

Randomized Trial of Pelvic Drainage After Rectal Resection

P. M. Sagar, F.R.C.S., M. N. Hartley, F.R.C.S., J. Macfie, F.R.C.S.,
B. Mancey-Jones, M.B., Ch.B., P. Sedman, F.R.C.S., J. May, F.R.C.S.

From the Royal Liverpool University Hospital, Liverpool, United Kingdom, and Scarborough Hospital, Scarborough, United Kingdom

Most surgeons continue to advocate routine use of drains after pelvic anastomoses. Several recent studies have, however, demonstrated that patients gain little or no benefit from such drainage and that drains may indeed be a source of morbidity to some. **PURPOSE:** The aim of this trial was twofold: 1) to determine whether use of a high pressure, closed suction pelvic drain was associated with reduced morbidity; 2) to investigate the influence of drainage on postoperative fluid collections after rectal resection. **METHODS:** A consecutive series of 100 patients was randomized to receive either no drain ($n = 48$) or a high pressure, closed suction intraperitoneal drain for seven days ($n = 52$). The two groups were similar in terms of age, sex, diagnosis, and type of anastomosis. Patients underwent postoperative pelvic ultrasound and water-soluble contrast studies on day 7. **RESULTS:** There were six deaths (three drain, three no drain). Clinically significant anastomotic leak occurred in seven patients (five drain, two no drain), and a radiologic leak was demonstrated in another five patients (two drain, three no drain), each of whom remained well. Presence or absence of a drain did not influence rate of morbidity and mortality. Pelvic fluid collections were more likely to be demonstrated if a drain was used; however, this did not reach statistical significance. Neither pus nor feces emerged from the drain in any patients in whom a leak occurred. **CONCLUSION:** Use of a pelvic drain after rectal resection did not confer any benefit to the patient. [Key words: Colorectal anastomoses; Morbidity; Intraperitoneal drains; Contrast studies; Restorative proctocolectomy]

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Routine use of intraperitoneal drains after colorectal resection remains debatable.¹ Proponents of this use maintain that they permit egress of fluid collections that have the potential of becoming infected, permit early recognition of anastomotic dehiscence, and do no harm. Objectors to the use argue that it can impede healing of the anastomosis, confer no benefit, and may cause harm.

Experimental studies in animals have shown increased risk of leakage, morbidity, and mortality

when drains are used.^{2,3} Prospective, randomized, controlled trials of the use of drains have failed to demonstrate benefit from routine use of drainage after colonic anastomoses.^{4,5} We previously carried out a prospective study that compared outcome in terms of morbidity and mortality in 145 patients who had undergone colonic or rectal resection. Prophylactic drainage of the anastomosis was not associated with reduced postoperative morbidity or mortality. Indeed, drains failed to allow the egress of pus or feces in patients in whom anastomotic dehiscence occurred.⁶ Colocolic anastomoses have the advantages of serosal coverings at both ends, protective peritoneum, and omentum in close proximity, whereas rectal anastomoses largely lack these absorptive and protective capabilities. Therefore, although drainage of colonic anastomoses may be of no benefit, there may be an advantage in the use of drains in patients after rectal excision. The aim of the current trial was to determine whether use of a high-pressure, closed-suction drain after rectal resection and primary anastomosis was associated with a decrease in incidence of postoperative morbidity and mortality and to assess the incidence and significance of pelvic fluid collections detected by means of ultrasound in the postoperative period.

PATIENTS AND METHODS

A prospective, randomized, clinical trial was carried out between May 1991 and November 1993 and involved a consecutive series of 100 patients, all of whom underwent entry of the presacral space with resection of either part or all of the rectum. The study was undertaken in two units simultaneously, with all appropriate patients being entered into the study. Patients were excluded from the study if they were found to have gross fecal contamination of the peritoneal cavity at the time of laparotomy ($n = 3$) or if the pelvis required hemostatic packing ($n = 1$).

Preoperative preparation of the bowel of patients undergoing elective surgery consisted of two sachets

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Address reprint requests to Mr. Sagar: Division of Colon & Rectal Surgery, East 6A, Mayo Clinic, Rochester, Minnesota 55905.

of Picolax[®] (sodium picosulphate, Ferring Pharmaceuticals, Malmo, Sweden) commenced 24 hours before surgery. Each patient received prophylactic antibiotics with three doses of 1.2 g of Augmentin Intravenous (Co-amoxiclav[®], Beecham Research, Mundells, Welwyn Garden City, Hertfordshire, England), which commenced at the time of induction of anesthesia and continued for 16 hours. Patients who presented as emergencies underwent on-table colonic lavage, with saline lavage introduced through the appendiceal stump, and received Augmentin for five days after the operation. The operations were carried out by consultant, senior registrar, or registrar through a midline incision, unless a pre-existing paramedian incision was present. All anastomoses were constructed either by hand with a single layer of extramucosal interrupted 3/0 Vicryl[™] (Ethicon UK Ltd, Edinburgh, UK) or with an EEA[™] (Autosuture UK Ltd., Ascot, England) stapling instrument. Fourteen of 100 patients underwent nonelective surgery.

