



Role of ileostomy in restorative proctocolectomy

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Abstract

Restorative proctocolectomy (RP) is the treatment of choice in patients affected with refractory ulcerative colitis or familial adenomatous polyposis. Surgery in elective settings is often performed in 2 stages, fashioning an ileostomy which is closed 2-3-mo later. It is still debated whether omitting ileostomy could offer advantages in the management of patients undergoing RP.

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INTRODUCTION

Restorative proctocolectomy (RP) with ileopouch-anal anastomosis (IPAA) is considered the treatment of choice for patients affected by ulcerative colitis (UC) and familial adenomatous polyposis (FAP) who require surgery. RP removes the disease, reduces the long-term risk of carcinogenesis and preserves transanal defecation^[1]. Short-term results demonstrate excellent functional outcomes with good quality of life, while some deterioration of function is reported in the long term. Pelvic sepsis is the most serious complication of RP, leading to pouch failure or malfunction^[2,3]. Since the first description of IPAA^[4], many techniques have been introduced to prevent or limit the consequences of an IPAA leak; the necessity of fashioning a covering ileostomy at the time of RP remains controversial. The aim of this review is to establish the role of a covering ileostomy in patients undergoing RP for UC or FAP.

ILEOSTOMY AND PELVIC SEPSIS/POUCH FAILURE

RP is generally performed in two stages in elective settings, but it can be performed as a single-stage procedure in order to avoid ileostomy and its complications^[5,6]. Sugarman *et al*^[5] reported a high rate of pelvic sepsis (12%) in 192 patients undergoing IPAA without covering ileostomy, with excellent function retained in 19 out of the 23 patients who developed pelvic sepsis. Teixeira *et al*^[7] suggested that ileostomy does not eliminate the risk of pelvic sepsis; they found that an IPAA stricture was more frequent in patients undergoing IPAA without a covering ileostomy (31.3% *vs* 4.7%). Furthermore, Ikeuchi *et al*^[8] found that the incidence of post-operative complications after the first intervention did not differ significantly between patients with or without an ileostomy: pouch-related complications affected 12 patients (8%) without ileostomy, with surgery being required in 5 cases (3.3%), and 4 patients (4.3%) with ileostomy, all of who were managed conservatively. Despite this, the authors reported that the

overall incidence of post-operative complications was significantly higher in the group with ileostomy than in the non-ileostomy group: 55.4% *vs* 32%.

It needs to be remembered that omitting ileostomy appears to expose the patient to a high risk of pouch failure due to early anastomotic leakage. In St. Mark's Hospital the rate of pouch failure was higher in patients undergoing IPAA without a covering ileostomy: 15% *vs* 8%^[9]. Data from the Cleveland Clinic of 1965 patients undergoing RP revealed that anastomotic leak occurred in 5.3% of the patients with ileostomy, but in > 14% when ileostomy was omitted^[10]. The global rate of complications after 1504 ileostomy closures was as high as 11.4%^[11,12].

COMPLICATIONS/CONSEQUENCES OF ILEOSTOMY

Fashioning a covering ileostomy can be burdened by complications due to diversion, such as dehydration from excessive stoma output, the need for a second intervention and hospitalization to undergo ileostomy closure, the risk of anastomotic leak and a presumed increased risk of subsequent small-bowel occlusion, which some authors attribute to either internal hernias around the stoma or to adhesions in the proximity of the stoma site^[5]. Complications such as irritation of the peristomal skin or stoma prolapse are well described in the literature^[13]. Ileostomy closure is associated with longer hospitalization, and some authors report that this can increase the cost of the procedure^[14]. Moreover, the preternatural anus, even if temporary, can have psychological effects and affect the patient's perception of their body^[15,16].

