Original Article

What is the quality of reporting in randomized controlled trials in spinal conditions

ABSTRACT

Purpose: Substandard quality across published randomized controlled trials (RCTs) is a major concern. Imperfect reporting has the potential to distort the evidence landscape and waste valuable health-care resources. In this study, we aim to assess the current quality of reporting in the field of spine using a modified version of the Consolidated Standards of Reporting Trials (CONSORT) checklist.

Materials and Methods: A list of published RCTs in the field of spine disease from January 1, 2013, to December 31, 2020, was built. Two reviewers scored the published RCTs against a modified CONSORT checklist. The mean adjusted CONSORT scores for each study, reporting category, and checklist item were calculated.

Results: The mean and median scores across all of the RCTs were 0.72 and 0.74 out of 1.00, respectively. The spectrum of scores was wide, ranging from 0.45 to 0.94. The reporting categories with the lowest score included randomization, blinding, and abstract. The items which were most under-reported included allocation sequence generation, type of randomization used, full trial protocol details, and abstract methodology. The inter-rater reliability between our reviewers was substantial ($\kappa = 0.7$, $\kappa = 0.71$).

Conclusion: Our findings correlate with only a moderate level of compliance to the CONSORT criteria on the quality of reporting for RCTs in spinal conditions. This is in line with previous reports on compliance, both within and outside the field of spinal conditions. Further continued and sustained efforts are still required to enhance the quality and consistency of RCT reporting, ultimately reducing health-care resource wastage and improving patient safety.

Keywords: Consolidated Standards of Reporting Trials checklist, Consolidated Standards of Reporting Trials statement, quality of reporting, randomized controlled trial, reporting practices, spine

INTRODUCTION

Spinal conditions involve a variety of pathophysiological mechanisms including degeneration, trauma, infection, oncology, autoimmunity, inflammation, and deformity. Patients can therefore present at various stages of disease severity to a spectrum of medical and surgical specialties, as well as allied health professions. Often complex, such multidisciplinary spinal health care ought to rely on evidence-based medicine.

A randomized controlled trial (RCT) is considered to provide the strongest level of clinical evidence on the effectiveness and safety of surgical and medical interventions.[1] It is valued as the most reliable clinical research method producing

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Andreas K. Demetriades[1,2,3], Jakov Tiefenbach[3,4], Jay J. Park[3,5], Mohammed Maarij Anwar[5], Sara Manzoor Raza[5]

[1]Department of Neurosurgery, University of Leiden, Leiden, The Netherlands, [2]Department of Clinical Neurosciences, Royal Infirmary of Edinburgh, [3]Edinburgh Spinal Surgery Outcomes Studies Group, Edinburgh, UK, [4]Neurological Institute, Cleveland Clinic, Ohio, USA, [5]Edinburgh Medical School, University of Edinburgh, Edinburgh, UK

Address for correspondence: Mr. Andreas K. Demetriades, Department of Neurosurgery, University of Leiden, Leiden, The Netherlands.
Department of Clinical Neurosciences, Royal Infirmary of Edinburgh, Edinburgh, UK.
E-mail: andreas.demetriades@gmail.com

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outcomes that reflect the true impact of an intervention, due to an RCT rigid design that minimizes the risk of influence upon the results which comes from both confounding and biases.[2] Because of its strict design requirements and processes, high-quality RCTs are a costly endeavor; enormous amounts of both private and public funding are invested every year into conducting clinical trials.[3] According to an estimate by Moore *et al*., the median cost of a pivotal clinical study is $19 million, with an interquartile range of $12.2–33.1 million.[4]

It is therefore concerning that there exists an exceedingly high rate of trial discontinuation and nonpublication, on the one hand, and that, on the other hand, the reporting quality of published RCTs can be recognized as substandard.[5-9] These are critical issues that waste valuable health-care resources while concurrently distorting the evidence landscape and compromising the processes of evidence synthesis and high-quality guideline development.

