

Is the right answer always correct: between primary endpoint and clinical validity



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We read with great interest the single-centre ROC'N'ROLL randomized controlled trial by Birgin and colleagues,¹ which assessed the perioperative outcomes and quality of life (up to 90 days) of robotic hepatectomy (RH) and laparoscopic hepatectomy (LH) for liver malignancies. It is the first trial of its kind, and the authors should be applauded for this accomplishment.

This study does, however, highlight an important element of RCTs design: choosing a clinically relevant primary endpoint with an appropriate hypothesis regarding the expected treatment effect of the experimental treatment (i.e., superiority, non-inferiority or equivalence). The overall study design must provide a clear answer to the main research question and provide valuable information to end-users. When these prerequisites are not met, the trial might lose its relevance, constituting a waste of time and resources.²

Considering this, the ROC'N'ROLL trial may have encountered a significant issue by hypothesizing superiority of robotic hepatectomy in the role functioning scale of the QLQ-C30 questionnaire. While quality of life (QoL) is undeniably one of the most important outcome parameters of any medical therapy, there is no substantial evidence or rationale to anticipate a difference in this primary endpoint between RH and LH. From the perspective of surgical trauma, RH could even be viewed as a laparoscopic procedure utilizing a very sophisticated (and expensive) instrument. Despite the robotic platform potentially offering some advantages over conventional laparoscopy in specific procedures, major clinically significant benefits are yet to be demonstrated.³ Moreover, to the best of our knowledge there is no prior evidence of any benefit of RH compared to LH in terms of QoL.

The author's assumption of a 13% QoL increase in the sample size calculation was in fact based on studies comparing laparoscopy to conventional open surgery. Any QoL differences in such a comparison can be attributed to laparoscopy's smaller incisions and short-term benefits over open surgery.⁴⁻⁶ However, this

assumption cannot be extended to comparisons between two minimally invasive approaches. Unfortunately, the results of the ROCK'N'ROLL trial are unable to shed light on the current knowledge-gap related to the exact role of RH in minimally invasive liver surgery.

In conclusion, the ROC'N'ROLL trial has significantly contributed to our understanding of the outcomes of RH and LH. However, further research is still needed, and future multicentre RCTs should focus on relevant clinical outcomes with an appropriate study hypothesis to advance the ongoing debate on the role of RH.

Contributors

TJH: conceptualisation, writing-original draft; JPS: conceptualisation, writing – review & editing; MAH: conceptualisation, writing – review & editing, supervision.

Declaration of interests

There are no conflicts of interest.

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