ILEOSTOMY AND PRE-TAKEDOWN ASSESSMENT (SECOND-STAGE SURGERY)

A covering ileostomy after RP should be taken down after a minimum of 8 wk to allow IPAA healing. Takedown is usually performed after a clinical examination (often including pouchoscopy) and a pouch enema (pouchogram/pouchography)^[17]; the latter can reportedly enable the detection of pouch or IPAA leaks and IPAA strictures^[18,19]. Few studies have investigated the role of pouchography in the assessment of patients with IPAA scheduled for ileostomy closure. It has been hypothesized that a discontinuous ileoanal anastomotic ring at pouchography is sensitive (88%) but not specific (57%) in predicting a subsequent pelvic sepsis, whereas a leak is quite specific (81%) but not sensitive (56%) in predicting pelvic collections^[20]. These data suggest that tiny tracts often heal spontaneously, and justify delaying ileostomy closure if a leak is observed. Pouch sinuses are tiny blind tracts originating from IPAA, and are seen at pouchography in < 8% of patients undergoing RP^[21]. A leak leading to pelvic sepsis can reportedly occur even after radiological healing of a sinus^[21]. A study from the Mayo Clinic suggests that pouch function is not affected by occult sinuses, ques-

tioning the utility of detecting asymptomatic defects^[13]. Moreover, managing these tiny tracks aggressively could result in overtreatment. Previous studies have not clearly compared clinical data - obtained through anamnesis plus clinical examination - and pouchography. In our experience, a preoperative pouchogram in patients at risk of developing complications adds valuable information^[20], but it should not be intended as a routine examination in symptomatic UC patients with negative results of a clinical/endoscopic examination.

Comparison of data from two groups of clinically negative UC pouch patients who did ($n = 37$) or did not ($n = 33$) undergo pouchography before ileostomy takedown in our centre revealed that 10.8% of patients in the former group exhibited an asymptomatic radiological abnormality that was otherwise undetected (four pouch sinuses). However, the failure rate was similar in the two groups (3% *vs* 2.7%, $P = \text{NS}$), as was the overall rate of complications. In addition, patients in the pouchography group who experienced failure had a normal pouchogram at the time of ileostomy closure^[22]. We follow the following algorithm in our practice: a clinical/endoscopic assessment is always applied to patients scheduled to undergo ileostomy takedown, and a pouchography study is carried out if symptoms or the clinical examination make us suspect that a complication has occurred. The ileostomy of asymptomatic, clinically negative patients is closed without radiological evaluation of the pouch.

ILEOSTOMY AND BASELINE DISEASE

Intuitively, patients undergoing a pelvic pouch procedure for non-inflammatory disease are at lower risk of developing septic complications, because they do not need to be treated with steroid medications. The findings of several studies suggest that a loop ileostomy can be safely omitted, even in patients undergoing IPAA for UC^[8,23-30]. However, a recent retrospective multivariate analysis of patients undergoing RP at the Cleveland Clinic and at St. Mark's Hospital revealed that FAP is associated with a higher probability of a safe one-stage RP (odds ratio, 2.6)^[31].

ILEOSTOMY AND STEROID DRUGS

Therapy for UC includes the use of steroid drugs, sometimes administered at a high dosage, and these patients are at risk of becoming steroid-dependent or steroid-refractory. Matikainen *et al*^[23] stated that steroid therapy at the time of RP does not contraindicate one-stage surgery. However, most experienced centres consider a daily prednisone dose of ≥ 20 mg an exclusion criterion for a one-stage procedure^[11,32]. Although not agreeing with this cut-off value, Sugerman *et al*^[5] suggested that treatment with steroids is relevant to evaluating patients scheduled for RP. Ziv *et al*^[33] considered that omission of ileostomy is an unacceptable procedure in patients treated with steroids at the time of RP. Ikeuchi *et al*^[8] showed that patients taking steroids at the time of IPAA are more likely to develop

complications. Although they did not establish a cut-off value for steroid therapy, those authors suggest that steroid treatment is a relevant factor in selecting patients who are suitable for a one-stage procedure.

