Comparison of Outcomes After Restorative Proctocolectomy With or Without Defunctioning Ileostomy

Gina K. Weston-Petrides, MBBS, PhD; Richard E. Lovegrove, MRCS; Henry S. Tilney, MRCS; Alexander G. Heriot, MD, FRCS; R. John Nicholls, MD, FRCS; Neil J. M. Mortensen, MD, FRCS; Victor W. Fazio, MD; Paris P. Tekkis, MD, FRCS

Objective: To evaluate postoperative adverse events and functional outcomes of patients undergoing restorative proctocolectomy with or without proximal diversion.

Data Sources: The literature was searched by means of MEDLINE, Embase, Ovid, and Cochrane databases for all studies published from 1978 through July 15, 2005.

Study Selection: Comparative (randomized and non-randomized) studies evaluating outcomes after restorative proctocolectomy with or without ileostomy were included.

Data Extraction: Three authors independently extracted data by using operative variables, early and late adverse events, and functional outcomes between the 2 groups. Trials were assessed by means of the modified Newcastle-Ottawa Score. Random-effects meta-analytical techniques were used for analysis.

Data Synthesis: The review included 17 studies comprising 1486 patients (765 without ileostomy and 721 with ileostomy). There were no significant differences in functional outcomes between the 2 groups. The development of pouch-related leak was significantly higher in the no-ileostomy group (odds ratio, 2.37; \( P = .002 \)). Small-bowel obstruction was more common in the stoma group but was not statistically significant (odds ratio, 0.65). The development of anastomotic stricture favored the no-stoma group (odds ratio, 0.31; \( P = .045 \)). On sensitivity analysis, pelvic sepsis was significantly less common in patients whose ileostomies were defunctioned; however, this finding was not mirrored by a significant difference in ileal pouch failure in this subgroup.

Conclusions: Restorative proctocolectomy without a diverting ileostomy resulted in functional outcomes similar to those of surgery with proximal diversion but was associated with an increased risk of anastomotic leak. Diverting ileostomy should be omitted in carefully selected patients only.

STUDY SELECTION

A MEDLINE, EMBASE, Ovid, and Cochrane database search was performed on all studies published from 1978 through July 15, 2005, comparing RPC with and without covering ileostomy. The following MeSH search headings were used: ‘restorative proctocolectomy, ileal pouch anal anastomosis/ileal pouch anal anastomosis, ileal pouch, ileostomy, and comparative’. These terms, and their combinations, were also used as text words. The “related articles” function was used to broaden the search, and all abstracts, studies, and citations scanned were reviewed. References of the articles acquired were also searched by hand. No language restrictions were made. The latest date for this search was the second week of July 2005.

DATA EXTRACTION

Three reviewers (G.K.W.-P., R.E.L., and H.S.T.) independently extracted the following from each study: first author, year of publication, study population characteristics, study design, inclusion and exclusion criteria, matching criteria, number of subjects operated on with and without stoma formation, male to female ratio, operative outcomes, adverse events, and functional outcomes.

INCLUSION AND EXCLUSION CRITERIA

To be included in the analysis, studies had to (1) compare RPC with and without covering ileostomy; (2) report on at least 1 of the outcome measures mentioned in the next section; and (3) clearly document the technique as ‘with covering ileostomy’ or ‘without covering ileostomy.’ When 2 studies were reported by the same institution and/or authors, either the more recent publication or the one of higher quality was included in the analysis.

Studies were excluded from the analysis if (1) the outcomes of interest were not reported for the 2 techniques; (2) it was impossible to extract or calculate the necessary data from the published results; or (3) there was considerable overlap between authors, centers, or patient cohorts evaluated in the published literature.

OUTCOMES OF INTEREST AND DEFINITIONS

The following outcomes were used to compare the RPC without covering ileostomy (no-stoma) group with the RPC with covering ileostomy (stoma) group:

1. **Operative outcomes** included total operative time excluding that for subsequent procedures to close the ileostomy, and length of postoperative hospital stay.
2. **Short-term adverse events** included anastomotic leak, defined as the presence of intestinal contents or contrast medium in the pelvis or pelvic drain after pouch-anal anastomosis, pouch-related septic complications, and perianal sepsis.
3. **Reoperation** was defined as subsequent surgery because of complications after RPC and was divided into those requiring a second laparotomy (owing to anastomotic leakage, abdominal sepsis, or obstruction) and other surgery (including operations for incisional and parastomal herniation and perineal procedures for abscess and fistula).
4. **Long-term adverse events** included pouch failure, defined as pouch excision or indefinite proximal diversion; pouchitis diagnosed by clinical, endoscopic, and/or histologic criteria; anastomotic stricture; and postoperative bowel obstruction, managed conservatively or operatively.
5. **Functional outcomes** included the frequency of defecation per 24 hours, soiling, anal incontinence, and the need for antidiarrheal medication.

