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Methodological and reporting quality of Latin American randomized controlled trials in surgery from 2012 to 2022: a meta-research study

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Background: Latin America is a region where an increasing number of randomized controlled trials (RCTs) in surgery are being conducted. However, there is no evidence regarding the methodological and reporting quality of this studies.
Methods: Meta-research study, including RCTs conducted in general surgery and subspecialties, conducted in Latin American centers and published from 2012 to 2022 with inclusion in PubMed and Scopus databases. The CONSORT and Joanna Briggs Checklist for Randomized Controlled Trials tools were used.
Results: 83 RCTs met the inclusion criteria. 67.5% (n = 56) were conducted in Brazil. 74.7% (n = 62) of RCTs demonstrated high methodological quality, while only 31.7% (n = 26) exhibited high reporting quality. Out of the 13 methodological quality items, 3 were not fulfilled in more than 50% of the RCTs. Meanwhile, of the 37 reporting quality items, only 15 were met in more than 75% of the RCTs.
Conclusions: While the methodological quality of Latin American RCTs in surgery included in PubMed and Scopus is relatively high, there is a predominance of moderate reporting quality. The common failure to comply with specific items in this sample is a phenomenon of great interest for surgical meta-research that warrants deeper exploration. These shortcomings the falsifiability and reproducibility of Latin American RCTs in surgery, which could be improved through scientific training.

Keywords: general surgery, latin America, methods, operative surgical procedures, randomized controlled trials as topic

Introduction

Surgery is a broad specialty that encompasses a significant number of diseases, interventions, and special technical considerations. Reproducibility and falsifiability in surgery are topics of great interest, considering that, technically and methodologically, surgical interventions and outcomes are operator-dependent when not using tools such as robotics, and clearly differ from non-surgical outcomes[1]. Rigor in the design and reporting of clinical surgical studies is essential to ensure the robustness of the evidence produced and shared within the academic community[2].

Randomized controlled trials (RCTs) constitute the pinnacle of primary data evidence to support interventions in medicine, including surgery. However, internal and external validity depends on the quality of the study's execution and publication (methodological and reporting quality, respectively), forming the basis for the reproducibility and critical approach of evidence-based medicine[3]. Latin America is a region where an increasing number of RCTs in surgery are being conducted[4]. Despite this, there is no clear evidence regarding the availability of data on the methodological and reporting quality of such studies in surgery, facilitating the critical approach of global evidence regarding surgical intervention and diagnosis in this region. Due to costs, efforts, and ethical implications, it is imperative to maintain and ensure the highest possible quality of RCTs. One way to gauge the overall landscape of evidence validity in surgery provided by RCTs is through meta-research, using validated tools for critical evidence assessment[3,5]. The aim of this study was to assess the methodological and reporting quality of Latin American RCTs in surgery and subspecialties from 2012 to 2022 included in PubMed and Scopus databases.

Methods

Study design

Meta-research study.

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Setting and participants

The study protocol was registered in PROSPERO (CRD42022376683). A structured and systematic search was designed and executed using Medical Subject Headings (MeSH) terms and keywords, employing PubMed and Scopus until December 2023, to identify RCTs conducted in general surgery and subspecialties, authored by Latin American authors and conducted in Latin American centers, and published between 2012 and 2022. The detailed search can be found in Supplementary Digital Content, Appendix 1, available at: http://links.lww.com/IJSOPEN/A37. It was used the operational and conceptual definition of "general surgery", as defined by MeSH, and registered under the taxonomy of Surgical Specialties. Inclusion criteria for analysis were defined as follows: (1) RCTs with explicit methodological design in the official publication; (2) full-text studies; (3) articles published in Spanish, English, or Portuguese; and (4) articles where it could be identified that the execution centers were in Latin America. Studies outside the scope of general surgery specialties, such as plastic surgery, orthopedics and traumatology, otolaryngology, urology, pediatric surgery, and gynecology and obstetrics, were excluded. This criterion was established based on the classification declared by the Latin American Federation of Surgery (FELAC), which is the official regional organization that involves the subspecialties related to general surgery residencies in Latin America (https://tinyurl.com/4fskfsd4).

