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REVIEW

Quality of Reporting of Randomized Controlled Trials of Herbal Medicine Interventions

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ABSTRACT

BACKGROUND: Public interest in herbal medicines has generated an increasing number of trials evaluating their efficacy. Trials with poor methodologic quality have exaggerated estimates of treatment effect, and incomplete reporting of trials causes difficulties in assessing trial methodologic quality. The objective of this project was to examine the quality of reporting of randomized controlled intervention trials of herbal medicine.
METHODS: MEDLINE (1966 to September 2003) was searched for randomized controlled trials of 10 herbal medicines. Two individuals (J. G. and J. D.) independently assessed trials using the Consolidated Standard of Reporting Trials checklist. Disagreements were resolved by consensus. The mean number of checklist items reported across all and for individual herbal medicines was calculated. The influence of decade of publication and species of herbal medicine tested was explored using an analysis of variance.
RESULTS: A total of 206 randomized controlled trials of herbal medicine were included. Interrater reliability on reporting quality assessment was high. A total of 45% of items were reported across all trials. The quality of reporting improved across decades from the 1970s to the 2000s. Individual herbal species differed in the total number of items reported, with echinacea, ginkgo, St. John's wort, and kava trials reporting the most items.
CONCLUSIONS: Important methodologic components of randomized controlled trials of herbal medicines are incompletely reported including allocation concealment, method used to generate the allocation sequence, and whether an intention-to-treat analysis was used. Also, key information unique to these trials may be missing, such as percentage of active constituents and type or form of the herbal medicine preparation. We suggest trialists consult a recent extension of the Consolidated Standard of Reporting Trials statement specific to herbal medicine trials when designing and reporting randomized controlled intervention trials of herbal medicines.

KEYWORDS: Reporting quality; Methodological quality; Herbal medicine; Controlled clinical trials; CONSORT guidelines; Complementary and alternative therapies

The amount of rigorous research on complementary and alternative medicine has greatly increased over the past 40 years, and each year since the mid-1980s the proportion of clinical trials of complementary and alternative medicine interventions published has increased.[1] More than 40,000 articles are indexed in MEDLINE as complementary and alternative medicine, and approximately 1500 new articles are indexed in MEDLINE each year.[1,2] As of January 2005, the Trial Registry of the Cochrane Collaboration Comple-

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mentary Medicine Field contained more than 6500 controlled trials.[3] In a systematic search for evidence underlying complementary and alternative medicine interventions for specific conditions, Katz and colleagues[2] found more than 4000 rigorous articles.

Many systematic reviews of complementary and alternative medicine therapies criticize the methodologic quality of complementary and alternative medicine trials.[4-8] In a review of systematic reviews of complementary and alternative medicine therapies, the mean Jadad score was 2.33/5 (standard deviation [SD] = 1.36) for homeopathy trials, 3.12/5 (SD = 1.33) for herbal trials, and 2.19/5 (SD = 1.17) for acupuncture trials.[8] It was found that higher quality complementary and alternative medicine trials tended to be larger, more recent, in the English language, and published in MEDLINE indexed journals.[8] In an assessment of 251 pediatric complementary and alternative medicine trials, Moher et al[9] (2002) found a mean Jadad score of 1.9/5 (SD = 1.3) for all trials, and methodologic quality seemed to increase from the 1970s (mean Jadad score =1.4/5) and 1980s (1.6/5) to the 1990s (2.0/5) and 2000s (2.0/5) (P = .174). These results support previous research suggesting that methodologic quality scores for complementary and alternative medicine trials are similar to those of conventional medicine trials, both of which are poor.[10,11]

CLINICAL SIGNIFICANCE

- Published reports of randomized controlled trials of herbal medicine interventions do not report all required information, as recommended by the CONSORT guidelines.
- A trial with good validity, that is, with clear and appropriate methods, may not adequately report characteristics (eg, level of active constituents, deliver form, dose, etc.) of the herbal intervention. Consequently, it may be difficult to determine what herbal product can be used in a clinical situation to elicit a specific effect.

