Background: Only 4 controlled trials have investigated whether prophylactic abdominal drainage was of value after colonic resection. None have been able to find any statistically significant difference, but the number of patients was small and the β error risk was high.

Objectives: To compare patients who underwent abdominal drainage with those who did not for the rate and severity of complications after elective colonic resection followed immediately by anastomosis of the suprapromontory colon and to compare suction drains with non-suction drains.

Patients: Between September 1990 and June 1995, 319 patients (135 men and 184 women), whose mean age was 67 years (range, 22-95 years), with carcinoma, benign tumors, or colitis, located anywhere between the ascending and sigmoid colons, were included in the study. Patients were comparable for demographic characteristics, except that there were more patients with ascites in the group that did not undergo abdominal drainage (P<.02).

Interventions: After 2 protocol violations, 156 patients were randomized to the abdominal drainage group and 161 to the no abdominal drainage group. All 317 anastomoses were tested for airtightness intraoperatively and repaired if leakage was found (n=71), and all patients with anastomoses received a routine diatriozate sodium enema to detect infraclinical leakage.

Results: Twenty-six patients overall (8%) had postoperative complications possibly influenced by drainage (9% in the group that underwent abdominal drainage and 8% in the group that did not). This difference was not statistically significant (P<.90). One patient had a fistula directly imputable to drainage. There was no difference between suction and nonsuction drainage (P<.90).

Conclusions: Routine abdominal drainage after colonic resection and immediate anastomosis decreases neither the rate nor the severity of anastomotic leakage. It can, occasionally, be detrimental.

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The colonic lumen contains between $10^8$ and $10^{10}$ aerobic and anaerobic germs per gram of feces. This might explain why postoperative infective complications, the prevalence of which ranges from 10% to 70%, may be higher in patients undergoing surgery of the colon than in those undergoing any other abdominal surgery. Anastomotic leakage is the leading cause of postoperative infective complications, responsible for 25% to 35% of deaths. Several procedures have been described to decrease the rate and the severity of postoperative complications, especially infective complications, as well as to decrease anastomotic leakage. These include antibiotic prophylaxis, antiseptic mechanical preparation, diverting stomas, omental wrapping around the anastomosis, and intraoperative airtightness testing leading to complete anastomotic airtightness integrity.

The prophylactic drainage of the abdominal cavity was proposed for these same reasons in the second half of the 19th century (by Sims in 1884 and by Billroth in 1881). Prophylactic drainage is thought to decrease the rate of anastomotic leak-
PATIENTS AND METHODS

PATIENT FACTORS

Patients

Between September 1990 and June 1995, 319 patients (135 men and 184 women), whose mean age was 67 years (range, 22-95 years), originating from 15 centers (1 university center, 11 teaching hospitals, and 3 private clinics) participated in the study. Data collection from all centers was completed by June 1995, but all the centers did not enroll in the study at the same time. The number of patients enrolled in this study by each center ranged from 5 to 35 per year.

Disease

All patients were aged 18 years or older; there was no upper limit for age. All patients with disease (carcinoma, benign tumors, or colitis) located anywhere along the colon (descending, transverse, or ascending) were eligible to participate in the study, as long as elective resection was immediately followed by intra-abdominal (above or at the level of the sacral promontory) anastomosis. Resection for carcinoma could be for either curative or palliative reasons. Patients undergoing an emergency operation or those with patent infection (abscess and peritonitis) (drainage would be considered as curative rather than prophylactic in these cases), those undergoing resection without immediate anastomosis or with anastomosis in the pelvis (below the sacral promontory), and those undergoing colostomy closure were not included in the study.

RISK FACTORS

The preoperative and intraoperative risk factors were recorded for all patients and are summarized in Table 1.

METHODS

Colonic Preparation

All patients underwent colonic mechanical preparation, including the administration of laxatives (sennosides) or polyethylene glycol, that included the administration of anti-septic enemas. Povidine-iodine was used for 80% of these enemas, while hypochlorite was used for the remaining 20%; the enemas were administered at 6 PM in the evening and in the morning (3 hours) before surgery. All patients received a 1-dose combination of systemic ceftriaxone sodium and metronidazole at the induction of anesthesia.

Resection and Anastomosis

The abdominal incision was left to the discretion of the participating surgeon. Ileocolic or colocolic anastomosis could be performed as long as the suture line was located in the abdomen.