Data collection and standardization

All initially identified citations were imported into Rayyan[6], where four authors independently removed duplicates and subsequently reviewed the title and abstract of the studies to verify compliance with the inclusion criteria. A full-text review of the trials was conducted, and finally, those trials were selected in which it could be corroborated that all the inclusion and exclusion criteria were met. In case of discrepancies, the studies were reviewed by two different authors than the initial ones. Subsequently, the general characterization and meta-research analysis of the included studies were performed.

Based on the data from the official publication, two authors identified and extracted general variables related to the

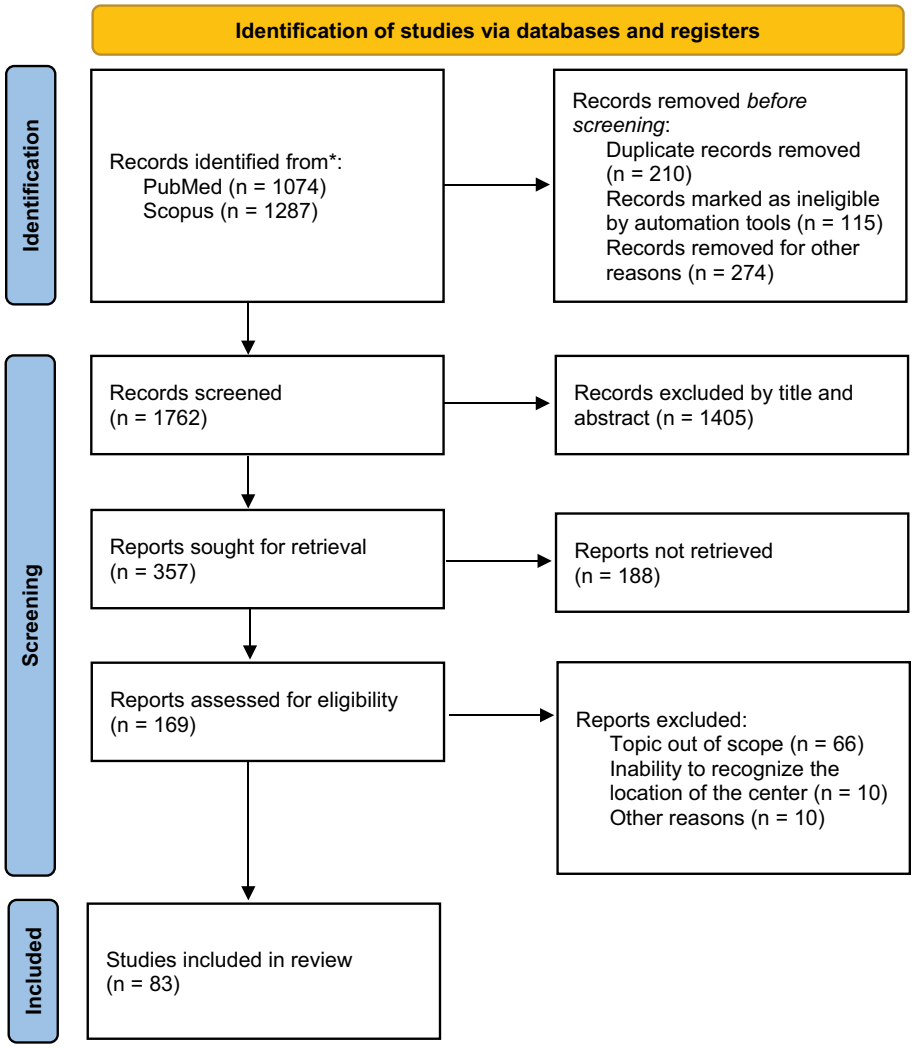

Figure 1. PRISMA 2020 flowchart.

execution and publication of the RCT. The CONSORT[7] and Joanna Briggs Checklist for Randomized Controlled Trials[8] tools were used to assess the reporting and methodological quality, respectively. Previously, these tools have been validated and used for this type of analysis[9,10], recommended as standards to ensure the value and validity of evidence-based medicine.

