

# Colon and Rectal Anastomoses Do Not Require Routine Drainage

## A Systematic Review and Meta-Analysis

David R. Urbach, MD,\*†‡ Erin D. Kennedy, MD,\*† and Marsha M. Cohen, MD, FRCPC†‡

From the \*Department of Surgery, the †Clinical Epidemiology and Health Care Research Program, and the ‡Maternal, Infant and Reproductive Health Research Unit at the Centre for Research in Women's Health, University of Toronto, Toronto, Ontario, Canada

### Objective

Many surgeons continue to place a prophylactic drain in the pelvis after completion of a colorectal anastomosis, despite considerable evidence that this practice may not be useful. The authors conducted a systematic review and meta-analysis of randomized controlled trials to determine if placement of a drain after a colonic or rectal anastomosis can reduce the rate of complications.

### Methods

A search of the Medline database of English-language articles published from 1987 to 1997 was conducted using the terms "colon," "rectum," "postoperative complications," "surgical anastomosis," and "drainage." A manual search was also conducted. Four randomized controlled trials, including a total of 414 patients, were identified that compared the routine use of drainage of colonic and/or rectal anastomoses to no drainage. Two reviewers assessed the trials independently. Trial quality was critically appraised using a previously published scale, and data on mortality, clinical and radiologic anastomotic leakage rate,

wound infection rate, and major complication rate were extracted.

### Results

The overall quality of the studies was poor. Use of a drain did not significantly affect the rate of any of the outcomes examined, although the power of this analysis to exclude any difference was low. Comparison of pooled results revealed an odds ratio for clinical leak of 1.5 favoring the control (no drain) group. Of the 20 observed leaks among all four studies that occurred in a patient with a drain in place, in only one case (5%) did pus or enteric content actually appear in the effluent of the existing drain.

### Conclusions

Any significant benefit of routine drainage of colon and rectal anastomoses in reducing the rate of anastomotic leakage or other surgical complications can be excluded with more confidence based on pooled data than by the individual trials alone. Additional well-designed randomized controlled trials would further reinforce this conclusion.

Many surgeons use a prophylactic drain routinely for colorectal anastomoses. Abundant evidence from animal studies<sup>1,2</sup> as well as controlled trials in humans<sup>3-8</sup> suggests that prophylactic drainage does not improve major morbidity outcomes, such as anastomotic leakage, and may even be harmful. A possible reason for the persistence of this practice may be that surgeons are not convinced by the negative results of the existing trials. The relatively small sample size and the rarity of the outcomes of interest in these studies limit their power to

exclude a true benefit, should one exist.<sup>9</sup> Pooling the results of similar trials using meta-analysis may be used to increase the confidence of a negative conclusion by increasing the overall sample size for analysis.<sup>9,10</sup>

This report uses a systematic review of the literature and meta-analysis of randomized controlled trials to answer the question of whether any appreciable benefit of prophylactic drainage of colorectal anastomoses can be found, based on the existing data.

## METHODS

### Literature Search

A computer search of the Medline database for the years 1987 to 1997 was carried out using the following MeSH

Correspondence: David R. Urbach, MD, Maternal, Infant and Reproductive Health Research Unit, Centre for Research in Women's Health, Suite 751, 790 Bay St., Toronto, Ontario M5G 1N8, Canada.

Accepted for publication April 15, 1998.

headings: "colon," "rectum," "postoperative complications," "surgical anastomosis," and "drainage." The combined set was limited to English-language publications on human subjects. All titles and abstracts were scanned, and appropriate citations were reviewed. Consultation with a content expert and a manual search of the bibliographies of relevant papers was also carried out to identify trials for possible inclusion.

## Inclusion Criteria

The inclusion criteria for this analysis were randomized controlled trials of any size that compared the prophylactic use of a drain for a colonic or rectal anastomosis to a control group of patients who did not receive a drain.

## Data Collection

Critical appraisal and data extraction were conducted independently by two reviewers, and discrepancies were resolved by consensus. Trials were evaluated according to criteria proposed by Detsky et al<sup>11</sup> and graded on an ordinal 22-point scale, with higher scores representing studies of higher quality.