STATISTICAL ANALYSIS

Meta-analysis was performed in line with recommendations from the Cochrane Collaboration and the Quality of Reporting of Meta-analyses guidelines. Statistical analysis for dichotomous variables was carried out with the odds ratio (OR) used as the summary statistic. This ratio represents the odds of an adverse event occurring in the no-stoma group compared with the stoma group. An OR of less than 1 favors the no-stoma group, and the point estimate of the OR is considered statistically significant at the P < .05 level if the 95% confidence interval (CI) does not include the value 1. For continuous variables, such as operative time or length of stay, statistical analysis was carried out with the weighted mean difference used as the summary statistic.

The Mantel-Haenszel method was used to combine the OR for the outcomes of interest by means of a “random-effects” meta-analytical technique. In a random-effects model, it is assumed that there is variation between studies and the calculated OR thus has a more conservative value. In surgical research, meta-analysis using the random-effects model is preferable because patients operated on in different centers have varying risk profiles and selection criteria for each surgical technique. Haldane’s correction was used for studies containing a 0 in 1 cell for the number of events of interest in 1 of the 2 groups. These “0 cells” created problems with the computation of ratio measure and its standard error of the treatment effect. This was resolved by adding the value 0.5 in each cell of the 2 × 2 table for the study in question. If there were no events for both no-stoma and stoma groups for an outcome of interest, then the study was discarded from the meta-analysis of that outcome.

The quality of the studies was assessed by using the Newcastle-Ottawa Scale with some modifications to match the needs of this study. The quality of the studies was evaluated by examining 3 items: patient selection, comparability of the 2 study groups, and assessment of outcome. Studies achieving 6 or more stars (from a maximum of 12) were considered to be of higher quality.

Three strategies were used quantitatively to assess heterogeneity. First, data were reanalyzed with the use of both random- and fixed-effects models. Second, graphical exploration with funnel plots was used to evaluate publication bias (results not shown). Third, sensitivity analysis was undertaken with the use of subgroups of studies with 100 or more patients, high-quality studies, and those published in or since 1995. Sensitivity analysis aimed to test the robustness of the conclusions drawn from meta-analysis by changing the criteria used for inclusion.

Analysis was conducted by using the statistical software Intercooled Stata version 8.0 for Windows (StataCorp, College Station, Texas) and Review Manager Version 4.2 (The Cochrane Collaboration, Software Update, Oxford, England).

RESULTS

STUDIES SELECTED

The literature search identified 21 studies that met the inclusion criteria. Four were excluded from further analysis; 2 did not contain extractable comparative data and 2 were excluded because of potential overlap with another included article from the same institution. The
remaining 17 studies were included for further analysis and comprised 1 randomized controlled trial, 5 retrospective studies, and 11 prospective nonrandomized trials. One trial combined both a retrospective and a prospective element in the study design.

A total of 1486 patients were included, with 721 undergoing formation of a diverting ileostomy at the time of RPC and 765 undergoing surgery without proximal diversion. Eight studies commented on previous colectomy, with 321 of 778 patients (41.3%) having previously undergone total or subtotal colectomy. The characteristics of the included studies are summarized in Table 1. Fourteen studies were matched for age, sex, diagnosis, previous colectomy, surgeon, systemic corticosteroid therapy, colitis activity index, pouch design and anastomotic technique, follow-up.

The characteristics of the included studies are summarized in Table 1. Fourteen studies were matched for age, sex, diagnosis, previous colectomy, surgeon, systemic corticosteroid therapy, colitis activity index, pouch design and anastomotic technique, follow-up. There were 688 males (51.0%) from 15 studies, and median follow-up ranged from 2 to 20 months across the studies. Mean age at surgery ranged from 13.8 to 37 years in the stoma group and 10.4 to 39 years in the no-stoma group. Mean age at surgery ranged from 13.8 to 37 years in the stoma group and 10.4 to 39 years in the no-stoma group.