Methodological quality assessment

The Joanna Briggs Checklist for Randomized Controlled Trials is a critical appraisal tool (for methodological quality assessment) with 13 items and three types of responses based on item fulfillment (yes, no, unclear)[8]. Based on previous studies[11,12], the quality of studies can be categorized as high quality (>70% yes [>9 points]), moderate quality (50–69% yes) [6.5–9 points], or low quality (<50% yes [<6.5 points]). One point was assigned for each yes, 0.5 points for each unclear, and 0 points for each no. The critical assessment was independently conducted by three authors. In case of discrepancies, a fourth author was consulted.

Reporting quality assessment

The CONSORT checklist is a tool used to validate the reporting quality of RCTs, consisting of 25 questions with a total of 37 items (some may not be applicable, depending on the approach and design of the RCT)[7]. One point was assigned for each fulfilled item (yes), 0.5 points for each unclear, and 0 points for each no. Based on previous studies[11,12], the quality of studies can be categorized as high quality (>75th percentile [>28 points]), moderate quality (50th–74th percentile [18.5–28 points]), or low quality (<50th percentile [<18.5 points]). The critical assessment was independently conducted by three authors. In case of discrepancies, a fourth author was consulted.

Statistical analysis

Considering the descriptive nature of the study, frequency and percentage calculations were performed for qualitative variables, and mean and standard deviation or median and interquartile range were applied to quantitative variables. The information from each study was described and summarized in tables.

Ethical statements

Ethical approval was not required for this study as it did not involve human subjects or animals, and the databases were open-access.

Results

General characteristics

Initially, a total of 2003 potential studies were identified. Following a rigorous review and application of inclusion and exclusion criteria, a total of 83 RCTs were included (Fig. 1). These were predominantly monocentric (n = 78; 94%), with limited international collaboration (n = 19; 22.9%), including fewer than 100 patients (n = 55; 66.3%), and over half did not have a study registration (n = 43; 51.8%). 67.5% (n = 56) of the studies were conducted in Brazil, and only 24.1% (n = 20) of all studies reported funding (Table 1). Since 2012, the highest number of trials were published in 2022 (n = 13) and 2016 (n = 12), respectively (Fig. 2).

Table 1

General characteristics of the included randomized controlled trials (N = 83).

	n	%
Funding		
Yes	20	24.1
No	63	75.9
Funder (N = 20)		
University	4	20
Government	5	25
Industry	8	40
Researchers	1	5
Hospital	2	10
Drug intervention		
Yes	21	25.3
No	62	74.7
Collaboration		
Single-center study	78	94
Multicenter study	5	6
International Collaboration		
Yes	19	22.9
No	64	77.1
Sample		
<100 patients	55	66.3
100–500 patients	28	26.7
Country		
Brazil	56	67.5
México	17	20.5
Argentina	6	7.2
Colombia	2	2.4
Chile	1	1.2
Venezuela	1	1.2
Authors per study, mean (SD)	8.4 (5.1)	–
Study registry		
Yes	40	48.2
No	43	51.8
Journal quartile		
Q1	48	57.8
Q2	12	14.5
Q3	19	22.9
Q4	4	4.8
Open access		
Yes	38	45.8
No	45	54.2

Methodological quality assessment

Of the 13 methodological quality items (M1 to M13), compliance with 10 items was identified in more than 75% of the studies. The items with the highest frequency of compliance were M13 (trial design appropriate, and any deviations from the standard RCT design accounted for in the conduct and analysis of the trial; 97.6%), M10 (outcomes measured in the same way for treatment groups; 96.4%), and M12 (appropriate statistical analysis used; 92.8%). In contrast, items M4 (blind to treatment assignment; 45.8%), M5 (delivering treatment blind to treatment assignment; 16.9%), and M6 (outcomes assessors blind to treatment assignment; 48.2%) were fulfilled in less than 50% of the studies. It was