## Analyses

Comparisons of results across studies were pooled for the following outcomes: mortality, clinical anastomotic leak, radiologic leak, wound infection, and respiratory complications. Rates of adverse events were based on data extracted directly from the various studies. Definitions of clinical leak, radiologic leak, wound infection, and respiratory complications were accepted as reported, with the understanding that there may be differences in these definitions between studies. All analyses were conducted on a personal computer using Review Manager 3.0 (The Cochrane Collaboration, Software Update, Oxford).

Statistical analysis was carried out with a fixed effects model using methods described by Yusuf et al<sup>12</sup> and Mantel and Haenszel.<sup>13</sup> The summary statistic used was the odds ratio, which represents the odds of an adverse event occurring in the treatment group compared with the control group. Odds ratios <1 favor the treatment group, and the point estimate of the odds ratio is considered statistically significant at the  $p < 0.05$  level only if the 95% confidence interval (95% CI) does not include the vertical bar at 1. Any value lying within the 95% CI is considered to be consistent with the data, in the sense that it cannot be rejected at the  $p < 0.05$  level.

Homogeneity of the data was confirmed using the chi square test of heterogeneity. The fixed effects model implies that variation between the results of different studies occurs only because of within-study sampling error (not because of systematic differences between studies), and may be employed if the test of heterogeneity is negative. Sensitivity

analyses were performed by omitting trials of lower quality, trials that included <50% rectal or anal anastomoses, and trials not using closed suction drains.

## Sample Size Considerations

Because anastomotic leakage rate is an infrequent categorical outcome, extremely large sample sizes would be required to have sufficient power to exclude a difference between treatment groups. Assuming a baseline leak rate of 5%, ruling out a 20% relative risk reduction in leak rate (from 5% to 4%) with a 5% significance level and 80% power would require 1080 patients in each treatment arm in a traditional randomized controlled trial. Higher baseline rates of anastomotic leakage, or accepting a larger minimal clinically important difference, would decrease the number of study patients required, whereas an increase in desired statistical power would demand a higher sample size.

## RESULTS

Six randomized controlled trials that evaluated the use of prophylactic drains in colorectal surgery were identified. Two studies were excluded because of the absence of a control group where no drain was used,<sup>3,4</sup> leaving four randomized trials that constitute the basis for this analysis. Characteristics of the studies, including quality score, are summarized in Table 1.

The studies dated from 1987 to 1995 and contained from 60 to 148 subjects, yielding a total of 414 patients for this analysis. Two studies used corrugated drains and two used closed suction-type drains. Drains were allowed to remain in place for variable periods of time in different studies, ranging up to 7 days. One study included only intraperitoneal colonic anastomoses,<sup>5</sup> one included only pelvic (rectal or anal) anastomoses,<sup>8</sup> and the other two studies reported pelvic anastomoses on 29%<sup>7</sup> and 52%<sup>6</sup> of subjects. Overall, 198 of 414 anastomoses (48%) evaluated in this meta-analysis were to the rectum or anus.

On review of the data extraction, there was 100% agreement between the two reviewers. Agreement on critical appraisal of the individual trials was also extremely high (weighted kappa = 0.96). In general, the quality of the studies was poor on critical appraisal (mean quality score 14 on a 22-point scale), a phenomenon that has been observed in other reviews of randomized controlled trials and meta-analyses of surgical trials.<sup>14,15</sup> Many of the shortcomings were related to inadequate randomization and the non-blinded and subjective assessment of outcomes.

The pooled odds ratios for all the outcomes are summarized in Figure 1. For only one outcome (respiratory complication rate) did the summary point estimate favor the treatment group, but the 95% CIs always include 1, indicating that there were no statistically significant differences between treatment groups for any outcome. The estimates of effect size (odds ratio of each event in the drained group vs.

