

Original article

Compliance of abstracts of randomized control trials with CONSORT guidelines: A case study of Balkan journals

Necdet Sut¹, Zafer Kocak², Selcuk Korkmaz³, Cem Uzun⁴

¹Trakya University, Medical Faculty, Department of Biostatistics, Edirne, Turkey

necdetsut@yahoo.com

orcid.org/0000-0001-6678-482X

²Trakya University, Medical Faculty, Department of Radiation Oncology, Edirne, Turkey

orcid.org/0000-0003-1918-7795

³Trakya University, Medical Faculty, Department of Biostatistics, Edirne, Turkey

orcid.org/0000-0003-4632-6850

⁴Koç University School of Medicine, Department of Otorhinolaryngology, Head and Neck Surgery, Istanbul, Turkey

orcid.org/0000-0003-3233-7049

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Competing interests

NS is the biostatistics editor and ZK is the chief editor of the *Balkan Medical Journal*. NS, ZK, and SK work at Trakya University School of Medicine, which owns the *Balkan Medical Journal*. ZK and CU are members of the editorial board of *European Science Editing*.

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Data sharing statement

The data sets used or analysed for the current study are available upon request at the discretion of the corresponding author.



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Abstract

Background: Published reports of randomized controlled trials (RCTs) are not compliant with the CONSORT checklist as much as they should.

Objective: To assess the quality, in terms of the level to which they are compliant with the CONSORT checklist, of abstracts of RCTs published in general medical journals in the Balkan region.

Methods: Two observers assessed the abstracts of RCTs published in five general medical journals of the Balkan region between 2012 and 2018 to determine the level to which the abstracts were compliant with the 16-item CONSORT abstracts checklist.

Results: Of the 183 studies that were identified for evaluation, 124 (67.8%) were excluded from the evaluation. The average compliance level was 44.5% (95% CI: 41.9%–47.1%), the lowest being that for randomization (1.7%), funding (1.7%), numbers analysed (11.0%), blinding (13.6%), and trial registration (18.6%). However, the compliance level was very high for conclusions (99.2%), objectives (96.6%), interventions (95.8%), and primary outcomes (83.9%). The length of the abstract (word count) and the level of compliance were positively correlated ($r_s = 0.43$; $p = 0.001$). Abstracts of trials published in journals that endorse CONSORT in their publication policies were more compliant than those published in other journals (47.5 ± 10.4 versus 40.8 ± 8.0 , $p = 0.024$).

Conclusion: The overall level of compliance with the CONSORT checklist was below 50%. To improve the quality of abstracts of RCTs, authors should be encouraged to use the CONSORT checklist, and editors should check compliance with the CONSORT guidelines as part the publishing workflow.

Keywords:

Abstract, CONSORT, editors, guidelines, randomized controlled trial, reporting quality

Introduction

A randomized controlled trial (RCT) is defined as a study in which people are randomly assigned to groups to receive one of several clinical treatments or a control and which helps to generate guidelines for the treatments. Such trials are considered to generate the strongest possible evidence of the efficacy, or otherwise, of the treatments being tested.¹ It is important that reports of such trials, and especially the abstracts of those reports, provide the most essential information, because readers initially assess a study based on its abstract: whether it is clear enough, transparent, and understandable.

CONSORT, short for consolidated standards of reporting trials, is an evidence-based reporting guideline comprising a 25-item checklist and a flow chart that seeks to improve the transparency of RCTs.² Moreover, the guideline can help to prevent poorly or improperly conducted RCTs that waste resources in medicine.^{2,3} More than half of the core medical journals indexed in Abridged Index Medicus or PubMed endorse the CONSORT statement.⁴ Journals ask authors to ensure that the reports of all RCTs comply with the CONSORT checklist.

However, the reporting of RCTs in medical journals continues to be far from satisfactory,⁵ the most common items that are found wanting being allocation concealment,⁶⁻¹¹ sample size,^{7,8,10,12} implementation of randomization,^{6,7,11,13} blinding,^{6,7,10,11} allocation generation,⁹⁻¹¹ effect size,^{8,12} trial registration number,^{6,13} and handling of dropouts.^{9,10} Many studies have reported such lack of compliance with the CONSORT abstracts checklist.¹⁴⁻²⁰ However, medical journals from the Balkan region have seldom been assessed for their compliance—a gap the present study seeks to bridge by assessing the level of compliance in general medical journals from the Balkan region.

