Quality of Reporting of Randomized Clinical Trials in Abstracts of the 2005 Annual Meeting of the American College of Rheumatology

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ABSTRACT. ***Objective.*** To determine the quality of abstracts reporting randomized clinical trials (RCT) at the 2005 Annual Scientific Meeting of the American College of Rheumatology.

Methods. All 2005 abstracts including late-breaking abstracts were assessed. An abstract was deemed to be reporting an RCT if it indicated that participants were randomized in the title or body of the abstract. RCT were excluded if they included only pharmacokinetic data. The CONSORT checklist was applied and relevant data extracted. We defined manufacturer support as acknowledgment of industry support or industry employee as co-author.

Results. Of 2146 abstracts, 143 (6.7%) reported RCT. Of these, 78.3% were drug trials, and 63.6% indicated manufacturer support. Only 30.8% of abstracts used "randomized" in the title, 44.1% did not explicitly state whether blinding was undertaken, and only 7.0% clearly stated who was blinded. Thirty percent of studies did not give an explicit definition of eligibility criteria of participants. While 84.6% explicitly described the experimental intervention, only 37.1% explicitly described the comparator intervention. Only 21% explicitly stated that an intention to treat analysis was performed. Baseline demographic and clinical characteristics were reported in 48.3%. While most abstracts reported summary results for each treatment group, only 35.7% reported effect size with its precision.

Conclusion. The quality of reporting is suboptimal in many RCT abstracts. Abstracts reporting RCT would benefit from a structured approach that ensures more detailed reporting of eligibility criteria, active and comparator interventions, flow of participants, and adequate summary and precision of results. (First Release Nov 1 2007; J Rheumatol 2007;34:2476–80)

Key Indexing Terms:
RANDOMIZED CLINICAL TRIALS QUALITY OF REPORTING RESEARCH DESIGN

Conference abstracts generally represent the first reports of novel therapies; thus they are frequently quoted and widely publicized in the medical and lay media. Studies in other areas of medicine demonstrate that as many as 50%–60% of abstracts of randomized clinical trials (RCT) will never be published as full-length articles, meaning that conference proceedings may represent the only published record of RCT for use by clinicians and in systematic reviews[1,2]. Therefore, an accurate comprehensive account of the RCT in its abstract form is imperative for clinicians and the wider community.

The CONSORT statement was first published in 1996, and updated in 2001[3]. It recommends a checklist of items to be reported in publications of RCT with the intention of improving the quality of RCT publications. Recent systematic reviews have shown that RCT published in journals that have mandated the use of the CONSORT statement have improved in quality since its adoption[4-6]. Currently, no CONSORT statement exists for use in abstracts, for either conference proceedings or journal publications.

Our aim was to determine the quality of reporting of abstracts describing RCT at the 2005 Annual Scientific Meeting of the American College of Rheumatology/ Association of Rheumatology Health Professionals (ACR/ARHP).

MATERIALS AND METHODS

We performed a hand search of all abstracts of the 2005 ACR/ARHP annual meeting, including late-breaking abstracts. An abstract was determined to be reporting an RCT if it was indicated in the title or body of the abstract that participants were randomized. We excluded RCT that included only pharmacokinetic data.

Evaluation of RCT quality. Each RCT abstract was assessed using a modified version of the CONSORT statement (Table 2), such that, for example, "randomization" must appear in the title, rather than the title and abstract as appeared in the revised CONSORT statement[3]. Analysis was classified according to the first analysis undertaken in the Results section. After 2 reviewers (CLH, RB) standardized data extraction using a sample of RCT

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abstracts, all trials were evaluated by one reviewer (CLH). A computer-generated random sample of RCT (n = 29) was evaluated by a second reviewer (RB) to determine interobserver reliability for allocation concealment, blinding, randomization, and intention to treat (ITT) analysis [kappa 0.68 for all features combined; 95% confidence interval (CI) 0.64 to 0.97].

Data extraction. Demographic data regarding the trial were extracted including disease, country of origin, type of intervention, number of participants, length of trial, and type of presentation (oral presentation or poster). We also collected information regarding manufacturer support, which was defined as acknowledgment of industry support or industry employee as a co-author[7]. The number of checklist items was recorded with a range from 0 to 31. Although the CONSORT checklist includes only 22 items, for some items, these were split for ease of scoring, to give a total score of 31. For example, description of the experimental intervention and comparator intervention is listed as one item. These were scored separately, as many abstracts described the experimental but not the comparator intervention.