It is well known that trials with low methodologic quality are subject to bias, which results in unreliable estimates of treatment effect.[12] Juni et al[12] note that methodologic quality of trials is intertwined with the quality of reporting. Empiric evidence indicates that reporting quality does not accurately predict methodologic quality.[13,14] It is not valid to make assumptions on methodologic quality when trials are inadequately reported. To accurately assess methodologic quality the report of a trial must explicitly describe specific aspects of the design, conduct, and analysis.[15]

Current research suggests that reporting quality of complementary and alternative medicine trials is poor.[8-10,16] Linde et al[8] found that most complementary and alternative medicine trials do not describe the generation of the random sequence, an adequate method of allocation concealment, and the number and reasons for dropouts and withdrawals. Moher et al[9] reported that a sample of pediatric complementary and alternative medicine randomized controlled

Table 1 Highly Sensitive Search Strategy for the Retrieval of Reports of Controlled Trials with PubMed[21]

(randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized controlled trials [mh] OR random allocation [mh] OR double-blind method [mh] OR single-blind method [mh] OR clinical trial [pt] OR clinical trials [mh] OR ("clinical trial" [tw]) OR ((singl* [tw] OR doubl* [tw] OR trebl* [tw] OR tripl* [tw]) AND (mask* [tw] OR blind* {tw})) OR ("latin square" [tw]) OR placebos [mh] OR placebo* [tw] OR random* [tw] OR research design [mh:noexp] OR comparative study [mh] OR evaluation studies [mh] OR follow-up studies [mh] OR prospective studies [mh] OR cross-over studies [mh] OR control* [tw] OR prospectiv* [tw] or volunteer* [tw]) NOT (animal [mh] NOT human [mh])

Table 2 Search Terms for the Ten Top-Selling Herbal Medicines

Herbal Medicine Name	Search Terms
Ginkgo biloba (Ginkgo)	Ginkgo biloba, ginkgo, ginkgolide, bilobalide
Serenoa repens (Saw palmetto)	Serenoa repens, Saw palmetto, Serenoa serrulata, Sabal serrulata, Permixon, stigmasterol, campesterol, brassicasterol
Silybum marianum (Milk thistle)	Silybum marianum, Milk thistle, silymarin, Carduus marianus
Eleutherococcus senticosus, Panax quinquefolius, Panax ginseng (Siberian ginseng, American Ginseng, Asian ginseng)	Eleutherococcus senticosus, Panax quinquefolius, Ginseng, Panax, Eleuthero, ginsenosides
Tanacetum parthenium (Feverfew)	Tanacetum parthenium, Feverfew, Parthenolide
Piper methysticum (Kava)	Piper methysticum, Kava, kavalactone, kawain, methysticine
Allium sativum (Garlic)	Allium sativum, *Garlic,* allicin, ajoene, aliin
Zingiber officinale (Ginger)	Zingiber officinale, Ginger, gingerol, shogaol, zingiberene, bisobolene
Hypericum perforatum (St. John's wort)	Hypericum perforatum, St. John's Wort, hypericin, hyperforin, Klamath weed
Echinacea angustifolia/purpurea (Echinacea)	Echinacea angustifolia, Echinacea purpurea Echinacea, purple cone flower, echinacoside, cichoric acid, rutoside

Table 3 CONSORT Checklist*

PAPER SECTION and Topic	Item	Description	Reported on Page No.
TITLE and ABSTRACT	1	How participants were allocated to interventions (eg, "random allocation," "randomized," or "randomly assigned").	
INTRODUCTION			
Background	2	Scientific background and explanation of rationale.	
METHODS			
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	
Objectives	5	Specific objectives and hypotheses.	
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomization: sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification).	
Randomization: allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Randomization: implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.	
RESULTS			
Participant flow	13	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. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group.	
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention to treat." State the results in absolute numbers when feasible (eg, 10/20, not 50%).	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (eg, 95% confidence interval).	