Methods

Sample

Reports of RCTs published in five leading general medical journals – Acta Clinica Croatica (Acta Clin Croat), Balkan Medical Journal (Balkan Med J), Croatian Medical Journal (Croat Med J), Hippokratia, and Serbian Archives of Medicine (Srp Arh Celok Lek) – from the Balkan region indexed under the category of general medical journals in Science Citation Index Expanded (SCIE) were examined (Table 1).

Table 1. Ranking of five general medical journals from the Balkan region, their endorsement of CONSORT guidelines, and number of randomized control trials published in each

Journal	Impact Factor ^a		Quartile in category (2018)	Endorsement of CONSORT in instructions to authors	No. of published RCTs
	2018	5-year			
Acta Clinica Croatica	0.403	0.577	Q4	No	13
Balkan Medical Journal	1.203	1.233	Q3	Yes	16
Croatian Medical Journal	1.624	1.770	Q2	Yes	7
Hippokratia	0.520	0.934	Q4	Yes	8
Serbian Archives of Medicine	0.299	0.393	Q4	No	15

^a Web of Science, Journal Citation Reports (June 2019)

Search strategies and eligibility criteria

Articles published between January 2012 and December 2018 and reporting RCTs from the five chosen journals were filtered using the following keywords: 'random', 'randomly', 'randomized', 'randomised', or 'clinical trial' in the title or in the abstract. We used the PubMed database for filtering, and chose only those RCTs that featured people as the subjects; trials with animals or other entities as subjects were excluded.

Reporting assessment tool and evaluation

The CONSORT 2010 checklist for abstracts, which comprised 16 items, was used in the study.²¹ Compliance with each item was rated as follows: 0 (not compliant), 0.5 (deficient in compliance), or 1 point (compliant). The primary outcome was the level of compliance with the checklist. The level of compliance for each item was calculated first, and then the overall average compliance was expressed as a percentage.

The level of compliance was assessed by two independent researchers (NS and SK). One month later, the same abstracts were evaluated yet again by the same researchers,

who were not privy to the scores they had assigned earlier. Whenever the score assigned to an item in the two rounds by the same assessor was different, the score was re-evaluated after looking up the relevant explanation from the CONSORT website, and a single score was finalized for each item. Intraclass correlation coefficient (ICC) was used for assessing observer reliability by comparing the scores assigned in the two rounds by the same observer.

Also taken into account were other related factors that may have influenced the scores, such as the length of abstracts (word count), the number of times the report had been cited in two years following the publication year (the number that directly affects the impact factor of a journal), and whether the journal in question endorsed compliance with the CONSORT guidelines in its instructions to authors. Word counts of the abstracts were those of the published articles; citations were obtained from the Web of Science database; and the endorsement was ascertained from the website of each journal.

Figure 1 is a flow chart of the study.

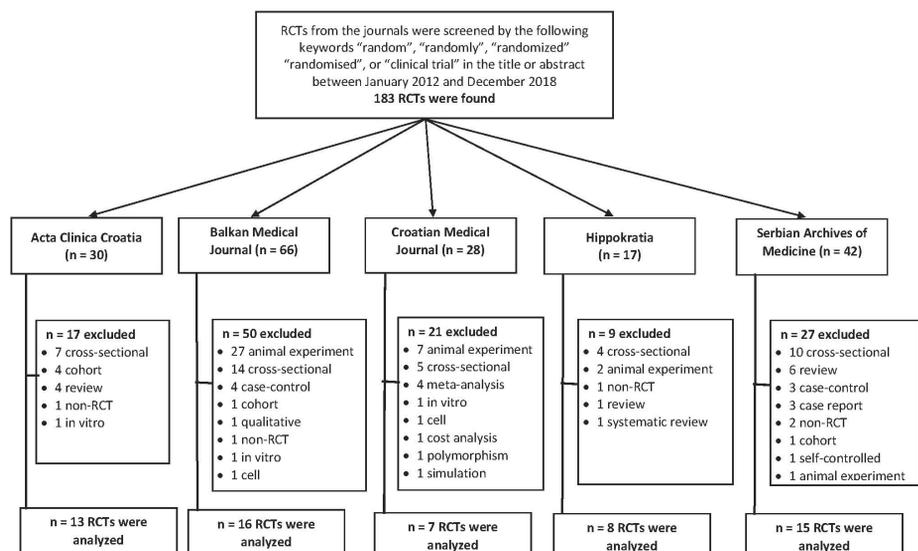


Figure 1. Flow chart of the study.