Table 1. SUMMARY OF TRIALS

	Hoffmann <sup>5</sup>	Johnson <sup>6</sup>	Sagar <sup>7</sup>	Sagar <sup>8</sup>
Year	1987	1989	1993	1995
Total number of subjects	60	106	148	100
Drain type	Corrugated latex	Corrugated Silastic	Closed suction	Closed suction
Duration of drainage (days)	5	Variable (median = 3)	3 or 7	7
% Rectal or anal anastomoses	0	52	29	100
% Cancer indication	63	64	73	56
% Stapled anastomoses	16	11	27	Not given
% Emergency operation	0	0	21	14
Mean quality score (maximum = 22)	14	12	16.5	14

the control group) were mortality 1.4 (95% CI 0.6 to 3.3), clinical leak 1.5 (95% CI 0.7 to 3.1), radiologic leak 1.0 (95% CI 0.5 to 2.3), wound infection 1.7 (95% CI 0.9 to 3.3), and respiratory complications 0.8 (95% CI 0.4 to 1.6). These results are summarized in Figures 2 through 6. Not every study reported data on each outcome. The size of the square on the point estimate of each odds ratio represents the weight attributed to that particular study, and the width of the horizontal bars reflects the 95% CI expressed on a logarithmic scale. The test of heterogeneity for each comparison revealed no significant differences between the studies, permitting pooling of the data using a fixed effects model.

All articles reported clinical leak rates (see Fig. 3), similarly defined across studies as discharge of pus or feces from the drain site, or presence of an abscess adjacent to an anastomosis and associated with localized or generalized peritonitis with tenderness, fever, and leukocytosis. The point estimates of odds ratio for clinical leak ranged from 1.1 to 2.3, suggesting that drainage is associated with an increased leak rate. However, the 95% CIs do not exclude 1, which means that any observed difference is not significant at the  $p < 0.05$  level.

The ability of an existing drain to "control" an anastomotic leak was evaluated by determining the frequency of pus or enteric content appearing in the drainage material of drains in place when an anastomotic leak occurred. Of 20 drains present at the time of anastomotic leak, only one (5%) drained pus or enteric content (Fig. 7).

In the sensitivity analysis, limiting the analysis to only the higher-quality studies,<sup>7,8</sup> omitting the studies that included <50% rectal or anal anastomoses,<sup>5,7</sup> or excluding studies using corrugated (not closed suction) drains<sup>7,8</sup> did not favor the treatment group with 95% confidence.

## DISCUSSION

This meta-analysis demonstrated that routine drainage of colonic or rectal anastomoses does not reduce the rate of adverse events, including clinical leak rate. However, the

question of greatest clinical importance to be answered in this review is whether it is of any use to place a prophylactic drain in the pelvis at the completion of an anastomosis to the rectum or anus, because most surgeons have already abandoned routine drainage of intraperitoneal colonic anastomoses.<sup>8</sup> Unfortunately, there are not enough randomized controlled trials aimed specifically at drainage of pelvic anastomoses to answer this question. Existing studies do not consistently report data in a manner that facilitates selective extraction of the results of rectal anastomoses. We therefore included in this analysis all trials looking at drainage of any colorectal anastomosis to increase the power of our conclusions. The results of the heterogeneity test and sensitivity analyses, which demonstrate that the data are robust to the omission of studies without a significant number of pelvic anastomoses, suggest that it is reasonable to pool these studies for meta-analysis.

There are several reasons why prophylactic drainage of the pelvis may be considered differently from drainage elsewhere in the abdomen. Rectal dissection results in exposure of the large raw surface of the presacral space. Previous authors have suggested that drainage is important to prevent accumulation of exudative fluid.<sup>16,17</sup> Also, anastomoses low in the pelvis are considered more tenuous than intraabdominal anastomoses, on the basis of increased ten-

