ARBITATE: A prospective double-blind trial was conducted in Crohn's disease subjects in whom a resection was being performed, to assess the hypothesis that marginal disease would adversely influence healing of the anastomosis. Of 106 eligible patients, 51 completed a protocol of pathological assessment of the surgical specimen and a water soluble contrast enema 10 to 15 days after the surgical procedure. Six were found to have radiological leaks and three additional subjects had clinical leaks from the anastomosis. The proportion of leaks, both clinical and radiological, was nine of 54. There was no trend to increasing rate of anastomatic breakdown with increasing marginal disease. Can J Gastroenterol 1989;3(3):95-97

Key Words: Anastomotic leaks, Crohn's disease, Marginal disease

Marge de résection dans la maladie de Crohn et intégrité anastomotique postopératoire

RESUME: Une étude prospective à double insu a été effectuée chez les patients souffrant de maladie de Crohn et subissant une résection, afin de vérifier l'hypothèse selon laquelle la maladie marginale a des effets fâcheux sur la guérison de l'anastomose. Sur un groupe de 106 patients admissibles, 51 ont été soumis à un protocole d'évaluation pathologique de la pièce chirurgicale et ont reçu un lavement avec un contraste soluble base d'eau 10 à 15 jours après l'intervention; des fuites radiologiques ont été notées chez six patients et chez trois autres sujets, les fuites provenaient de l'anastomose. La proportion de fuites, cliniques et radiologiques, était de neuf de 54. Il ne semblait pas y avoir augmentation de la détérioration anastomotique avec une augmentation de la maladie marginale.
By 11 general surgeons were notified to a central office. As far as the authors are aware, these surgeons performed no resections for Crohn’s disease during this period which were not reported. If the proposed procedure involved an anastomosis to the colon (common ileocolic or colocolic) the patient was asked to cooperate in the trial according to a protocol approved by the University of Calgary Ethics Committee. One hundred and six subjects were approached and 96 agreed to take part in the trial. Of the remaining subjects who agreed to enter, three cases were excluded because the radiological diagnosis of Crohn’s disease was not confirmed at laparotomy and a further 17 were excluded because the actual procedure performed differed from that planned and a resection with anastomosis was not performed (commonly an ileostomy was carried out).

Anastomoses were performed according to the preference of the individual surgeon and were both stapled and sewn. Each resection specimen was examined by a pathologist in the fresh, unfixed state. Having been opened, the segment was fixed after stretching on a cork board. Sections were taken as dictated by the gross appearance and in a routine fashion from each resection margin. A written report was made on each specimen without reference to either the operative record or the postoperative progress.

Marginal disease was defined as the microscopic or macroscopic presence of mucosal ulceration or regeneration within 1 cm of the cut edge, together with either submucosal or transmucosal acute inflammation. Perivascular and serosal acute inflammation was not taken into account, and generalized nonspecific increase in chronic inflammatory cells of the lamina propria was also ignored.

Ten to 15 days after the resection, each eligible subject had a water soluble contrast enema using an iodine containing proprietary contrast agent (iothalamate meglumine 17%). The radiologist was informed of the site of the anastomosis, but had no access to the pathological diagnosis or the records of the subject’s postoperative course. Prior to the x-ray, oral intake was restricted to fluids for 12 to 18 h, but no attempt was made at other bowel preparation.

Of the 76 subjects eligible following a suitable resection with anastomosis, three developed clinical signs and symptoms of a major anastomotic leak before the 15th day and, as previously agreed, were not subjected to contrast radiology. In two subjects, the radiologist was unable to reach the site of the anastomosis and the examination was abandoned. A further 11 subjects withdrew from the trial at this stage and nine did not have a contrast enema performed within the 10 to 15 day postoperative period because of miscellaneous problems, including missed appointments and administrative errors. This left 51 subjects in whom both pathological and radiologic assessment was completed and three who had pathological evaluation but developed a clinical leak.

A radiological leak was defined as extravasation of contrast from the presumed anastomotic site for a distance of at least 1 cm. Trends in both clinical and radiological leaks were related to marginal involvement and are listed in Table 1 (19).

### RESULTS

There were no deaths in the postoperative period in this study. Of the 54 subjects who completed pathological evaluation and had contrast radiology, or had a clinical leak, margins were clear of disease in 34 (63%), one margin was involved in 17 (31%) and both margins were involved in three (6%). Evidence of disruption of anastomotic integrity were termed ‘clinical’ in three subjects (clear evidence of leak of bowel contents in first 15 days following surgical procedure) and ‘radiological’ in another five subjects (extravasation of contrast as defined above 10 to 15 days after the surgical procedure). As noted elsewhere (20-24), radiological leaks were not associated with any discernible effect on the subjects’ postoperative course.

The results are tabulated in Table 1 which shows a leak rate (both clinical and radiological) of 17% when both margins were clear, 13% when one margin was involved and one leak in two cases where both margins were diseased. Assessment of subgroups according to anatomical segment resected, method of anastomosis (stapled versus sewn), individual surgeon’s results, degree of disease activity in the resected intestine, sex or age provided no further useful information.

The three subjects with clinical leaks all were covered with parenteral hydrocortisone in the perioperative period: four of the five subjects with radiological leaks also had steroid cover. Of the 54 subjects who completed the trial, 48 received perioperative steroids. This small series, therefore, does not permit any conclusion about the role of perioperative steroid therapy on the presence or absence of leaks at intestinal anastomoses in Crohn’s disease.

The proportion of eligible subjects who chose not to participate in the trial, either when approached initially or who withdrew later, was high (21 of 106) and nine others failed to complete the protocol. Retrospective review of these patients showed no obvious differences from those included in the analysis.

### DISCUSSION

Evidence to suggest that histological Crohn’s disease at the intestinal margins

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**TABLE 1**

<table>
<thead>
<tr>
<th>Anastomotic integrity related to marginal disease in Crohn’s subjects treated by resection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both margins</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Both margins clear</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Anastomosis intact</td>
</tr>
<tr>
<td>Anastomotic leak</td>
</tr>
</tbody>
</table>

Ordered 2x3 contingency table. Null hypothesis: no change in proportion of leaks with increased marginal involvement. $r = -1.945; \chi^2 = 0.11; \ p > 0.5$ (one-tail). $\chi^2$ accepted.
increased the likelihood of anastomotic leaks has been primarily anecdotal (1, 2). The present findings support the view that intestinal anastomoses heal without difficulty even in the presence of active disease (13-18). This concept is upheld by reports (25, 26) that plastic procedures carried out in areas of stricture caused by Crohn's disease (stricturoplasty) heal without increased the likelihood of radiological leaks occurred in subjects in whom the margins were free from disease (Table 1).

During the three year period of this study, 106 patients were identified who were electively proposed for a resection of a segment of Crohn's disease with an anastomosis. Of this group only 51 completed the protocol for a postoperative water soluble enema. Twenty-one patients refused to participate and the others were excluded for miscellaneous reasons. After review of the results, it appeared unlikely that continuation of the study to increase the number of participants would add significantly to the conclusions and the trial was terminated.

REFERENCES

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