroids or biologic exposure within 180 days), general per operative (surgical approach, time, conversion, transfusion) and specific per operative data (total mesorectum excision, mucosectomy, anastomosis type, fecal diversion or not) were compared. Duration of
hospitalization and post-operative events were examined. Morbidity was classified using the Dindo Clavien method.\(^{23}\) Overweight patients were defined as having a BMI > 25kg/m\(^2\).

The primary endpoint was anastomotic leakage or pelvic abscess rates. Leakage was defined as a defect at the anastomosis or ileal pouch, with a pelvic abscess defined as a collection associated with sepsis, confirmed by imaging or during surgical re-intervention. Patients presenting with a leakage or pelvic abscess were treated with antibiotics, with or without radiological or surgical drainage. Radiological drainage was performed in case of accessible abscess associated with non-severe sepsis. In cases of surgical re-intervention, an ileostomy was commonly formed in patients without one.

The secondary endpoints were early morbidity (within 30 days following IPAA or during the hospitalization if the hospital stay was longer than 30 days) and late morbidity rates, mortality, re-intervention rates (early re-intervention, defined as within 90 days following IPAA, and late re-intervention), secondary ileostomy formation, definitive ileostomy and length of hospital stay.

**Statistics**

Quantitative data was expressed as means ± standard deviation (minimum-maximum). The comparison of quantitative variables in univariate analysis was performed by a student t test after checking normal distribution. Since the normal distribution was always respected, no non-parametric tests were used. Qualitative data was reported as frequencies and percentages and compared in univariate analysis using \(\chi^2\) test or the Fisher exact test as appropriate. In order to determine the variables on which the propensity score should be calculated, univariate and multivariate analysis was carried out on all pre- and intraoperative factors that could influence the surgeon to perform a protective stoma (age >50 years old, sex, overweight, diagnosis, ASA score, history of subtotal colectomy, corticosteroids or biologics...
usage, year, surgical approach and anastomosis type). Variables with a p-value < 0.10 in this
univariate analysis were entered into a multivariate analysis conducted by a binary logistic
regression. The propensity score for each patient was calculated from all variables statistically
associated with a protective ileostomy on multivariate analysis. A 1:1 matching from the
propensity score (caliper size of 0.1) was carried out between patients in the ileostomy group
and patients in the non-ileostomy group. After matching, the two groups were compared on
all pre- and intraoperative characteristics by univariate analysis to ensure the reliability of the
matching. Finally, comparison of postoperative events between the groups was performed
using \( \chi^2 \) or Fisher’s as appropriate for qualitative variables and student t-test for normally
distributed variables. All tests were 2 sided. A p-value of <0.05 was considered statistically
significant. Statistical analyses were performed using SPSS (version 23, IBM Corp, Armonk,
NY).

**RESULTS**

*Population, pre-operative data*

Between 2005 and 2017, 427 patients had an IPAA in our unit (Figure 1). 39 patients were
excluded from the study, 11 patients had a redo IPAA with 28 patients having an IPAA for
another pathology. Therefore, 388 patients were included, 203 with UC (52.3%) and 185 with
FAP (47.7%). An ileostomy was created for 149 patients (38.4%). 66.4% of patients with an
ileostomy had UC and 33.6% had FAP (p<0.001). Preoperative characteristics and univariate
analysis are detailed in Table 1.

*Per operative data*

Laparoscopic IPAA was performed in 58% of patients, with a 9.3% conversion rate. (Table 2)
Total mesorectum excision was performed in 42.6% of patients, with no significant difference
between groups (p=0.408). A handsewn IPAA was performed in 90.7% of cases, the majority
of which were performed in patients without a protective ileostomy (94.6% versus 84.6%;
p=0.001). The average operating time was 353.2 minutes with no significant difference
between groups with or without an ileostomy (p=0.798).