To address the problem of substandard quality across published RCTs, a group of medical journal editors, clinical trialists, epidemiologists, and methodologists developed the Consolidated Standards of Reporting Trials (CONSORT) statement.[10] This statement contains a detailed checklist and a flowchart diagram, outlining the important points every published RCT should attempt to report upon. Other efforts to improve the quality of RCTs have also been recognized; for instance, the Standard Protocol Items: Recommendations for Interventional Trials statement, developed in 2007, aims to provide guidance to enhance the completeness and quality of trial protocols,[11] while the Enhancing the QUAlity and Transparency Of health Research Network aims to promote the use of established reporting guidelines.[12]

Poor adherence to these reporting tools, including the CONSORT checklist, has been associated with a poor quality of published RCTs.[13] Incomplete reporting compromises the validity of RCT results, which can lead to inaccurate conclusions about the effectiveness of a treatment and any associated adverse effects. Furthermore, the lack of reporting standardization across published RCTs makes it more challenging to directly compare the results between individual trials or to draw meaningful conclusions. Finally, poorly reported trials may need to be revised and redone, incurring significant additional financial costs which could have otherwise been avoided.

Despite the widespread endorsement of the CONSORT checklist by established medical journals,[14] improper adherence has remained a long-standing concern within the medical community. A number of studies have identified insufficient adherence and lack of robustness in RCT reporting across a large number of medical and surgical specialties.[15-19] In this study, we attempted to evaluate the level of adherence to the modified 2010 CONSORT checklist across RCTs in the field of spinal conditions. This will provide an overview of the current state of RCT reporting quality within this field. As a secondary aim, we attempted to identify the common trends and pitfalls in RCT reporting, as well as to discuss potential strategies which would improve the consistency and quality of RCT reporting.

MATERIALS AND METHODS

A list of published RCTs in the field of spinal conditions was compiled from ClinicalTrials.gov spanning the period from January 1, 2013, to December 31, 2020. Full-text papers were retrieved through Google Scholar, PubMed, and the University of Edinburgh Interlibrary Loan service. A total of 39 papers were evaluated by two independent reviewers (S.R. and M.A.) using a modified CONSORT checklist (Online Resource 1). The CONSORT checklist was chosen as it offers a comprehensive, evidence-based method to evaluate the quality and consistency of trial design, analysis, and interpretation. Furthermore, this checklist has been validated and utilized by previous studies attempting to assess the quality of trial reporting.[15-19] Our modified checklist combined the official CONSORT 2010 checklist and the associated CONSORT abstract extension; no direct changes were made to any of the listed items. There was a total of 52 items divided across 16 reporting categories – 3 categories for the abstract and 13 categories for the main text.

The main characteristics of published RCTs included in our analysis were extracted, such as trial subtopic, country of study registration, type of intervention, funding status (e.g., public or private), and the number of centers involved. We then converted the checklist into a scoring system where each item received 2 points if adequately reported, 1 point for inadequately reported, and 0 point when not addressed at all. The nonapplicable items were flagged up to be excluded from further analysis. The "adjusted CONSORT score" was calculated by adding up the points scored by the paper, and dividing this total by the highest achievable score. Thus, each paper received a score on a scale between 0 and 1, with 0 representing the worst score and 1 representing the best score. Finally, the mean adjusted CONSORT was calculated by averaging the scores assigned by each reviewer. A simplified step-by-step breakdown of our methodology is shown in Figure 1.

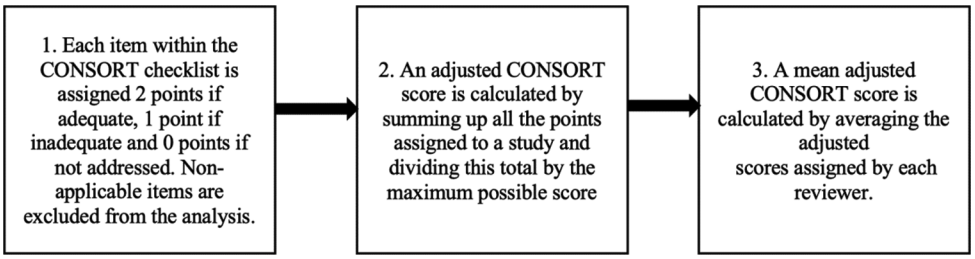

Figure 1: A step-by-step breakdown of methodology used to calculate the mean adjusted Consolidated Standards of Reporting Trials score. CONSORT - Consolidated Standards of Reporting Trials

In addition to assessing the mean adjusted CONSORT score for each individual study, a similar approach was applied to calculate how all the studies jointly performed across each of the 16 reporting categories within the CONSORT checklist. This analysis was also extended to all of the 52 items within the checklist, in order to obtain a more granular understanding of reporting trends and common pitfalls.