ILEOSTOMY AND TYPE OF ILEOPOUCH-ANAL ANASTOMOSIS

During RP, the IPAA can be either hand-sewn (with or without mucosectomy) or stapled using a circular stapler introduced transanally. Some authors have reported that the type of IPAA can affect the outcome of patients undergoing RP with or without ileostomy. A hand-sewn IPAA is technically more difficult to perform, which has resulted in there being few reports of patients undergoing RP with a hand-sewn IPAA in the literature. Ikeuchi *et al*^[8] reported one of the largest series, since they routinely use a hand-sewn technique. They compared 150 patients undergoing hand-sewn IPAA without ileostomy with 92 hand-sewn IPAA patients operated on with a two-stage procedure. While the rate of pouch-related complications was high, it did not differ significantly between the two groups. Some authors have reported that fashioning a hand-sewn IPAA leads to an unacceptably high risk of complications if a covering ileostomy is omitted, especially if steroid medications are taken at the time of RP. However, there is no definitive evidence regarding the impact of this factor on patient selection^[11,33,34].

With respect to the pouch shape, patients with a W-pouch are at higher risk of complications when ileostomy is omitted than those with a stapled J-pouch^[31].

ILEOSTOMY AND TECHNOLOGICAL ADVANCES IN SURGERY

Surgical technology has made huge advances in recent years. Laparoscopic RP is widely used nowadays. Pouch surgery can be performed as a totally laparoscopic three-/four-trocar access procedure, as a laparoscopic-assisted procedure (with the pouch being constructed outside the body through a Pfannenstiel incision^[35]), as a hand-assisted laparoscopic proctocolectomy (HALP), by means of a special port designed to allow the surgeon to introduce his or her hand inside the body while preserving the pneumoperitoneum^[36], and as single-access laparoscopic surgery (SILS)^[37]. A recently introduced technique uses a laparoscopy-assisted robotic surgery approach to RP^[38]. In the context of a minimally invasiveness, the omission of a protective ileostomy has definite advantages regarding the overall cosmetic result. Kienle *et al*^[35] performed 59 laparoscopic RP procedures with extracorporeal pouch construction, omitting a primary ileostomy in 16 patients: 3 FAP (18.75%) and 6 UC (37.5%) patients developed complications (7 pelvic sepsis) requiring reoperation and secondary ileostomy. Agha *et al*^[36] reported that HALP is a safe procedure with a rapid learning curve; in their experience of 19 patients undergoing RP, a protective ileostomy

was always fashioned. SILS RP is a viable procedure that produces good results if the surgeon is highly skilled in laparoscopic surgery. Gash *et al*^[37] found that fashioning a protective ileostomy at the site of SILS trocar introduction seemed to be a prudent choice in their series of ten patients.

The minimally invasive approach *per se* probably does not reduce the need for a protective ileostomy. The selection criteria for the addition or omission of a protective ileostomy in minimally invasive RP remain to be clearly defined. In our opinion further studies are needed before definitive conclusions can be drawn about the advisability of avoiding an ileostomy using the most recent techniques^[36-38], with this also being dependent on the acquisition of better technical skills by surgeons and the use of longer follow-ups.

ILEOSTOMY AND SAMPLE SIZE/STATISTICAL POWER

It should be noted that studies promoting a one-stage procedure generally lack significant statistical power, which thus renders evaluation of the pelvic sepsis rate unreliable. Heuschen *et al*^[24] compared the results of 57 one-stage procedures with 114 controls and found that the rate of IPAA stricture was higher in patients with a covering ileostomy, but this finding could have been due to the selection of case patients.

Failure was more common at St. Mark's Hospital^[9] when higher ileostomy was omitted (15% *vs* 8%). Conversely, in concurrent experience MacRae *et al*^[39] found that the pouch failure rate was < 1% in patients undergoing one-stage RP. Recent multicentre studies^[30,31] have involved wider series but only retrospective analyses. The lack of randomization, which is often incompatible with acceptable ethical conduct in such patients, represents a limitation that has yet to be overcome.