*Risk factors independently associated with performing an ileostomy*

In multivariate analysis, several criteria were independently associated with the creation of a
diverting ileostomy: overweight or obesity (BMI>25) (OR=2.30, 95%CI[1.36-3.89]), ASA score
> 2 (OR=1.87, 95%CI[1.27-2.77]), laparotomy (OR=1.94, 95%CI[1.30-2.90]), the period 2011-
2017 (OR=2.34, 95%CI[1.45-2.79]) and UC (OR=2.08, 95%CI[1.27-3.45]). (Table 1)

*Outcomes*

One death from a pulmonary embolism was reported in a patient with FAP who underwent
surgery in a classic two stage approach. Overall morbidity rate was 33.9% (n=115). Post-
operative anastomotic leakage and/or pelvic abscess was 12.8% with no significant difference
between groups. (Table 2) There was no significant difference in morbidity, severe morbidity
and anastomotic leakage between UC patients and FAP patients (respectively p=0.214,
p=0.341 and p=0.070). Early reintervention was required in 46 patients (11.9%), including 30
patients for anastomotic leakage, with no significant difference between the groups (p=0.237).
A secondary ileostomy was needed for 23 patients (9.6%). The use of corticosteroids or
biologic agents was the only risk factor associated with secondary ileostomy formation.
(p=0.026). (Table 3)

At least one late reintervention (excluding ileostomy closures) was required in 11 patients
(2.8%): 4 in the group without ileostomy (1.7%) and 7 in the group with ileostomy (4.7%;
p=0.081). At one year of follow up, 9 patients (2.3%) had an ileostomy, one patient from the non-ileostomy group and eight patients from the ileostomy group. (Table 2)

**Propensity score analysis**

A total of 254 patients were included in the analysis after matching. (Figure 1) Matched patients had similar pre- and intraoperative characteristics, with no significant difference between the two groups (Table 4).

After matching, the rate of anastomotic leakage and overall morbidity was not influenced by stoma formation (p=0.363 and p=0.247). Thirteen patients with a modified two-stage surgery had a secondary ileostomy (10.2%). Persistent stoma rates at 1 year were identical to non-matched analysis. One patient initially operated on without ileostomy had an ileostomy at one year compared to eight patients in the ileostomy group (p=0.036). (Table 4)

**DISCUSSION**

The present study reported on 388 RPC patients, of which 62% did not require an ileostomy with a further 69% having a one staged procedure. There was no significant difference in leakage rate or post-operative morbidity independent of a protective ileostomy. Ileostomy rates at one year were significantly higher following an RPC with diversion.

In the present series, overall morbidity was 33.9% with a post-operative leakage rate of 12.8%. After matching, a morbidity rate of 34.1% and a post-operative leakage or abscess rate of 13.1% was seen which was similar to the unmatched group. Independent of the surgical approach adopted, there was no significant difference in leakage rate or post-operative morbidity in the presence or absence of a protective ileostomy in both the matched and unmatched groups. In Fazio et al. series of 3707 patients, 88.2% had a protective ileostomy formed, with an overall morbidity rate of 33.5%. This complication rate was significantly
comparable to the present study, with only 38% of patients having an ileostomy formed during an IPAA.

Post-operative leakage is usually the most feared complication of colorectal surgery due to the risk of pelvic sepsis and impact on patient outcomes. Therefore, a protective ileostomy is recommended by rectal surgeons in the case of IPAA. Matthiessen et al. has shown that it not only reduces the leakage rate in proctectomy for rectal cancer, it also reduces the rate of early re-intervention. Furthermore, a review by Weston-Petrides et al. showed a lower leakage rate in cases of protective ileostomy for IPAA (OR=2.37, p=0.002). In the present series, there was no significant difference in the rate of reoperation independent of a protective stoma formation. Although ileoanal and coloanal anastomosis are comparable, there seems to be a difference in healing in favour of the small intestine compared to the colon and rectum. In the GRECCAR 5 trial, pelvic sepsis rates were 17.1% compared to 12.8% in the present series and 12.5% in Fazio et al.

