

Laparoscopic Surgery Compared with Open Surgery

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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 sponsor 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 methodologic 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 50 articles and reviews which can be accessed at any time. Each 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* and the other four will be published in the *Journal of the American College of Surgeons* each year.

REFERENCE

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

SELECTED ARTICLE

Laparoscopic surgery is associated with a lower incidence of venous thromboembolism compared with open surgery

Nguyen NT, Hinojosa MW, Fayad C, et al. *Ann Surg* 2007;246:1021–1027

ABSTRACT

Question: Is the risk of post operative venous thromboembolic events (VTE) during hospitalization different in patients undergoing laparoscopic procedure vs. open procedures for similar diagnosis?

Design: Cohort study.

Participants: Patients 18 years and older who underwent one of 4 commonly performed gastrointestinal inpatient procedures – appendectomy, cholecystectomy, anti-reflux surgery and Roux-en-Y gastric bypass between January 2002 and December 2006.

Assessment of Risk Factors: Open and laparoscopic surgery. Primary diagnosis of venous thrombosis and/or pulmonary embolus were excluded.

Outcome Measures: Venous thrombosis or pulmonary embolus occurring during the initial hospitalization after laparoscopic and open surgery based on the presence

of a secondary diagnosis of International Classification of Diseases, 9th Revision Clinical Modification (ICD-9-CM) code for venous thrombosis and/or pulmonary embolus.

Results: Overall, the incidence of VTE was significantly higher in open cases 271 of 46,105, 0.59% compared with laparoscopic cases (259 of 92,490, 0.28%, $p < 0.01$). The odds ratio (OR) for VTE in open vs. laparoscopic procedures was 1.8 (95% CI; 1.3–2.5). On subset analysis of individual procedures, patients with minor/moderate severity of illness level who underwent open cholecystectomy, anti-reflux surgery and gastric bypass had a greater risk for developing peri-operative VTE than patients who underwent laparoscopic cholecystectomy (OR 2.0; 95% CI; 1.2–2.3; $p < 0.01$) anti-reflux surgery (OR 24.7; 95% CI; 2.6–580.9; $p < 0.01$) and gastric bypass (OR 3.4; 95% CI; 1.8–6.5 $p < 0.01$).

Conclusion: The frequency of peri-operative VTE is lower after laparoscopic surgery compared to open surgery. The findings can provide a basis to assist surgeons to estimate the risk of VTE and implement appropriate prophylaxis for patients having laparoscopic surgery.

Commentary: The major risk factor for pulmonary embolus [PE] is deep vein thrombosis [DVT]. It is estimated that fatal PE occurs in 0.1% to 0.8% of all surgeries, which makes it an important complication in surgical patient and worthy of further study. The exact incidence of VTE in laparoscopic surgery is not known. There is a clinical belief, supported by early venous flow studies and laboratory data that patients undergoing laparoscopic surgical procedures are at higher risk for DVT compared with similar patients undergoing open surgery. This was believed to be related to the physiologic impact of the pneumoperitoneum which may increase intraabdominal pressure and decrease venous flow. It is thought that this low flow state, coupled with a Trendelenberg position, promotes venous stasis and thus thromboembolic events. However, little evidence supports this assertion and this uncertainty has challenged the clinicians' ability to provide adequate and evidence based DVT prophylaxis for the patients undergoing a laparoscopic procedure. The objective of this study was to determine the risk of VTE in laparoscopic surgery compared with open procedures, using a large administrative database.

Data were extracted from an administrative database (The University Health System Consortium) which includes information from 138,595 patients in both academic health science centres and community hospitals. This dataset provides a wide cross section of severity and complexity of disease and a large variability in operative technique. The data presented were from inpatients prior to discharge who underwent one of 4 index operations: open or laparoscopic cholecystectomy, appen-

dectomy, antireflux surgery and bypass surgery. There was no information for events which occurred after discharge. Severity of illness was reported and included in the analysis, but was based on classification of primary and secondary diagnosis. All patients in the data base were included in the analysis, and the four index operations were decided on in advance, which adds to the strength of the methodology of the study.

Although these authors provide compelling evidence of a higher risk for patients undergoing open procedures compared with laparoscopic surgery, there are some caveats. Certainly, this study is noteworthy in that it includes a large population of patients undergoing very common operations. The event rate is low and reflects the expected rate of VTE in the open surgery population. By extension this infers validity of the results in the laparoscopic group. The largest challenge in the interpretation of these data, however, lies in the fact that they are generated from an administrative database, so important details are not available. For example, there is no information about the whether DVT prophylaxis was given to patients in the perioperative period. The use or absence of a prophylactic regimen is a major confounding variable that could influence the results especially if different interventions were given to the two cohorts of patients. This limits the internal validity of the results as well as the recommendations that can be based on these data.

Another confounding variable is the authors' use of severity of illness, which was used to perform the subgroup analyses. Certainly an increased number of important comorbidities increases the risk of VTE, but the method used for classification of severity of illness may be misleading in this study because of the reliance on codified data.

Other confounders are also present in this study. Length of stay differed between the patients undergoing open versus laparoscopic procedures for all four index operations. Prolonged hospitalization is a risk factor for development of DVT. Because this is an administrative database which does not include information on patients after discharge, this may lead to an ascertainment bias against open surgery, patients who remained in the hospital longer had a longer observation time during which complications may have occurred and been recorded. Certainly however the reverse could be true – early discharge could make the risk of VTE lower. This dataset does not have sufficient information or details to discern between these two possibilities.

Finally, there are limitations to analyses using aggregate data. The cohort nature of this study means that patients were assigned to open or laparoscopic repair for reasons that are not clear. Therefore, there may be confounding factors that swayed the clinician's decision to perform one type of procedure over the other which would also have an effect on the

outcomes studied. Furthermore, the true rate of DVT is unknown because all patients were not screened after surgery – the best estimate that an administrative database can provide is those events that are identified clinically, which may underestimate the actual incidence of disease.

In conclusion, this is an interesting study that provides some evidence which may dispel the belief that patients undergoing laparoscopic surgery are at higher risk for VTE than those undergoing open repair. However, these conclusions may not be valid based on the limitations described above. The next step for investigation of this clinical question would be a prospective trial with both a standardized prophylaxis regime, as well as perioperative screening protocol to avoid ascertainment bias. Given the size and magnitude that such a study would entail, it is likely that these authors have provided the best estimate of VTE risk in these index populations.

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