Table 3 CONSORT Checklist - continued*

PAPER SECTION and Topic	Item	Description	Reported on Page No.
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.	
Adverse events	19	All important adverse events or side effects in each intervention group.	
DISCUSSION			
Interpretation	20	Interpretation of the results, taking into account the study hypotheses, sources of potential bias or imprecision, and dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

CONSORT = Consolidated Standard of Reporting Trials.
*Adopted from Altman, DG, Schulz, KF, Moher, D, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med.* 2001;134(8):663-694.

trials (RCTs) scored a mean of 12.7 of 32 on the Consolidated Standard of Reporting Trials (CONSORT) checklist items (the checklist was expanded from 22 items to 32 for the purposes of this study). Also, a recent study by Wolsko et al[16] found that trials of herbal medicines fail to completely report specific characteristics of the herbal product used. These results suggest that a large proportion of complementary and alternative medicine trial reports are less than adequate at reporting all necessary information, which results in difficulties in assessing internal and external validity. It is noteworthy that the quality of reporting of RCTs of complementary and alternative medicine interventions seems to be as good as that for conventional medicines.[17]

Reporting quality may vary across different types of complementary therapies with herbal medicine trials being somewhat superior to homeopathy and acupuncture trials.[8] Systematic review of herbal medicine interventions suggests that these trials often underreport important information.[18,19] This may partially explain discrepancies found between systematic reviews of herbal medicines.[20] To date, there have been no attempts at systematically assessing the quality of reporting of RCTs of herbal medicines. The purpose of the present study was to assess the reporting quality of RCTs of herbal medicines.

METHODS

One individual identified the top used herbal medicines in North America.[21] This list was cross-referenced with a published bibliography of herbal medicine systematic reviews.[22] With these methods, we hoped to identify the 10 most commonly used and studied herbal medicines. Although *Ephedrae herba* (ephedra) was a top-selling botanical medicine, a systematic review had not been done on it, and, therefore, it was not included in the current search. Two individuals searched MEDLINE (PubMed version; 1966 to December 2003) for relevant trials. The search strategy used was a combination of the highly sensitive search strategy for the retrieval of reports of controlled trials using PubMed[23] (Table 1) and various terms for each of the top 10 used herbal medicines identified above (Table 2). The search terms for each herbal medicine were developed with the aid of several librarians and information specialists.

We included only English language RCTs that tested herbal medicine interventions. Herbal medicines include herbs, herbal materials, herbal preparations, and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations used for medicinal purposes and taken by ingestion, injection, or applied topically. This definition does not include single compounds derived from plants or compounds based on specific constituents of plants.[24]

Two individuals reviewed titles and abstracts to determine trial inclusion. Where inclusion could not be determined by title or abstract, full texts were retrieved and reviewed. Disagreements were resolved by consensus.

Reporting quality was assessed using the CONSORT statement checklist (Table 3).[15] CONSORT checklist items were reviewed, and individual concepts were extracted from each resulting in a modified checklist. This resulted in the original 22 items being divided into 42 separate and independent concepts (Table 4). Two individuals independently assessed the reporting of each included trial. Items were rated as yes (Y) if the information was reported and no (N) if not. The 2 assessors then met, and disagreements were resolved by consensus.

Table 4 Modified CONSORT Checklist for Reporting Controlled Clinical Trials

Title and abstract
1 How participants were allocated to interventions (eg, "random allocation," "randomized," or "randomly assigned")
Introduction
Background
2 Scientific background
3 Explanation of rationale
Methods
Participants
4 Eligibility criteria for participants
5 Setting where the data were collected
6 Locations where the data were collected
Interventions
7 Precise details of the interventions intended for each group
8 How interventions were actually administered
9 When interventions were actually administered
Objectives
10 Specific objectives
11 Specific hypotheses
Outcomes
12 Clearly defined primary outcome measures
13 When applicable any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors) for primary outcomes (bonus point)
14 Clearly defined secondary outcome measures
15 When applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors) for secondary outcomes (bonus point)
Sample size
16 How sample size was determined
17 When applicable, explanation of any interim analyses and stopping rules (bonus point)
Randomization
Sequence generation
18 Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification)
Allocation concealment
19 Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned
Implementation
20 Who generated the allocation sequence
21 Who enrolled participants
22 Who assigned participants to their groups
Blinding (masking)
23 Whether or not participants were blinded to group assignment
24 Whether or not those administering the interventions were blinded to group assignment
25 Whether or not those assessing the outcomes were blinded to group assignment
26 If done, how the success of blinding was evaluated
Statistical methods
27 Statistical methods used to compare groups for primary outcome(s)
28 Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results
Participant flow
29 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.
30 Describe protocol deviations from study as planned, together with reasons.
Recruitment
31 Dates defining the periods of recruitment
32 Dates defining the periods of follow-up (bonus)
Baseline data
33 Baseline demographic and clinical characteristics of each group
Numbers analyzed
34 Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention to treat"
35 State the results in absolute numbers when feasible (eg, 10 of 20, not 50%).
Outcomes and estimation
36 For each primary and secondary outcome, a summary of results for each group
37 For each primary and secondary outcome the estimated effect size and its precision (eg, 95% confidence interval)