There is increased morbidity and mortality following re-intervention for pelvic sepsis and secondary ileostomy formation. Den Dulk et al. have shown an ostomy closure rate of 81% for diverting stoma performed during the first procedure. However, only half of the patients re-operated for pelvic sepsis with secondary ostomy had an ileostomy reversal at four years. In the present series, 32 patients who did not have an initial ileostomy (13.4%) underwent early reintervention with 23 of them (9.6%) requiring a secondary ileostomy. During follow-up, 22 patients had a stoma closure. Therefore, only one patient (0.4%) in the group without ileostomy developed a chronic leakage requiring maintenance of the secondary ileostomy at 1 year. Thus, an ileostomy was avoided in the vast majority of patients (90.4%) undergoing a one or modified two-stage procedure. Ileostomy reversals were performed early with no mortality encountered. Furthermore, 14 patients with an ileostomy at index surgery required early re-intervention, with 8 patients (5.4%) having an ileostomy at 1 year. Thus, the omission
of ileostomy at the time of the IPAA reduced the risk of an ileostomy at one year. The authors believe that close post-operative follow-up makes it possible to detect both minor and major complications and in the event of re-intervention for leakage, lavage and drainage with a secondary ileostomy makes it possible to effectively manage the patient with no future sequelaes.

The mortality rate in this series was very low (0.3%). This rate is in line with national data (1.2% in France and 0.3% in specialized centers with more than 10 procedures per year).24 The importance of surgical management of these patients in expert centers is undeniable.

For FAP patients, it is now accepted that the majority (who generally have few co-morbidities) have an RPC with IPAA. In UC cases, patients are often more fragile and are at a higher risk of developing sepsis in post-operative period. However, in recent years, several studies have shown that protective ileostomy does not provide better results on morbidity or long-term functional outcome.12, 13, 15, 16 These teams therefore advocate the value of modified two-stage surgical management in patients with UC who have had subtotal colectomy in the past, especially since ileostomy morbidity is now well defined.10, 25 However, the diverting ileostomy is necessary and can prevent potentially serious sepsis when the intraoperative conditions are difficult or the anastomosis has been performed under tension.

The present study has a number of limitations. Firstly, it is retrospective. However, it has included a large population with outcomes easy to extract, such as overall morbidity, leakage and reintervention which provides reliable data. Secondly, it is a monocentric study, with recruitment biases and the decision of a stoma or not was necessarily linked to the experience of surgeons operating in an expert center. Thirdly, the propensity score has reduced some biases of this study, but it did not include some intraoperative considerations, such as tension at the time of anastomosis and tissue fragility. Laparotomy or conversion can influence the confection of an ileostomy and this factor was taken into account in the propensity score...
matching analysis. These factors observed during the operation remain subject to the evaluation of the surgeon who will decide whether or not to make an ileostomy. These are confounding factors that can only be eliminated in the case of a randomized prospective trial. In the literature, only one old randomized study looked in 1992 at this subject and showed no difference in the rate of sepsis whether or not a protective ileostomy was performed in the case of IPAA. In addition, a randomized trial is currently underway and will probably improve the selection of patients candidate for an IPAA without protective ileostomy. This trial will provide information on the functional result of an IPAA with or without stoma.

CONCLUSION

Since the first total coloproctectomy with IPAA and ileal reservoir was performed more than forty years ago, numerous developments have improved surgical management of patients with FAP and hemorrhagic UC. However, the interest of the protective ileostomy in this intervention remains debated. Our study confirmed that regardless of the surgical strategy adopted, there is no significant difference in leakage rate and post-operative morbidity whether or not a protective ileostomy is performed. Systematic ileostomy for IPAA is probably not justified and its place will be redefined in an ongoing randomized trial by the GETAID Chirurgie group.