ILEOSTOMY AND EVIDENCE BASED MEDICINE

Several factors make it difficult to perform randomized controlled trials around this topic: (1) the difficulty in enrolling sufficient patients for revealing statistically relevant differences; (2) omitting a stoma is not indicated in some patients because of surgical safety; and (3) the unethical problems of randomizing patients at risk. With regard to UC, the most recent Consensus Paper of the European Crohn's and Colitis Organization stated that a diverting ileostomy is generally recommended, but that it can be avoided in selected patients (Evidence Level 3b, Recommendation Grade C)^[40]. Currently the best way to select patients remains unclear.

ILEOSTOMY AND PATIENTS

The responsibility regarding surgical outcomes has gained

such importance that it is now deemed necessary to involve the patient in surgical decision-making. Obese patients (body mass index $\geq 30 \text{ kg/m}^2$) could benefit from stoma omission, since fashioning an ileostomy in these patients could be technically more difficult^[5]. Most importantly, the patient's will to avoid ileostomy should be considered in light of the psychological implications, such that if complications do arise following one-stage surgery, the eventual subsequent need for an ileostomy will certainly affect a patient who has also undergone reintervention in an emergency setting^[16].

PERSONAL EXPERIENCE

Between 1987 and 2011, we performed 241 RPs for UC, FAP or cancer (1 S-pouch, 121 W-pouches, and 119 J-pouches); 23 (9.5%) of these patients underwent one-stage RP. The global rates of pelvic sepsis were 7.7% and 13% among patients with or without ileostomy, respectively, while failure occurred in 5% and 4.3% of case. However, there were no statistically significant differences. Since our series covered a very long period of time (24 years), and considering the recent technical advancements, we stratified our experience into two periods, focusing on stoma omission. Between 1987 and 2000, we performed nine one-stage RPs, with a pelvic sepsis rate of 22.2% and a failure rate of 11.1%; these figures are higher than those for staged procedures (9.2% and 7%, respectively), although the difference did not reach statistical significance. Between 2001 and 2011, we performed 14 straight RPs: 7.1% of patients developed pelvic sepsis, while none of them experienced failure. Again, these data did not differ significantly from those of patients undergoing two-/three-stage procedures (pelvic sepsis in 6% and failure in 4%).

In addition to the increased level of expertise among surgeons, these improved findings are due to increasingly careful patient selection among those who could benefit from stoma omission. Most of the selected patients were female, overweight, young, affected with FAP and undergoing stapled J-pouch with stapled IPAA. Patients taking steroids were not considered suitable for a one-stage procedure. The type of surgery (laparoscopic, open or HALP) was not *per se* a selection criterion, since the choice was patient-tailored. Any bias could be attributable to us omitting ileostomy more frequently as our experience with the pelvic pouch procedure increased, especially when the surgeon had reached the plateau of the learning curve for the RP surgical technique. This is relevant, since we believe - in agreement with the great majority of the reported studies - that it is as now impossible to predict preoperatively whether a patient would be suitable for one-stage surgery. A straightforward surgery (e.g., contained blood loss, short operative time, lack of tension and good vascularization of the IPAA, no contamination, intraoperative testing of the anastomosis) is a desirable condition when choosing to omit ileostomy. These factors are definitively surgeon-related.

CONCLUSION

At the present time, given the information in the literature and wider described series under the critical light of the EBM, the decision to omit ileostomy substantially represents an exercise in risk management. Most surgeons opt for a protective ileostomy because this is reported to diminish the risk of detrimental pelvic contamination, even if it does not abolish the risk of pelvic sepsis. Centres specializing in pelvic pouch procedures have reported that the rate of patients undergoing one-stage RP ranges between 15% and 25%^[29,30]. By adopting stringent selective criteria, the rate of patients undergoing RP without an ileostomy did not reach 10% in our series. It is our opinion that omitting ileostomy is a viable alternative in a very limited number of patients who fit specific selection criteria; they must be highly motivated to avoid a stoma and well informed regarding the eventual subsequent risks. This option could be proposed to them, but it is only at the end of each pelvic pouch procedure that the surgeon will be able to take the final decision.

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