ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΙΑΣ
ΤΜΗΜΑ ΙΑΤΡΙΚΗΣ
ΠΜΣ «Μεθοδολογία Βιοϊατρικής Έρευνας,
Βιοστατιστική και Κλινική Βιοπληροφορική»

Assessment of the reporting quality of RCTs for endovascular versus surgical management in intracranial aneurysms published from 2000 to 2021 using the CONSORT statement

Αξιολόγηση της ποιότητας καταγραφής των δημοσιευμένων από το 2000 έως το 2021 τυχαιοποιημένων κλινικών δοκιμών που αφορούν την ενδαγγειακή έναντι της χειρουργικής αντιμετώπισης στα ενδοκράνια ανευρύσματα χρησιμοποιώντας τη δήλωση CONSORT

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Λάρισα, 2022

Περίληψη

ΕΙΣΑΓΩΓΗ: Οι τυχαιοποιημένες κλινικές δοκιμές (ΤΚΔ) αποτελούν τον χρυσό κανόνα στην εκτίμηση της αποτελεσματικότητας των κλινικών παρεμβάσεων και η διαφανής αναφορά τους είναι άκρως σημαντική. Η δήλωση CONSORT (Consolidated Standards of Reporting Trials) είναι μία βασισμένη σε αποδείξεις προσέγγιση για να βελτιώσει την ποιότητα των ΤΚΔ.

ΣΤΟΧΟΙ: Η αξιολόγηση της ποιότητας αναφοράς των δημοσιευμένων ΤΚΔ σχετικά με την ενδαγγειακή αντιμετώπιση των ενδοκράνιων ανευρυσμάτων έναντι της χειρουργικής αντιμετώπισης σύμφωνα με τη δήλωση CONSORT.

ΜΕΘΟΔΟΙ: Πραγματοποιήσαμε αναζήτηση σε 3 ηλεκτρονικές βάσεις δεδομένων (PubMed, Scopus, Web of Science) τυχαιοποιημένων κλινικών μελετών που αφορούσαν την διαχείριση (χειρουργική ή ενδαγγειακή) ενδοκράνιων ανευρυσμάτων. Το ερωτηματολόγιο CONSORT με τις 37 ερωτήσεις χρησιμοποιήθηκε για την αξιολόγηση της ποιότητας αυτών των ΤΚΔ. Πιθανοί παράγοντες ποιότητας αναφοράς εξερευνήθηκαν: διάγραμμα ροής συμμετοχής, αριθμός συγγραφέων, συντελεστής βαρύτητας περιοδικού, έτος έκδοσης, μέγεθος δείγματος, πολυκεντρικός σχεδιασμός

ΑΠΟΤΕΛΕΣΜΑΤΑ: Η αναζήτηση αναγνώρισε 11 κατάλληλα άρθρα για ανάλυση. Μόνο 3 δημοσιεύσεις (21.43%) εμφάνισαν επαρκή αναφορά (πάνω από 75%) καθώς υπήρξαν 11 μελέτες (78.57%) με εναρμόνιση με το COSNORT παραπάνω από 50%. Η μονοπαραγοντική ανάλυση ανέδειξε ότι μόνο ο αριθμός των συγγραφέων είχε μία σημαντική συσχέτιση με την ποιότητα αναφοράς.

ΣΥΜΠΕΡΑΣΜΑΤΑ: Η ποιότητα των αναφορών των τυχαιοποιημένων κλινικών μελετών σχετικών με την διαχείριση των ενδοκράνιων ανευρυσμάτων παραμένει μη ικανοποιητική. Η βελτίωση της ποιότητας της αναφοράς τους κρίνεται αναγκαία για την εκτίμηση της εγκυρότητας της κλινικής έρευνας.

ΛΕΞΕΙΣ ΚΛΕΙΔΙΑ: CONSORT, τυχαιοποιημένες κλινικές δοκιμές, Ποιότητα, Ενδοκρανιακά ανευρύσματα, Ενδαγγειακή, Χειρουργική, Αντιμετώπιση

Abstract

INTRODUCTION: Randomized controlled trials (RCTs) are considered the gold standard in evaluating the effectiveness of clinical interventions, and their transparent reporting is of paramount importance. The CONSORT (Consolidated Standards of Reporting Trials) statement is an evidence-based approach to improving RCTs' quality.