Table 1. Demographic Features of Studies Reporting Comparative Outcomes for Patients Undergoing Restorative Proctocolectomy With or Without Covering Ileostomy

<table>
<thead>
<tr>
<th>Source</th>
<th>Study Type</th>
<th>Matchinga</th>
<th>Quality Scoreb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Everett and Pollard, 1990</td>
<td>PNR</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Matikainen et al, 1990</td>
<td>PNR</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Galandiuk et al, 1990</td>
<td>PNR</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Cohen et al, 1992</td>
<td>PNR</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Grobber et al, 1992</td>
<td>RCT</td>
<td>6</td>
<td>6</td>
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<tr>
<td>Tjandra et al, 1993</td>
<td>Retro</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Gulberg et al, 1995</td>
<td>Retro/PNR</td>
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<td>4</td>
</tr>
<tr>
<td>Williamson et al, 1997</td>
<td>PNR</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Hainsworth and Bartolo, 1998</td>
<td>Retro</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Antos et al, 1999</td>
<td>Retro</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Dolpin et al, 1999</td>
<td>PNR</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Heuschen et al, 2001</td>
<td>PNR</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Lepisto et al, 2002</td>
<td>Retro</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Gorline et al, 2003</td>
<td>PNR</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Kiene et al, 2003</td>
<td>PNR</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Ikeuchi et al, 2005</td>
<td>PNR</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Swenson et al, 2005</td>
<td>Retro</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

Abbreviations: NS, no stoma; PNR, prospective nonrandomized study; RCT, randomized controlled trial; Retro, retrospective study; S, stoma.
a Matching criteria: 1, age; 2, sex; 3, diagnosis; 4, previous colectomy; 5, surgeon; 6, systemic corticosteroid therapy; 7, colitis activity index; 8, pouch design and anastomotic technique; 9, follow-up.
b On a scale of 1 (lowest quality) to 12 (highest quality).

PERIOPERATIVE COMPLICATIONS

All of the included studies reported on 1 or more perioperative complications. The results of these are summarized in Table 2, together with the functional outcomes. Sixty-five of 579 patients (11.2%) required a second laparotomy for adverse postoperative events, whereas 29 of 149 patients (19.5%) required other surgical procedures for postoperative adverse events (including lower-limb compartment syndrome, presacral abscess, and parastomal abscess). There was no significant difference between the 2 groups (OR, 1.31; 95% CI, 0.54-3.15; P = .55; and OR, 0.49; 95% CI, 0.19-1.28; P = .14, respectively).

Anastomotic leakage from either the pouch-anal anastomosis or the pouch itself occurred in 72 of 1017 patients (7.1%). This complication was significantly more common in the group without a stoma at the time of pouch surgery (OR, 2.37; 95% CI, 1.39-4.04; P = .002). Pouch-related sepsis occurred in 120 of 1161 patients (10.3%), but this did not reach significance between the 2 groups (OR, 1.38; 95% CI, 0.91-2.07; P = .13).

A stricture developed at the pouch-anal anastomosis in 46 of 446 patients (10.3%). This was significant, favoring the no-stoma group (OR, 0.31; 95% CI, 0.10-0.98; P = .045). Failure of the ileal pouch occurred in 26 of 832 patients (3.1%) from 11 studies and was less common in the no-stoma group (OR, 0.30; 95% CI, 0.12-0.74; P = .009).

FUNCTIONAL OUTCOMES

Functional outcomes were assessed at least 12 months after pouch surgery in both groups. Twenty-four–hour
frequency of defecation was reported in 7 studies, with a mean difference of 0.42 (95% CI, −0.13 to 0.98) stools per 24 hours. A weighted mean difference of 0.42 (95% CI, −0.98 to 0.13) was shown to favor the no-stoma group, but this did not reach statistical significance (P = .14).

