Hypothesis: A model could be developed to identify patients who can safely undergo restorative proctocolectomy (RPC) without proximal diversion.

Design: Logistic regression analysis was used to identify independent factors favoring omission of ileostomy at the time of RPC. A propensity nomogram was developed and validated using measures of calibration, discrimination, and subgroup analysis.

Setting: Two tertiary referral centers.

Patients: A total of 4013 patients undergoing RPC between January 1977 and December 2005 were included in the study sample.

Main Outcome Measure: The decision to omit loop ileostomy at the time of RPC.

Results: After study group exclusions, proximal diversion was performed in 3196 of 3733 patients (85.6%) undergoing RPC; 45.4% of 3733 patients were women. The mean (SD) age at surgery was 37.4 (12.8) years. Ulcerative colitis was the indication for RPC in 2304 patients (61.7%) and familial adenomatous polyposis in 364 patients (9.8%), and a J pouch was performed in 2657 patients (71.2%). The following were found to be associated with ileostomy omission: stapled anastomosis (odds ratio [OR], 6.4), no preoperative corticosteroid use (OR, 3.2), familial adenomatous polyposis diagnosis (OR, 2.6), cancer diagnosis (OR, 3.4), female sex (OR, 1.6), and age at surgery younger than 26 years (OR, 2.1) (P < .01 for all). The model discriminated well (area under the receiver operating characteristic curve, 74.9%), with no significant differences between observed and expected outcomes (P = .49). Omission of proximal diversion demonstrated no significant effect on postoperative adverse events, although it was associated with a 2-day increase in the median length of hospital stay (P < .01).

Conclusion: Incorporation of a 5-point nomogram in the preoperative assessment of patients undergoing RPC may aid clinicians in identifying a select group of patients who may be candidates for ileostomy omission during RPC.

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FORMATION OF AN ILEOANAL pouch has become the procedure of choice for patients with ulcerative colitis and familial adenomatous polyposis requiring proctocolectomy.1 Since its original description,2 several refinements have been made in the techniques of pouch construction and ileal pouch–anal anastomosis.3,4 More recently, controversy has surrounded the undertaking of a 1-stage procedure with omission of a proximal diverting ileostomy.5 Restorative proctocolectomy (RPC) is known to be associated with a risk of anastomotic separation in approximately 6.9% and pelvic sepsis in 7.2% of cases,6 and it has been shown that both of these factors are independent predictors of ileal pouch failure.8 Some surgeons consider that performing a diverting ileostomy at the time of RPC may reduce the rate of these complications.9,10 Investigations have considered outcomes following ileal pouch formation in which a proximal stoma was omitted, and findings of a recent meta-analysis11 suggested that, while the incidence of anastomotic leak was higher when a stoma was omitted, the rates of anastomotic stenosis were reduced in that group. Arguments against routine use of a diverting ileostomy include the need for a subsequent surgical procedure to restore bowel continuity, an additional hospital admission, further reoperative morbidity,12,13 physiological disturbance,14 and psychological difficulties associated with a stoma.15,16

While some authors have shown that factors such as preoperative corticosteroid use17,18 and a hand-sewn anastomosis19 were associated with unacceptably
high rates of complications if a diverting ileostomy was omitted, to date no universally accepted recommendations are established regarding which patients may be suitable for ileostomy omission during RPC. The objectives of this study were (1) to identify factors in favor of omitting ileostomy in RPC, (2) to develop and validate a model to aid preoperative counseling of patients, and (3) to provide a nomogram as a graphical means of application and interpretation of the model in the clinical setting.

METHODS

DATA SOURCES

The institutional review boards for the Cleveland Clinic, Cleveland, Ohio, and the North West London Hospitals NHS Trust, London, United Kingdom, approved the merging of ileal pouch databases from 2 large tertiary referral centers to create a series of 4013 patients undergoing surgery over a 28-year period between January 1977 and December 2005. A comprehensive data set was available comprising patient demographics, preoperative assessment, and surgical treatment and postoperative course, including pathologic findings, complications, and functional outcomes.

STUDY DESIGN

All patients who had operative details entered in the database were considered suitable for inclusion in the study sample. The study population was divided into the following 2 groups: those undergoing RPC with ileostomy and those undergoing surgery without ileostomy.