AIMS: Evaluation of the reporting quality of published RCTs concerning endovascular management of intracranial aneurysms versus surgical management according to the CONSORT statement.

METHODS: Three electronic databases (PubMed, Scopus, Web of Science) were searched for RCTs involving the management (endovascular vs. surgical) of intracranial aneurysms. The 37–item CONSORT checklist was used to assess the reporting quality of these RCTs. Possible determinants of reporting quality were explored: Participant flowchart, number of authors, Impact factor of the journal, Publication year, Sample size, Multicentric design

RESULTS: The search identified 14 eligible articles for analysis. Only three publications (21.43%) presented adequate reporting (above 75%), while there were 11 studies (78.57%) with CONSORT compliance more than 50%. Univariate analysis revealed that only the number of authors had a significant association with the reporting quality.

CONCLUSIONS: The quality of reporting in RCTs focusing on the management of intracranial aneurysms remains unsatisfactory. Further improvement of reporting is necessary to assess the validity of clinical research.

Keywords: CONSORT, Randomized Controlled Trials, Quality, Intracranial aneurysms, Endovascular, Surgical, Methodology

Introduction

Randomized Control Trials (RCTs) are at the top level of the evidence hierarchy and constitute a valuable tool in modern clinical research. [1] Their ability to randomize patients to different interventions in a stratified way allows the researcher to correlate outcome events with interventions, excluding unknown factors. [2] However, problems such as selection bias, publication bias, or funding bias may arise. [3, 4] Readers need written information on a study's methodology and findings to assess the quality of the provided information. [5] Also, since RCTs play a significant role in healthcare providers' clinical practice and treatment guidelines, the determination of the validity of a trial must be a straightforward procedure. [6, 7]

Considering the previous concerns about the clarity of reporting of RCTs, the CONsolidated Standards of Reporting Trials (CONSORT) statement was published in 1996. [6] The CONSORT statement underwent two revisions, the first in 2001 [8] and the second in 2010 [9], each accompanied by a detailed explanation and elaboration document. [10, 11] The last version consists of a 37-item checklist grouped into five categories and a flow diagram. [12] The CONSORT statement intends to facilitate the transparent reporting of trials and aid readers and reviewers in their appraisal and interpretation. [13] However, the CONSORT statement constitutes a guide for reporting RCTs, and its use as a quality appraisal tool should be avoided.[9]

Unruptured aneurysms' prevalence is estimated to be between 2 and 5%, whereas the incidence of subarachnoid hemorrhage (SAH) per 100,000 people is approximately 9 to 20, harboring a mortality rate of about 60% within six months. [14] The neurosurgeon must be informed of the natural history and in the management. For the management of intracranial aneurysms, two primary treatments are proposed: surgical management with clipping of the aneurysm and endovascular treatment consisting of several techniques such as simple coiling, flow diversion, or complex coiling. [14, 15] Guidelines relevant to the management of SAH reported recommendations for the treatment modalities of intracranial aneurysms based on retrospective studies, prospective observational studies, and large multicenter RCTs. [14, 15] It is essential to assess the reporting clarity of the RCTs used in making these guidelines and of those that would be available for the creation of revised versions of guidelines.

Many publications have used the CONSORT statement to evaluate the quality of reports of RCTs in various subspecialties of medicine. [16–21] However, to our knowledge, there is no assessment of publications regarding intracranial aneurysms management. In the present study, we analyzed the quality of publications published between 2000 and 2021, reporting of RCTs regarding the management (surgical or endovascular) of patients with intracranial aneurysms using the revised CONSORT 2010 statement checklist.

Methods

Literature search

SCOPUS, PUBMED, and Web of Sciences databases were searched to identify all relevant RCTs published from January 1st, 2000, to December 31st, 2021. The implemented search criterion that was used was the following: ((intracranial OR cerebral) AND aneurysm) AND (surgical OR clipping) AND (endovascular OR coiling). All titles and abstracts were visually inspected for eligibility, followed by a review of the complete manuscripts. Finally, the retrieved RCTs were manually searched for relevant references.

