The term "evidence-based medicine" was first coined by Sackett and colleagues as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."[1] The key to practicing evidence-based medicine is applying the best current knowledge to decisions in individual patients. Medical knowledge is continually and rapidly expanding and it is impossible for an individual clinician to read all the medical literature. For clinicians to practice evidence-based medicine, they must have the skills to read and interpret the medical literature so that they can determine the validity, reliability, credibility and utility of individual articles. These skills are known as critical appraisal skills. Generally, critical appraisal requires that the clinician have some knowledge of biostatistics, clinical epidemiology, decision analysis and economics as well as clinical knowledge.

In October 2005 the American College of Surgeons joined with the Canadian Association of General Surgeons to sponsor a program entitled "Evidence Based Reviews in Surgery (EBRS)," supported by an educational grant from Evidence Based Reviews in Surgery is supported by an educational grant from Ethicon and Ethicon Endo-surgery, both units of Johnson & Johnson Medical Products, a Division of Johnson & Johnson and Ethicon Inc, and Ethicon Endo-Surgery Inc, divisions of Johnson & Johnson Inc. The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. During the academic year, 8 clinical articles are chosen for review and discussion. They are selected not only for their clinical relevance to general surgeons but also because they cover a spectrum of issues important to surgeons; for example, causation or risk factors for disease, natural history or prognosis of disease, how to quantify disease (measurement issues), diagnostic tests and the diagnosis of disease, and the effectiveness of treatment. A methodological article is supplied that will guide the reader in critical appraisal of the clinical article. Both methodological and clinical reviews of the article are performed by experts in the relevant areas and posted on the EBRS website. As well, a listserve discussion is held where participants can discuss the monthly article. Members of the College and the Canadian Association of General Surgeons can access Evidence Based Reviews in Surgery through the American College of Surgeons website (www.facs.org) or the Canadian Association of General Surgeons website (www.cags-accg.ca). All journal articles and reviews are available electronically through the EBRS website. We also have a library of past articles and reviews that can be accessed at any time. Surgeons who participate in the monthly packages can obtain CME credits or RCPSC Maintenance of Certification credits for the current article only, by reading the monthly articles, participate in the listserv discussion, complete the monthly online evaluation, and answer the online MCQ. For further information about EBRS the reader is directed to the ACS website or should email the administrator, Marg McKenzie at mmckenzie@mtsinai.on.ca.

In addition to making the reviews available through the ACS and CAGS websites, 4 of the reviews are published in condensed versions in the *Canadian Journal of Surgery* and four in the *Journal of the American College of Surgeons* each year. We hope readers will find EBRS useful in improving their critical appraisal skills and also keeping abreast new developments in general surgery. Comments regarding EBRS may also be directed to mmckenzie@mtsinai.on.ca.

## REFERENCE

1. Evidence Based Medicine Working Group. Evidence-based medicine. JAMA 1992;268:2420–2425.

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## SELECTED ARTICLE

Evidence-based Value of Prophylactic Drainage in Gastrointestinal Surgery. A Systematic Review and Meta-analysis. Petrowsky H, Demartines N, Rolusson V, Clavien PA. Ann Surg 2004;240(6):1074–1085.

### Reviewed by

Mark Taylor MD; Bill Fitzgerald MD; Michael Sarr MD; for Members of the Evidence Based Reviews in Surgery Group.

## ABSTRACT

**Objective:** To determine value of prophylactic drainage in gastrointestinal (GI) surgery.

**Data Source:** An electronic search of the Medline database from 1966–2004 was performed to identify articles comparing prophylactic drainage to no drainage in GI surgery.

**Study Selection:** Studies were reviewed and classified according to their quality of evidence, using the classifi-


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cation from the Oxford Centre for Evidence-based Medicine.

**Data Extraction:** Two independent reviewers extracted data from original articles.

**Main Results:** There is level la evidence (systematic reviews of randomized controlled trials) (RCTs) that drains do not reduce complications after hepatic, colonic, or rectal resections with primary anastomosis or following appendectomy. Three trials in liver resection were combined and found no significant difference, in the risk of bile collections, (OR=1.15, 95% CI 0.36, 3.68) or for infected collections, (OR=2.83, 95% CI 0.82, 9.71). Eight trials in colorectal resections were combined and showed no significant difference in the risk of leaks (OR=1.38, 95% CI 0.77, 2.49) or wound infections, (OR=1.41, 95% CI 0.87, 2.29). Three trials in appendectomy were combined and showed no significant difference in the risk of wound infections, (OR=1.75, 95% CI 0.96, 3.19) or intra-abdominal infections, (OR=1.43, CI 95% 0.39, 5.29) and an increased risk of fecal fistulas, (OR=12.4, 95% CI 1.14, 135). There is level V evidence (expert opinion) for the need of prophylactic drainage after esophageal resection and total gastrectomy due to the high risk of an anastomotic leak.