Randomization was carried out after completion of anastomosis. Each patient was allotted randomly either to receive an intraperitoneal drain for seven days or to receive no drain. The method of drainage used was a closed-suction, high-pressure, 0.25-inch internal diameter, Redivac[®] (Biomed Ltd., Bridgend, South Glamorgan) drainage system. The original design of the trial permitted drains to be left *in situ* longer if the volume of drainage after seven days was considered to be clinically significant; however, this did not prove to be necessary. Drains were placed close to the anastomosis, without pressing on the bowel, and brought out through the abdominal wall *via* a stab incision at a site remote from the abdominal wound. The pelvis was lavaged with one liter of saline solution, which contained 1 g of tetracycline. The pelvic peritoneum was closed when possible. There were no perineal wounds. All patients gave informed consent.

Nasogastric tubes were not used postoperatively in elective cases.⁷ Oral fluids were encouraged from the first postoperative day and increased as intestinal activity returned as manifested by passage of flatus. However, patients in whom restorative proctocolectomy had been carried out were fasted for seven days and given total parenteral nutrition until a satisfactory water-soluble contrast enema was obtained. In addition, these patients had a 24-F Foley[®] (Bard Urological Co., Covington, GA) catheter placed into the pelvic ileal reservoir per anum to prevent accumulation of mucus and other secretions within the pouch.

Details of the operative procedure and histologic analysis of the resected specimen were recorded. Volume and nature of any drainage fluid was noted each day until removal. Wounds were inspected daily, and any discharge fluid was sent for microbiologic assessment. Wound infection was defined as discharge of pus from the wound. Chest infection was defined as production of purulent sputum with appropriate clinical and radiographic changes. Pelvic ultrasound examinations were carried out between five and seven days after surgery. Scans were carried out by means of real-time scanning techniques. Patients also underwent water-soluble contrast enema (Gastrografin[®], Schering Health Care Ltd., Burgess Hill, West Sussex, UK) on the fifth to seventh postoperative day to test the integrity of the anastomosis. Presence of a leak on the gastrografin enema in a patient who had no clinical evidence of problems with the anastomosis was recorded as a radiologic leak. A clinically significant anastomotic leak was defined as discharge of feces from the drain site or presence of an abscess in close proximity to the anastomosis and localized or generalized peritonitis with tenderness, fever, and leukocytosis.

All patients were followed for at least six weeks after discharge from the hospital. The two groups of patients were similar in terms of age and sex distribution, operative procedure, diagnosis, hand *vs.* stapled anastomosis, and urgency of procedure (Table 1).

All grouped data were expressed as medians and interquartile ranges, and intergroup comparisons were carried out by means of Mann-Whitney *U* test or chi-squared test with Yates' correction.⁸ Randomization was based on random number tables without stratification. Method of randomization involved opening a sealed envelope, drawn from a box of envelopes, that had been filled on the basis of random numbers.

RESULTS

There were six deaths within 30 days of surgery (6 percent). Cause of death was myocardial infarction in three patients, pulmonary embolus in one patient, and septicemia in two patients, which occurred after anastomotic dehiscence despite relaparotomy and resection of the anastomosis and construction of an end colostomy. Both of these latter two patients had been randomized to receive a drain, although drainage of

Table 1.
Details of the Patients

	No Drain (n = 48)	Drain (n = 52)
Male	22	28
Female	26	24
Median age, years, (range)	58 (17-82)	64 (19-89)
Diagnosis		
Rectosigmoid cancer	25	31
Diverticular disease	6	7
Ulcerative colitis	8	9
Crohn's disease	4	3
Ischemic colitis	1	0
Constipation	1	1
Endometriosis	1	0
Familial adenomatous polyposis	2	1
Operation		
High anterior resection	22	24
Low anterior resection	10	15
Total colectomy and ileorectal anastomosis	7	2
Restorative proctocolectomy	6	7
Reversal of Hartmann's procedure	3	4
Timing of surgery		
Emergency surgery	8	6
Elective surgery	40	46

fluid had ceased by the time dehiscence was recognized.

There were five other cases of anastomotic dehiscence (two no drain, three drain). All of these patients survived. Relaparotomy with take-down of the anastomosis was necessary in two patients, whereas the other five patients were managed conservatively with total parenteral nutrition, antibiotics, and intestinal rest. One other patient, who had undergone restorative proctocolectomy with duplicated pelvic ileal reservoir, required a relaparotomy on the second postoperative day for suspected peritonitis. Although this proved to be negative, the pelvic drain was found to lie firmly pressed against the ileoanal anastomosis. It was replaced in the postpouch space. Anastomotic dehiscence and the associated pelvic sepsis did not appear to be related to the presence or absence of malignancy, preoperative nutritional status, perioperative blood transfusion, or use of high-dose steroids.

No significant differences were found between the drain and no drain groups in incidence of postoperative complications, clinical or radiologic anastomotic leak, mortality, or length of hospital stay after opera-

tion. Morbidity and mortality after surgery is shown in Table 2.