Eligibility criteria

Studies fulfilling the following criteria were considered eligible:

- They were published from January 1st, 2000, to December 31st, 2021
- They were classified as RCTs
- They involved two interventions (surgical and endovascular)
- The recruited patients with intracranial aneurysms

Studies were excluded according to the following criteria:

- reports not in English
- conference abstracts
- studies performed on animals
- pilot trials
- other study designs
- study protocols
- retracted papers
- sub-group and posthoc analysis of published RCTs

Data extraction

The reporting quality of the retrieved RCTs was assessed using the revised CONSORT 2010 checklist, which includes 25 items, 12 of which are separated into two parts. Also, the 37-item questionnaire is divided into five categories: Title and abstract, Methods, Randomization-blinding, Results, and Other information. (http://www.consort-statement.org) Each item was appraised by 1 point when adequately reported. If the item was absent, was reported partially, or was reported in a different article section, it was appraised by 0. Furthermore, when an item was reported using an external reference that was consistent, it was assessed by 1.
We assessed Item 1b (Structured summary) separately based on the CONSORT extension for abstracts. Instead of its original 17-item version, a more suitable 16-item

version was used after removing the item regarding contact details specific to conference abstracts (Table 1). According to our checklist, item 1b was assessed by 1 when more than seven items were present in the abstract. Further information collected included journal ranking for the publication year (according to Clarivate Analytics (Thomson Reuters) via Journal Citation Reports), publication year, number of authors, sample size, the presentation of a participant flow diagram, and the presence of a multicentric design.

Table 1: Modified CONSORT checklist to report an RCT in a journal abstract

Item	Description
Title	Identification of the study as randomized
Trial design	Description of the trial design (e.g., parallel, cluster, non-inferiority)
Methods	S
Participants	Eligibility criteria for participants and the settings where the data were collected
Interventions	Interventions intended for each group
Objective	Specific objective or hypothesis
Outcome	Clearly defined primary outcome for this report
Randomization	How participants were allocated to interventions
Blinding (masking)	Whether or not participants, caregivers, and those assessing the outcomes were blinded to group assignment
Results	
Numbers randomized	Number of participants randomized to each group
Recruitment	Trial status
Numbers analyzed	Number of participants analyzed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision
Harms	Important adverse events or side effects
Conclusions	
Conclusions	General interpretation of the results
Trial registration	Registration number and name of the trial register
Funding	Source of funding

Statistical analysis

Compliance above 75% was defined as adequate and below 75% as inadequate. Univariate analysis for possible determinants was performed. Journal's impact factor (IF) was transformed into a dichotomous variable (classified as low <3.48 and high >3.48). The use of IF=3.48 was based on the median of our sample. Also, publication period (before and after 2010), sample size (dichotomous variable based on the median of our sample, <300 randomized patients vs. ≥300 randomized patients), and the number of authors (dichotomous variable based on the median of our sample, <8 authors vs. ≥8 authors) were transformed similarly. Additionally, Participant flowchart and multicentric design were explored as categorical variables. All the variables were analyzed using Fisher's exact test. Also, an exploratory analysis was performed to investigate the existence of a linear correlation between abstract and article reporting quality, determining Pearson Correlation Coefficient (Pearson's r). The statistical analysis was made on the IBM SPSS v.21 packages and EXCEL. The cutoff point for statistical significance was set at the two-sided 0.05 level.

Results

Literature search retrieved a total of 15,623 articles (Figure 1). After removing the duplicate records, 8,471 articles were screened based on their title and abstract. Finally, 14 publications were included in our qualitative analysis after assessing 30 full-text eligible articles. The manual search of references did not provide any additional reports of RCTs.