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The author have no conflict of interest to report

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REFERENCES


**Figure Legend:**

**Figure 1.** Flowchart of the study.
<table>
<thead>
<tr>
<th>Variables</th>
<th>Total n = 388</th>
<th>No stoma n = 239</th>
<th>Stoma n = 149</th>
<th>Univariate analysis</th>
<th>Multivariate analysis</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>36 (12.81)</td>
<td>31 (12.76)</td>
<td>44 (14.81)</td>
<td>0.001</td>
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</tr>
<tr>
<td>Age &gt; 50 years old</td>
<td>101 (26.0%)</td>
<td>46 (19.2%)</td>
<td>55 (36.9%)</td>
<td>&lt; 0.001</td>
<td>NS</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>167 (43.0%)</td>
<td>112 (46.9%)</td>
<td>55 (36.9%)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>221 (57.0%)</td>
<td>127 (53.1%)</td>
<td>94 (63.1%)</td>
<td>0.054</td>
<td></td>
</tr>
<tr>
<td>Body mass index</td>
<td>23.5 (13.9–66.7)</td>
<td>22.4 (13.9–60.9)</td>
<td>24.9 (15.2–66.7)</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>Overweight</td>
<td>101 (26.0%)</td>
<td>48 (20.1%)</td>
<td>53 (35.6%)</td>
<td>0.001</td>
<td>0.002</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- UC</td>
<td>203 (52.3%)</td>
<td>104 (43.5%)</td>
<td>99 (66.4%)</td>
<td>&lt; 0.001</td>
<td>0.004</td>
</tr>
<tr>
<td>- FAP</td>
<td>185 (47.7%)</td>
<td>135 (56.5%)</td>
<td>50 (33.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA Score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 1 or 2</td>
<td>364 (93.8%)</td>
<td>229 (96.2%)</td>
<td>135 (90.6%)</td>
<td>&lt; 0.001</td>
<td>0.002</td>
</tr>
<tr>
<td>- 3 or 4</td>
<td>24 (6.2%)</td>
<td>10 (3.8%)</td>
<td>14 (9.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of STC</td>
<td>144 (37.1%)</td>
<td>74 (31.0%)</td>
<td>70 (47.0%)</td>
<td>0.001</td>
<td>NS</td>
</tr>
<tr>
<td>Steroids, IS</td>
<td>58 (15.1%)</td>
<td>28 (11.9%)</td>
<td>30 (20.1%)</td>
<td>0.027</td>
<td>NS</td>
</tr>
<tr>
<td>Period</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 2005-2011</td>
<td>194 (50%)</td>
<td>129 (54%)</td>
<td>65 (43.6%)</td>
<td>0.047</td>
<td>0.001</td>
</tr>
<tr>
<td>- 2011-2017</td>
<td>194 (50%)</td>
<td>110 (46%)</td>
<td>84 (56.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>- Open</td>
<td>163 (42.0%)</td>
<td>84 (35.1%)</td>
<td>79 (53.0%)</td>
<td>0.001</td>
<td>1.94</td>
</tr>
<tr>
<td>- Laparoscopy</td>
<td>225 (58.0%)</td>
<td>155 (64.9%)</td>
<td>70 (47.0%)</td>
<td>&lt;0.001</td>
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</tr>
<tr>
<td>- Conversion</td>
<td>21 (9.3%)</td>
<td>9 (5.8%)</td>
<td>12 (17.1%)</td>
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<td></td>
</tr>
<tr>
<td>Transfusion</td>
<td>26 (7.1%)</td>
<td>12 (5.4%)</td>
<td>14 (9.8%)</td>
<td>0.109</td>
<td></td>
</tr>
<tr>
<td>Type of anastomosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- handsewn</td>
<td>352 (90.7%)</td>
<td>226 (94.6%)</td>
<td>126 (84.6%)</td>
<td>0.001</td>
<td>NS</td>
</tr>
<tr>
<td>- stapled</td>
<td>36 (9.3%)</td>
<td>13 (5.4%)</td>
<td>23 (15.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total mesorectum excision</td>
<td>166 (42.6%)</td>
<td>102 (42.3%)</td>
<td>64 (43.0%)</td>
<td>0.408</td>
<td></td>
</tr>
<tr>
<td>Average operating time (min)</td>
<td>353.2 (140-660)</td>
<td>353.9 (180-540)</td>
<td>351.7 (140-660)</td>
<td>0.798</td>
<td></td>
</tr>
</tbody>
</table>

UC: ulcerative colitis; FAP: familial adenomatous polyposis; STC: subtotal colectomy; IS: immunosuppressive agents.