Finally, Cohen's kappa coefficient was used to assess inter-rater reliability. Both the level of agreement on whether the study reported on an item within the checklist, and the level of agreement on whether the reported item was adequate or inadequate, were evaluated. All the analysis in the study was strictly descriptive and conducted in Microsoft Excel 2020 Software.

As this study did not involve patients, informed consent was not required.

Institutional Review Board approval was not required as the study involved analysis of already published data.

RESULTS

Randomized controlled trial characteristics

Back pain, ankylosing spondylitis, and postoperative pain management were the most commonly investigated subfields within the field of spinal diseases, accounting for over 80% of identified RCTs. Nearly 50% of trials were conducted in the United States. Three-quarters of RCTs evaluated the effects of a novel medication. There was an almost even split between industry- and nonindustry-funded trials. Similarly, there was a close split between the single- and multi-center RCTs. A more detailed breakdown of the key characteristics is shown in Table 1.

Table 1: Analyzed randomized controlled trial characteristics across a range of parameters

Parameter	*n* (%)
Topic	
Back pain	18 (46.5)
Ankylosing spondylitis	8 (20.5)
Postoperative pain management	6 (15.5)
Radiculopathy	2 (5)
Congenital spinal diseases	2 (5)
Spinal tumors	1 (2.5)
Neck pain	1 (2.5)
Spinal cord injuries	1 (2.5)
Country	
USA	19 (49)
International	8 (20.5)
China	4 (10.5)
Norway	2 (5)
Egypt	1 (2.5)
Thailand	1 (2.5)
Turkey	1 (2.5)
Denmark	1 (2.5)
South Korea	1 (2.5)
Russia	1 (2.5)
Intervention type	
Drug	29 (74)
Others	5 (13)
Procedure	4 (10.5)
Device	1 (2.5)
Funding status	
Nonindustry	21 (54)
Industry	18 (46)
Number of centers	
Single center	21 (54)
Multi-center	18 (46)

Inter-rater reliability

The inter-rater reliability pertaining to the level of agreement on whether the study reported on a checklist item was 0.70, while the agreement on whether a reported item was adequate or inadequate was 0.71. Both of these kappa coefficients should be interpreted as substantial,[20] particularly for a study that relies heavily on the interpretation of medical literature such as this one.

Mean adjusted Consolidated Standards of Reporting Trials score: Published randomized controlled trials

The mean adjusted CONSORT score for each of the forty RCTs included in the analysis is presented in Table 2. The mean and median scores across all of the RCTs were 0.72 and

Table 2: The list of analyzed randomized controlled trial publications with their corresponding mean adjusted Consolidated Standards of Reporting Trials score (highest to lowest)