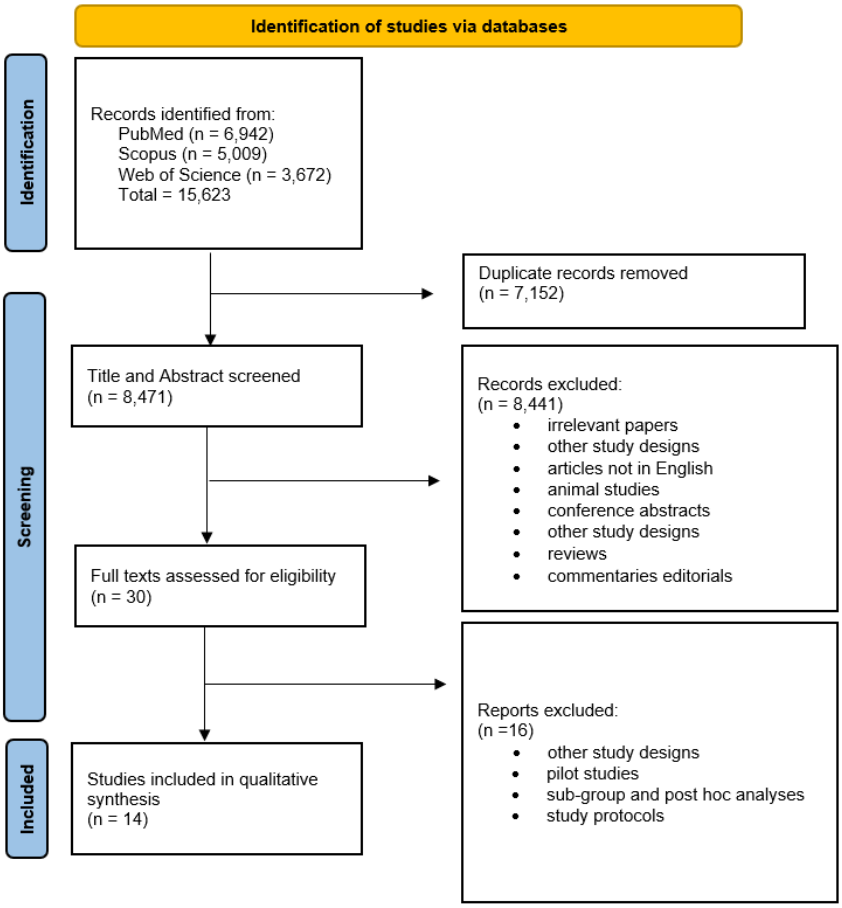

Figure 1: Flow Diagram

CONSORT compliance

Out of the 14 articles, 4 (28.57%) were published before 2010, while the rest were published the period after. The Mean consort adherence for all the publications was 60.61% (SD=15.20), while the minimum and maximum adherence were 29.73% and 81.08%, respectively. Three publications (21.43%) presented an adequate reporting (above 75%), while there were 11 studies (78.57%) with CONSORT compliance more than 50%. (Table 2)

Adherence per consort item was evaluated and presented in Figure 2 and Table 3. Items 1a and 1b were reported in 50% and 85.71% of the articles, respectively, whereas items 2a and 2b in every publication. Regarding methodological items, only 6 (35.29%) were reported by 75% or more of the publications, while items 6b, 10, and 11b were not reported in any article. Also, description of the trial's design and important changes (3a and 3b correspondingly) were underreported. Only four items of the results section (40%) were reported by 75% or more of the studies. Items 14b, 17b, and 18 were severely underreported. Trial limitations (item 20) had the lowest report rate of discussion domain (57.14%), while item 22 was reported in all the articles. Finally, other information (trial registration, trial protocol, sources of funding) were rated as reported in 57.14%, 64.48%, and 50% of the studies, respectively.