The anastomosis could be made with interrupted or continuous sutures, with absorbable or nonabsorbable suture material, in 1 layer, with stapling devices (Gastrointestinal Anastomosis/Terminal Anastomosis, Autosuture France, Elancourt) for ileocolic anastomoses, or with a double-rowed circular stapling device (especially for distal colocolic anastomoses). The anastomosis was protected by omentoplasty or a diverting stoma, according to surgeon preference.

Testing for Airtightness

The participating surgeons were asked to test for airtightness by looking for bubbles appearing when the colon wall was distended with air injected into the colonic lumen, by a needle inserted through the colon wall between 2 supple intestinal clamps, by fingers placed on either side of ileocolic or colocolic anastomoses, or by means of a balloon-inflated Foley catheter inserted through the anus for distal colocolic anastomoses clamped proximally. If anastomotic leakage was detected, extra sutures were added until complete airtightness was obtained.

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Random Allotment

After the resection and anastomosis had been performed and tested for airtightness, patients underwent drainage (D+) or they did not undergo drainage (D−), as indicated under the folded upper right corner of a questionnaire rather than the envelope method. The randomization order was determined according to random number tables with 2 strata, ileocolic and colocolic anastomosis. When patients were placed in D+, they were further randomized to undergo suction or nonsuction drainage. Random assignment was balanced by blocks of 4 in each center. This study was approved by the ethics committee of the coordinating center.

Drainage

A multiperforated, tubular, 14F polyvinyl chloride catheter was inserted for suction drainage, while a silicon, multitudinal, flat drain that wrapped around a 10-mm silicon tube was used for nonsuction drainage. Drains were not placed in contact with the area in which anastomosis was performed, and the distance between the end of the drain and the area in which anastomosis was performed was noted (median, 5 cm; range, 2-10 cm). The drains could exit in either latus, and they were fixed to the skin by sutures. All nonsuction drains were inserted into a colostomy bag, while the suction drains were connected to vacuum bottles emptied 3 to 4 times a day. Nonsuction drains were mobilized and shortened starting on postoperative day 2. All drains were removed on postoperative day 5 at the latest.

End Points

The primary end point was the number of patients with 1 or more postoperative complications eventually related to drainage, including (1) Deep complications that were possibly influenced by drainage and for which drainage could lead to early diagnosis, including anastomatic leakage, generalized or localized infections, intra-abdominal hematomas, or wound disruption. Anastomatic leakage was diagnosed by the egress of fecal fluid through drains, by a subsequent operation or an autopsy (performed routinely for all patients who died during their hospital stay), or by a diatrizoate sodium enema administered routinely close to postoperative day 8 for asymptomatic patients. All radiological images demonstrating less than a perfectly regular and uniform caliber at the level of the anastomosis were considered to be anastomotic leakage. (2) Complications possibly enhanced by drainage, including those related to the operative wound (an abscess, disruption, or incisional hernia), pulmonary complications based on evidence of clinical or radiological changes, and intestinal obstruction. (3) Drains are thought to promote infection from outside to within, and promote intestinal adhesions. (3) Complications directly due to drains, including ulcerations of the gastrointestinal tract tube leading to fistulas, hemorrhages, or infections of the drainage tract; difficulty in drain removal; intra-abdominal retention of the whole drain or a part of it; and wound disruption through the drain tract. Subsidiary end points were the severity of these complications as assessed by the number of associated subsequent operations and related deaths and extra-abdominal complications.

The postoperative period included the total hospital stay, irrespective of its duration, and the 30 days after discharge from the hospital. All patients were seen on that date because wound (abscesses or incisional hernias) or deep (abscesses, hematomas, and fistulae) complications are known to occur after patients are discharged from the hospital.

Number of Patients Required

According to the explicative method, with a 1-tailed analysis, to decrease the rate of patients with complications from approximately 15% to 5%, with an α risk of .05 and a β risk of .10, 146 patients were required in each group (ie, 292 patients in all).

Statistical Analysis

Groups were compared with the χ² test for discrete variables and the Student t test for continuous variables.

RESULTS

Two patients in D− were withdrawn from analysis after random allotment because of protocol violation. Three hundred seventeen patients (161 in D+ and 156 in D−) remained for final analysis.