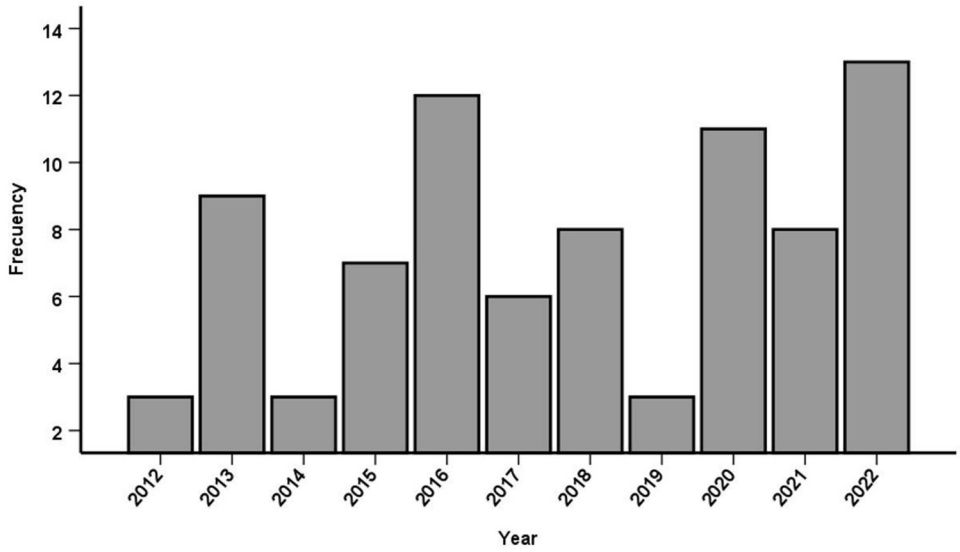

Figure 2. Publication of Latin American randomized controlled trials in surgery and subspecialties over time.

identified that 74.7% (n = 62) of the RCTs were of high quality, followed by moderate quality (n = 19; 22.9%) (Table 2). The mean compliance score was 10.1 ± 1.71, with an average compliance percentage of 78.2% ± 13.2.

Reporting quality assessment

Of the 37 reporting quality items (R1a to R25), only 15 were met in more than 75% of the RCTs. The items with the highest frequency of compliance were R2a (scientific background and explanation of rationale; 98.8%), R1b (structured summary of trial design, methods, results, and conclusions; 96.4%), and R22 (interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence; 95.2%). In contrast, items R10 (who generated the random allocation sequence, enrolled participants, and assigned participants to interventions; 22.9%), R24 (where the full trial protocol can be accessed; 24.1%), and R14b (why the trial ended or was stopped; 27.7%), had the lowest percentage of compliance (Table 2). The mean reporting quality score across all studies was 24.7 ± 6.23, with an average compliance percentage of 66.8 ± 16.8.

Discussion

The findings of this study reveal an interesting overview of the current status of the design, implementation, value, and validity of Latin American RCTs in surgery. Initially, it was identified that less than 25% of the RCTs reported funding, with funding more frequently coming from the industry (40%). Additionally, only 6% of the RCTs were multicenter, and only approximately 23% engaged in international collaboration, which may explain the trend of including fewer than 100 patients in 66.3% of the RCTs. Brazil leads the execution of RCTs in this specialty in the region (67.5%), and importantly, it was found that more than 50% of the studies did not have study registration available.

RCTs constitute the highest level of evidence for primary data to address questions about medical interventions. Surgery is a specialty with high technical and scientific rigor. Despite advancements in the use of minimally invasive techniques, open surgery is still common in low- and middle-income countries such as those in Latin America[13]. Therefore, RCTs in surgery must be sufficiently rigorous, detailed, and explicit in their methodology and implications of findings. It is acknowledged that economic factors, hospital infrastructure, access to funding, limited collaboration with high-income countries, and the exclusive availability of a research team for surgical investigation are among the many limitations in developing an RCT[13]. Nevertheless, solutions and opportunities have been described to promote experimental medical research[1].

It was found that universities and hospitals have a very low frequency of funding for these studies, despite being potential entities involved in the production of clinical evidence. At the local level, due to the costs of an RCT and the limited availability of annual resources, funding an RCT would possibly be a last resort compared to other studies, such as observational or biological studies[1]. For this reason, the proposal of multicenter and collaborative studies is essential, especially with high-income countries that can contribute to or support the technical and organizational costs of RCTs. The limited collaboration observed could be the result of difficulties inherent in the execution of science, such as language barriers, lack of agreements, or restrictions in institutional policies. Nevertheless, there are many RCTs involving Latin centers and hospitals that collaborate internationally and manage to develop robust large-scale studies. However, the restriction in collaboration and the limitation in technical and academic discussion with international advisors or peers facilitate the presence of preventable errors, affecting the quality and rigor of the studies[3,5]. For example, the finding that study registration is present in just under 50% of RCTs, despite it being a mandatory criterion for quality and ethical and scientific standards. This finding could be explained by several reasons, such as ethical or legal concerns, concerns

Table 2

Summary of compliance with methodological and reporting quality items of Latin American randomized controlled trials in surgery and subspecialties, and quality category (*N* = 83).