Table 2: List of the included publications reporting RCTs along with their characteristics and Consort Score

Authors	Year	Journal	IF	Multicenter Trial	Sample Size	Average compliance score (%)
Darsaut et al. [22]	2017	Journal of Neurology, Neurosurgery, and Psychiatry	7.144	Yes	136	81.08
Proust et al. [23]	2018	Neurochirurgie	0.948	No	41	59.46
Molyneux et al. [24]	2002	Lancet	15.397	Yes	2143	67.57
Darsaut et al. [25]	2019	Neurochirurgie	1.214	Yes	103	81.08
Wadd et al. [26]	2015	Journal of the College of Physicians and Surgeons Pakistan	0.343	No	140	29.73
Li et al. [27]	2012	The Journal of International Medical Research	0.958	No	192	35.14
Molyneux et al. [28]	2014	Lancet	45.217	Yes	1644	64.86
Molyneux et al. [29]	2005	Lancet	23.878	Yes	2143	64.86
Koivisto et al. [30]	2000	Stroke	6.008	No	109	48.65
McDougall et al. [31]	2012	Journal of Neurosurgery	3.148	No	472	62.16
Darsaut et al. [32]	2021	World Neurosurgery	2.104	Yes	171	78.38
Spetzler et al. [33]	2013	Journal of Neurosurgery	3.227	No	408	59.46
Molyneux et al. [34]	2009	The Lancet. Neurology	18.126	Yes	2143	56.76
Spetzler et al. [35]	2015	Journal of Neurosurgery	3.737	No	408	59.46

IF: Impact Factor

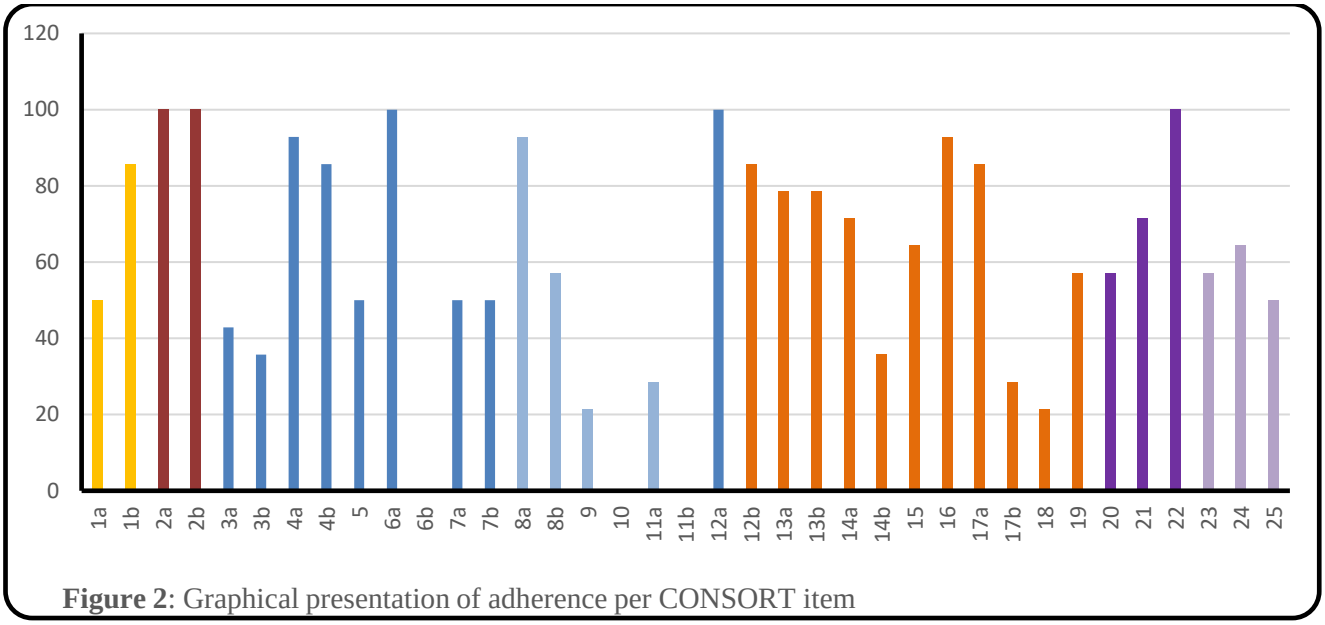

Figure 2: Graphical presentation of adherence per CONSORT item

Table 3: Proportion of reported 37 items in a total of 14 randomized controlled trials grouped by publication period