EXCLUSIONS

Patients for whom there was no documentation of ileostomy use were excluded from the analysis. Patients operated on before January 1, 1990, were excluded from development of the logistic regression model, because ileostomy omission at the time of RPC was infrequent before this date. In addition, patients with a diagnosis of Crohn disease were excluded from the model development because their inclusion would not be applicable to current practice.

STUDY END POINT AND PREDICTORS

The primary outcome of interest was the decision to perform RPC with or without ileostomy. Predictors were considered those factors that would normally be present or planned for before the patient underwent surgery so that the model may be of use in preoperative counseling of patients. Preoperative factors that were considered included age, sex, diagnosis, pathologic anal condition (perianal abscess, fistula in ano, fissure in ano, or significant hemorrhoids or skin tags), comorbidities (cardiac disease, renal disease, respiratory disease, or diabetes mellitus [separately and their cumulative number]), and medication use at the time of ileal pouch formation (corticosteroids or other immunosuppressants). Intraoperative factors that would normally be planned in advance, including the type of pouch design (I, S, or W) and whether a hand-sewn or stapled ileal pouch–anal anastomosis would be performed, were also considered. Secondary end points included anastomotic stricture, pouch failure (defined as excision of the pouch or indefinite proximal diversion), pelvic sepsis (defined as the presence of purulent material or abscess formation within the pelvis), and anastomotic separation rates (defined as the presence of contrast medium of fecal matter at the level of the anastomosis or ileal pouch during radiologic examination or reoperation).

STATISTICAL ANALYSIS

Patient characteristics (categorical variables) were compared between the 2 groups using Pearson product moment correlation χ² test and the Fisher exact test. Independent-samples t test was used to compare age at surgery, and Mann-Whitney test was used to compare total duration of follow-up. Univariate logistic regression analysis was performed to identify factors that may be significant predictors of ileostomy omission. Factors with univariate P < .25 and those thought to be of clinical significance were included in the multivariate logistic regression analysis. Only factors that remained significant within the multivariate model were retained to produce the final predictive nomogram.

VALIDATION OF THE REGRESSION MODEL

The model was internally validated by dividing the data set into 2 distinct sets. The regression estimates were generated on a random sample of 60% drawn from the study populations, and data on the remaining 40% were used to test the performance of the multivariate model. The performance of the model was evaluated by measures of calibration, discrimination, and subgroup analysis.

Calibration, or goodness of fit, was assessed using Hosmer-Lemeshow goodness-of-fit statistic. This demonstrated the ability of the nomogram to assign the correct predicted outcome to individual patients. To obtain this statistic, the probability of undergoing RPC without ileostomy for each patient based on the model was computed. These were ranked into 8 equal groups (octiles) of ascending likelihood, and the expected and observed numbers of outcomes in each octile were then statistically evaluated.

Discrimination was evaluated by measuring the area under the receiver operating characteristic curve. Values ranging from 70% to 80% represented adequate discrimination, and those exceeding 80% represented very good discrimination.

Subgroup analysis was performed by comparing the observed and expected outcomes across subgroups of various pouch designs. Statistical software packages were used to develop the risk model (SPSS, version 14 for Windows; SPSS Inc, Chicago, Illinois; and STATA SE, version 9.0 for Windows; StataCorp LP, College Station, Texas).

RESULTS

A total of 4013 patients were identified who underwent RPC over the study period. Documentation of the presence or absence of an ileostomy was unavailable in 280 patients (7.0%), all of whom underwent RPC before 1990. Therefore, analysis was performed on 3733 patients (93.0%), of whom 537 (14.4%) received no proximal diversion and 3196 (85.6%) received a temporary ileostomy at the time of pouch surgery. The study population comprised 2650 patients (71.0%) from the Cleveland Clinic, Cleveland, Ohio, and 1083 patients (29.0%) from St Mark’s Hospital, Middlesex, United Kingdom. From this patient population, 3043 patients have undergone RPC since January 1, 1990, of whom 2549 (83.8%) had an ileostomy fashioned and 494 (16.2%) did not.
A total of 2304 patients (61.7%) underwent RPC with a histologic diagnosis of ulcerative colitis, 364 (9.8%) with familial adenomatous polyposis, 769 (20.6%) with indeterminate colitis, 123 (3.3%) with Crohn disease, and 76 (2.1%) with cancer (data were missing for 149 patients [5.7%]). A total of 1522 patients (40.8%) were using corticosteroid medication at the time of primary ileal pouch surgery. Demographic characteristics of patients in the groups with and without ileostomy are summarized in Table 1.