Analysis. Categorical data were analyzed using chi-square tests for categorical data (or Fisher's test when numbers were small). Continuous measures were analyzed using t test or Wilcoxon test for nonparametric data. P values reported are 2-sided.

RESULTS

There were 143 abstracts reporting RCT from a total of 2146 abstracts (6.7%). Of these, 62 (43.4%) abstracts reported data from trials that were reported in more than one abstract (see Table 1). Only 2 abstracts reported RCT in pediatric populations. Fifty-nine (41.2%) were presented as oral presentations, and the remainder as posters. The median number of items included from the CONSORT checklist was 9/32 (range 4–20). There was no difference between those with and without manufacturer support. In addition, there was no difference in the median number of included items from the CONSORT checklist between those abstracts presented as oral presentations (median 9, range 5–20) or poster presentations (median 9, range 4–18). There were more included items in those abstracts only reporting data from a study for the first time (median 10, range 4–20) than those abstracts in which data from the same study were presented in more than one abstract (median 8, range 5–11; $p < 0.001$). There was no difference between drug and non-drug trials in the item inclusion ($p = 0.16$).

Table 1. Characteristics of trials (n = 143).

Adult Rheumatic Disease, n (%)	141 (98.6)
Single-report RCT	81 (56.6)
Disease type	
Rheumatoid arthritis	68 (47.6)
Osteoarthritis	23 (16.1)
Fibromyalgia	17 (11.9)
Connective tissue disease/vasculitis	10 (7.0)
Other	25 (17.5)
Oral presentation	59 (41.3)
Drug therapy	112 (78.3)
No. of participants, median (range)	211 (12–1609)
Duration of trial, weeks, median (range)	26 (1–208)
Manufacturer support[7], n (%)	91 (63.6)
Blinding to treatment allocation, n (%)	
Open	15 (10.5)
Single (i.e., participant was blind)	3 (2.1)
Double (i.e., both participant and outcome assessor/s were blind)	62 (43.4)
Unstated	63 (44.1)
Stated type of analysis in methods section, n (%)	
Intention-to-treat analysis	30 (21.0)
Per-protocol analysis	13 (9.1)
Unstated	100 (69.9)

Table 2 describes some of the features in the CONSORT checklist. Many features were described more fully in the intervention group, compared to the comparator group. For example, 84% of abstracts explicitly described the intervention (dose, route of administration) compared to 31% explicitly describing the comparator intervention. In over 50% of abstracts, there were inadequate baseline demographic and clinical data, leaving it unclear whether the 2 groups were comparable at baseline. In less than one-third of abstracts it was not possible to determine the flow of participants through RCT and analysis.

With regard to analysis, 30 (21.0%) abstracts stated that they had undertaken an ITT analysis in the Methods section; however, only in 24 (16.8%) was it clear that ITT analysis had actually been performed. In most, the type of analysis was not stated (69.9%). The majority reported a summary of results for each group for primary outcome. However, reporting of effect size with its precision, as recommended by the CONSORT statement (e.g., mean difference between groups with 95% CI) was only performed in 35.7%. An example of a deficient report is "Intervention A participants, compared to placebo, demonstrated improvements in outcomes X, Y, and Z (all $p < 0.5$)." Less than one-third described important adverse events in each group.

Following from these results, we have proposed a checklist for RCT abstracts submitted to scientific meetings (Table 3.) The median number of items from this proposed checklist for the abstracts in our study was 8 out of a possible score of 15 (range 3–15). Therefore, even after exclusion of CONSORT items that would not be deemed necessary for an abstract (as opposed to full publication), 50% of abstracts reported only 50% of the required features.

DISCUSSION

Our study demonstrates that the quality of abstracts of RCT at a major international scientific meeting varied substantially, indicating that proper assessment of the trial would not be possible. In many abstracts, some areas were well described, but few adequately reported all relevant elements of RCT methods and results, as outlined by the CONSORT statement[3]. The apparent incompleteness of abstract reporting according to our modified CONSORT checklist suggests that it may not be feasible to report some elements of trial methodology in the restricted format of an abstract, as few abstracts in our study were able to address these. Examples of infrequently reported items include the method of randomization (e.g., random number table), method of allocation concealment (e.g., central allocation), and sample size calculation.