Consort Item	All reports (n=14)	Time period: Before 2010 (n=4)	Time period: After 2010 (n=10)	P-value
Title and abstract				
1a. Identification as a randomised trial in the title	7 (50%)	3 (75%)	4 (40%)	0.559
1b. Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	12 (85,71%)	4 (100%)	8 (80%)	0.560
Introduction				
2a. Scientific background and explanation of rationale	14 (100%)	4 (100%)	10 (100%)	-
2b. Specific objectives or hypotheses	14 (100%)	4 (100%)	10 (100%)	-
Methods				
3a. Description of trial design (such as parallel, factorial) including allocation ratio	6 (42,85%)	0 (0%)	6 (60%)	0.085
3b. Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5 (35,71%)	0 (0%)	5 (50%)	0.221
4a. Eligibility criteria for participants	13 (92,85%)	3 (75%)	10 (100%)	0.286
4b. Settings and locations where the data were collected	12 (85,71%)	2 (50%)	10 (100%)	0.066
5. The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7 (50%)	0 (0%)	7 (70%)	0.070
6a. Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	14 (100%)	4 (100%)	10 (100%)	-
6b. Any changes to trial outcomes after the trial commenced, with reasons	0 (0%)	0 (0%)	0 (0%)	-
7a. How sample size was determined	7 (50%)	3 (75%)	4 (40%)	0.559
7b. When applicable, explanation of any interim analyses and stopping guidelines	7 (50%)	3 (75%)	4 (40%)	0.559
8a. Method used to generate the random allocation sequence	13 (92,85%)	4 (100%)	9 (90%)	1.000
8b. Type of randomisation; details of any restriction (such as blocking and block size)	8 (57,14%)	3 (75%)	5 (50%)	0.580
9. Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3 (21,42%)	1 (25%)	2 (20%)	1.000
10. Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	0 (0%)	0 (0%)	0 (0%)	-
11a. If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes), and how	4 (28,57%)	1 (25%)	3 (30%)	1.000
11b. If relevant, description of the similarity of interventions	0 (0%)	0 (0%)	0 (0%)	-
12a. Statistical methods used to compare groups for primary and secondary outcomes	14 (100%)	4 (100%)	10 (100%)	-
12b. Methods for additional analyses, such as subgroup analyses and adjusted analyses	12 (85,71%)	2 (50%)	10 (100%)	0.066
Results				
13a. For each group, the numbers of participants who were randomly assigned received intended treatment and were analyzed for the primary outcome	11 (78,57%)	3 (75%)	8 (80%)	1.000
13b. For each group, losses and exclusions after randomisation, together with reasons	11 (78,57%)	3 (75%)	8 (80%)	1.000
14a. Dates defining the periods of recruitment and follow-up	10 (71,42%)	3 (75%)	7 (70%)	1.000
14b. Why the trial ended or was stopped	5 (35,71%)	2 (50%)	3 (30%)	0.580
15. A table showing baseline demographic and clinical characteristics for each group	9 (64,28%)	2 (50%)	7 (70%)	0.580
16. For each group, the number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	13 (92,85%)	4 (100%)	9 (90%)	1.000

17a. For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	12 (85,71%)	4 (100%)	8 (80%)	1.000
17b. For binary outcomes, presentation of both absolute and relative effect sizes is recommended	4 (28,57%)	2 (50%)	2 (20%)	0.520
18. Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	3 (21,42%)	2 (50%)	1 (10%)	0.176
19. All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	8 (57,14%)	2 (50%)	6 (60%)	1.000
Discussion				
20. Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	8 (57,14%)	0 (0%)	8 (80%)	0.015
21. Generalisability (external validity, applicability) of the trial findings	10 (71,42%)	3 (75%)	7 (70%)	1.000
22. Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14 (100%)	4 (100%)	10 (100%)	-
Other information				
23. Registration number and name of trial registry	8 (57,14%)	2 (50%)	6 (60%)	1.000
24. Where the full trial protocol can be accessed, if available	9 (64,28%)	4 (100%)	5 (50%)	0.221
25. Sources of funding and other support (such as a supply of drugs), the role of funders	7 (50%)	3 (75%)	4 (40%)	0.559