COMPARABILITY OF GROUPS

The 2 groups of patients were comparable for preoperative characteristics, except that there were significantly (P<.02) more patients with ascites in D− (Table 1). Other characteristics, including weight loss (P<.20), use of corticosteroids (P<.10), Crohn disease (P<.30), intraoperative fecal soiling (P<.10), and leakage on testing for airtightness (P<.50), were encountered more frequently in D−, but these differences were not significant. On the other hand, there were fewer patients who underwent omentoplasty (P<.10) in D+.

END POINTS

No statistically significant (P<.90) difference was found between D+ and D− for postoperative complications or their severity (Table 2). (1) The overall rate of patients with 1 or more complications was 8.2%. (2) The overall rate of deep complications possibly influenced by drainage was 6.6%. Leakage was detected clinically in 3 patients and radiologically in 1 patient. (3) The overall rate of complications possibly enhanced by drainage was 9.0%. (4) There was 1 complication directly due to drains: an intestinal fistula (1.0%).

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SUBSEQUENT OPERATIONS

Seventeen subsequent operations (5%) were performed, 3 (18%) for anastomotic leakage; 3 of 4 leakages required a subsequent operation. The other reasons for a subsequent operation included hemoperitoneum (n=5), a deep abscess without leakage (n=3), intestinal obstruction (n=2), a wound abscess (n=2), wound disruption (n=1), and acute cholecystitis (n=1).

DEATHS

There were 14 deaths (4%), 7 in each group. Only 1 death was due to anastomotic leakage in D− (ie, 7% of deaths overall). One fourth of the patients with leakage ultimately died. In 5 other patients, the cause of death was intra-abdominal but unrelated to anastomotic leakage, including 2 patients with hepatic failure (1 due to metastases and 1 to cirrhosis), 1 patient with nonresected hepatic metastases who experienced a secondary hemorrhage of the gallbladder bed following cholecystectomy for cholelithiasis, 1 patient with a deep abscess, and 1 patient with acute biliary pancreatic necrosis.

The cause of death in the 8 remaining patients was extra-abdominal, including 3 patients with blood-borne infections secondary to urinary infection, 2 patients with myocardial infarction, 1 patient with respiratory tract failure, 1 patient with a pulmonary embolism, and 1 patient with lower extremity vascular compromise.

EXTRA-ABDOMINAL COMPLICATIONS

The overall rate of other extra-abdominal complications was 4.1%, with no statistical difference between the 2 groups. Irrespective of the type of complications considered, no statistically significant differences were found between suction and nonsuction drains (Table 2).

COMMENT

Prophylactic drainage after elective intra-abdominal suprapromontary anastomosis following colonic resection reduces neither the rate of patients with 1 or more postoperative complications possibly influenced by drainage nor the severity of these complications. There was no difference found between suction and nonsuction drains.

Our study confirms the results of the 4 controlled studies on the use of prophylactic drainage, but with greater power (90%) because of the many patients included (n=317), almost the total of the 4 other studies combined (n=326).
Whereas the tendency in the 4 other studies\textsuperscript{21-24} seemed to be against drainage, the slight difference (Table 2) in favor of drainage in our series might be due to the many high-risk patients (ie, those with ascites) in D\textsuperscript{−} (Table 1). The complication rates found in our series were similar to those reported in other trials\textsuperscript{21-24} regarding (1) the rate of incisional complications, which was 4\% compared with 4\%\textsuperscript{23} to 10\%\textsuperscript{21-24}; and (2) the rate of deep abscesses or generalized peritonitis, which was 3\% compared with 2\%\textsuperscript{22} and 3\%.\textsuperscript{21}

In our series, 1 of 157 patients had a complication directly due to drains, similar to that reported in other controlled trials: 0 of 49 patients,\textsuperscript{22} 1 of 60 patients\textsuperscript{23} (1 subsequent operation was performed to remove a lost drain), 3 of 94 patients\textsuperscript{24} (1 difficult drain removal and 2 drainage wound infections), and 1 of 28 patients\textsuperscript{21} (a drainage wound infection). Early postoperative intestinal obstruction\textsuperscript{11} was found in 1 patient in our series, whereas there were none in the other controlled trials.\textsuperscript{21-24} On the other hand, nothing can be said about late intestinal obstruction or drainage wound protrusion\textsuperscript{11} because in our series, as well as in the other controlled series, patients were not observed for longer than 1 month after discharge from the hospital.