Study title	Mean adjusted consort score
A randomized, placebo-controlled trial of ibuprofen plus metaxalone, tizanidine, or baclofen for acute low back pain	0.94
Analgecine, the extracts of vaccinia-inoculated rabbit skin, effectively alleviates the chronic low back pain with little side effect - a randomized multi-center double-blind placebo-controlled phase 3 clinical trial	0.89
SUMMIT-07: A randomized trial of NKTR-181, a new molecular entity, full mu-opioid receptor agonist for chronic low-back pain	0.89
Effectiveness of tapentadol prolonged release compared with oxycodone/naloxone prolonged release for the management of severe chronic low back pain with a neuropathic component: A randomized, controlled, open-label, phase 3b/4 study	0.87
A randomized, double-blind, placebo-controlled trial of naproxen with or without orphenadrine or methocarbamol for acute low back pain	0.83
Maintenance of clinical remission in early axial spondyloarthritis following certolizumab pegol dose reduction	0.83
Nicoboxil/nonivamide cream effectively and safely reduces acute nonspecific low back pain - a randomized, placebo-controlled trial	0.83
Intraoperative S-ketamine for the reduction of opioid consumption and pain 1 year after spine surgery: A randomized clinical trial of opioid-dependent patients	0.82
Efficacy and safety of fasinumab in patients with chronic low back pain: A Phase II/III randomised clinical trial	0.82
Secukinumab provided significant and sustained improvement in the signs and symptoms of ankylosing spondylitis: Results from the 52-week, phase III China-centric study, MEASURE 5	0.80
Randomized, double-blind, placebo-controlled study of interferon-γ 1b in Friedreich ataxia	0.80
Effectiveness of a back care pillow as an adjuvant physical therapy for chronic nonspecific low back pain treatment: A randomized controlled trial	0.79
Efficacy and safety of diclofenac+capsaicin gel in patients with acute back/neck pain: A multicenter randomized controlled study	0.78
PROMISE study group. Multicolumn spinal cord stimulation for predominant back pain in failed back surgery syndrome patients: A multicenter randomized controlled trial	0.78
Efficacy, safety, and tolerability of secukinumab in patients with active ankylosing spondylitis: A randomized, double-blind phase 3 study, MEASURE 3	0.78
Implications of amantadine sulfate usage on intraoperative hemodynamics in patients undergoing corrective surgeries for spine deformities: A randomized-controlled trial	0.77
Open-label placebo treatment in chronic low back pain: A randomized controlled trial	0.76
Bupivacaine field block with clonidine for postoperative pain control in posterior spine approaches: A randomized double-blind trial	0.76
Diazepam is no better than placebo when added to naproxen for acute low back pain	0.74
Comparative study of the efficacy of transdermal buprenorphine patches and prolonged-release tramadol tablets for postoperative pain control after spinal fusion surgery: A prospective, randomized controlled noninferiority trial	0.74
Randomized prospective trial of cooled versus traditional radiofrequency ablation of the medial branch nerves for the treatment of lumbar facet joint pain	0.72
Effects of bupivacaine on opioid patient-controlled intrathecal analgesia in chronic pain patients implanted with drug delivery systems	0.72
Double-blinded, placebo-controlled crossover trial to determine the effects of midodrine on blood pressure during cognitive testing in persons with spinal cord injury. *Spinal cord*	0.72
Use of low level of continuous heat and ibuprofen as an adjunct to physical therapy improves pain relief, range of motion and the compliance for home exercise in patients with nonspecific neck pain: A randomized controlled trial	0.71
Efficacy of intravenous paracetamol, metamizol and lornoxicam on postoperative pain and morphine consumption after lumbar disc surgery	0.71
Efficacy and safety of adalimumab in Chinese adults with active ankylosing spondylitis: Results of a randomised, controlled trial	0.71
The effect of intravenous golimumab on health-related quality of life and work productivity in adult patients with active ankylosing spondylitis: Results of the phase 3 GO-ALIVE trial. *Clin Rheumatol*	0.71
Ibuprofen plus acetaminophen versus ibuprofen alone for acute low back pain: An emergency department-based randomized study	0.70
Efficacy of antibiotic treatment in patients with chronic low back pain and modic changes (the AIM study): Double blind, randomised, placebo controlled, multicentre trial	0.70
Efficacy and safety of a hydrocodone extended-release tablet formulated with abuse-deterrence technology in patients with moderate-to-severe chronic low back pain	0.66
Tanezumab for chronic low back pain: A randomized, double-blind, placebo- and active-controlled, phase 3 study of efficacy and safety	0.64
A prospective randomized comparative trial of targeted steroid injection via epidural catheter versus standard C7-T1 interlaminar approach for the treatment of unilateral cervical radicular pain	0.58
Safety of selective nonsteroidal anti-inflammatory drugs	0.57
Safety and efficacy of prefilled liquid etanercept-biosimilar Yisaipu for active ankylosing spondylitis: A multi-center phase III trial	0.56
Three multicenter, randomized, double-blind, placebo-controlled studies evaluating the efficacy and safety of ustekinumab in axial spondyloarthritis	0.55
Clinical effectiveness and safety of intraoperative methadone in patients undergoing posterior spinal fusion surgery: A randomized, double-blinded, controlled trial	0.52
Patient-controlled intermittent epidural bolus versus epidural infusion for posterior spinal fusion after adolescent idiopathic scoliosis: Prospective, randomized, double-blinded study	0.51

Contd...