Soothing was reported in 8 studies of 591 patients, with incontinence in 5 studies of 388 patients, and the use of antidiarrheal medication in 3 studies comprising 185 patients. There were no significant differences between the 2 groups in the number of patients developing pouchitis (OR, 1.01; 95% CI, 0.54-1.90; P = .97). The development of pelvic sepsis after pouch surgery did not demonstrate a significant difference between the 2 groups when all of the included studies were considered (P = .86). However, on sensitivity analysis, the difference becomes statistically significant (P = .04) favoring the ileostomy group, with no significant heterogeneity between the studies (P = .53) in studies published since 1995.

From the overall analysis, it appeared that the development of an anastomotic stricture at the level of the pouch-anal anastomosis might be decreased by omitting a proximal stoma (OR, 0.31; 95% CI, 0.10-0.98; P = .045). However, when this outcome was reviewed in sensitivity analysis, it no longer held statistical significance at the 95% level (Table 3).

**SEXUAL FUNCTION**

Only 1 study reported outcomes on sexual function, and these were combined with urologic dysfunction. In that study, a total of 13 patients (7.6%) developed urogenital dysfunction from a group of 171. There was no significant difference between the 2 groups (OR, 0.34; 95% CI, 0.07-1.59; P = .17).

**SENSITIVITY ANALYSIS**

Sensitivity analysis was performed by comparing studies of high quality (≥6 stars), studies with 100 patients or more, and studies published since 1995 (Table 3). The.

| Table 2. Results of Meta-analysis Comparing Stoma vs No Stoma for Patients Undergoing Restorative Proctocolectomya |
|-------------------------------------------------|---------------------------------|---------------------------------|-------------------------------|-------------------------------|-----------------|-----------------|-----------------|
| Outcome of Interest                             | No. of Studies                  | Total No. of Patients            | No. of Patients Affected       | OR/WMD (95% CI)               | P Value | HG P Value |
| Operative details                               |                                 | NA                              | NA                            | −17.55 (−53.92 to 18.82)      | .34     | <.001       |                 |
| Operative time, min                             | 6                               | 320                             | 315                           | NA                            | NA      | NA          |                 |
| Length of stay, d                               | 10                              | 507                             | 496                           | NA                            | NA      | NA          |                 |
| Short-term adverse events                       |                                 |                                 | NA                            | −1.87 (−0.41 to 2.77)         | .15     | <.001       |                 |
| Anastomotic leak                                | 11                              | 556                             | 461                           | 52                            | 20      | NA          |                 |
| Pouch-related sepsis                            | 14                              | 567                             | 594                           | 64                            | 56      | NA          |                 |
| Perianal sepsis                                 | 5                                | 256                             | 192                           | 13                            | 3       | NA          |                 |
| Reoperation                                     | 8                                | 316                             | 263                           | 40                            | 25      | NA          |                 |
| Long-term adverse events                        | 4                                | 79                              | 70                            | 11                            | 18      | NA          |                 |
| Functional outcomes                             |                                 |                                 | NA                            | −1.87 (−0.41 to 2.77)         | .15     | <.001       |                 |
| Frequency of defecation per 24 h                | 7                                | 244                             | 215                           | NA                            | NA      | NA          |                 |
| Soiling                                         | 8                                | 270                             | 287                           | 41                            | 51      | NA          |                 |
| Anal incontinence                               | 5                                | 196                             | 192                           | 2                             | 5       | NA          |                 |
| Antidiarrheal medication use                    | 3                                | 89                              | 96                            | 35                            | 59      | NA          |                 |

Abbreviations: CI, confidence interval; HG, heterogeneity; NA, not applicable; NS, no stoma; OR, odds ratio; S, stoma; WMD, weighted mean difference.

a Statistically significant results are shown in boldface type.

b Weighted mean difference. Negative values favor no stoma; positive values favor stoma.

c Odds ratio. Values less than 1 favor no stoma; values greater than 1 favor stoma.

Many groups have published evidence in favor of performing the entire operation of RPC without any form of protecting ileostomy in the belief that the complication rate is reduced. Some maintain that, provided certain perioperative protocols are followed, such as placement of a 30-F catheter in the pouch for 7 to 10 days and maintenance with intravenous fluids until the ileus has resolved, the risk of leakage from the ileoanal anastomosis is no greater than when using a covering loop ileostomy. Gorfine et al at Mount Sinai Hospital, New York, New York, strongly supported avoidance of loop ileostomy. In their nonrandomized comparison, the laparotomy rate for small-bowel obstruction was reduced from 10% to 1%, but leak rates and sepsis were comparable.24