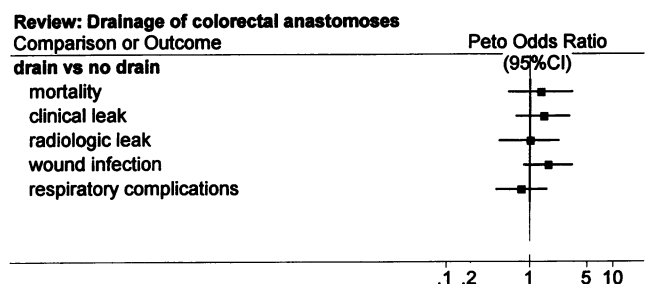
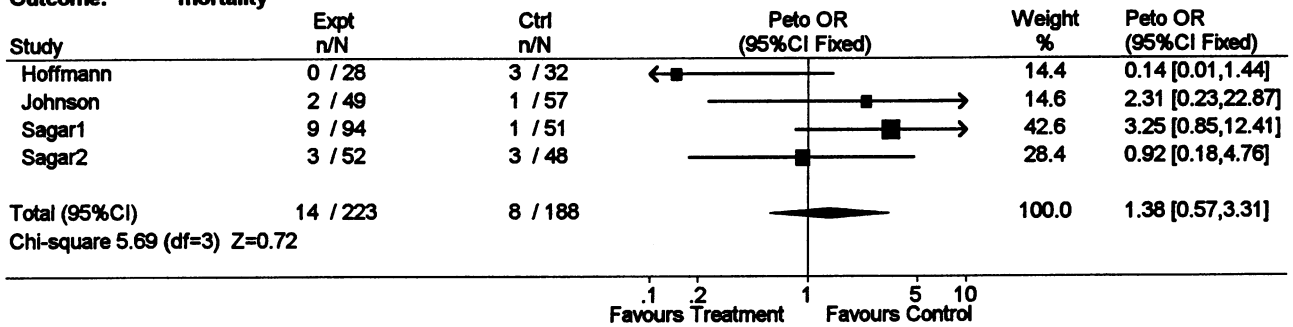


Figure 1. Meta-analysis of all outcomes. Squares indicate point estimates of odds ratio and horizontal bars signify 95% confidence intervals. Values <1 favor the treatment (drainage) group. Point estimates are significant at the  $p < 0.05$  level if their confidence intervals exclude the vertical line at 1 ("no effect").

**Review: Drainage of colorectal anastomoses**  
**Comparison: drain vs no drain**  
**Outcome: mortality**



**Figure 2.** Pooled estimates of mortality risk. Squares indicate point estimates of treatment effect (odds ratio), with the size of the square representing the weight attributed to each study. Ninety-five percent confidence intervals are indicated by horizontal bars. The summary odds ratio from the pooled studies with 95% confidence intervals is represented by the diamond. Values to the left of the vertical line at 1 favor the treatment (drainage) group. Point estimates are significant at the  $p < 0.05$  level if their confidence intervals exclude the vertical line at 1 ("no effect").

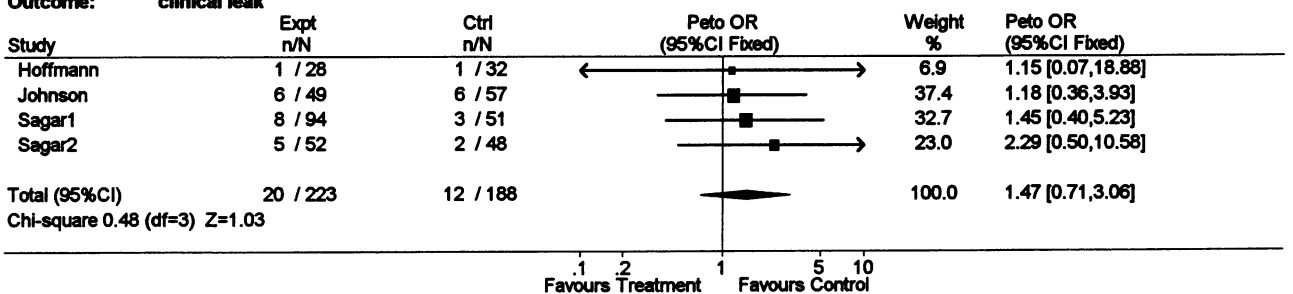
sion, poorer blood supply, lack of serosa on the distal segment of intestine, and less proximity to protective omentum.<sup>8,18</sup> However, the randomized studies that examined pelvic fluid accumulation in the presence and absence of a drain demonstrated no reduction in fluid accumulation despite the presence of a functioning drain.<sup>7,8</sup> Further, there is no evidence that fluid exuded from the presacral fascia will remain in the pelvis rather than communicate with the free peritoneal cavity, and may therefore not be susceptible to capture by a pelvic drain.<sup>19,20</sup> The assumption that some anastomotic dehiscences are caused by infection of adjacent fluid collections may not be correct, and the finding of an abscess communicating with a disrupted anastomosis may be due to infection of a sterile collection by an anastomotic leak. In addition, a drain will usually not serve to "control" an anastomotic leak as many surgeons expect, reflected by the fact that in only one instance of all of the 20 leaks among drained patients evaluated in this analysis did pus or

