

REVIEWER'S REPORT

Manuscript No.: IJAR-52379

Date: 21-06-2025

Title: Les essais cliniques randomisés en chirurgie

Recommendation:

Accept as it is.....**YES**.....
 Accept after minor revision.....
 Accept after major revision
 Do not accept (*Reasons below*)

Rating	Excel.	Good	Fair	Poor
Originality			√	
Techn. Quality		√		
Clarity			√	
Significance			√	

Reviewer's Name: Dr Aamina

Reviewer's Decision about Paper: **Recommended for Publication.**

Comments (*Use additional pages, if required*)

Reviewer's Comment / Report

General Overview:

This article addresses a critical and often underexplored topic: the methodological and ethical challenges in designing randomized controlled trials (RCTs) within the surgical field. It highlights the contrast between the progressive nature of surgical innovation and the structured demands of evidence-based clinical research, particularly randomized trials. The work is timely, relevant, and contributes meaningfully to ongoing discussions in clinical methodology, medical ethics, and surgical practice.

Relevance and Originality:

The paper brings forward an important issue in the intersection of surgical advancement and clinical research standards. While pharmacological interventions routinely undergo rigorous RCT phases before clinical implementation, surgical techniques often do not follow this path, which raises unique ethical and methodological questions. The article's focus on adapting RCTs to surgery reflects current debates in

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medical research and provides a valuable analytical perspective for healthcare professionals, researchers, and bioethicists.

Structure and Clarity:

The abstract and introduction are clearly written, concise, and effectively communicate the article's purpose. The flow of thought—from the observational nature of traditional surgical practice to the need for RCTs, followed by the challenges of implementing these trials in a surgical context—is logically organized. The use of references to well-established clinical trial phases provides a helpful foundation and sets the stage for a nuanced discussion.

The language is accessible and professionally appropriate for an academic audience. Key concepts such as methodological bias, ethical considerations, and technological evolution are well-articulated.

Content and Analytical Value:

The article underscores the discrepancy between surgical innovation and formal clinical validation. By pointing out the increased necessity of RCTs due to technological development and heightened healthcare expectations, it raises awareness about the ethical responsibility of proving clinical efficacy and safety.

The mention of practical and ethical difficulties specific to surgical RCTs—such as standardization of procedures, surgeon experience variability, and informed consent—introduces the reader to the complexity of this domain. The acknowledgment that solutions are being discussed in literature sets a promising premise for a more detailed review or exploration in the subsequent sections.

Methodological Insight:

The paper is grounded in sound clinical reasoning. It clearly distinguishes the multi-phase structure of traditional clinical trials and reflects on its adaptability to surgical settings. The structure shows an appreciation for both the epistemological and operational constraints of surgical research.

Scholarly Contribution:

This work contributes to a growing body of literature advocating for more rigorous validation processes in surgery, aligning surgical practices with the evidence-based standards common in pharmacology and general medicine. It fosters a necessary dialogue between surgical expertise and clinical research ethics, encouraging the development of more appropriate and feasible methodologies for evaluating surgical interventions.

Conclusion:

This is a well-conceptualized and relevant article that opens important discussions on the challenges and necessity of randomized controlled trials in surgical practice. It provides a clear foundation for further

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exploration of practical solutions and methodological innovations. Its emphasis on the ethical obligation to rigorously test new interventions is especially valuable in today's complex clinical landscape.