Table 2. Results of modified CONSORT checklist review (n = 143 trials).

Section and Topic	Item	Description	Percentage of Abstracts (n = 143), n (%)
Title and abstract	1	How participants were allocated to interventions ("random allocation," "randomized," or "randomly assigned")	44/143 (30.8)
Introduction			
Background	2	Scientific background and explanation of rationale	81 (56.6)
Methods			
Participants	3a	Eligibility criteria for participants	99 (69.2)
	3b	Settings and locations where the data were collected	18 (12.6)
Interventions	4a	Experimental intervention described	121 (84.6)
	4b	Comparator intervention described	53 (37.1)
Objectives	5	Specific objectives and hypotheses	125 (87.4)
Outcomes	6a	Clearly defined primary and secondary outcome measures	122 (85.3)
	6b	Any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)	4 (2.8)
Sample size	7a	How sample size was determined	2 (1.4)
	7b	When applicable, explanation of any interim analyses and stopping rules	1 (0.7)
Randomization — sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification)	4 (2.8)
Randomization — allocation concealment	9	Method used to implement the random allocation sequence (numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned	2 (1.4)
Randomization —	10a	Who generated the allocation sequence	2 (1.4)
Implementation	10b	Who enrolled participants	2 (1.4)
	10c	Who assigned participants	2 (1.4)
Blinding (masking)	11a	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	10 (7.0)
	11b	When relevant, how the success of blinding was evaluated	2 (1.4)
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	64 (44.8)
Results			
Participant flow	13a	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome	42 (29.4)
	13b	Describe protocol deviations from study as planned, together with reasons	8 (5.6)
Recruitment	14	Dates defining the periods of recruitment and followup	1 (0.7)
Baseline data	15	Baseline demographic and clinical characteristics of each group	69 (48.3)
Numbers analyzed	16a	Number of participants (denominator) in each group included in each analysis. State the results in absolute numbers when feasible (e.g., 10/20, not 50%)	61 (42.7)
	16b	And whether the analysis was "intention to treat"	24 (16.8)
Outcomes and estimation	17a	A summary of results for each primary and secondary outcome group	128 (89.5)
	17b	For each primary and secondary outcome, the estimated effect size and its precision (e.g., 95% confidence interval)	51 (35.7)
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory	28 (19.6)
Adverse events	19	All important adverse events or side effects in each intervention group	45 (31.5)
Discussion			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	1 (0.7)
Generalizability	21	Generalizability (external validity) of the trial findings	0
Overall evidence	22	General interpretation of the results in the context of current evidence	133 (93.0)

Table 3. Proposed checklist for use with submission of randomized clinical trial abstracts to scientific meetings.

Component	Description
Title	Must include "randomized" in the title if participants have been randomized to experimental intervention
Purpose	Clear, concise statement of purpose of study
Study design	This must include a statement regarding randomization and blinding (open-label, participant-blinded, assessor-blinded)
Patients	Eligibility criteria (disease specification, disease duration, disease activity, defined DMARD use)
Intervention	Description of experimental and comparator intervention (this requires dose and route for drugs, including placebo)
Outcome measures	Description of primary outcome measure (ACR20) and other important secondary outcome measures
Statistical analysis	Statistical methods used to compare groups for primary outcome(s) (intention-to-treat, per-protocol) and methods for additional reported analysis (such as subgroup and adjusted analyses)
Results	
Baseline data	Baseline demographic and clinical characteristics in each group
Outcome and participant flow	Summary of results of primary analysis for each group (with numbers in each final analysis of each group with estimated effect size and its precision (e.g., 95% confidence interval). Use of a table can facilitate this
Adverse events	All important adverse events or side effects in each intervention group
Conclusions	Short statement outlining the interpretation of the results

DMARD: disease modifying antirheumatic drugs; ACR: American College of Rheumatology.

