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Assessment of the Methodological Quality of Reporting of Randomized Trials in Four Iranian Healthcare Journals

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Objective: To assess the quality of reporting randomized trials in four Iranian healthcare journals.

Setting: Iran.

Design: Short survey.

Method: Four Iranian healthcare journals were handsearched for reports of randomized controlled trials classified using The Cochrane Collaboration eligibility criteria for studies for inclusion in systematic reviews. Quality of reporting of the trials was assessed independently by two authors (MN, AA) for four dimensions: randomized sequence generation, allocation sequence concealment, blinding of outcome assessment and intention to treat analysis. Any disagreements were resolved through discussion with a third author (ZF).

Result: In total, reports of 75 randomized controlled trials reported in the four Iranian healthcare journals were assessed. Blinding was the best reported dimension (32%, 24/75) and intention to treat analysis the least (0% 0/75). Sequence generation and allocation sequence concealment were infrequently reported (12%, 9/75 and 3%, 2/75 respectively).

Conclusion: There is room for improving the reporting of randomized trials in four Iranian healthcare journals. Authors and editors should be encouraged to follow guidance in the CONSORT Statement for improving the quality of reporting of parallel-group randomized trials (RCTs) and in the recent extension to CONSORT for reporting RCTs in abstracts in journals and conference proceedings.

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The quality assessment of randomized controlled trials, the raw material of systematic reviews, is necessary to limit bias in the review process and to guide the interpretation of results. Careful design, conduct and analysis of a randomized controlled trial will help to minimize bias so that any differences observed between participants may, apart from random error, be attributed to the intervention. These concepts plus the clinical relevance and quality of reporting of the trial are part of the multidimensional concept of quality in controlled trials. Assessing the validity of a study as an important dimension may help explain the extent to which its design and conduct are likely to prevent systematic errors or bias[1,2].

Inadequate methodological quality of trials introduces bias and may cause over- or under-estimation of treatment-effect sizes, and lead to a distortion of the results in systematic reviews.

Four principal sources of bias in trials are: selection bias, performance bias, attrition bias and detection bias. Inadequate reporting and the rather limited empirical evidence of any relationship between parameters that are thought to measure validity and actual study outcomes, are two major difficulties associated with assessing the validity of studies[2].

Inadequate reporting may reflect inadequate methods, but a well conducted trial may just be badly reported or a biased trial may be well reported. Assessing the recent guidelines on the reporting of trials (CONSORT) by authors and editors may have improved the quality of reporting (http://www.consort-statement.org/)[3].

METHOD

Identification of studies: Four Iranian healthcare journals were handsearched for reports of randomized trials (RCTs). We defined randomized controlled trials according to Cochrane criteria as studies in which the patients were reported to have been prospectively assigned to one of two (or more) groups with random allocation. We excluded studies that were reported to be randomized controlled trials but did not allocate the participants into two groups with random allocation; were conducted on animals or did not investigate the effectiveness of a healthcare intervention i.e. bioavailability studies.

Quality assessment: The methodological quality of the reporting of the trials was assessed independently by two of the authors (MN, AA) for the following dimensions: randomized generation (Adequate, Unclear, and Inadequate) and concealment of treatment allocation (Adequate, Concealment not reported/Unclear), blinding of outcome assessment (Adequate, Unclear, and Inadequate) and handling withdrawals/intention-to-treat analysis (Yes, No). Disagreements were resolved by discussion or after consultation with a third author (ZF).

RESULT

The results displayed in Tables 1 to 4 include the quality assessment of the reporting of 21 RCTs found by handsearching the *Archives of Iranian Medicine* (January 1998 to January 2006) (Table 1), 9 RCTs found by handsearching the DARU (January 1992 to January 2006) (Table 2), 22 RCTs found by handsearching the *Iranian Journal of Medical Sciences* (January 1990 to January 2005) and 23 RCTs found by handsearching

the *Medical Journal of the Islamic Republic of Iran* (January 2001 to January 2005), yielding a total of 75 reports of randomized controlled trials.