**Table 1.** Demographic, pre and peroperative patients data
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total n= 388</th>
<th>No stoma n = 239</th>
<th>Stoma n = 149</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leak or abscess</td>
<td>49 (12.8%)</td>
<td>33 (14.0%)</td>
<td>16 (10.9%)</td>
<td>0.369</td>
</tr>
<tr>
<td>Mortality</td>
<td>1 (0.26%)</td>
<td>0 (0%)</td>
<td>1 (0.67%)</td>
<td>0.384</td>
</tr>
<tr>
<td>Early morbidity</td>
<td>115 (33.9%)</td>
<td>71 (35.7%)</td>
<td>44 (31.4%)</td>
<td>0.416</td>
</tr>
<tr>
<td>Severe morbidity</td>
<td>64 (16.5%)</td>
<td>40 (16.7%)</td>
<td>24 (16.1%)</td>
<td>0.503</td>
</tr>
<tr>
<td>Surgical morbidity</td>
<td>95 (24.5%)</td>
<td>63 (26.4%)</td>
<td>32 (21.5%)</td>
<td>0.277</td>
</tr>
<tr>
<td>Small bowel obstruction</td>
<td>29 (7.5%)</td>
<td>17 (7.1%)</td>
<td>12 (8.1%)</td>
<td>0.741</td>
</tr>
<tr>
<td>Early surgical reintervention</td>
<td>46 (11.9%)</td>
<td>32 (13.4%)</td>
<td>14 (9.4%)</td>
<td>0.237</td>
</tr>
<tr>
<td>Early surgical reintervention for leak or abscess</td>
<td>29 (7.5%)</td>
<td>21 (8.8%)</td>
<td>8 (5.4%)</td>
<td>0.222</td>
</tr>
<tr>
<td><strong>Secondary ileostomy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- leakage (abscess, non efficiency of radio-guided drainage, IPAA leakage)</td>
<td>23 (9.6%)</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>- hematoma/hemoperitoneum</td>
<td>2 (0.8%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- uroperitoneum</td>
<td>1 (0.4%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Late surgical reintervention for leakage</td>
<td>11 (2.8%)</td>
<td>4 (1.7%)</td>
<td>7 (4.7%)</td>
<td>0.081</td>
</tr>
<tr>
<td>- chronic/paucisymptomatic leak</td>
<td>8 (2.1%)</td>
<td>2 (0.8%)</td>
<td>6 (4.0%)</td>
<td></td>
</tr>
<tr>
<td>- disunion of the ileal-ileal anastomosis</td>
<td>3 (0.8%)</td>
<td>2 (0.8%)</td>
<td>1 (0.7%)</td>
<td></td>
</tr>
<tr>
<td>- re IPAA</td>
<td>2 (0.5%)</td>
<td>0 (0%)</td>
<td>2 (1.3%)</td>
<td></td>
</tr>
<tr>
<td>Persistent ileostomy at 1 year</td>
<td>9 (2.3%)</td>
<td>1 (0.4%)</td>
<td>8 (5.4%)</td>
<td>0.002</td>
</tr>
<tr>
<td>- chronic leak</td>
<td>6 (1.5%)</td>
<td>1 (0.8%)</td>
<td>5 (3.4%)</td>
<td></td>
</tr>
<tr>
<td>- refusal to ostomy closure</td>
<td>1 (0.3%)</td>
<td>0 (0%)</td>
<td>1 (0.7%)</td>
<td></td>
</tr>
<tr>
<td>- delayed ostomy closure</td>
<td>1 (0.3%)</td>
<td>0 (0%)</td>
<td>1 (0.7%)</td>
<td></td>
</tr>
<tr>
<td>- lost to follow-up</td>
<td>1 (0.3%)</td>
<td>0 (0%)</td>
<td>1 (0.7%)</td>
<td></td>
</tr>
<tr>
<td>Hospitalization length of stay (days)</td>
<td>12.0 +/- 6.1</td>
<td>12.4 +/- 6.5</td>
<td>11.3 +/- 5.6</td>
<td>0.097</td>
</tr>
</tbody>
</table>