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mediate use of the anal sphincter may avoid a period of
that (1) only 1 hospital admission is needed; (2) the im-
quent laparotomy in the nondiverted group.21,35,38,42
sion of ileostomy, all reporting a higher rate of subse-
sure to omit a covering ileostomy.41
of stapled ileoanal anastomosis has further encouraged
morbidity from ileostomy closure. The now-widespread use
that morbidity is not increased by avoiding fecal diver-
grounds that (1) closure of a loop ileostomy has mini-
not used. The proponents of a covering ileostomy assert
reporting that rates of ileoanal anastomotic leakage
strongly defended their policy of pouch diversion,
logical benefit of living for a short time with a
continuity is restored; and (4) the patient has the psy-
vic sepsis; (3) the function of the anal sphincter and
mal morbidity; (2) the consequences of leakage from a
disuse atrophy; (3) the risk of pouch ischemia is re-
duced, because a proximal loop ileostomy may compo-
mise the blood flow to the distal small bowel; (4) diver-
slations, which could impair ileal transport mechanisms,
be avoided; and (5) the complications of ileostomy
closure are avoided.

The present meta-analysis reviewed 17 independent
studies including a total of 1486 patients. The purpose
of each study was to determine outcomes after procto-
colectomy with or without defunctioning ileostomy. Ana-
lytical techniques were used to identify any significant
differences in these outcomes and therefore to add a quan-
titative assessment of the policy of selective omission of
a stoma in these patients. None of the included studies
in this analysis provided details on intention to treat be-
cause the decision to undertake an ileostomy was usu-
ally made preoperatively. We were therefore unable to
account for this during the analysis.

The incidence of anastomotic leakage was clearly
greater in the group without a protective ileostomy, and
further subgroup analysis also showed a significant in-
crease in pouch-related sepsis in the nonprotected group.
Perianal sepsis rates, however, were no different in the
2 groups. It is important to note that the only random-
ized trial52 showed no difference between groups regard-
ing anastomotic leakage and pelvic sepsis. The patient
groups in that study varied somewhat from the other 16
in that all patients were suitable for either technique ow-
ing to the exclusion of 2 subgroups, and, furthermore,
only 45 patients were included.

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Table 3. Effect of Sensitivity Analysis on Meta-Analysis Comparing Stoma vs No Stoma for Patients
Undergoing Restorative Proctocolectomy

<table>
<thead>
<tr>
<th>Outcome of Interest</th>
<th>Total No. of Patients</th>
<th>No. of Patients Affected</th>
<th>OR/WMD (95% CI)</th>
<th>P Value</th>
<th>HG</th>
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<td>NS</td>
<td>S</td>
<td>NS</td>
<td>S</td>
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<td>High-quality studies, ≥ 6 stars</td>
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<td>179</td>
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<td>10</td>
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<td>381</td>
<td>375</td>
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</table>

Abbreviations: See Table 2.

a Statistically significant results are shown in boldface type.
b Odds ratio. Values less than 1 favor no stoma; values greater than 1 favor stoma.
c Weighted mean difference. Negative values favor no stoma; positive values favor stoma.

Nonrandomized comparisons of loop ileostomy and
no ileostomy for sutured ileoanal anastomosis indicate
that morbidity is not increased by avoiding fecal diver-
sion, and both highlight the potentially increased mor-
bidity from ileostomy closure. The now-widespread use
of stapled ileoanal anastomosis has further encouraged
surgeons to omit a covering ileostomy.41