The CONSORT statement recommends a flow diagram to adequately report information regarding flow of participants through the RCT. While this is not feasible to report in abstracts, judicious use of tables within the abstract with numbers in each cell can demonstrate the course of subjects through the RCT and analysis. The fact that some investigators were able to report many aspects of trial methodology demonstrates that this is possible within the confines of an abstract. However, the majority of the abstracts reported less than 50% of the items on the CONSORT checklist, suggesting that they were accepted for presentation at the meeting with inadequate information. Previous studies, including in the rheumatology setting, have demonstrated variability in the evaluation of conference abstracts, even when peer-reviewed[8,9]. Use of a checklist would aid consistent abstract review. As these abstracts may represent the only published record of the RCT, it is imperative that they be as accurate and comprehensive as possible within the restrictions of the abstract length.

Although our study was limited to rheumatology RCT abstracts, similar studies in other fields have revealed similar findings. A study of all abstracts presented at the 1996 Annual Meeting of the American Academy of Orthopaedic Surgeons found that less than half reported key methodological issues, and two-thirds were not followed by a full-text publication[10]. A review of conference RCT abstracts from the American Society of Clinical Oncology (ASCO) Meeting in 2002 revealed similar deficiencies in reporting[11]. A subsequent comparison of these 1992 conference abstracts with their full publications revealed that only 22% reported the same number analyzed in the conference abstract and the full publication[12]. RCT abstracts presented at the American College of Cardiology scientific meetings (1999-2002) demonstrated discrepancy in the effect estimate reported in the conference abstract when compared to subsequent publications (mean change in effect of 0.44 SD)[13]. Further, RCT abstracts with positive results were more likely to be subsequently published as full-length articles than those with negative results[14]. A recent assessment of the extent of use of data from conference abstracts and presentations in health technology assessments provided as part of the National Institute for Health and Clinical Excellence (NICE) appraisal process highlighted difficulty in searching for abstracts, difficulty in determining methodological quality, and discrepancy in data reporting[15]. These issues of publication bias and inaccuracy have implications for the use of conference abstracts in metaanalyses, where use of this data may influence the outcome of the review[16] and make accurate, complete reporting of RCT abstracts at scientific meetings vital. To overcome some of the issues, inclusion of all RCT on the clinical trials registers is now being recommended. As of January 1, 2007, the ACR has mandated that all prospective, interventional studies must be registered at either www.clinicaltrials.gov or www.controlled-trials.com in order to be considered for publication in *Arthritis Care and Research* and *Arthritis and Rheumatism*. A similar policy for RCT reported at scientific meetings such as the ACR Annual Scientific Meeting would also be appropriate.

What would improve the quality of RCT abstracts at scientific meetings? Each abstract that is submitted to the ACR annual meeting is reviewed simultaneously. Multiple abstracts

using data from the same RCT may be judged by different abstract review subcommittees. As a consequence, RCT abstracts that are reporting secondary outcomes still need to adequately outline trial methodology, as the RCT abstract reporting the primary outcome/s may not appear simultaneously or may not in fact be accepted for inclusion at the scientific meeting. Identification that an abstract reports data from an RCT during the abstract submission process, e.g., by means of a check box, would aid reviewers and would also allow the College to use a structured approach to submission. In particular, more detailed reporting of eligibility criteria, active and comparator interventions, outcome measures, flow of participants, and adequate summary and precision of results would aid judgment of abstracts of RCT. The inclusion of more subheadings might aid more comprehensive reporting of results, as we observed that authors of abstracts with more comprehensive reporting often included more subheadings. The current recommended subheadings are Purpose, Methods, Results, and Conclusions. An alternative set of subheadings could include Purpose, Study Design, Patients, Interventions, Outcome Measures, Statistical Analysis, Results, Adverse Events, Conclusions. We have outlined a proposed checklist for use during submission of RCT abstracts to scientific meetings (Table 3). This checklist was developed on the basis of our best judgment after reviewing our study results. Ideally, this checklist needs to undergo a more extensive development process with input by experts in the field and a further study of validity. Krzyzanowska, *et al* have proposed minimal guidelines for reporting of abstracts after their survey found deficiencies in reporting in almost all of 510 abstracts reporting large RCT at ASCO meetings from 1989 to 1998[17]. We understand that a "Mini-CONSORT for abstracts" is under development. Such a checklist for abstracts would improve reporting of RCT in abstract form, and therefore, improve the quality and comprehensiveness of information for abstract reviewers, conference attendees, researchers, and the wider rheumatology community. The implications of inadequate RCT reporting of scientific meetings are manifest in presentation of poorly substantiated and inaccurate results that are publicized in both the medical and lay community.

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