**Table 2.** Outcomes after IPAA
<table>
<thead>
<tr>
<th>Patients’ characteristics</th>
<th>Secondary ileostomy n = 23</th>
<th>No stoma, without secondary ileostomy n = 216</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>38.7 (17-73)</td>
<td>33.9 (12-76)</td>
<td></td>
</tr>
<tr>
<td>Age &gt; 50 years old</td>
<td>6 (26.1%)</td>
<td>38 (17.6%)</td>
<td>0.696</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Female</td>
<td>12 (52.2%)</td>
<td>101 (46.8%)</td>
<td>0.591</td>
</tr>
<tr>
<td>- Male</td>
<td>11 (47.8%)</td>
<td>115 (53.2%)</td>
<td></td>
</tr>
<tr>
<td>Body mass index</td>
<td>23.1 (16.9 – 41.8)</td>
<td>22.5 (13.9 – 60.9)</td>
<td></td>
</tr>
<tr>
<td>Overweight/Obesity</td>
<td>5 (21.7%)</td>
<td>43 (19.9%)</td>
<td>0.907</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- UC</td>
<td>12 (52.2%)</td>
<td>93 (43.1%)</td>
<td>0.661</td>
</tr>
<tr>
<td>- FAP</td>
<td>11 (47.8%)</td>
<td>123 (56.9%)</td>
<td></td>
</tr>
<tr>
<td>ASA Score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 1 or 2</td>
<td>23 (100.0%)</td>
<td>207 (95.8%)</td>
<td>0.112</td>
</tr>
<tr>
<td>- 3 or 4</td>
<td>0 (0%)</td>
<td>9 (4.2%)</td>
<td></td>
</tr>
<tr>
<td>History of STC</td>
<td>6 (26.1%)</td>
<td>68 (31.5%)</td>
<td>0.595</td>
</tr>
<tr>
<td>Steroids, IS</td>
<td>6 (26.1%)</td>
<td>22 (10.2%)</td>
<td>0.026</td>
</tr>
<tr>
<td>Period</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 2005-2011</td>
<td>10 (43.5%)</td>
<td>119 (55.1%)</td>
<td>0.133</td>
</tr>
<tr>
<td>- 2011-2017</td>
<td>13 (56.5%)</td>
<td>97 (44.9%)</td>
<td></td>
</tr>
</tbody>
</table>

UC: ulcerative colitis; FAP: familial adenomatous polyposis; STC: subtotal colectomy; IS: immunosuppressive agents.

