Lack of Improvement Over Time in Methodological Quality of Randomized Trials on Laparoscopic Surgery Training

Stavros Athanasios Antoniou^{a,b} Alexandros Andreou^b George Athanasios Antoniou^d
Oliver Owen Koch^e Gernot Köhler^e Ruzica-Rosalina Luketina^e Antonios Bertsias^c
Rudolph Pointner^f Frank-Alexander Granderath^a

^aCenter for Minimally Invasive Surgery, Hospital Neuwerk, Mönchengladbach, Germany; ^bDepartment of General Surgery, University Hospital of Heraklion, and ^cDepartment of Social Medicine, Biostatistics Laboratory, Faculty of Medicine, University of Crete, Crete, Greece; ^dLiverpool Vascular and Endovascular Service, Royal Liverpool University Hospital, Liverpool, UK; ^eDepartment of General Surgery, Sisters of Charity Hospital, Linz, and ^fDepartment of General Surgery, Hospital Zell am See, Zell am See, Austria

Dear Editor,

We have previously investigated the trend in the volume and the quality of randomized controlled trials (RCTs) published in 2002 and 2012 in select journals [1, 2]. For this analysis, we used the Scottish Intercollegiate Guidelines Network tool for controlled trials, which indicated a significant improvement of overall quality over time [3].

Upon quality assessment, we noticed that RCTs on surgical training were often of poor methodological quality. We therefore retrospectively reviewed the collected data and performed a subset analysis of RCTs on surgical training. The Pearson's chi-square test and the 2-tailed Fisher exact test for independent samples were used, as applicable, with the significance level set at an α value of 0.05.

From a total of 66 and 114 RCTs on minimally invasive surgery published in 2002 and 2012, 10 and 22 RCTs regarded surgical training, respectively. Although a significant improvement of methodologi-

cal quality was noted for non-training RCTs over time (OR 0.50, 95% CI 0.26–0.98, $p = 0.043$), a similar improvement was not evident for the subset of RCTs on surgical training (OR 0.25, 95% CI 0.03–2.42, $p = 0.374$). Furthermore, RCTs on surgical training had almost 3 times higher odds of being unacceptable quality than intervention studies in 2012 (OR 2.90, 95% CI 1.07–7.85, $p = 0.032$), although such an association was not present in 2002 (OR 0.17, 95% CI 0.20–1.47, $p = 0.137$). It may thus be suggested that, although an improvement of quality over time could be demonstrated for interventional studies, RCTs on surgical training showed no such trend. Comparative evaluation of important components of methodological quality, such as concealment, blinding (of at least the outcome assessor or the subjects), similar baseline characteristics, dropout rate and experience level of participants, did not demonstrate improvement over time (analytical data are available by the authors).

The research community needs to be alert on the need for quality evidence on surgical training. Relevant pooled data in the field of surgery are scarce. Available systematic reviews of RCTs on general surgical training have similarly suggested inadequate methodological quality [4, 5]. However, the dissemination of minimally invasive surgery and the surgical training of residents and novice laparoscopic surgeons in technically demanding surgical modalities rely largely on RCTs, which therefore need to be reliable and with low risk of bias.

Source of Funding

None.

Disclosure Statement

None.

References

- 1 Antoniou SA, Andreou A, Antoniou GA, Koch OO, Köhler G, Luketina RR, Bertsias A, Pointner R, Granderath FA: Volume and methodological quality of randomized controlled trials in laparoscopic surgery: assessment over a 10-year period. *Am J Surg* 2015; 210:922–929.
- 2 Antoniou SA, Andreou A, Antoniou GA, Bertsias A, Köhler G, Koch OO, Pointner R, Granderath FA: A systematic review and analysis of factors associated with methodological quality in laparoscopic randomized controlled trials. *Dig Surg* 2015;32:217–224.
- 3 Scottish Intercollegiate Guidelines Network, Healthcare Improvement Scotland. http://www.sign.ac.uk/methodology/checklists/20121206_Checklist_for_controlled_trials.doc (accessed June 2014).
- 4 Thomas RE, Crutcher R, Lorenzetti D: A systematic review of the methodological quality and outcomes of RCTs to teach medical undergraduates surgical and emergency procedures. *Can J Surg* 2007;50:278–290.
- 5 Sutherland LM, Middleton PF, Anthony A, Hamdorf J, Cregan P, Scott D, Maddern GJ: Surgical simulation: a systematic review. *Ann Surg* 2006;243:291–300.