enteric content drain to the exterior through an existing drain (see Fig. 7).

The pooled odds ratio for clinical leak, the primary outcome of this study, was 1.5, with 95% CIs ranging from 0.7 to 3.1 (see Fig. 3). The fact that the point estimate is  $>1$  favors the control (no drain) group, but the inclusion of unity within the confidence intervals precludes the finding of a statistically significant difference. Clearly, the evidence does not suggest that drainage is of any significant benefit.

The more important issue to consider, however, is to what extent these data can conclude that drainage is *not* beneficial. The most extreme value of the odds ratio within the 95% CI favoring the treatment group is 0.7. This means that a true odds ratio of 0.7 or better in favor of drainage is not consistent with the data evaluated here. The relative risk reduction associated with an odds ratio of 0.7 is 30%, so this study can exclude a risk reduction of  $>30\%$ . If any benefit of routine drainage of anastomoses does exist, it must there-

**Review: Drainage of colorectal anastomoses**  
**Comparison: drain vs no drain**  
**Outcome: clinical leak**

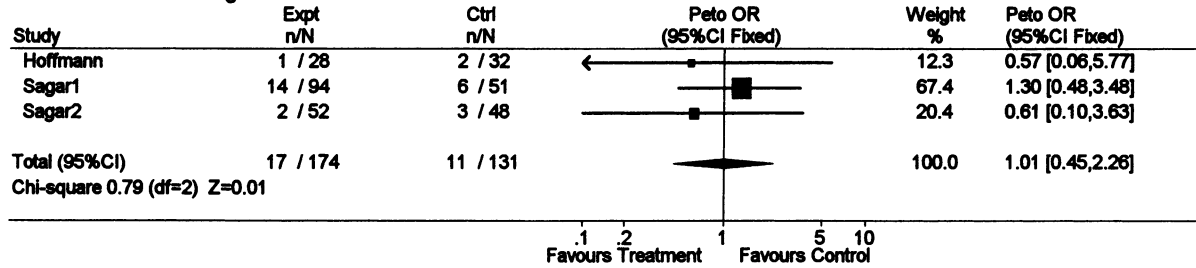


**Figure 3.** Pooled estimates of risk of clinical leak. Squares indicate point estimates of treatment effect (odds ratio), with the size of the square representing the weight attributed to each study. Ninety-five percent confidence intervals are indicated by horizontal bars. The summary odds ratio from the pooled studies with 95% confidence intervals is represented by the diamond. Values to the left of the vertical line at 1 favor the treatment (drainage) group. Point estimates are significant at the  $p < 0.05$  level if their confidence intervals exclude the vertical line at 1 ("no effect").

**Review: Drainage of colorectal anastomoses**

**Comparison: drain vs no drain**

**Outcome: radiologic leak**



**Figure 4.** Pooled estimates of risk of radiologic leak. Squares indicate point estimates of treatment effect (odds ratio), with the size of the square representing the weight attributed to each study. Ninety-five percent confidence intervals are indicated by horizontal bars. The summary odds ratio from the pooled studies with 95% confidence intervals is represented by the diamond. Values to the left of the vertical line at 1 favor the treatment (drainage) group. Point estimates are significant at the  $p < 0.05$  level if their confidence intervals exclude the vertical line at 1 (“no effect”).