Several groups, however, remain advocates for inclu-
ion of ileostomy, all reporting a higher rate of subse-
quent laparotomy in the nondiverted group.21,35,38,42
Tjandra et al43 at the Cleveland Clinic (Cleveland, Ohio)
strongly defended their policy of pouch diversion,
reporting that rates of ileoanal anastomotic leakage
and pelvic sepsis were only 4% in the defunctioned
group compared with 14% when loop ileostomy was
not used. The proponents of a covering ileostomy assert
that it is safer to use a defunctioning ileostomy on the
grounds that (1) closure of a loop ileostomy has min-
imal morbidity; (2) the consequences of leakage from a
suture-line dehiscence in the pouch or from the anasto-
mosis are reduced, thereby minimizing the risk of pel-
vic sepsis; (3) the function of the anal sphincter and
ileal mucosa is allowed to recover before intestinal
continuity is restored; and (4) the patient has the psy-
chosocial benefit of living for a short time with a
stoma so that the advantages of the operation can be
fully appreciated.21,24,35,38
The incidence of small-bowel obstruction was not significantly different between the stoma and no-stoma groups in this meta-analysis. It has been previously shown that formation of a loop ileostomy at the time of ileal pouch surgery was associated with an increase in the incidence of small-bowel obstruction.44 One of these studies found that rotation of the ileostomy through 180° at the time of formation was the only significant factor on regression analysis.45 This practice has since been largely abandoned. More recently, the use of hyaluronic acid films, such as Seprafilm (Genzyme Corp, Cambridge, Massachusetts), has been shown to reduce the incidence of intra-abdominal adhesions and acute small-bowel obstruction.46 None of the included studies commented on these factors, which may otherwise reduce the incidence of small-bowel obstruction in patients who underwent temporary proximal diversion of the ileal pouch.

Pouch failure, defined as pouch excision or indefinite diversion, appeared more likely to occur in patients who had a protective stoma. This observation seems to contradict the lower rate of early postoperative sepsis in the ileostomy group because subsequent failure was most often due to pelvic sepsis and anastomotic leakage. When analyzed within the different subgroups, however, the difference between the 2 groups became insignificant. It is also possible that some patients may have chosen for various reasons not to have their stomas reversed. We were not able to assess the effect of these decisions from the analysis.

Despite the foregoing significant differences in outcome, the rate of reoperation, whether a second laparotomy or another procedure, was no different in either group. There was insufficient information on the indications for reoperation to analyze any possible differences that might have existed. Similarly, pouchitis and bowel obstruction at any point were no more likely to occur in either group.

Of the 5 studies commenting on anastomotic strictures, only 1 described the clinical management.22 In that study, 3 of 102 patients were reported as having an anastomotic stricture, of whom 2 were treated by pouch advancement and 1 by dilation. Two further studies commented on the degree of stenosis at the anastomosis.26,28 The remaining 2 studies did not comment as to whether the stricture was clinically significant. It is also possible that some patients may have chosen for various reasons not to have their stomas reversed. We were not able to assess the effect of these decisions from the analysis.

With regard to functional outcomes, the frequency of defecation per 24 hours, the incidence of incontinence, and the use of antidiarrheal medication were no different in either group. Operative time and length of stay were not significantly different between the groups when readmission for stoma closure was excluded.

The meta-analysis allowed published data from a number of institutions worldwide to be pooled, enabling the number of patients within the study population to be maximized. This has improved statistical power reducing the type II error that is characteristic of small comparative studies. A large randomized controlled trial would be difficult to justify. The study suggests that the exclusion of a protective stoma may be appropriate only for a specific and possibly much smaller set of patients within the total population of patients undergoing RPC. This group is likely to include patients in whom the ileal pouch may be technically easier to perform, such as in young women who are not taking corticosteroids and who have no additional comorbidities, and for noninflammatory conditions such as neoplastic transformation.

In conclusion, the present meta-analysis supports the use of a protective ileostomy in view of the improvement in short-term outcomes, particularly sepsis. However, the omission of a covering ileostomy may still be justified in patients defined as low risk. The definition of low risk is a point for further discussion and quantitative analysis.

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Correspondence: Paris P. Tekkis, MD, FRCS, Department of Biosurgery and Surgical Technology, St Mary’s Hospital, 10th Floor, QEQM Wing, Praed Street, London W2 1NY, England (p.tekkis@imperial.ac.uk).

Author Contributions: Study concept and design: Weston-Petrides, Heriot, Nicholls, and Fazio. Acquisition of data: Weston-Petrides. Analysis and interpretation of data: Weston-Petrides, Lovegrove, Tilney, Heriot, Nicholls, Mortensen, and Tekkis. Drafting of the manuscript: Weston-Petrides, Lovegrove, Tilney, and Heriot. Critical revision of the manuscript for important intellectual content: Weston-Petrides, Heriot, Nicholls, Mortensen, Fazio, and Tekkis. Statistical analysis: Tekkis. Obtained funding: Tilney. Study supervision: Lovegrove, Tilney, Heriot, Nicholls, Mortensen, Fazio, and Tekkis.

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