Table 4 Modified CONSORT Checklist for Reporting Controlled Clinical Trials - continued

Ancillary analyses	
38	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.
Adverse events	
39	All important adverse events or side effects in each intervention group
Discussion	
Interpretation	
40	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and dangers associated with multiplicity of analyses and outcomes
Generalizability	
41	Generalizability (external validity) of the trial findings
Overall evidence	
42	General interpretation of the results in the context of current evidence

CONSORT = Consolidated Standard of Reporting Trials.

All statistical procedures were performed by one individual (J. G.) using SPSS 11.0 (SPSS Inc, Chicago Ill). Raw agreement and Cohen's kappa were calculated for interrater reliability on reporting quality assessments. We calculated the number of items reported or not for each report, the mean number of items reported across all reports, the mean number of items reported for each decade of publication of trial reports, and the mean number of items reported for each individual herbal medicine. By using analyses of variance, we tested the influence of decade of publication, the type of herbal medicine, and the decade X herbal medicine interaction on the total number of items reported.

RESULTS

A total of 1321 article titles were retrieved from the initial search. On examination of the title and abstracts, 1090 were excluded because of improper design or not testing an herbal medicine, which left 231 trials. On review of the full reports of these 231 trials, an additional 25 were excluded. This resulted in a total of 206 trials being included.

Raw agreement was greater than 80%, and Cohen's kappa was 0.597 (95% confidence interval, 0.581-0.614) for the 8642 ratings completed by each assessor. The mean number of items reported across all trials was 18.92 of a total of 42 items (SD = 5.45), which is equivalent to 45.05% of the items. Table 5 outlines the number and percentage of trials reporting each of the 42 items.

Figure 1 outlines the mean number and percentage of items reported within each decade of publication. The analysis of variance indicated a difference in the mean number of items reported between decades ($F = 6.17$; $P < .001$). The number of items reported increases from the 1970s to the 2000s.

Post hoc testing using the Tukey honestly significant difference procedure revealed significant differences in the mean number of items reported for the 1980s and 1990s, 1990s and 2000s, and 1980s and 2000s. Given that only a single trial was published in the 1970s, we excluded it from the post hoc analyses.

Figure 2 displays the percentage of items reported for each individual herbal medicine. The results of the analysis of variance indicate that the mean number of items reported varies according to the type of herbal medicine intervention that tested in the trial ($F = 4.57$; $P < .001$). A test for an interaction between the decade of publication and the type of herbal medicine intervention was nonsignificant ($P = .101$).

DISCUSSION

We found that reports of RCTs of herbal medicine interventions reported less than half of the necessary information in their published reports. Also, the amount of information reported in the trials increased across time and varied according to the type of herbal intervention being tested.

This project has several strengths. First, we used a commonly used biomedical database. Several North American surveys indicate that MEDLINE is a database frequently used by academics, medical students, and primary care practitioners.[25-27] Second, we included a large number of reports of herbal medicine RCTs (N = 206). Third, the high level of agreement between assessors on ratings suggests a high degree of reliability in the reporting quality assessments. Last, we included reports on the most frequently used and studied herbal medicines. Therefore, this analysis of reporting quality of these herbal RCT reports likely represents the best available evidence base of herbal medicines. Alternatively, this may be viewed as a drawback given that our analysis represents only the best trials and, therefore, is not generalizable to all herbal medicine trials. That is, the overall reporting quality of the trials in the current study may be biased toward better reporting. Future research can test this hypothesis by exploring the reporting of a wider sample of herbal medicine RCTs.