Determinants of reporting quality

The association of several factors with the overall reporting quality was investigated in this study. The results provided by univariate analysis are presented in Table 4. Analysis revealed that the number of authors had a significant association with the reporting quality. The publication period, participant flowchart, impact factor of the journal, multicentric design, and sample size were not associated with CONSORT compliance. Also, further analysis was performed to reveal possible associations between the publication period and every individual item. (Table 3)

An exploratory analysis was performed to investigate for linear correlation between abstract and article reporting quality. Pearson's r was estimated $r = 0.839$, $p < 0.001$, which indicates a strong, positive correlation with statistical significance. The trend between abstract and article reporting quality is graphically demonstrated in the scatter plot diagram (Figure 3)

Table 4: Univariate analysis of possible determinants of reporting quality

Parameter	Adequate CONSORT compliance (3)	Inadequate CONSORT compliance (11)	P-value
Participant Flowchart	3/3	5/11	0.258
Number of authors more than 8	3/3	2/11	0.027
Impact Factor more than 3.48	1/3	6/11	1.000
Publication after 2010	3/3	7/11	0.505
Multicentric design	3/3	4/11	0.192
Sample size larger than 300	0/3	7/11	0.192

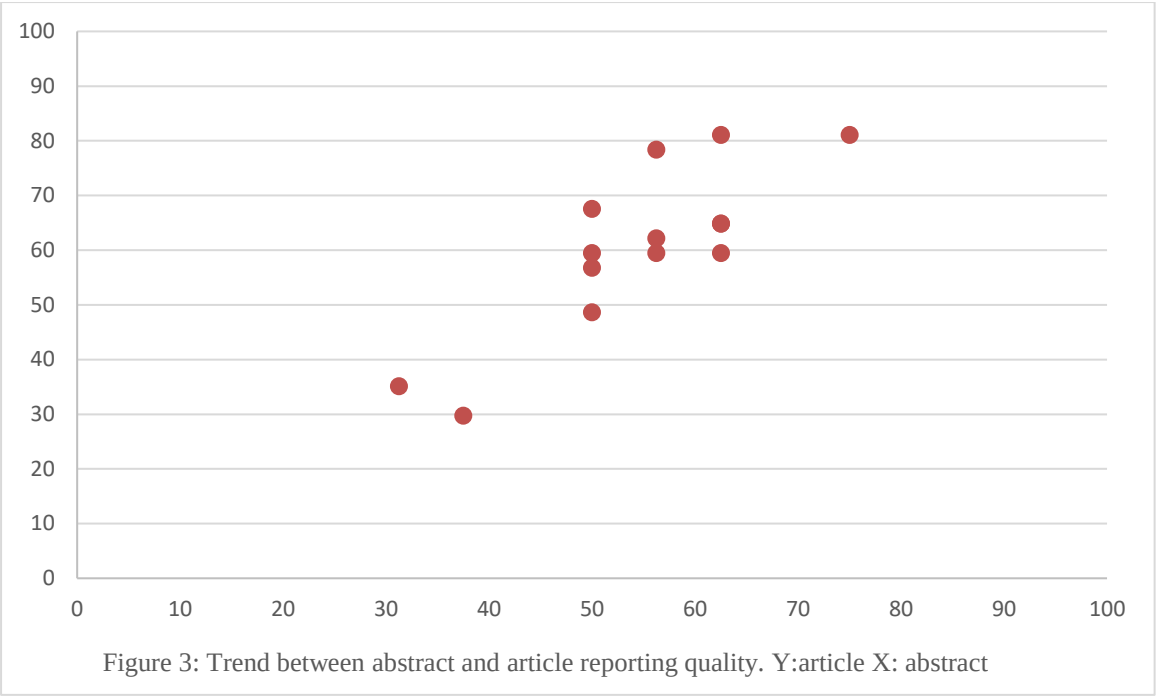

Figure 3: Trend between abstract and article reporting quality. Y:article X: abstract

Discussion

CONSORT compliance

The present study constitutes an effort to assess the reporting quality of RCTs for managing cerebral aneurysms based on the revised version of the CONSORT statement of 2010. Fourteen articles were reviewed, and the overall compliance to the CONSORT statement was moderate. Unfortunately, only three publications (21.43%) presented adequate reporting (above 75%), while the mean CONSORT adherence for all the publications was as low as 60.61%. Out of the 37 items on the checklist, only 14 items were addressed in 75% or more of the publications.

