

Meta-analysis comparing healing by primary closure and open healing after surgery for pilonidal sinus

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The term “evidence-based medicine” was first coined by Sackett and colleagues¹ as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.” 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.

The Canadian Association of General Surgeons and the American College of Surgeons jointly sponsors a program entitled “Evidence-Based Reviews in Surgery (EBRS),” supported by an educational grant from Ethicon Inc. and Ethicon Endo Surgery Inc. The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. During the academic year, eight 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. Both methodological and clinical reviews of the article are performed by experts in the relevant areas and posted on the EBRS website. A listserv discussion is held where participants can discuss the monthly article. Fellows and candidates of the College can access Evidence-Based Reviews in Surgery through the American College of Surgeons website (www.facs.org). All journal articles and reviews are available electronically through the website. Currently we have a library of 80 articles and reviews which can be accessed at any time. Beginning each year in October, a new set of articles will be available each month until May. Surgeons who participate in the current (modules) packages can receive CME credits by completing a series of multiple choice questions. Additional information about EBRS is on the ACS website or by email to the administrator, Marg McKenzie at mmckenzie@mtsinai.on.ca.

In addition to making the reviews available through the ACS and CAGS websites, four of the reviews are published in condensed versions in the *Canadian Journal of Surgery*, four will be published in the *Journal of the American College of Surgeons*, and four in the *Diseases of Colon and Rectum* each year.

REFERENCE

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

SELECTED ARTICLE

Healing by Primary Closure versus Open Healing After Surgery for Pilonidal Sinus: Systematic Review and Meta-analysis.

McCallum IJD, King PM, Bruce J. *BMJ* 2008; 336:868-871.

ABSTRACT

Objective: To determine the relative effects of open healing compared with primary closure for pilonidal sinus and optimal closure method (midline vs. off midline).

Data Sources: Cochrane register of controlled trials, Cochrane Wound group specialized trials register, Medline (1950-2007), Embase and CINAHL bibliographic databases, without language restrictions.

Study Selection: Randomized controlled trials evaluating surgical treatment of pilonidal sinus in patients aged 14 years or more.

Methods: Data were extracted independently by two reviewers and assessed for quality. Meta-analyses used fixed and random effects models, dichotomous data

were reported as relative risks or Peto odds ratios and continuous data were given as mean differences; all with 95% CI.

Outcome Measures: Time to wound healing, rate of surgical site infection (SSI) and recurrence rate.

Results: Eighteen trials were included ($n = 1573$). Twelve trials compared open healing with primary closure. Time to healing was quicker after primary closure although data were unsuitable for aggregation. Rates of SSI did not differ; recurrence was less likely to occur after healing (RR 0.42, 0.26-0.66). Six trials compared surgical closure methods (midline vs. off midline). Wounds took longer to heal after midline closure than after off-midline closure (mean difference 5.4 days, 95% CI 2.3-11.24).

Conclusions: Wounds heal more quickly after primary closure than after open healing but at the expense of increased risk of recurrence. Off-midline closure has clear benefits over midline closure and the off-midline closure should become the standard management for pilonidal disease when closure is desired.

COMMENTARY

The treatment of pilonidal disease has been the subject of debate for many years. There is controversy as to whether the wound should be left open and packed or whether it should be closed primarily. For those in favor of primary closure, there are several options: midline closure or a variety of off-midline flap closures. The objective of this meta-analysis was to determine the optimal treatment method for pilonidal sinus. To identify relevant trials, the authors searched the Cochrane Wounds Group specialized register, the Cochrane central register of controlled trials (3006), Medline (1950-2006), Embase (1980-2006) and CINAHL (1982-2006). The strategy specifically excluded pilonidal abscess and considered only randomized clinical trials. It is interesting to note that one of the exclusion criteria was "wrong type of surgery", the meaning of which is not described. The search strategy identified 1367 potentially relevant studies of which 18 were included in the review. Noting these exclusions, it is reasonable to assume that this strategy has identified all potentially relevant clinical trials investigating the surgical treatment of pilonidal disease.

One of the perceived benefits of meta-analysis is that multiple studies, performed at different sites and possibly including different patients and with somewhat different ancillary care, are included. Thus, the generaliz-

ability of the results may be increased. On the other hand meta-analysis may be of limited value if there is too much variability in the studies. This is called heterogeneity. Heterogeneity may be assessed by simply looking at the variability in the inclusion criteria, how the treatments were performed and the duration of follow-up. Statistical tests which assess heterogeneity may also be performed. If there is too much heterogeneity then the results from individual studies should not be combined. In this situation it may still be valuable to perform a systematic review of the individual results. With regards to this meta-analysis, one of the difficulties with drawing useful conclusions is indeed the heterogeneity of the included studies.