Table 2: Contd...

Study title	Mean adjusted consort score
A randomized comparative trial of targeted steroid injection via epidural catheter versus standard transforaminal epidural injection for the treatment of unilateral cervical radicular pain: 6-month results	0.48
Efficacy and safety of diclofenac+capsaicin gel in patients with acute back/neck pain: A multicenter randomized controlled study	0.45

The scores range from 0 to 1, with 0 representing the lowest, and 1 representing the highest score

0.74, respectively. The spread of scores was wide, ranging from 0.45 to 0.94.

Mean adjusted Consolidated Standards of Reporting Trials score: Reporting categories

The mean adjusted CONSORT score across each of the 16 CONSORT reporting categories is shown in Figure 2. The best-reported category was "Introduction – background and objectives," while "Randomization," "Blinding," and "Abstract-Results" received the lowest scores.

Mean adjusted Consolidated Standards of Reporting Trials score: Checklist items

The mean adjusted CONSORT score across each of the 52 items within the CONSORT checklist is shown in Figure 3. The items that scored the highest were related to the introduction sections, and certain elements within the methods sections, such as the number of participants, eligibility criteria, and statistical analysis. The lowest-scoring items included allocation sequence generation, the type of randomization used, full trial protocol details, and abstract methodology.

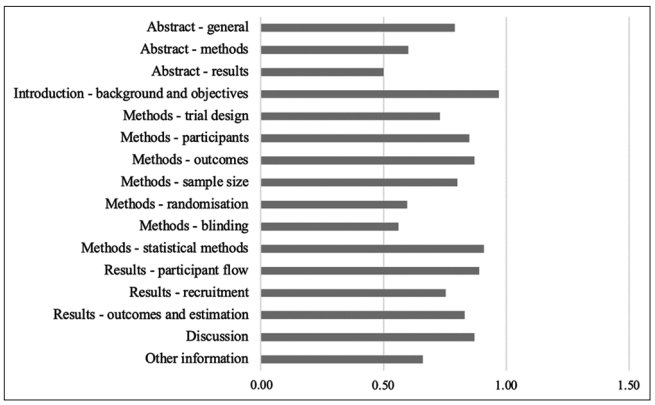

Figure 2: The mean adjusted Consolidated Standards of Reporting Trials (CONSORT) score for each of the 16 CONSORT reporting categories. The scores range from 0 to 1, with 0 representing the lowest, and 1 representing the highest score. CONSORT - Consolidated Standards of Reporting Trials

DISCUSSION

The reporting quality across published randomized controlled trials

The mean adjusted CONSORT score for spinal RCTs published between January 1, 2013, and December 31, 2020, was found to be 0.72. We consider this score to correspond to a moderate level of adherence to the CONSORT checklist. While this result suggests that published RCTs adhere to some elements of the CONSORT checklist, a significant scope for improvement remains. A particularly concerning finding was the wide range of observed scores, with the highest-rated study scoring 0.94, and the lowest-rated study scoring 0.45. The studies at the lower end of the spectrum are likely to offer a weaker quality of evidence, and their results are interpreted with caution.

To the best of our knowledge, there is only one other study that attempted to evaluate the quality of published RCTs in the spinal literature, conducted by Naunheim *et al*. They analyzed 32 spinal RCTs published in 2008, using 40 criteria derived from the CONSORT checklist.[21] Similar to our work, Naunheim *et al*. identified a large number of reporting inconsistencies across analyzed RCTs, concluding that the overall reporting quality is suboptimal. However, due to a number of methodological differences, it is not possible to make a direct comparison and provide reliable insight on how the quality of spine RCT reporting has changed since 2008. The main lesson nonetheless remains that the quality of reporting still requires further substantial improvements.