Complications occurring in the 2 groups are summarized in Table 2. A total of 139 patients (3.7%) had perioperative hemorrhage, which was significantly more common in the ileostomy group (4.0% vs 2.0%, P = .03). Incidences of small-bowel obstruction and anastomotic stricture were significantly higher among patients receiving an ileostomy. Anastomotic stricture occurred among 583 patients (18.2%) in the group with ileostomy compared with 49 patients (9.1%) in the group without ileostomy (P < .001). Small-bowel obstruction occurred among 607 patients (19.0%) in the group with ileostomy compared with 58 patients (10.8%) in the group without ileostomy (P < .001). Incidences of anastomotic leak, pelvic sepsis, fistulation, and pouch failure did not differ significantly between the 2 groups. Postoperative length of stay was longer in the ileostomy group by 2 days, a finding that was statistically significant (P < .01).

Univariate analysis of potential predictors of stoma omission identified the following 8 factors (Table 3): age, sex, preoperative diagnosis, hepatobiliary disease, steroid therapy, resection type, pouch type, and pouch-anal anastomosis type. These were then included in a multivariate analysis. Those potential predictors no longer retaining statistical significance were excluded, and the final predictive model is summarized in Table 4. Patients with a stapled ileal pouch–anal anastomosis were 6.4 times more likely not to have an ileostomy than those with a hand-sewn anastomosis, and patients not using (63.4%) undergoing a stapled anastomosis (data were missing for 212 patients [5.7%]).
corticosteroid medication were 3.2 times less likely to have proximal diversion at the time of RPC. Younger patients (age younger than 26 years) were 2.08 times more likely to avoid an ileostomy than those older than 49 years. In generating the model, first-order interactions between the independent predictors of outcomes were considered, but none exceeded the significance threshold for inclusion in the model. The area under the receiver operating characteristic curve obtained using the multifactorial model was 74.9% (95% confidence interval, 72.2%–77.5%). The calibration plot of observed vs expected outcomes for stoma omission during primary RPC is shown in Figure 1, with good agreement between the observed and predicted outcomes for stoma omission (Hosmer-Lemeshow goodness-of-fit C statistic, 5.45; P = .49).

Subgroup analysis of the model is shown in Figure 2, which illustrates the observed and predicted stoma omission rates for each of 3 pouch designs used. In each of 3 subgroups, the predicted outcomes lie within the observed range, indicating good agreement between predicted and observed rates of ileostomy formation across pouch designs.

A nomogram that allows ready conversion of scored points to a predicted probability for omission of diverting ileostomy is shown in Figure 3. This allows the surgeon to read off the top “Points” scale the corresponding points for each of the factors shown on the left-hand side. The total score is calculated by adding these together, and this score can be converted to a predicted probability using the bottom scale. Using the predictive nomogram, a male patient who is older than 49 years, using corticosteroids, diagnosed as having ulcerative colitis, and undergoing a hand-sewn ileal pouch–anal anastomosis has a total score of 0 and would have a 0.0% probability of ileostomy omission from the surgeons in this group. In contrast, a female patient who is younger than 26 years, not using corticosteroids, diagnosed as having colon cancer, and undergoing a stapled ileal pouch–anal anastomosis has a total score of 56 and would have a 60.5% probability of ileostomy omission.

**COMMENT**

Restorative proctocolectomy without proximal ileostomy was first described by Metcalf et al in 1986, and outcomes published by proponents are generally favorable in selected cases. The present study identified factors that were associated with the decision by surgeons from 2 tertiary referral colorectal centers to omit the diverting loop ileostomy following RPC. Most important, this decision was associated with no increase in adverse outcomes among the patients with ileostomy omission. Rates of pouch failure were similar between the groups, and this is of key importance, as pouch survival is a long-term outcome measure that is of significant importance to the patient and the surgeon. In a previously published predictive model of ileal pouch failure, the decision to include ileostomy was not found to be a significant risk factor.