fore be extremely small. Assuming a rate of anastomotic disruption of 10%, a 30% reduction in risk would reduce this to 7%, for an absolute risk reduction of 3%. The number needed to treat associated with this value is 33, which means that 33 patients would have to have drains placed to prevent one anastomotic leak (given a lower overall rate of clinical leaks, the number needed to treat would increase further). Although this may seem like a reasonable number given the devastating impact of this complication, one must remember that drains themselves have been associated with considerable morbidity, such as wound infection, pain, bleeding, and hernia formation.<sup>5</sup> Moreover, even this magnitude of benefit is extremely unlikely. In fact, the data presented here suggest that placement of a drain may be harmful, possibly increasing the rate of clinical leak by up to 210% (the excess risk associated with the upper limit of the 95% CI in Fig. 3). Therefore, we conclude that any important benefit of routine drainage on reducing the anastomotic leak rate may be more effectively excluded on the basis of this study than by the individual trials. Because so few prophylactic drains actually drained material if a leak occurred (one out of 20 possible events), it is unlikely that prophylactic drains are useful even for the purpose of “controlling” a leak if one occurs.

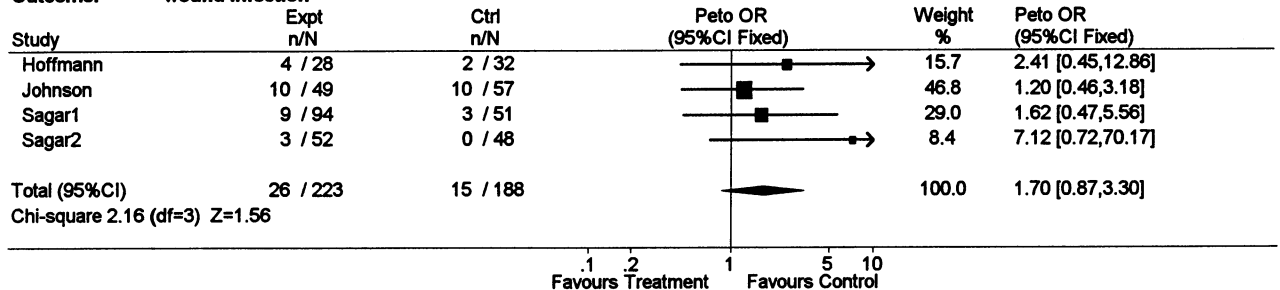
Although the technique of meta-analysis is useful when existing trials are conflicting or inconclusive,<sup>10</sup> there are potential problems with the use of meta-analysis that must be considered. Raw data were not extracted from all the studies and pooled for this meta-analysis; rather, treatment effects from individual trials were weighted and compared between studies. Therefore, one must be certain that the studies are, in fact, comparable.

There are many possible sources of heterogeneity that may, in theory, have been responsible for some of the results observed. Factors that have been associated with outcome in colorectal surgery, such as experience of the surgeon, emergency operation, cancer indication, and location and technique of anastomosis, may have been unevenly allocated between treatment groups or between studies. Most of the studies demonstrated equivalence of the treat-

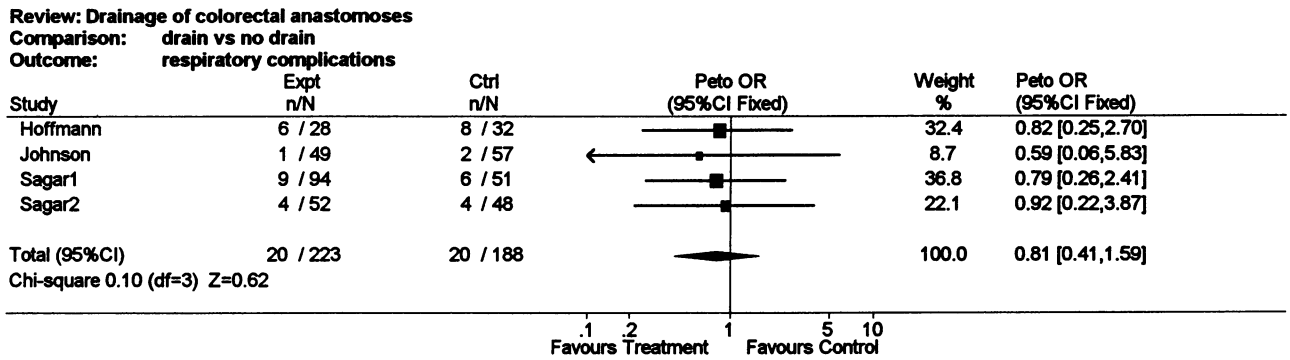
**Review: Drainage of colorectal anastomoses**