Looking beyond the field of spinal conditions, a significant number of studies have been published attempting to assess the level of adherence to the CONSORT checklist in many other medical and surgical specialties.[15-19] Regardless of the field of study, the year of publication, or the methodology used to evaluate this adherence, all papers reported a poor-to-moderate level of adherence. This suggests that the problem of inadequate reporting is not limited to the spinal literature, but rather extends to many other medical and surgical fields.

Common trends and pitfalls in randomized controlled trial reporting

One of the strengths of our study is that we analyzed how the published RCTs performed across a range of reporting categories and checklist items. The area with the highest mean adjusted CONSORT score was the "Introduction-background and objectives." This is likely attributed to the CONSORT checklist containing only two items pertaining to the introduction section, making it much easier to fulfill the criteria and obtain the maximum number of points. Certain

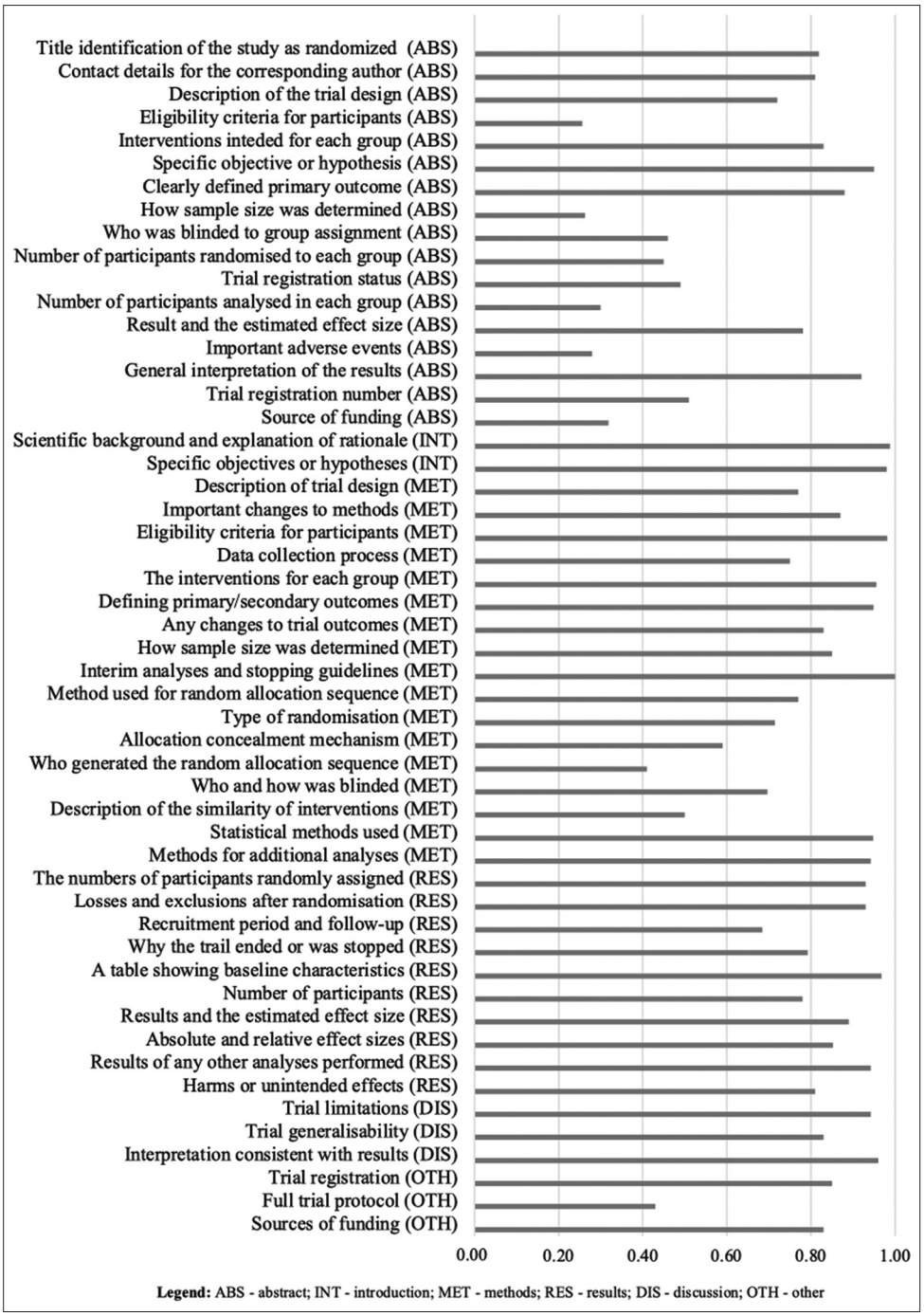

Figure 3: The mean adjusted Consolidated Standards of Reporting Trials (CONSORT) score across each of the 52 CONSORT checklist items. The scores range from 0 to 1, with 0 representing the lowest, and 1 representing the highest score. CONSORT - Consolidated Standards of Reporting Trials

items in the methodology section, such as the number of participants, eligibility criteria, interventions, and statistical methods, were also well reported. This might be due to implicit rules and research etiquette within the medical community, who put a lot of emphasis on identifying and describing these elements of the methodology.

It is counterintuitive that some of the weakest reporting areas were randomization and blinding, especially since we are discussing RCTs *per se*. The RCTs frequently failed to report on who generated the allocation concealment sequence, what type of randomization was used, as well as who and how was blinded. Similar results were noted by Naunheim *et al*., where the poorly reported items included the methodology of random sequence generation, blinding of subjects, treatment providers, assessors, and analysts. In addition, the current literature emphasizes this long-standing problem across published RCTs.[21-23]

The reporting quality of randomization and blinding ought to be addressed as soon as possible, as these steps are both integral to conducting a RCT and constitute the main pillars of its internal validity and generalizability.

The abstract was another category that was under-reported; most abstracts were lacking a sufficient level of detail regarding their methodology and results. This is likely due to stringent abstract word count limits imposed by most medical journals, which prevent authors from discussing the nuances of their methods and results.