Item 1a was reported in 50% of the publications, while a well-structured abstract according to the CONSORT for Abstracts extension (item 1b) was present in 12 studies (85.71%). Abstracts play the role of a filtration tool for readers, and their compliance to the CONSORT guidelines has been previously studied. [36–39] Regarding methodological items, 7 out of 17 items (41.17%) were underreported. Specifically, blinding (Item 11a), allocation concealment mechanism (Item 9), and trial design (Item 3a) were reported in 28.57%, 21.42%, and 42.85%, respectively, while changes to trial outcomes (Item 6b), implementation (Item 10) and description of the similarity of interventions (Item 11b) were not reported in any article. Implementation of randomization constitutes the central issue in several studies [40–43], whereas other researchers similarly reported item 3a (trial design). [44, 45]

Most items regarding the results section were sufficiently reported (above 60%). Only 17b (binary outcomes), 18 (the result of any other analyses), and 14b (reason for trial stopping) were underreported. In our study, items with respect to trial registration (23), protocol (24), and funding (25) were moderately reported by 57.14%, 64.28%, and 50% of the articles, respectively. Although their importance is tremendous and constitute the most objectively assessed items, they tend to be frequently underreported. [16, 46] On the contrary, discussion and introduction items were more adequately reported. However, this finding should be interpreted with caution, given the subjective nature of these items. [20]

It is essential to highlight that compliance with the CONSORT statement does not improve the quality of a trial but its methodological reporting. A well-conducted but inadequately reported RCT may be misclassified, its reproduction will not be feasible, and its data will not be easily applied in the clinical setting. [47]

Determinants of reporting quality

Univariate analysis indicated that more authors were associated with superior reporting quality ($p = 0.027$). However, in our study, the presence of a participant flowchart or multicentric design, a more significant impact factor (more than 3.48), a sample size larger than 300, and the publication after 2010 showed no statistically significant association with reporting quality.

Several studies have already investigated the relationship between the CONSORT compliance and date of publication providing results compatible with superior reporting following publication of the CONSORT guidelines. [21, 48–50] Journal impact factor was previously studied, and a significant association between IF and reporting quality was demonstrated. [16, 18, 21, 49, 51, 52] Although the number of authors [20, 43, 53] was previously investigated by several researchers with no concluding results, some publications correlate scientific collaboration with superior reporting quality. [20, 54] This finding appears consistent with our results.

Finally, it is a fact that most readers decide to acquire or not a full text based on its abstract, explaining why its reporting quality is important. [55] Liambas et al., in 2018, found a significant correlation in reporting quality between the abstract and article. [20] In our study, an exploratory analysis was carried out to investigate the linear relationship between abstracts and the article's proportion of compliance based on CONSORT guidelines. A statistically significant, strong, positive correlation was established ($r = 0.839$, $p < 0.001$).

Limitations

Our study has several limitations. Firstly, the sample size of our study was small because of the limited number of relevant RCTs in the literature, limiting our ability for further statistical analysis, including multivariate analysis. Secondly, the CONSORT statement checks only whether an item is reported rather than carried out in the trial so that a well-conducted trial may be misjudged. Thirdly, several checklist items regarding blinding or concealment may not always be applicable in RCTs of surgical interventions where the investigators or the patients cannot be blinded to their treatment method. Finally, we used the revised version of the CONSORT statement for all the articles, even those published before 2010. The applicability of this version of the tool may be questionable.

Conclusion

In conclusion, this study shows that the quality of reporting according to the CONSORT statement of most RCTs focusing on the management of intracranial aneurysms remains unsatisfactory. Further improvement of reporting is necessary to assess the validity of clinical research, and transparent reporting will enable readers to critically appraise the procedural quality and interpret the results of published studies.

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