**Conclusions:** Drains can be omitted after hepatic, colonic, rectal operations and appendectomy. Randomized controlled trials are required to determine the value of drains following esophageal and gastric surgery.

**Commentary:** Petrowsky and associates set out to determine whether drains placed at the time of gastrointestinal surgery reduce the risk of postoperative complications. The question of whether or not to place a drain after elective abdominal surgery has been debated for many years. This systematic review was intended to help resolve this controversy.

The use of drains in abdominal surgery continues to be common practice. Many surgeons in the last few years began to reduce their use of drains after surgery because of studies which have shown their lack of usefulness in many clinical scenarios, as well as the surgeon's anecdotal impression that drains really do not seem to make much difference. Cholecystectomy, splenectomy, and appendectomy are examples of procedures for which most surgeons appear to have abandoned prophylactic drainage. Most surgeons who operate on the GI tract are aware of situations and anecdotal patient scenarios in which a well-placed drain failed to prevent a serious complication. The authors carried out an electronic search of the MEDLINE database from 1966 to February 2004. The search terms used included surgical drainage, intraperitoneal drainage, prophylactic drainage, and abdominal drainage in various combinations and in combination with GI organ systems and procedures. Trauma surgery was excluded. The outcomes variables considered were mortality, morbidity, complications, anastomotic leaks, wound infection, intra-abdominal collections and abscesses, pulmonary complications, reoperation, and hospital stay. They used manual cross-referencing in the MEDLINE search to identify further studies. This strategy likely identified most of the important publications in this area; a number of other sources could have been searched, including EMBASE, and the Cochrane Controlled Trials Register and University of York/NHS Centre for Reviews and Dissemination and SCISEARCH. Other databases are available that summarize doctoral theses that might include important information.

The data from all the identified studies were extracted by two independent reviewers. Discrepancy between the reviewers was resolved by consensus. All studies were classified according to the level of evidence using the currently accepted classification from the Oxford Centre for Evidence-based Medicine. This classification system provides objective grading criteria used to assign a level of evidence to studies. These levels of evidence range from 1a to 5. The best 1a evidence comes from systematic reviews of randomized controlled trials including meta-analyses. The conclusions from these studies support an A grade recommendation. Expert opinion only on a subject is assigned the lowest level of evidence, a score of 5, and leads to a D grade recommendation. While this Grade D is a very low level of evidence, often it may be the best or only type of evidence available. In the current review, a randomized controlled trial was assigned a level of evidence of 1b if the study had a narrow confidence interval, had an appropriate sample size calculation, the method of randomization was described, and precise definitions of exclusion/inclusion criteria were outlined. If a randomized controlled trial did not meet these criteria, it was assigned a 2b level of evidence, leading to a B grade recommendation. Studies were compared for defined end points including mortality, hospital stay, and rates of the following: overall complications, anastomotic leakage, infection, pulmonary complications, and reoperation.

The grading of quality of the articles in this paper was very well done. This approach ensured that high quality studies were regarded more favorably than those of lower quality. Evidence suggests that studies with less rigorous methodology tend to over estimate the effectiveness of the intervention under consideration. The issue of randomization is also particularly important, and it is crucial that whoever performed the randomization had no way of predicting into which group any individual patient would be randomized. The articles were reviewed appropriately by two reviewers to reduce the likelihood that the assessment of quality was biased and that important factors were missed. Disagreement over the assessment of an article was resolved by consensus. Unfortunately, the authors did not provide us with the number of times discrepancies occurred, or how often they had trouble reconciling their differences.

The authors of this review went to great lengths to assess the similarity of the results of studies on liver resection, cholecystectomy, pancreatic resection, upper GI surgery, colorectal surgery, and appendectomy. The studies in each of these areas were examined independently. Meta-analysis was performed if no meta-analysis had been published recently or if new RCTs had been published after a previous meta-analysis. Meta-analyses are often performed if individual studies fail to detect a difference. The validity of a meta-analysis is only as good as the exhaustiveness of the search and quality of the studies included. Meta-analysis assumes that the magnitude of the effect of treatment is similar across the range of patients, interventions, and ways of measuring outcomes; the decision to pool results from different studies is justified only if the treatment effect is similar from study to study. When deciding whether the decision to combine the results into a single point estimate of treatment effect is reasonable, three issues need to be considered. First, it is important to examine if the best estimates of the treatment effect from the individual studies are similar. The more they diverge from one another, the more suspect is the decision to combine them into one estimate. Next, the extent to which the confidence intervals overlap must be assessed. The greater the overlap between the confidence intervals, the more powerful becomes the rationale for pooling the results. Third, one must assess whether the differences between the results of the studies are due to chance alone, or whether they are truly different. If the differences in the observed results among the studies are due to factors other than chance, it is not appropriate to combine them into a single value. The statistical techniques used to assess similarity are called tests of heterogeneity. If p value is $<0.05$, it suggests that there is heterogeneity or differences between the studies. If so, generally the results should not be combined and the reasons for the heterogeneity should be explored.

