

Comment on “Prospective randomized clinical trial comparing laparoscopic cholecystectomy and hybrid natural orifice transluminal endoscopic surgery (NOTES) (NCT00835250)” (doi:10.1007/s00464-012-2359-4)

Mark A. Carlson

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To the Editor,

I read with the interest the article by Noguera et al. [1] in which they describe a randomized trial of conventional laparoscopy and two hybrid NOTES approaches for cholecystectomy. The authors found no significant differences in outcomes among the three treatment groups. The authors are to be commended for the performance of a randomized controlled trial (RCT) on this controversial topic.

While one could quibble over the article’s minor non-adherence to the CONSORT Statement [2, 3], my primary criticism is that the authors made conclusions that have no basis. Here is a quote from the final paragraph of the Discussion section: “...it is safe to conclude that the transvaginal approach with the flexible endoscope is not inferior to conventional laparoscopy in either effectiveness or safety, and that the transumbilical approach with the flexible endoscope is as effective and safe as the transvaginal approach.” With 20 patients per group, this study was underpowered to make such a conclusion. Based on the authors’ own power analysis, the estimated sample size to see a difference of 1 versus 3 % in complication rates would have been 285 patients per group. Incidentally, these numbers would have been even higher if the authors wanted to rule out differences in bile duct injury. The authors stated that their study was done as a “pilot study,” since the calculated sample size was too high. While I

would not accept such a statement as justification for an underpowered trial, my main objection is that the authors’ data do not support their conclusions.

The only conclusion that can be drawn from this paper is simply this: in a trial of 60 women, no differences in outcome among three cholecystectomy techniques were observed. After this statement, the authors would have to make the concession that their study, by their own admission, was underpowered to make any conclusion that could be generalized beyond their 60-patient experience. To reiterate, it is not valid to extrapolate the data of this study and instruct the general readership that gallbladder technique A is not inferior to technique B, or that various techniques are safe and effective, and so forth.

The other major concern that I have is why the data–conclusion incongruity was not corrected during the *Surgical Endoscopy* peer review process. This suggests an issue with the manuscript’s peer review. Unfortunately, we now have an article that has been vetted, published, and is searchable on the internet, a paper that contains the laudable “prospective randomized clinical trial” in its title, yet makes unfounded conclusions that could mislead surgeons and patients. The adequacy of planning, performing, and reporting surgical clinical trials has been under increasing scrutiny [4–6]. Unfortunately, it appears that this article is not helping this situation or surgical science in general.

M. A. Carlson (✉)

Department of Surgery, University of Nebraska Medical Center,
VA Nebraska Western Iowa Health Care System, Surgery 112,
VA Medical Center, 4101 Woolworth Ave, Omaha, NE 68105,
USA

e-mail: macarlso@unmc.edu

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