Another laparoscopic trial report: what have we learned?

The surgeons in the Colorectal cancer Laparoscopic or Open Resection II (COLOR II) trial are to be congratulated for their second major clinical trial success. It is no minor accomplishment to design a proper study, recruit a league of surgeons, engage a broad community of patients, and maintain equipoise as the world of surgery undergoes rapid change. Indeed, undertaking trials, such as reported by van der Pas and colleagues, requires dedication, determination, and substantial financial support. Have we learned enough from this trial and other trials like it to justify the time and effort? From the results of COLOR II trial, we learn that patients with rectal cancer treated with laparoscopic resection had small gains in short-term outcomes, specifically shorter times to their bowel function returning and discharge from hospital, but no decrease in perioperative complications. These results are consistent with previous findings from the laparoscopic colectomy trials, which is understandable because of the similarities of the trial methods. By standardising eligibility criteria, random assignment, surgical methods, and outcome measures, results became reproducible and the effect of the test procedure can be measured accurately. It might be argued that large databases could also be used to estimate the effect of a new procedure in the context of real-world practice, but they cannot be used to estimate the effect of the new procedure as precisely as the results of prospective randomised studies, or with the same level of attribution, particularly when the old procedure is the default. This difference likely accounts for why results of database studies show fewer complications for patients treated with laparoscopic resection than do the large prospective studies. In many situations, such a difference would not matter, but when the new procedure is associated with new or potentially greater risks, the benefit-to-risk ratio should be established with a higher degree of precision. Indeed, this reason is why these laparoscopic trials were pivotal and likely explains why so many surgeons and funding agencies supported them. It is no coincidence that trials of laparoscopy began when the frequency of wound tumour implants with laparoscopic resection peaked at 21%. So what have we learned from the COLOR II trial about cancer outcomes and is this trial definitive? Primarily, we learned that the same pathological specimen can be obtained with laparoscopic surgery as with open surgery. This is an important step forward because it refutes the earlier concerns raised by the findings of the CLASICC trial in which rates of positive circumferential radial margins were higher in the subset of laparoscopic patients undergoing anterior resection. The COLOR II results are not definitive, but primary endpoint data on locoregional recurrence rates are expected by the end of 2013. Most of us assume from the COLOR II data, long-term CLASICC results, and single institution data, that the 3-year results from COLOR II and the pending data from American College of Surgeons Oncology Group Z6051 will support the view that laparoscopic proctectomy is not worse than open proctectomy for cancer outcomes. It would seem that most colorectal surgeons are making this assumption too because almost three-quarters report that they are already performing laparoscopic proctectomy.

After 20 years of laparoscopic trials, what have we learned about surgical trials in general and their role in surgical innovation? We know that surgeons will always innovate to find better, faster, and safer means of providing surgical care to their patients and, hence, there will always be a need for rigorous surgical trials. We also know that the resources needed to undertake such trials will not always be available. If trials are too cumbersome and expensive and do not estimate real world experiences, and database studies contain too many variables and cannot test the effect of the intervention separate from patient selection, surgeon’s expertise, or institutional effects, we have to ask if there is an alternative option. In view of the investments made in building large national databases and in undertaking clinical trials, the time is probably right to bring these two assets together. We have sufficient proof that both high-quality data can be generated from databases and that surgeons can work together towards prospective standardisation. Indeed, it was probably the standardisation of technical aspects of surgery and the quality assurance and control programmes that curtailed the harmful effects of laparoscopic cancer surgery more than any other aspect of the trial. In conclusion, I propose that it is time to unite these prospective standardisation processes with existing databases to build new models for systematically introducing new surgical procedures. We have more electronic tools than ever before to bring surgical science to a new level, so we just have to do it.
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I declare that I have no conflicts of interest.


