

Primary Outcome in a Randomized Controlled Trial: A Critical Issue

Sir

We read the original article titled “Laparoscopic versus open appendectomy: a comparison of primary outcome measures” by Khalil *et al.*,^[1] with great interest.

Randomized controlled trials (RCTs) are principal tools to identify effectiveness of one treatment over another as they bestow least biased estimates of treatment effects.^[2] Absence of selection bias and random distribution of confounding factors among different groups make these scientifically rigorous RCTs a preferred choice over case controlled studies.^[3] Unfortunately, design of RCTs usually gets less attention than what it deserves. An RCT may involve a number of outcomes. It is of utmost importance to differentiate a primary outcome from a secondary outcome. Primary outcome (end point) is a very critical issue in the design of RCTs. A primary outcome is one which will be used to arrive at a decision on the overall result of the study.^[4] Moreover, a primary outcome will also serve the basis to calculate the sample size for a particular RCT. So, a RCT must have only one primary outcome, which should be decided at the outset of the study.

Khalil *et al.*,^[1] involved a number of primary outcomes including operative duration, length of hospital stay, and postoperative complications. They have also not mentioned how sample size was calculated. In a review of 42 RCTs comparing open versus laparoscopic appendectomy, Sadr-Azodi *et al.* concluded that most of these RCTs had low quality.^[5] They recommended that adherence to the CONSORT statement^[6] and registration of the trial protocol are important tools to improve the quality of trials in the field of surgery.

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