**Comparison: drain vs no drain**

**Outcome: wound infection**



**Figure 5.** Pooled estimates of risk of wound infection. Squares indicate point estimates of treatment effect (odds ratio), with the size of the square representing the weight attributed to each study. Ninety-five percent confidence intervals are indicated by horizontal bars. The summary odds ratio from the pooled studies with 95% confidence intervals is represented by the diamond. Values to the left of the vertical line at 1 favor the treatment (drainage) group. Point estimates are significant at the  $p < 0.05$  level if their confidence intervals exclude the vertical line at 1 (“no effect”).



**Figure 6.** Pooled estimates of risk of respiratory complications. Squares indicate point estimates of treatment effect (odds ratio), with the size of the square representing the weight attributed to each study. Ninety-five percent confidence intervals are indicated by horizontal bars. The summary odds ratio from the pooled studies with 95% confidence intervals is represented by the diamond. Values to the left of the vertical line at 1 favor the treatment (drainage) group. Point estimates are significant at the  $p < 0.05$  level if their confidence intervals exclude the vertical line at 1 ("no effect").

ment groups. However, one study included more stapled rectal anastomoses in the drained group,<sup>6</sup> and one study included significantly more anastomoses performed by trainees in the drained group<sup>7</sup>; both of these factors might bias the results toward demonstrating a benefit of no drainage. The similarity of the studies with respect to these variables and the homogeneity of the data offer reassurance that between-study variation was not a significant factor in the observed results.

The issue of publication bias must be addressed in a meta-analysis that relies primarily on published studies.<sup>21-23</sup> Publication bias arises because trials with a positive result are more likely to be published than negative trials, which makes meta-analyses susceptible to finding a treatment benefit when none exists (making a type I error). However, the fact that the trials analyzed in this review were all negative suggests that publication bias was not a significant factor.

The methodologic quality of the studies was low, a disappointing but common finding in the review of surgical

trials.<sup>14,15</sup> Surgical treatments have inherent problems, such as nonblinding of subjects to treatment allocation, that make designing a "perfect" randomized controlled trial impossible. However, many of the methodologic shortcomings observed here related to the inadequate documentation of inclusion criteria, randomization, and full treatment regimen. More complete reporting of these areas, as well as a diligent attempt to make outcome assessment blinded and objective, would have greatly improved these trials.

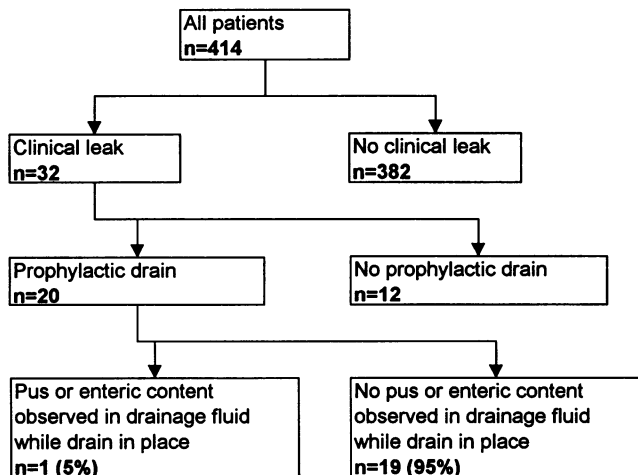
Additional large, well-designed randomized controlled trials, focusing on draining pelvic anastomoses, would give further credibility to our conclusion that prophylactic drainage of colon and rectal anastomoses is not a useful practice and should be abandoned.

**Acknowledgment**

The authors thank Dr. Robin S. McLeod for her assistance.