Drawbacks of the present study include assessing only English reports of 10 botanical medicines and using numeric summary scores for the CONSORT checklist. First, it is possible that English language reports of herbal medicine RCTs may differ in reporting quality than reports in other

Table 5 Number and Percentage of Trials Reporting Each Item

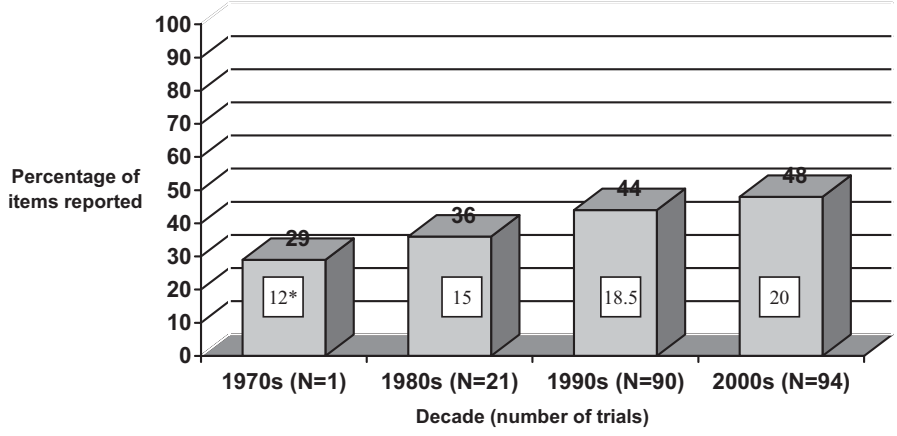
Item No.*	Item Description	Number of Trials Reporting Item	Percentage of Trials Reporting Item
3	Explanation of rationale.	203	98.5
36	For each primary and secondary outcome, a summary of results for each group.	201	97.6
42	General interpretation of the results in the context of current evidence.	198	96.1
27	Statistical methods used to compare groups for primary outcome(s).	197	95.6
10	Specific objectives.	193	93.7
8	How interventions were actually administered.	185	89.8
2	Scientific background.	184	89.3
35	State the results in absolute numbers when feasible (eg, 10 of 20, not 50%).	184	89.3
23	Whether or not participants were blinded to group assignment.	167	81.1
33	Baseline demographic and clinical characteristics of each group.	161	78.2
29	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.	155	75.2
4	Eligibility criteria for participants.	153	74.3
40	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.	141	68.5
1	How participants were allocated to interventions (eg, “random allocation,” “randomized,” or “randomly assigned”).	140	68.0
38	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.	136	66.0
39	All important adverse events or side effects in each intervention group.	132	64.1
41	Generalizability (external validity) of the trial findings.	119	57.8
7	Precise details of the interventions intended for each group.	112	54.4
34	Number of participants (denominator) in each group included in each analysis and whether the analysis was by “intention to treat.”	105	51.0
37	For each primary and secondary outcome the estimated effect size and its precision (eg, 95% confidence interval).	104	50.5
9	When interventions were actually administered.	102	49.5
5	Setting where the data were collected.	77	37.5
6	Locations where the data were collected.	75	36.4
12	Clearly defined primary outcome measures.	71	34.5
24	Whether or not those administering the interventions were blinded to group assignment.	58	28.2
14	Clearly defined secondary outcome measures.	49	23.8
28	Methods for additional analyses, such as subgroup analyses and adjusted analyses.	46	22.3
19	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions.	45	21.8

Table 5 Number and Percentage of Trials Reporting Each Item - continued

Item No.*	Item Description	Number of Trials Reporting Item	Percentage of Trials Reporting Item
18	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification).	43	20.9
31	Dates defining the periods of recruitment.	43	20.9
30	Describe protocol deviations from study as planned, together with reasons.	37	18.0
25	Whether or not those assessing the outcomes were blinded to group assignment.	28	13.6
16	How sample size was determined.	26	12.6
11	Specific hypotheses.	26	12.6
17	When applicable, explanation of any interim analyses and stopping rules (bonus point).	26	12.6
32	Dates defining the periods of follow-up (bonus point).	26	12.6
13	When applicable any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors) for primary outcomes (bonus point).	23	11.2
15	When applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors) for secondary outcomes (bonus point).	16	7.8
20	Who generated the allocation sequence.	16	7.8
22	Who assigned participants to their groups.	8	3.9
21	Who enrolled participants.	5	2.4
26	If done, how the success of blinding was evaluated.	3	1.5