In contrast, other complication rates in our study were lower than those reported in the previous trials. Our overall leakage rate was 1.3\%, much lower than that of the 4 other series, which ranged from 4\% to 21\%.\textsuperscript{21-24} All of our patients were required to receive a routine diatrizoate enema, as were the patients in the series by Hagmu¨ller et al.\textsuperscript{23} Two series\textsuperscript{21,24} required this enema for patients undergoing a colectomy of the descending colon only, thus underestimating the true overall leakage rate in their series. No contrast studies were performed in the remaining trial.\textsuperscript{22}

Explanations for these discrepancies include the following: (1) The absence of emergency operations in our trial, whereas 21\% of the patients described in one article\textsuperscript{24} were operated on emergently, circumstances under which leakage has been reported to occur more frequently.\textsuperscript{5,40} (2) Eighty percent of our patients received povidone-iodine enemas; these enemas have been shown to significantly decrease the rate of leakage and postoperative infective complications.\textsuperscript{6} (3) No anastomoses were placed in the pelvis in our series, in contrast with the suprapерitoneal,\textsuperscript{21} infraperitoneal,\textsuperscript{22,24} and coloanal\textsuperscript{22,24} anastomoses in other series; these are well known to be prone to higher leakage rates.\textsuperscript{5,41} (4) In contrast with all the other trials,\textsuperscript{21-24} airtightness was tested in all patients; when leaks were found, they were repaired immediately. This test associated with repair has been shown to decrease the final leakage rate.\textsuperscript{5,41} (5) In one trial,\textsuperscript{24} all deep abscesses were routinely attributed to leakage in the absence of contrast studies; therefore, the true leakage rate was overestimated.

Our pulmonary complication rate was 5\%, notably less than the rates of 10\%\textsuperscript{24} and 23\%\textsuperscript{21} in 2 series; this rate was not mentioned in the 2 other trials.\textsuperscript{22,23}

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<th>Table 2. End Points for the 317 Patients*</th>
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<td><strong>End Points</strong></td>
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<td>Patients with ≥1 of the following complications</td>
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<td>Deep complications possibly influenced by drainage</td>
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<td>Leakage</td>
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<td>Overall</td>
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<td>Radiological alone</td>
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<td>Generalized peritonitis</td>
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<td>Hematoma and hemorrhage</td>
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<td>Complications possibly enhanced by drainage</td>
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<td>Wound abscesses, dehiscence, and incisional hernias</td>
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<td>Pulmonary complications</td>
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<td>Intestinal obstructions</td>
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<td>Without leakage</td>
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<td>Other septic extra-abdominal complications (urinary tract or catheter related)</td>
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*All data are given as the number of patients.
†One patient had more than 1 complication.
differences might be explained by the fact that the definition of pulmonary complications differed in the literature or by the fact that our fistula rate, known to promote pulmonary complications, was lower.

The hypothesis concerning the expected difference of 5% between the 2 treatments was not met. Moreover, our overall rate of complications was 8.2% (8.7% and 7.7% in D− and D+, respectively). This 1% difference in favor of drainage is clinically irrelevant; to conduct a clinical trial on the several thousand patients necessary to demonstrate such a small difference would be difficult if not impossible.

The postoperative mortality in our series was 4.4%, which was within the postoperative death rates recorded in the other controlled trials: 3% to 6%.21-24 Our 0.30% death rate due to anastomotic leakage was lower than the 0.85% to 2.00% rates reported elsewhere.23,24 On a small difference would be difficult if not impossible. Several thousand patients necessary to demonstrate such a small difference would be difficult if not impossible.

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To our knowledge, an indication for a subsequent operation has not been used to evaluate the severity of the postoperative course, especially in controlled trials. In these trials, anecdotal complications requiring a subsequent operation included deep hemorrhage, anastomotic leakage,23 and removal of abdominal drains;22 no complications were mentioned by Sagar et al.24

Suction drains have been said to be better than non-suction drains,23 but, to our knowledge, no controlled intra-abdominal drainage trials have been performed to date, except ours. The only controlled trial22 was conducted after anterior resection, a procedure that was not included in our trial. The results showed that neither type of drainage reduced the amount of collected fluid. The results of our study are in agreement with these data, as no significant difference in outcome was noted according to the type of drain used (Table 2).

Prophylactic abdominal drainage does not seem to be able to improve the postoperative course after elective colonic resection and intra-abdominal anastomosis.

Corresponding author: Abe Fingerhut, MD, Centre Hospitalier Intercommunal, 78303 Poissy Cedex, France (e-mail: abefinger@aol.com).

REFERENCES


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