Methodological quality items	Yes	No	Partial compliance
	n (%)		
M1	71 (85.5)	10 (12.1)	2 (2.4)
M2	47 (56.6)	24 (28.9)	12 (14.5)
M3	71 (85.5)	12 (14.5)	0
M4	38 (45.8)	28 (33.7)	17 (20.5)
M5	14 (16.9)	58 (69.9)	11 (13.3)
M6	40 (48.2)	29 (34.9)	14 (16.9)
M7	71 (85.5)	11 (13.3)	1 (1.2)
M8	70 (84.3)	8 (9.6)	5 (6)
M9	64 (71.1)	6 (7.2)	13 (15.7)
M10	80 (96.4)	1 (1.2)	2 (2.4)
M11	78 (94)	0	5 (6)
M12	77 (92.8)	4 (4.8)	2 (2.4)
M13	81 (97.6)	2 (2.4)	0
Methodological quality	***n***		**%**
High quality	62		74.7
Moderate quality	19		22.9
Low quality	2		2.4

Reporting quality items	Yes	No	Partial compliance
	n (%)		
R1a	68 (81.9)	15 (18.1)	0
R1b	80 (96.4)	3 (3.6)	0
R2a	82 (98.8)	1 (1.2)	0
R2b	78 (94)	5 (6)	0
R3a	57 (68.7)	26 (31.3)	0
R3b	32 (38.6)	51 (61.4)	0
R4a	75 (90.4)	8 (9.6)	0
R4b	73 (88)	10 (12)	0
R5	73 (88)	10 (12)	0
R6a	62 (74.7)	21 (25.3)	0
R6b	34 (41)	49 (59)	0
R7a	63 (75.9)	20 (24.1)	0
R7b	33 (39.8)	50 (60.2)	0
R8a	71 (85.5)	12 (14.5)	0
R8b	42 (50.6)	41 (49.4)	0
R9	52 (62.7)	31 (37.3)	0
R10	19 (22.9)	61 (73.5)	3 (3.6)
R11a	28 (33.7)	53 (63.9)	2 (2.4)
R11b	47 (56.6)	36 (43.4)	0
R12a	75 (90.4)	8 (9.6)	0
R12b	48 (57.8)	35 (42.2)	0
R13a	75 (90.4)	8 (9.6)	0
R13b	53 (63.9)	30 (36.1)	0
R14a	64 (77.1)	17 (20.5)	2 (2.4)
R14b	23 (27.7)	60 (72.3)	0
R15	61 (73.5)	22 (26.5)	0
R16	64 (77.1)	18 (21.7)	1 (1.2)
R17a	61 (73.5)	22 (26.5)	0
R17b	40 (48.2)	43 (51.8)	0
R18	44 (53)	38 (45.8)	1 (1.2)
R19	48 (57.8)	34 (41)	1 (1.2)
R20	65 (78.3)	18 (21.7)	0
R21	62 (74.7)	21 (25.3)	0
R22	79 (95.2)	4 (4.8)	0
R23	54 (65.1)	29 (34.9)	0
R24	20 (24.1)	63 (75.9)	0
R25	44 (53)	39 (47)	0
Reporting quality	***n***		**%**
High quality	26		31.3
Moderate quality	46		51.8
Low quality	14		16.9

SD, standard deviation.

over intellectual property, lack of institutional or regulatory oversight, or delays in registration, all of which need to be explored in future studies to identify evidence-based causes with the potential to be addressed. These same reasons could be related to the low proportion of RCTs that reported funding (24.1%). This issue is of significant importance, as it limits the transparency, reproducibility, and credibility of research findings. A more active discussion, including working groups with greater experience and academic training in this study design, would reduce the likelihood of making such errors. This has been demonstrated previously in other medical specialties when a methodologist physician has been included in the development of these studies[14].