In the current review, the authors carried out their meta-analyses using a random-effects model. This model assumes a normal distribution for the estimates of the logarithm of the odds ratio. This technique is believed to be superior to the other model possibility, which is a fixed-effects model. The authors tested heterogeneity between studies using the Q statistic. Figures 1, 2, and 3 demonstrate the point odds ratio and the confidence intervals for each individual study and for the pooled data. The odds ratios for the combined results of each meta-analysis are depicted by the open diamonds at the bottom of the figures. An odds ratio greater than 1 favored "no drain." In the majority of the figures, the diamonds are on the "no drain" side of the margin, but the confidence interval spans across "1." This observation suggests that there is a possibility that the noted effect favoring not using drains was from random variation. In many cases, it is possible that the true effect favors the use of a drain. However, even if that were the case, the true answer would still be very close to unity, suggesting that at best there is only a very small benefit to the use of a drain.

The authors calculated 95% confidence intervals for every outcome considered in each type of operation. This technique is considered currently to be the optimal way of determining the precision of the results. Because of the larger sample size of a meta-analysis the confidence intervals are narrower than with each individual study.

In these meta-analyses, the clinically important outcomes of concern to general surgeons have been considered. Quality of life is always a desirable outcome but was not considered. However, it seems unlikely that the drain would make any significant difference to the quality of life in the short time frame of a month or two around the time of operation. Other outcomes not considered were costs, duration of stay, and time until return to work. These outcomes were not considered by the authors in their analyses because they were not reported in the individual studies.

The authors' analysis suggested that there is little risk in not leaving a drain in place after gastrointestinal surgery. Indeed some studies suggested there is a greater risk when a drain is used However, one must remember that the conclusion that there is no benefit in using drains does not necessarily mean that there is no benefit of drains either for those procedures that have not been studied nor even for some of the procedures considered by these authors. For example, only two articles were identified for pancreatic resection, both originating from the same highly specialized cancer centre. Virtually all of the patients in both studies had cancer of the head of the pancreas. Only one of these studies was a randomized controlled trial; the other was a retrospective, cohort study. The same results may not be seen in other centres, particularly those that perform a lesser volume of these procedures, or when the indication for operation is not cancer of the pancreas. Indeed, most pancreatic surgeons continue to use prophylactic drains. In contrast, the data the authors considered for colorectal surgery appears more substantial. Eight RCTs were identified from a variety of institutions, demonstrating convincingly no advantage to the use of drains, particularly for intraperitoneal anastamoses. However, most surgeons long ago abandoned the use of drains in this situation, although many continue to use drains for anastamoses deep in the pelvis below the peritoneal reflection. Three randomized trials were found of pelvic anastamoses, none of which reported any advantage to drains, but a meta-analysis of these specific studies was not perfomed, which may lead to reluctance on the part of some surgeons to abandon the practice of leaving drains in the area of intraperitoneal anastamoses.

The authors concluded that many GI operations can be performed safely with prophylactic drainage but that a drain should be omitted after choleceystectomy, hepatic resection, colorectal resection with primary intrapertioneal anastomosis, and appendectomy for any stage of appendicitis. They recommend that prophylactic drainage continue after esophageal resection and total gastrectomy.

Generally speaking, the evidence provided supports their conclusions; their conclusions about esophagectomy and gastrectomy however are not consistent with the evidence. The rationale for their conclusion that drains should continue to be used is that the consequences of a leak, particularly in the mediastinum, can be catastrophic, and that experts believe that drains should be used after these operations. In no other area of the body, however, have drains been shown to reduce the likelihood of leak or to decrease the morbidity of an anastomotic leak. Drains seem to increase the risk of leak for fecal fistulas after appendectomy. It is possible that drains left after esophagectomy in fact, may increase the risk of an anastomotic leak but there is no way of answering this question definitely because proper studies have not been done. A more rational conclusion in this area would be that it remains unknown whether or not drains are useful for this group of patients and that further studies are needed in this area.

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