Finally, the majority of studies did not provide information on how the full trial protocol can be accessed. Failing to report on this item compromises the overall transparency of any study, as trial protocols frequently include important additional information about the RCT.

Future direction and study limitations

Based on the results of this study and other similar publications in other medical fields, it is clear that the standard of RCT reporting needs to be improved. Better reporting will achieve greater transparency as well as minimize the risk of reaching incorrect conclusions regarding treatment benefits and adverse effects. Furthermore, improved reporting practices do ensure a higher level of patient safety, as well as reduce health-care resource wastage.[24]

The best way, arguably, to increase the quality and consistency of reporting would be by improving adherence to the CONSORT checklist.[25] Perhaps, the most effective way would be for established medical journals to require evidence of CONSORT checklist completion at the time of manuscript submission. It is also important for journals and their editors to specify which checklist extensions ought to be used, and to further evaluate for any inconsistencies between the submitted checklist and the actual manuscript.[26] If implemented successfully, this would go a long way in ensuring that all published clinical trials become compliant to the recommended CONSORT checklist.

It is important to acknowledge that our study did have some limitations. First, the papers analyzed in this study may not represent all of the spinal RCTs published between January 1, 2013, and December 31, 2020, as the list of RCTs was obtained from a single clinical trial registry (i.e., ClinicalTrials.gov); the comprehensive nature of this registry, however, is acknowledged. Second, instead of reporting the percentage of items addressed, we opted to calculate the mean adjusted CONSORT score; while this arguably made it harder to directly compare our findings to other published studies, only one similar study existed in this field, and overall we feel that our results became more robust and informative.

CONCLUSION

We found only a moderate level of compliance to the CONSORT criteria on the quality of reporting for RCTs in spinal conditions. This is consistent with previously published studies, both within and outside the field of spine. Further continued and sustained efforts are still required to enhance both the consistency and quality of RCT reporting, ultimately reducing health-care resource wastage and improving evidence synthesis toward increased patient safety. We, therefore, encourage all medical journals to require robust evidence of CONSORT checklist compliance at the point of relevant manuscript submission.

This research paper does not involve any ethical considerations or implications as it solely focuses on a review of publicly available RCTs. No human or animal subjects were involved in this study.

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Conflicts of interest

There are no conflicts of interest.

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