**References**

1. Smith SRG, Connolly JC, Crane PW, Gilmore OJA. The effect of surgical drainage materials on colonic healing. *Br J Surg* 1982; 69: 153-155.
2. Berliner SD, Burson LC, Lear PE. Use and abuse of intraperitoneal drains in colon surgery. *Arch Surg* 1964; 89:686-690.
3. Galandiuk S, Fazio VW. Postoperative irrigation-suction drainage after pelvic colonic surgery. *Dis Colon Rectum* 1993; 34:223-228.
4. Allen-Mersh TG, Sprague DB, Mann CV, Turner MJ. Pelvic drainage after anterior resection of the rectum. *Dis Colon Rectum* 1989; 32: 223-226.
5. Hoffmann J, Shokouh-Amiri MH, Damm P, Jensen R. A prospective, controlled study of prophylactic drainage after colonic anastomoses. *Dis Colon Rectum* 1987; 30:449-452.
6. Johnson CD, Lamont PM, Orr N, Lennox M. Is a drain necessary after colonic anastomosis? *J R Soc Med* 1989; 82:661-664.
7. Sagar PM, Couse N, Kerin M, May J, MacFie J. Randomized trial of drainage of colorectal anastomosis. *Br J Surg* 1993; 80:769-771.



**Figure 7.** Flow chart demonstrating efficacy of prophylactic drains in controlling anastomotic leakage.

8. Sagar PM, Hartley MN, MacFie J, et al. Randomized trial of pelvic drainage after rectal resection. *Dis Colon Rectum* 1995; 38:254–258.
9. Detsky AS, Sackett DL. When was a “negative” trial big enough? How many patients you needed depends on what you found. *Arch Intern Med* 1985; 145:709–712.
10. Naylor CD. Two cheers for meta-analysis: problems and opportunities in aggregating results of clinical trials. *Can Med Assoc J* 1988; 138:891–895.
11. Detsky AS, Naylor CD, O'Rourke K, McGeer A, L'Abbe KA. Incorporating variations in the quality of individual randomized trials into meta-analysis. *J Clin Epidemiol* 1992; 45:255–265.
12. Yusuf S, Peto R, Lewis J, Collins R, Sleight P. Beta blockade during and after myocardial infarction: an overview of the randomized trials. *Prog Cardiovasc Dis* 1985; 27:335–371.
13. Mantel N, Haenszel W. Statistical aspects of the analysis of data from retrospective studies of disease. *J Natl Cancer Inst* 1959; 22:719–748.
14. Solomon MJ, McLeod RS. Clinical studies in surgical journals: have we improved? *Dis Colon Rectum* 1993; 36:43–48.
15. MacRae HM, McLeod RS. Comparison of hemorrhoidal treatment modalities: a meta-analysis. *Dis Colon Rectum* 1995; 38:687–694.
16. Hilsabeck JR. The presacral space as a collector of fluid accumulations following rectal anastomosis: tolerance of rectal anastomosis to closed suction pelvic drainage. *Dis Colon Rectum* 1982; 25:680–684.
17. Sehapayak S, McNatt M, Carter HG, Bailey W, Baldwin A Jr. Continuous sump-suction drainage of the pelvis after low rectal resection: a reappraisal. *Dis Colon Rectum* 1973; 16:485–489.
18. Hawley PR. Causes and prevention of colonic anastomotic breakdown. *Dis Colon Rectum* 1973; 16:272–277.
19. Duthie HL. Drainage of the abdomen. *N Engl J Med* 1972; 287:1081–1083.
20. Foster ME. To drain or not after colorectal surgery. *Ann R Coll Surg Engl* 1988; 70:158–160.
21. Sacks HS, Berrier J, Reitman D, Ancona-Berk VA, Chalmers TC. Meta-analyses of randomized controlled trials. *N Engl J Med* 1987; 316:450–455.
22. Chalmers TC, Levin H, Sacks HS, et al. Meta-analysis of clinical trials as a scientific discipline. I: Control of bias and comparison with large co-operative trials. *Stat Med* 1987; 6:315–325.
23. Cook DJ, Guyatt GH, Ryan G, et al. Should unpublished data be included in meta-analyses? Current convictions and controversies. *JAMA* 1993; 269:2749–2753.