Statistical analysis

Compliance with the CONSORT checklist was expressed as a percentage (%). Average level of compliance and 95% confidence intervals were calculated. Intraclass correlation coefficient (ICC) was used for assessing the reliability of scoring between the two observers and between the two rounds of assessment by the same observer.

Because the data did not conform to normal distribution, the Mann–Whitney U test was used for comparing the level of compliance between journals that endorsed the CONSORT statement and those that did not.

Spearman correlation (r_s) coefficient was used for ascertaining the relationship, if any, between word counts or the number of citations and the level of compliance.

The compliance percentages were converted into the following categories: Poor, 20% or less; Fair, 21%–40%; Average, 41%–60%; Good, 61%–80%; and Excellent, 81%–100%.

Statistical analyses were performed using SPSS ver. 20.0 for Windows (IBM, Armonk, New York).

Results

Of the 183 studies identified initially, 124 (67.8%) were excluded from the assessment: 40 were cross-sectional studies; 37 involved experiments on animals; 11 were reviews; 7 were case-control studies; 6 were cohort studies; 5 each were either not RCTs or were meta analyses or systematic reviews; 3 each were in-vitro studies or case reports, 2 involved cells, and 1 each involved cost analysis, was related to polymorphism, was a qualitative study, a simulation, or was a self-controlled study.

Intra-class correlation coefficients were 0.974 for Observer NS and 0.921 for Observer SK, which shows that the observers were consistent in their ratings in the two rounds of assessment. The reliability between the ratings as given by the two observers was 0.983, which shows good agreement between them.

Mean compliance with the CONSORT checklist (Figure 2) was 44.5% (95% CI: 41.9%–47.1%). Compliance was excellent (>80%) with respect to reporting the conclusions, objectives, interventions, and primary

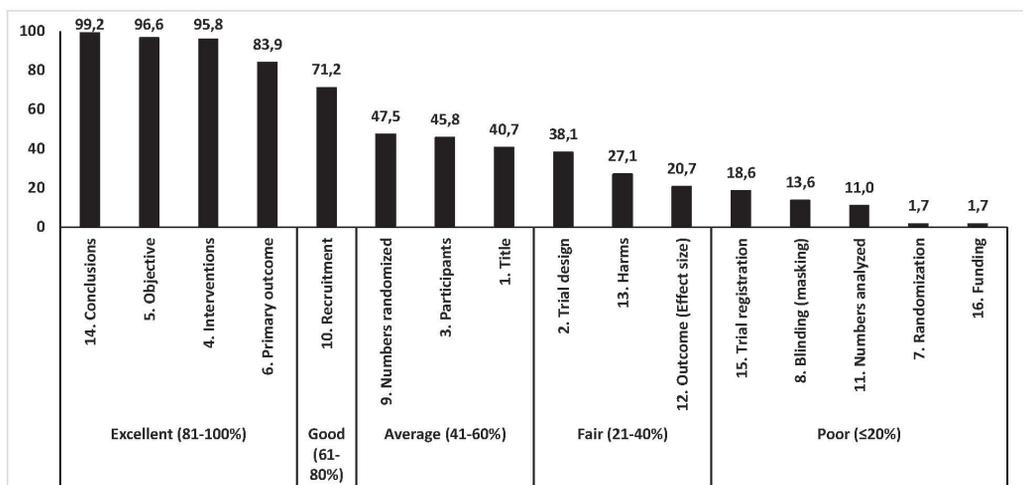


Figure 2. Compliance of the abstracts of RCTs with the CONSORT checklist.

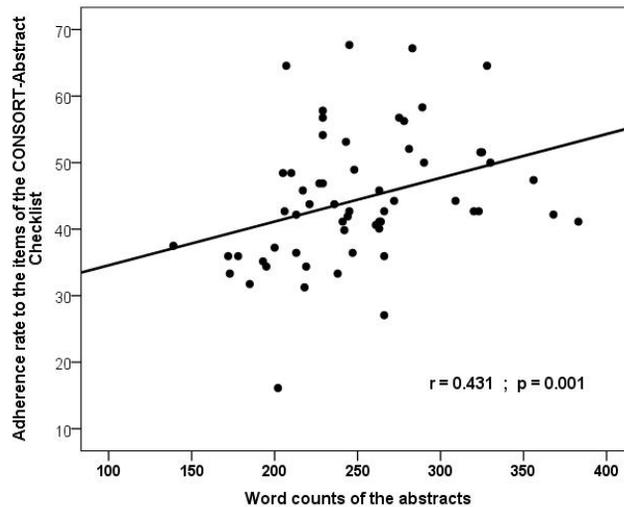


Figure 3. Relationship between compliance with the CONSORT checklist and word counts (r).

outcomes but poor (20% or less) with respect to randomization, funding, numbers analysed, blinding, and trial registration.