The results of the present study represent a consensus view of surgeons from 2 specialist international colorectal centers as to the circumstances in which the benefits of loop ileostomy omission following RPC outweigh the risks. The major advantage of this series is the many patients included, allowing sufficient data for the creation of a predictive model when previous attempts at individual institutions have not been feasible.22 The results may be applicable to a range of possible clinical scenarios. The nomogram presented herein may be used by individual surgeons to assess the appropriateness of stoma omission for a given patient. Clearly, the decision in any given case would depend on the experience and attitude of the operating surgeon about stoma omission, but just as important is the opinion of the patient and his or her prefer-
ence to avoid a temporary stoma. A potential limitation of the predictive nomogram is that it was developed predominantly among patients operated on in the United States, which could potentially bias its predictions toward institutional strategies specific to the center where it was developed. Although the model was validated among patients from Europe and the United States, its applicability requires further external validation at institutions different from those where this model was developed.

While the ideal tool for determining the best method of treatment is a randomized controlled trial, such a trial in this setting would be difficult to conduct for several reasons, such as difficulties in accruing a sufficient number of patients to show any statistical difference. Stoma omission may not be a viable option in some patients because of safety issues, and it would be unethical to randomize the “at risk” patient undergoing RPC.

The benefits of RPC without ileostomy include reduced overall length of hospitalization, fewer operative procedures, and avoidance of the psychological effects of stoma formation. Marked difficulty in stoma creation can be experienced, especially in obese patients, and the effects of a high-output stoma and skin complications are well described. Although ileos-
Some authors have attributed to internal herniation around the time of their original procedure should not be underestimated. The present study supports the findings of the necessity of stoma formation in a patient already undergoing emergency surgery because of a complication, but a recent series showed no significant differences in rates of emergent laparotomy between groups with and without ileostomy, and only 50% of those experiencing leaks in the group without ileostomy required stoma formation. This benefit did not extend to improved ileal pouch survival, in tandem with reduced stoma-related complications.

Advocates of routine ileostomy inclusion argue that omission of a stoma is associated with an increased risk to life and that, should a leak develop at any anastomoses performed in ileal pouch construction, the risk of serious sequelae is reduced owing to diversion of the fecal stream. In contrast to the present series, Tjandra et al found the incidence of septic complications to be increased among patients in whom ileostomy was omitted and identified corticosteroid use as an additional risk factor for complications if a stoma is omitted. A leak in a patient with stoma omission requires prompt intervention, but a recent series showed no significant differences in rates of emergent laparotomy between groups with and without ileostomy, and only 50% of those experiencing leaks in the group without ileostomy required stoma formation. Despite this, the psychological effects of stoma formation in a patient already undergoing emergency surgery because of a complication of their original procedure should not be underestimated. The potential technical difficulty associated with fashioning a stoma in patients who have recently undergone laparotomy is also considerable.

However, among nonrandomized patients undergoing RPC with or without ileostomy, there is potential for bias in the reported outcomes. Patients deemed to be at high risk would invariably have an ileostomy placed at the time of RPC, and this may lead to a reduction in the complication rate in this group. However, we believe that, if selection of patients for ileostomy omission is adequate, this should not lead to an increase in the rate of complications.

In an era of increased accountability for surgical outcomes, involvement of the patient at all levels of the surgical decision-making process is paramount. As well as forming a tool to aid individual surgeons in their decisions about the appropriateness of avoiding a stoma, this model aids the consent process. By considering only preoperative variables or those on which the surgeon is likely to be able to decide in the surgical planning phase, the score can be calculated before surgery, and the probability of surgery being performed without a stoma, with no excess risk of pouch-related complications, can be determined. By doing so, the rationale as to why the surgeon may believe that stoma omission carries an unacceptable risk can be quantified and illustrated for the patient.

While all surgeons performing RPC hold views on the safety of ileostomy omission, the use of a model, such as that described herein, should allow better selection of patients for such a strategy. Although this model does not provide absolute quantification of complication risk among patients in whom a 1-stage surgical strategy is used, it allows determination of the strategy that would have been used in a given clinical scenario by the surgeons whose patients comprise the present study sample. Most important, these decisions are made in the context of a patient series in which adverse events were lower in the group with stoma omission. Future analysis of prospectively collected data that incorporate the decision to omit stoma formation in predictive models of adverse outcomes following RPC may allow more detailed quantification of preoperative risk for potential surgical candidates. In its present form, the model will aid surgical decision making and will give patients and clinicians a better understanding of the consequences of treatment choices.

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