Table 1: Quality Assessment of Reporting of Randomized Controlled Trials in the Archives of Iranian Medicine

Quality criteria	Number of trials including quality criteria (as % of all trials)		
	Adequate	Not reported or unclear	Inadequate
Randomization	3/21(14%)	16/21(76%)	2/21(10%)
	Yes	Not reported or unclear	No
Blinding (single or double)	8/21 (38%)	5/21 (24%)	8/21 (38%)
	Adequate	Concealment not used/Unclear	
Concealment of allocation	0	21/21 (100%)	
	Yes	No	
handling of withdrawals/ intention-to-treat analysis	0	21/21 (100%)	

Table 2: Quality Assessment of Reporting of Randomized Controlled Trials in DARU

Quality criteria	Number of trials including quality criteria (as %of all trials)		
	Adequate	Not reported or unclear	Inadequate
Randomization	1/9 (11%)	8/9 (89%)	
	Yes	Not reported or unclear	No
Blinding (single or double)	4/9 (44%)	2/9 (22%)	3/9 (33%)
	Adequate	Concealment not used/Unclear	
Concealment of allocation	2/9 (22%)	7/9 (78%)	
	Yes	No	
handling of withdrawals/ intention-to-treat analysis	0	9/9 (100%)	

Table 3: Quality Assessment of Reporting of Randomized Controlled Trials in the Iranian Journal of Medical Sciences

Quality criteria	Number of trials including quality criteria (as % of all trials)		
	Adequate	Not reported or unclear	Inadequate
Randomization	2/22 (9%)	20/22 (91%)	0
	Yes	Not reported or unclear	No
Blinding (single or double)	4/22 (18%)	1/22(5%)	17/22(77%)
	Adequate	Concealment not used/Unclear	

Concealment of allocation	0	22/22 (100%)
	Yes	No
handling of withdrawals/ intention-to-treat analysis	0	22/22 (100%)

Table 4: Quality Assessment of Reporting of Randomized Controlled Trials in the Medical Journal of the Islamic Republic of Iran

Quality criteria	Number of trials including quality criteria (as % of all trials)		
	Adequate	Not reported or unclear	Inadequate
Randomization	3/23(13%)	20/23 (87%)	0
	Yes	Not reported or unclear	No
Blinding (single or double)	8/23 (35%)	0	15/23(65%)
	Adequate	Concealment not used/Unclear	
Concealment of allocation	0	23/23 (100%)	
	Yes	No	
handling of withdrawals / intention-to-treat analysis	0	23/23 (100%)	

The reporting of the generation of the randomization sequence was rare (12%, 9/75), but not as rare as the methods used to conceal the allocation sequence (3%, 2/75), and the handling of withdrawals (0%, 0/75). The dimension that was reported best was blinding, which was reported in one third of the studies (32%, 24/75).

DISCUSSION

A crucial component of the body of evidence for clinicians, consumers and decision makers are randomized clinical trials; therefore, it is essential that trials are designed carefully and reported clearly and conducted in the light of other similar research[4-7].

A number of studies have illustrated how methodological flaws and biases can significantly distort the results of clinical trials[1]. A meta-analysis of four studies has shown that inadequate or unclear concealment of treatment allocation is related to an exaggeration of treatment effects[1]. The effect of blinding is more diverse in different studies, ranging from no detected effect to moderate bias but this can often be explained by the different types of outcomes examined and the person who was blinded.

These forms of systematic P. biases are relevant to the internal validity of studies, whilst the external validity of the study relates to the applicability or generalisability of the results of a study to other settings and populations.

Future research into methodological quality of trials is still needed but the investigators should be careful to distinguish between methodological quality and the quality and completeness of reporting in clinical trials. Authors may often omit methodological details in their report and consequently any methodological deficiencies may be confounded by reporting deficiencies[1]. Further research is needed to investigate

whether these preliminary findings from the four journals in this study are indicative in a larger sample of healthcare journals from this and other regions using the dimensions of the Cochrane risk of bias tool.

The importance of adequate reporting of randomized controlled trials led to initiatives to improve quality of reports of RCTs and the subsequent development and publication of the CONSORT statement[6], recently extended to include reporting of RCTs in journal and conference abstracts[8]. The recent emergence of the EQUATOR network (Enhancing the Quality and Transparency Of health Research), should also be influential in helping to improve the reliability of scientific publications by promoting transparent and accurate reporting of health research through the efficient use of robust reporting guidelines (www.equator-network.org/).

CONCLUSION

There is a room for improving the reporting of randomized trials in four important Iranian journals. Authors and editors should be encouraged to follow guidance in the CONSORT Statement[6].

Deficiencies in the reporting of trials make it difficult for clinicians to critically appraise the risk of bias in these trials and may lead to errors in translation of that research into clinical practice.

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