The absence of methodologist surgeons in RCTs in surgery is an underexplored phenomenon. This could be correlated with the low frequency of compliance found in critical items such as blinding, enrollment, and outcome assessment, impacting methodological quality. It could be inferred that, due to the design and execution efforts of an RCT, a percentage greater than 20% of moderate quality is high, given that all omitted items are preventable. A more pronounced event was the compliance with reporting quality, which was more affected but related to methodological quality items with low compliance. Random allocation sequence, description of enrolled participants and participants to interventions, as well as study registration reporting, are critical points in the falsifiability and reproducibility of medical evidence and were the items with the lowest compliance percentage.

It is necessary to highlight that compared to other regions of the world where a decrease in the risk of bias in surgical RCTs has been described in the last two decades[15], this scenario had not been previously studied in Latin America. In some high-income countries in Europe and Asia, an improvement over time has been observed in both the methodological quality and reporting of RCTs in surgery[15]. However, this improvement should become a more widespread process, given the availability of checklists and the enhanced rigor in research brought about by the progressive introduction of clinical research guidelines over the past decade[16]. Although the factors associated with this improvement have not been specifically studied, it is presumed that the quality and multidisciplinary nature of research teams could be an important factor to consider[5,17].

These findings serve as a foundation for the design and implementation of evidence-based strategies for the rigorous construction and execution of future RCTs in surgery. These strategies

aim to prevent the omission of the items described in this study, ultimately achieving a higher percentage of RCTs with both high methodological and reporting quality. As future research ideas, analytical approaches could be employed based on these findings to identify associated factors influencing the triggers for these shortcomings in methodology and reporting[18-20]. Additionally, increasing international collaboration to conduct multicenter RCTs with high-income countries or centers with defined standards of the highest quality for research development could be an interesting solution to explore in the future. These questions could lead to proposing definitive solutions depending on the research context.

Study limitations

As limitations, it should be noted that this study only included subspecialties of general surgery derived from the specialties that make up the FELAC. Additionally, there is subjectivity in the assessment by the authors regarding the compliance with the reviewed items (the lack of inter-rater reliability measurement). However, this was addressed through third-party consultation to resolve discrepancies. These results should be interpreted on the basis of the study design, the conceptual and operational definitions, and the variables of interest studied. Therefore, the generalization of results should be made with caution.

Conclusions

While the methodological quality of Latin American RCTs in surgery included in PubMed and Scopus is relatively high, there is a predominance of moderate reporting quality. This compromises the falsifiability and reproducibility of Latin American RCTs in surgery. The design and implementation of educational strategies in scientific writing and research methodology, as well as timely and high-quality guidance during the design, execution, and publication of RCTs in surgery, could be a possible solution to enhance the methodological and reporting quality of Latin American RCTs in surgery.

Ethical approval

Not applicable.

Consent

Not applicable.

Sources of funding

The research did not receive funding from any sources.

Author contribution

Ivan David Lozada Martinez: Conceptualization; investigation; methodology; data curation; formal analysis; investigation, writing – original draft; writing – review and editing; Fabriccio Visconti Lopez, Alexandra C. Rojas-Cueva, Jorge Castrillón-Lozano, Nicolas Andrés Cañas Pedroza, Ruth Liliana Yela Ordoñez, Alexandra Mutis García, Benjamin Ortiz Santana: conceptualization; investigation; data curation; writing – original draft; writing – review and editing Franco Ausejo: Conceptualization; investigation; investigation; data curation; writing – original draft; writing – review and editing; Maria Carolina Diazgranados-García, Danilo Acevedo-Parrales, Patricia Delgado: Investigation; supervision; validation; writing – original draft; writing – review and editing.

Conflicts of interest disclosure

All authors declare that there exist no commercial or financial relationships that could, in any way, lead to a potential conflict of interest.

Research registration unique identifying number (UIN)

Not applicable.

Guarantor

Universidad Nacional Autónoma de Nicaragua, Managua, Nicaragua.

Provenance and peer review

Commentary, internally reviewed.

Data availability statement

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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