The length of the abstract (number of words) was significantly and positively correlated to compliance ($r_s = 0.431$; $p = 0.001$, Figure 3). However, the number of citations showed no such correlation ($r_s = 0.155$; $p = 0.242$).

Compliance was also higher for journals that endorse the CONSORT guidelines (47.5 ± 10.4) than that for journals that carry no such endorsement (40.8 ± 8.0 , $p = 0.024$).

Discussion

Three of the five general medical journals endorsed the CONSORT guidelines, and the overall level of compliance with the guidelines in these journals was 44.5%. This level was reported to be 70.0% for the five top general medical journals,¹⁴ 69.1% for major orthodontics journals,¹⁵ 46.0% for plastic-surgery journals,¹⁶ 43.8% for age-related macular degeneration healthcare,¹⁷ 37.5% for anaesthesia journals in 2016,¹⁸ 32.2% for otorhinolaryngology journals,¹⁴ and 28.3% for leading laser medical journals.¹⁹ Thus, compliance varies greatly depending on the field of medicine, and the overall compliance

cannot be considered satisfactory. These figures also indicate that although generally journals endorse the CONSORT guidelines, the journals are lax in demanding compliance with the guidelines.

Randomization, funding, and numbers analysed were the three items that showed the least compliance in the present study. A careful review of literature substantiates these findings because it showed that randomization,^{14,16,22,23} funding,^{14,16,22,23} and numbers analysed^{14,22} were the most inadequately reported items in the abstracts of RCTs. Reporting of these items needs to be improved for raising the quality of reporting of RCTs. Authors and editors should pay special attention to these three items.

On the other hand, the following items showed excellent compliance in top medical journals: interventions, objectives, primary outcomes, blinding, outcomes, conclusions, and trial registration.¹⁴ In the present study, conclusions, objectives, interventions, and primary outcome items fell in the same category, and outcomes showed a fair level of compliance, whereas blinding and trial registration showed poor compliance. In

earlier research, trial registration was shown to be poorly reported,^{14,17,23} whereas blinding showed a fair level of compliance.¹⁸ These results show that conclusions, interventions, objectives, and primary outcomes are generally reported adequately in the abstracts of RCTs, whereas outcomes, trial registration, and blinding are not.

Similar to that in the top general medical journals,¹⁴ recruitment showed a good level of compliance in the present study. However, three earlier studies reported poor compliance with respect to recruitment.¹⁷⁻¹⁹ Reporting of trial design, numbers randomized, participants, and harm items in the five journals in the present study was not as good as that seen in top medical journals.¹⁴ Balkan medical journals need to improve the reporting of these items.

The word count of abstracts was found to be related to reporting quality.¹⁷ In the present study, we found a moderate positive correlation between word count and overall compliance with the CONSORT checklist. Short abstracts, either because of authors' choice or because of the limit stipulated by the journal, may lower their quality, and editors may well consider raising the word limit if that helps to improve the quality of abstracts.

Kuriyama et al.²⁴ compared the abstracts of reports published in four major journals related to critical care before and after the announcement of the CONSORT guideline. Improvement was confined to only seven items in the list. Similar studies of abstracts from journals in oncology,²⁵ emergency medicine,²⁶ and anesthesiology²⁷ reported only suboptimal improvements in quality after publication of the CONSORT guidelines.

Although greater compliance with the guidelines was observed in the present study in journals that endorse the CONSORT guidelines, such endorsement by itself may not be enough to improve the quality of abstracts of RCTs.

It is clear that greater efforts are required to improve the quality and transparency of the methods reported in RCTs. Readers too need to be familiar with the CONSORT requirements,²⁸ and editors and reviewers should check compliance with the checklist as part of the publication workflow.

Among the limitations of the present study are the following. (1) Compliance with the CONSORT guidelines validates the method of running RCTs; it is not a measure of the quality of the articles that report RCTs. (2) The sample (59 abstracts and five journals) was small. (3) The study focused only on the abstracts of papers; full texts of the RCTs were not perused.

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