**Table 3.** Univariate analysis of factors associated with creation of a secondary stoma after restorative proctectomy without diverting stoma.
Characteristics | Total n = 254 | No stoma n = 127 | Stoma n = 127 | p
--- | --- | --- | --- | ---
Age > 50 years | 78 (30.7%) | 36 (28.3%) | 42 (33.1%) | 0.414
Gender | | | | 0.162
- Female | 107 (42.1%) | 59 (46.5%) | 48 (36.9%) | 0.589
- Male | 147 (57.9%) | 68 (53.5%) | 79 (62.2%) | 0.162
Overweight or obesity Diagnosis | | | | 0.807
- UC | 162 (63.8%) | 82 (64.6%) | 80 (63.0%) | 0.794
- FAP | 92 (36.2%) | 45 (35.4%) | 47 (37.0%) | 0.794
 ASA score | | | | 0.589
- 1 or 2 | 233 (91.7%) | 117 (92.1%) | 116 (91.3%) | 0.952
- 3 or 4 | 21 (8.3%) | 10 (7.9%) | 11 (8.7%) | 0.952
History of STC | 121 (47.6%) | 59 (46.5%) | 62 (48.8%) | 0.706
Steroids, IS | 44 (17.5%) | 21 (16.9%) | 23 (18.1%) | 0.807
Period | | | | 0.807
- 2005-2011 | 134 (52.8%) | 69 (54.3%) | 65 (51.2%) | 0.615
- 2011-2017 | 120 (47.2%) | 58 (45.7%) | 62 (48.8%) | 0.615
Surgical approach | | | | 1.000
- Open | 130 (51.2%) | 65 (51.2%) | 65 (51.2%) | 1.000
- Laparoscopy | 124 (48.8%) | 62 (48.8%) | 62 (48.8%) | 1.000
- Conversion | 18 (14.5%) | 9 (14.5%) | 9 (14.5%) | 1.000
Anastomosis type | | | | 1.000
- handsewn | 232 (91.3%) | 116 (91.3%) | 116 (91.3%) | 1.000
- stapled | 22 (8.7%) | 11 (8.7%) | 11 (8.7%) | 1.000
Leakage or abscess | 33 (13.1%) | 19 (15.1%) | 14 (11.2%) | 0.363
Mortality | 1 (0.39%) | 0 (0%) | 1 (0.79%) | 1.000
Early morbidity | 79 (34.1%) | 43 (37.7%) | 36 (30.5%) | 0.247
Severe morbidity (Clavien 3, 4 and 5) | 41 (16.1%) | 21 (16.5%) | 20 (15.7%) | 0.865
Surgical morbidity | 65 (25.6%) | 38 (29.9%) | 27 (21.3%) | 0.114
Small bowel obstruction | 22 (8.7%) | 12 (9.5%) | 10 (7.9%) | 0.641
Early surgical reintervention | 30 (11.8%) | 18 (14.2%) | 12 (9.4%) | 0.243
Early surgical reintervention for leak or abscess | 20 (7.9%) | 12 (9.4%) | 8 (6.4%) | 0.371
Secondary ileostomy | 13 (5.1%) | 13 (10.2%) | - | -
Late surgical stoma at 1 year | 9 (3.5%) | 3 (2.4%) | 6 (4.7%) | 0.310
Persistent ileostomy at 1 year | 9 (3.3%) | 1 (0.8%) | 8 (6.3%) | 0.036

UC: ulcerative colitis; FAP: familial adenomatous polyposis; STC: subtotal colectomy; IS: immunosuppressive agents.

**Table 4.** Characteristics of the population and outcomes after propensity score matching
IPAA n = 427

- Other indications: n=28
- Redo-IPAA: n=11

IPAA for UC or FAP (n=388)

No ileostomy (n=239, 61.6%)

- 1 stage (n=165, 69%)
- Modified 2 stages (n=74, 31%)

Ileostomy (n=149, 38.4%)

- 2 stages (n=79, 53%)
- 3 stages (n=70, 47%)

Propensity score matching 1/1

IPAA for UC or FAP (n=254)

No ileostomy (n=127, 50%)

- 1 stage (n=68, 53%)
- Modified 2 stages (n=59, 47%)

Ileostomy (n=127, 50%)

- 2 stages (n=65, 51%)
- 3 stages (n=62, 49%)
1. Please confirm that you have mentioned all organizations that funded your research in the Acknowledgements section of your submission, including grant numbers where appropriate. 

I confirm that I have mentioned all organizations that funded my research in the Acknowledgements section of my submission, including grant numbers where appropriate.

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Defunctioning ileostomy for IPAA does not reduce leakage rate or post-operative morbidity independent of the surgical strategy

The importance of this study is to show that systematic diverting stoma among ileal-pouch-anal anastomosis may be omitted in selected patients.

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