Canadian Association of General Surgeons Evidence Based Reviews in Surgery. 1

R.S. McLeod, MD; L. Smith, MD; for Members of the CAGS Evidence Based Reviews in Surgery Group*

CAGS Evidence Based Reviews in Surgery

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 practising 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 of the medical literature. For clinicians to practise 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 September 2000, the Canadian Association of General Surgeons (CAGS) initiated a program

entitled "CAGS Evidence Based Reviews in Surgery," supported by an unrestricted educational grant from Ethicon Inc. and Ethicon Endo-Surgery Inc. The primary objective of this project is to help practising clinicians 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 clinicians; for example, causation or risk factors for disease, the 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 distributed to readers. It is hoped that readers of the Evidence Based Reviews in Surgery (EBRS) will find the clinical discussion useful and also learn skills that can be used to evaluate other articles. In September 2000, the EBRS were made available to all of the general surgical programs in Canada to be used to fulfil the requirement of the Royal College of Physicians and Surgeons of Canada that critical appraisal be taught to residents. The reviews were made available to a limited group of CAGS members and in September 2001, they became available to all members of the CAGS.

In addition, beginning with this issue, 4 reviews each year will be published in the *Canadian Journal of Surgery*. Each review will consist of an abstract of the selected article and a summary of the methodologic and clinical reviews. We hope that readers will find these useful. For more information about the CAGS-EBRS or information about participating in the program, send an email to mmckenzie@mtsinai.on.ca.

Reference

1. Evidence-Based Medicine Working Group. Evidence-based medicine. A new approach to teaching the practice of medicine. JAMA 1992;268:2420-5.

^{*}The CAGS Evidence-Based Reviews in Surgery Group comprises Drs. J.S.T. Barkun, G.W.N. Fitzgerald , H.J.A. Henteleff, A.B. Hill, H.M. MacRae, R.S. McLeod, C.S. Richard, M.C. Taylor and E.M. Webber, and Ms. M.E. McKenzie.

Correspondence to: Ms. Marg McKenzie, RN, Administrative Assistant, CAGS-EBRS, Mount Sinai Hospital, 1560–600 University Ave., Toronto ON M5G 1X5; fax 416 586-5932

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Selected article

Chung RS, Rowland DY. Metaanalyses of randomized controlled trials of laparoscopic vs conventional inguinal hernia repairs. *Surg Endosc* 1999;13(7):689-94.

Abstract

Objective: To compare operating time, pain, days off work and early recurrence rates in laparoscopic versus open inguinal hernia repairs. Data sources: Studies were identified by searching MEDLINE, Current Contents and society abstracts between May 1994 and March 1997. Study selection: Studies were included if there was random allocation of patients to laparoscopic or conventional open hernia repair. **Outcome measures:** Operating time, postoperative pain in the first 2 days, time to return to work or normal activity, early recurrence rate (first 12-18 mo). Results: Fourteen trials were included: 6 comparing transabdominal preperitoneal (TAPP) versus tension-free repairs; 6 comparing TAPP/TPP (total preperitoneal) versus the Shouldice repair; and 2 comparing laparoscopic repair versus any open repair. For the results of all laparoscopic versus all open repairs see Table 1. Similar trends were observed when TAPP repairs were compared with tension-free repairs and TAPP/TPP repair were compared with sutured repairs, but the results were not statistically significant. Conclusions: Laparoscopic hernia repair results in less pain and earlier return to work but takes longer to perform without any significant difference in early recurrence rate.

Commentary

Meta-analysis is a relatively new method for synthesizing information from multiple studies.¹ Meta-analyses differ from the usual qualitative clinical reviews in that an explicit question is addressed and statistical methods are used to quantitatively combine and summarize the results of several studies (usually randomized controlled trials [RCTs]). Also, the methodology is explicit, and there is a conscientious effort to retrieve and review all studies on the topic without a preconceived prejudice. The value of meta-analysis is that study results are combined so conclusions can be made about therapeutic effectiveness or, if there is no conclusive answer, to plan new studies. Meta-analyses are especially useful when results from several studies disagree with regard to the magnitude or direction of the effect, when individual studies are too small to detect an effect and label it as statistically not significant or when a large trial is too costly or time-consuming to perform.

There are some basic steps that should be followed in performing a meta-analysis.² First, a specific health care question should be explicitly stated. Second, to ensure that all appropriate studies on the topic are retrieved, all relevant databases should be searched, proceedings of meeting and reference lists should be checked, and content experts and clinical researchers should be consulted to ensure all non-published as

Table	1
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Results of All Laparoscopic Versus All Open Inguinal Hernia Repairs			
Variable	Effect size	95% CI	<i>p</i> value
Operating time*	0.48	0.20 to 0.75	< 0.05
Pain	-0.37	–0.68 to –0.06	< 0.05
Recovery time	-0.31	–0.51 to –0.12	< 0.05
Recurrence rate	0.61†	-1.93 to 0.72	NS
*Favours open repair. †Odds ratio			

well as published trials are identified. Third, inclusion criteria as to which studies will be included should be set *a priori*. Fourth, the quality of studies should be assessed and data from the individual studies extracted by 2 blinded investigators. Fifth, the data should be combined using statistical techniques. Before doing so, statistical tests to determine the "sameness" or "homogeneity" of the individual studies should be performed.