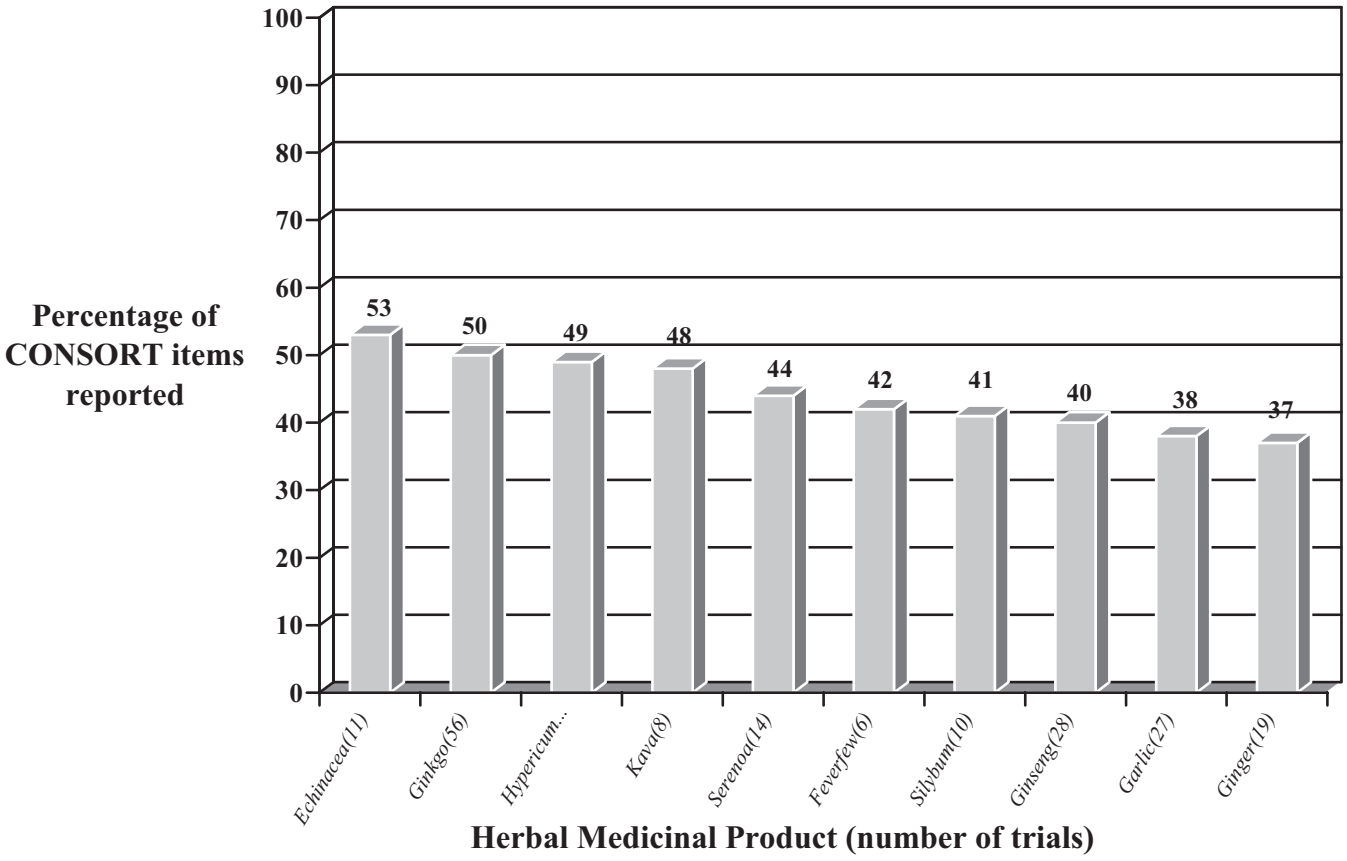
*Item numbers represent items listed in Table 4. All items are derived from the Consolidated Standard of Reporting Trials (CONSORT) checklist.