Median volume of fluid collected from suction drains was 290 (range, 0-675) ml. Pelvic collections of fluid were detected in 3 of 48 patients without a drain and in 8 of 52 patients with a drain (chi-squared = 1.29; *P* = not significant). The presence of fluid collection in the pelvis on ultrasound scans was not related to presence of clinical leak.

DISCUSSION

The principal finding of this study was that the presence of a closed-suction, high-pressure pelvic drain had no impact on postoperative morbidity. Several factors are implicated in anastomotic dehiscence and pelvic sepsis. Formation of fluid within the pelvis after rectal mobilization and resection clearly provides a splendid culture medium for enteric organisms. Bacteria released at the time of surgery are cleared rapidly and destroyed by peritoneal defenses, but if conditions confine bacteria to the pelvic cavity with a hematoma present then sepsis, collagen degradation, and a weakened anastomosis may result.⁹ Routine use of pelvic lavage on completion of the procedure may have been an important factor in the removal of clot and debris and dilution of any bacterial contamination from the pelvic space before closure of the laparotomy wound. Although infection of a pelvic collection with formation of a pelvic abscess and its subsequent spontaneous drainage through the anastomosis may account for some cases of anastomotic leakage,¹⁰ it is likely that the reverse is more often the case, that is, infection of a pelvic collection occurring after anastomotic dehiscence. Poor blood supply and tension on the anastomosis remain the principal factors that predispose to dehiscence of any intestinal anastomosis.¹¹ The risk is compounded in rectal excision with primary anastomosis by factors such as difficult or limited access, absence of a peri-

Table 2.
Postoperative Complications

	No Drain (n = 48)	Drain (n = 52)
Death (%)	3 (6.3)	3 (5.8)
Clinical leak (%)	2 (4.2)	5 (9.6)
Radiologic leak (%)	3 (6.3)	2 (3.8)
Wound infection (%)	0 (0)	3 (5.8)
Chest infection (%)	4 (8.3)	4 (7.7)
Length of in-hospital stay, days (interquartile range)	11 (9-13)	13 (10-14)

toneum,¹¹ and technical difficulty, particularly in low rectal and ileoanal anastomoses.¹² Routinely, we attempted to close the pelvic peritoneum to exclude the anastomosis from the abdominal cavity. This often proved impossible, particularly after total mesorectal excision for cancer and restorative proctocolectomy. Pelvic ileal reservoirs invariably filled the pelvis, and this made closure of the peritoneum unnecessary.

We were surprised at the low overall incidence of pelvic collections demonstrated by ultrasound scans. A large, raw, oozing surface is left after rectal resection, and the accumulation of some fluid is surely inevitable. Our failure to detect much fluid could be explained by 1) scans were performed too late; 2) views obtained were inadequate; 3) resorption of fluid was sufficient to remove fluid by the seventh postoperative day; 4) there was no fluid. Our previous study⁶ of drainage of colonic and rectal anastomoses used routine ultrasound scans at three and seven days. The extra scans in that study did not provide any additional, clinically significant information. Ultrasonographers did experience some difficulty in visualizing the pelvis, particularly after restorative proctocolectomy, and commented that it was often difficult to distinguish fluid and semisolid stool within the pelvic ileal reservoir from fluid or hematoma within the pelvis.

Previous studies have suggested that drainage of the presacral area reduces the incidence of anastomotic dehiscence and pelvic sepsis.^{13, 14} The volume of drainage fluid was independent of age, sex, extent of resection, anastomotic level, and intestinal pathology.¹³ Use of continuous irrigation and drainage of the presacral area have been shown to reduce the accumulation of blood and serum within the pelvis and to be associated with relatively low rates of anastomotic dehiscence after low anterior resection.^{15, 16} A prospective, randomized trial of postoperative irrigation-suction after rectal excision compared morbidity in patients who either received pelvic suction alone or irrigation and suction. No reduction in incidence of local pelvic septic complications was observed by addition of irrigation of the presacral space.¹⁷ The authors of this latter study commented that inclusion of a third study arm of a group of patients in whom no drainage was used would have been desirable. Although presacral drains were found to be used routinely in a study of colorectal teaching services in the course of restorative proctocolectomy, we wonder whether this is always necessary. Although it would not be appropriate to subject patients in our study

with pelvic ileal reservoirs to subgroup analysis, we did not observe any problems in such patients in whom drains were omitted. In addition, we were concerned to find the drain abutting on the ileoanal anastomosis in our one patient who required a relaparotomy, and it is quite conceivable that, had this not been rectified, the drain may have eroded through into the pouch.

CONCLUSIONS

The presence or absence of a drain is but one of many factors that influence postoperative development of local pelvic septic complications. Although introduction of presacral drainage led to a reduction of low rectal anastomotic leakage,¹⁶ more recent studies have questioned its value.^{6, 17} Perhaps greater awareness of the need for a good blood supply, absence of tension on the anastomosis, and good pelvic hemostasis with a dry operative field on completion of the procedure has reduced the current value of presacral drains. Although a case can be made for the use of presacral drains in specific circumstances, routine use of closed-suction drains may be unnecessary.

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