Characteristics of Randomized Clinical Trials in Surgery From 2008 to 2020: A Systematic Review

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This systematic review analyzed 212 randomized clinical trials in surgery from 2008 to 2020, providing valuable insights into key characteristics and potential areas for improvement.

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Discrepancies in Published Protocols

Discrepancies with the published protocol were identified in 81 trials (33.5%), revealing the importance of adherence to the established protocol.

Outcome Measures in Trials

Usage of Major Clinical Events

Only 123 trials (31.7%) used major clinical events as the primary outcome, suggesting room for improvement in outcome measure selection.

Bias and Risk Assessment

1 Bias Concerns

Most trials (54.4%) had some concern of bias, highlighting the need for robust trial design and implementation to minimize bias.

2 High Risk of Bias

Additionally, 91 trials (23.5%) had a high risk of bias, emphasizing the importance of stringent quality control in surgical trials.

Sample Size

The trials were generally small, with a median sample size of 122 patients, indicating the need for larger and more representative samples.

Surgeon's Experience and Trial Intervention

Surgeon's Experience

Most trials did not adopt any method to control for surgeons' experience (78.1%), suggesting a potential lack of consideration for this crucial factor.

Trial Intervention Quality

Surprisingly, 95.6% of trials did not assess the quality of the intervention performed, indicating a critical area for improvement in trial reporting and evaluation.

Details of Trial Intervention

Moreover, 58.2% of trials provided only limited details of the trial intervention, highlighting the need for comprehensive and transparent reporting.

Blinding and Interpretation Bias

Lack of Blinding Information

Notably, 33.0% of trials did not report any information about blinding, signaling a potential oversight in trial methodology and transparency.

Interpretation Bias

In more than half of the 212 trials with neutral results, evidence of interpretation bias was found, emphasizing the importance of unbiased interpretation and reporting of trial outcomes.