languages. Although preliminary evidence suggests that the reporting quality of English language reports of conventional medicine interventions does not differ from reports in other languages,[28,29] the influence of language of publication on herbal medicine reports is unknown. Therefore, the results of our research only can be applied to English reports of herbal medicine RCTs. Future studies can explore the influence of language of publication on the quality of reporting of herbal medicine RCTs. Second, the CONSORT checklist was not meant to generate summary scores, but to act as a guide for the type of information required in reports of 2-group parallel design RCTs. Numeric summary scores for the number of items reported do not clearly indicate where deficiencies are in the reports. Instead, one must refer



* Mean number of items reported across trials out of a total of 42

Figure 1 Percentage of items reported across trial publication decade.



Key: Hypericum = *Hypericum perfoliatum* (St. John's Wort); Serenoa = *Serenoa repens* (Saw palmetto); Silybum = *Silybum marianum* (Milk Thistle)

Figure 2 Percentage of Consolidated Standard of Reporting Trials (CONSORT) items reported for each herbal medicine.

to each item to determine how trials report specific information.

Herbal medicine trials often fail to report information outlined in those items with empiric evidence showing that not reporting them biases the estimates of treatment effect. Greater than 80% of herbal trials reported sufficient information regarding participant blinding and more than 50% reported the number of participants in each group and if an intention-to-treat analysis was completed. In contrast, less than one third of trials adequately reported information regarding whether those administering the intervention were blind (28%); the methods for implementation (22%) and generation (21%) of the random allocation sequence; whether there were protocol deviations (18%), blinding of outcome assessors (14%), and any methods to determine the success of blinding (<2%). Not reporting this information leaves the reader guessing as to their completion. This information must be reported for the reader to adequately assess the influence of bias on the results of the trial.

The results of our study are similar to those found by Moher et al,[9] who assessed a sample of 251 reports of RCTs in pediatric complementary and alternative medicine, although the reporting in these trials seems to be slightly inferior to our sample of herbal trials.[10] Moher and colleagues reported that the sample of RCTs reported approximately 40% of the information suggested in the CONSORT statement compared with 45% for herbal trials. For pediatric complementary and alternative medicine trials, 74.5% adequately reported a title compared with 68% for our herbal trials; 25% reported information on allocation concealment compared with 21% in our herbal trials; and 22.4% reported information regarding adverse events compared with 64.1% for our sample of herbal RCT reports.[9] As in the present study, Moher et al also reported a significant increase over time in the number of checklist items included in reports, but in contrast with their study,[9] a decrease in reporting quality from the 1990s to the 2000s was not found in our study. Differences between these studies may have arisen

because herbal RCTs, as one specific type of complementary and alternative medicine RCT, are better reported than complementary and alternative medicine trials in general. Another possibility is that pediatric RCTs are generally more poorly reported than trials including other patient populations. Although we have shown that herbal RCTs more completely report their trials than pediatric complementary and alternative medicine RCTs, further research can clarify the reasons for these differences.

Several studies have explored the reporting of conventional medicine trials.[30,31] One study found that conventional trials adequately report approximately 42% of the information outline in the 1996 CONSORT.[30] When the analysis focused on trials published in one of the 5 leading general medicine journals, the reporting quality increased to 56.6%. Similarly, another study found that conventional medicine trials published in four of the leading internal/general medicine journals reported 58.4% and 67.7% of the information outlined in the revised CONSORT checklist in 1994 and 1998, respectively.[31] At first glance, it seems that conventional trials are more completely reported than herbal trials. On further inspection we see that when the sample of journals is similar, the reporting quality of conventional and herbal medicine trials is similar, 42% versus 45%, respectively. It is clear that the reporting quality of trials published in the top internal/general medicine journals is better than in trials published in other journals. Future research could sample herbal trials from top journals and compare their reporting quality with conventional medicine trials published in these same journals.

Complete reporting of RCTs is essential to allow reviewers, editors, and clinicians to reliably appraise and interpret results of these trials. Although herbal trials seem to report more information than complementary and alternative medicine trials in general, and to a similar level as conventional medicine trials, these reports are inadequate in many areas. We suggest that those designing and reporting RCTs of herbal medicines refer to the recently published extension of the CONSORT statement for guidance.[32,33]

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