Generally, the included studies were small and the quality was poor. As it is difficult if not impossible to blind surgeons and patients to the type of surgical treatments, blinding was not assessed as a measure of methodologic quality. The method of randomization, concealment of allocation, and completeness of follow-up were used to determine methodologic quality. Of the 18 included studies, only 2 adequately fulfilled all methodologic requirements and were considered as having low risk of bias. Four had a high risk of bias, and the remaining 12 had a moderate risk of bias. Each individual study was quite small, with sample sizes ranging from 33-200. The total number of patients included in the analysis was 1573. The studies were performed in a variety of countries including 3 in the United Kingdom, one each in Norway, Denmark, and Pakistan, and the remainder in southern Europe and the Middle East. This heterogeneity increases the likelihood that perioperative surgical care differed between studies, potentially compromising the ability to combine results.

Information on how the inclusion and exclusion criteria were applied is not presented, so it is not possible to determine the reproducibility of the study sample. Two authors independently assessed the methodologic quality of each study, with disagreements resolved by a third author. This is the accepted method for determining methodologic quality, although no data on intraclass correlations or inter-rater reliability are presented so it is not possible to determine whether the assessment is actually reproducible.

There were a large number of primary and secondary outcomes considered including time to healing, recurrence rate, complications including SSI, pain, length of stay and return to work. Cost was considered in one trial.

Only one study considered a patient centered outcome: patient satisfaction. The most frequent outcome considered was recurrence.

The authors concluded that wounds heal more quickly and patients return to work more quickly after primary closure than after open healing but at the expense of an increased risk of recurrence of pilonidal disease. Because of heterogeneity, it was not possible to combine the studies that considered time to healing, but seven of the ten studies which reported this result showed a significant (4) or non significant difference (3) that favored primary closure. Five studies reported on return to work and overall, patients who had primary closure returned to work 10.48 days (95% CI 5.75-15.21 days) faster than those whose wounds were left open. On the other hand, as stated previously, this was at the expense of an increased recurrence rate. Eleven trials which included 994 patients reported on recurrence. Ten trials had follow-up of more than 80% of patients. There was a 58% decrease in the risk of recurrence with open healing (OR 0.42, 95% CI 0.26-0.66). Thus, 14 patients would require their wound to heal by open healing rather than primary closure to prevent one recurrence.

The authors then compared outcome following midline closure versus off-midline closure. The recurrence rate was significantly higher after midline closure (OR 4.95, 95% CI 2.18 to 11.24) when 5 trials which included 413 patients were combined. The rate of surgical site infections was significantly higher after midline closure (OR 4.70, 95% CI 1.93-11.45) when four trials which included 380 participants were combined. Only one trial which included 100 patients reported on time to healing and found that midline wounds took significantly longer to heal (mean difference 5.4 days, 95% CI 2.3-8.5). Based on these results, the authors concluded that off-midline closure has clear benefits over midline closure and that off-midline closure should become standard management for pilonidal disease when closure is desired.

The only treatment options examined in this analysis are surgical so this meta-analysis does not address whether recurrent abscess drainage and antibiotics are a potential treatment alternative worthy of comparison to open or closed surgical treatment, particularly given that a balance between benefit and risk is of particular importance given the lack of a dominant strategy. Interestingly, in the one study which measured patient satisfac-

tion, patients preferred off midline over midline closure of the wound.

As the authors state in their discussion, the results must be interpreted with caution since the studies included in the meta-analysis are fraught with bias. There were variable interventions; therefore, the optimal specific technique cannot be inferred from the data presented. The methodological quality of the studies was disappointing and due to small sample size, there was a risk of failing to detect clinically significant differences. Poor randomization techniques and lack of standardization limited interpretation of their findings. Recurrence rates were more than likely underestimated since follow up periods were short and did not extend beyond four years.

The evidence to support shorter time to healing and increased recurrence for primary closure is reasonable, although based on a small number of studies each with a small number of patients and with significant heterogeneity. It is also worth noting that many of the specifics of surgical treatment and perioperative care—use of drains, degree of excision, length of bed rest, degree of mobility—were not discussed, and can significantly influence both healing and recurrence. The strength of the conclusion advocating for off-midline versus midline closure is certainly overstated given there were only 5 trials which included fewer than 500 patients. It may well be that off-midline closure is superior, but given the imprecision of the results and the lack of similarity across trials for some of the outcomes, better evidence is needed before suggesting it become standard of care. Unfortunately, choosing the option for an individual patient remains an exercise in clinical judgment, suggesting that patient satisfaction should be included as a primary outcome when faced with this decision and when performing future clinical trials.

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