Whereas some have embraced meta-analysis as a systematic approach to synthesizing published information from individual trials. others have expressed caution about the results of meta-analysis. Results of some meta-analyses have not been replicated in subsequent large trials.³ Meta-analyses on the same clinical question have sometimes led to different conclusions. Some of these discrepancies may be the result of methodologic problems — failure to include all relevant trials due to inadequate search strategies, omission of unpublished trials or those published in non-English journals or inclusion of trials of variable quality. Although the value of meta-analysis is that results may be more generalizable, this is also a weakness in that it may lead to invalid conclusions if trials are inappropriately combined because of differences in patient selection, treatment regimen or follow-up.

Chung and Rowland stated that this review was performed to determine whether a large RCT is necessary to determine whether laparoscopic hernia repair is superior to open inguinal hernia repair. However, the practising clinician may find this meta-analysis useful because the results of individual trials are combined so that it is not necessary to retrieve, evaluate and synthesize the results of all studies on the topic, thus increasing the efficiency of the clinician in keeping abreast of recent advances.

As with other study designs, the validity of the results depends on the rigour of the methodology. In addition, the validity of a meta-analysis also depends on the quality of trials available for inclusion. In this metaanalysis, the inclusion criteria were quite broad, "true randomized design comparing laparoscopic hernia repair with conventional open operation and having usable statistical data." The authors searched MED-LINE, *Current Contents* and society abstracts for relevant articles. They provide no data on how many articles they retrieved with this search strategy although they did state that 4 studies were excluded because patients were not truly randomized or key data were missing. A quality assessment was not performed nor is any information given about how the data were extracted (i.e., blinded, 1 or 2 extractors).

Before combining the data, the authors found significant heterogeneity among the studies with some variables but nevertheless combined them. Although they used a random effects model, the reader should be wary of the results because of the heterogeneity (i.e., apples-andoranges effect). One of the reasons for the heterogeneity may be the variability of measuring pain and return to work times in the trials. This is a common problem in metaanalyses, especially if less objective data or data that are not measured uniformly are combined.

In this meta-analysis, an effect-size statistic was used to combine the data for operating time, pain and time to recovery. Readers may be more familiar with the use of an odds ratio for combining data in a metaanalysis. This is the usual statistic used for combining dichotomous data (e.g., yes or no, alive or dead) but the effect-size statistic is appropriate for combining continuous data (e.g., time to return to work or operating time). An odds ratio was calculated for early recurrence rates.

Thus, the reader must interpret the results of this meta-analysis with caution. To the authors' credit, they looked at the results overall as well as by comparing laparoscopic herniorrhaphy with tension-free as well as sutured repairs. In all analyses, operating time was longer whereas pain and recovery times were shorter with a laparoscopic repair. In the subgroup analyses, the results did not reach statistical significance. Furthermore, in the comparison with tension-free repair, the decrease in pain and time to recovery in favour of laparoscopic repair was quite modest (-0.18, 95% CI -0.79 to 0.43 and -0.29, 95% CI -0.58 to 0.01 respectively). The trials only report a short (12–18 mo) follow-up, but there was no difference in the early recurrence rate overall or in the subgroups.

What do these results tell us? Laparoscopic herniorraphy was first performed in Canada in 1991. The technique gained popularity as surgeons looked for ways of reducing postoperative morbidity and recovery in the same way that laparoscopic cholecystectomy had affected gallbladder surgery. At one point, approximately 20% of hernia repairs in Canada were performed this way. The popularity of the technique has now declined to approximately 5% to 10% of hernia repairs. Several factors have probably contributed to this decline. As mentioned by Chung and Rowland, laparoscopic hernia repair is technically difficult, and, at least initially, very slow to perform. The operation involves dissection and mesh placement in an unfamiliar anatomic area, and at least 50 procedures must be performed before the surgeon has competence in the technique.

The article is relevant in that it shows that laparoscopic hernia repairs offer very little advantage over tension-free hernia repairs in the areas where laparoscopic hernia repairs were touted to be superior (pain and return to work). Thus, the findings are consistent with current clinical practice. Tension-free hernia repair appears to be the preferred method to minimize postoperative morbidity and cost. However, this meta-analysis deals only with uncomplicated hernias. For recurrent or bilateral hernias, laparoscopic herniorraphy may be the preferred option.

Conclusions

Tension-free inguinal hernia repair is the preferred surgical treatment for uncomplicated inguinal hernias given the shorter operating time and only modest increase in pain relief and recovery time. However, more long-term follow-up is required.

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