Value of Flow Diagrams in Reports of Randomized Controlled Trials

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THE CONSOLIDATED STANDARDS for Reporting of Trials (CONSORT) criteria were published in 1996 to assist authors in reporting randomized controlled trials (RCTs). The CONSORT statement consists of a checklist for items in the methods, results, and discussion sections of a trial report and a diagram to show the flow of participants through the various stages of the trial (Figure, A). The CONSORT statement has been endorsed by an increasing number of journals, but it is unclear whether the use of CONSORT has improved the quality of reports of RCTs. We examined to what extent 5 leading medical journals adopted flow diagrams, analyzed the information contributed by these diagrams, and assessed completeness of reporting overall. The results guided our attempt to improve the design of the flow diagram (Figure, B).

METHODS

One of us (C.B.) searched each issue published in 1998 of the Annals of Internal Medicine (AIM), BMJ, JAMA, The Lancet, and The New England Journal of Medicine (NEJM) for published reports of RCTs. A study was defined as an RCT if the assignment of participants to interventions was described as randomized by words such as randomly, random, and randomization. Two of us (M.E., P.J.) independently extracted data on the characteristics of reports and examined whether a flow diagram was included. Articles were examined in random sequence with 1 assessor examining trials in the opposite order. We searched each journal’s Web site for diagrams that were published electronically but did not appear in print.

We examined whether 6 counts were provided in diagrams: (1) number of patients assessed for eligibility, (2) number found to be eligible, (3) number randomized (per group), (4) number who received allocated intervention (per group), (5) number who were lost to follow-up (per group), and (6) number included in the main analysis of primary outcomes (per group). In a separate step, we assessed whether these counts were provided either in a flow diagram or anywhere else in the article.

Each article was read independently by 2 of us in an incomplete randomized Latin square design, and interrater reliability was assessed.

information in flow diagrams and overall was determined. Disagreements were resolved by consensus. We compared overall completeness of reporting between journals using $\chi^2$ tests and used logistic regression to assess the association of flow diagrams with completeness of reporting.

RESULTS

The hand search of these journals identified 290 articles. We excluded 1 quasi-randomized trial, 10 cluster trials, and 9 reports for which the focus was not on randomized comparisons. Our study sample thus consisted of 270 reports of RCTs. Most trials were of parallel group design (256 [94.8%]) and evaluated pharmacological interventions (173 [64.1%]). A total of 139 reports (51.5%) included a flow diagram but this varied widely among journals (TABLE 1). Five (29.4%) of 17 short reports included a flow diagram. No additional diagrams were found on the journals’ Web sites. Interrater reliability\(^6\) for the assessment of information provided in flow diagrams was good ($k$ values ranging from 0.60 to 0.81), but showed more disagreement for assessment of overall completeness of reporting ($k$, 0.21-0.71).

Characteristics of flow diagrams were similar across journals. Sixty-five diagrams (46.8%) included the number of patients assessed for eligibility, and 94...
(67.6%) reported the number found to be eligible. The number assigned to each study group was reported in 129 flow diagrams (92.8%), and 73 (52.5%) indicated whether interventions had been received as allocated. Most flow diagrams (114 [82.0%]) indicated how many patients in each group were lost to follow-up, but only 32 (23.0%) reported the number included in the analysis.

Overall reporting was more complete in journals that publish flow diagrams more frequently (Table 1). However, there is clearly room for improvement in all journals, in particular with regard to the number receiving the allocated intervention and the number lost to follow-up. Independent of journal, reporting tended to be less complete if the trial was published as a short report. In logistic regression analysis, completeness of reporting was associated with both the original design of the flow diagram and its implementation by authors. For example, most flow diagrams provided the number of individuals randomized, although this count was not explicitly requested. Conversely, only about half of flow diagrams included the number of participants who actually received treatments as allocated, an item included in the original template. The number of participants included in the main analysis was not an item in the recommended flow diagram, and this number was included in only a few diagrams (23.0%).

The CONSORT criteria are an evolving tool designed to help improve the quality of reporting of RCTs. Based on the findings of our present study and earlier criticism of CONSORT, we submit that the flow diagram is useful but in need of revision. We revised the template in collaboration with the CONSORT Group (Figure). Three tiers of boxes cover the enrollment phase and 1 box each is set apart for allocation of interventions, follow-up, and analysis. At enrollment a distinction is made between the exclusion of persons not meeting the criteria specified in the protocol and persons excluded for other reasons. The revised flow diagram explicitly includes the number of participants allocated to each group, the number initially receiving the intervention as assigned, and, if applicable, the reasons why some participants did not receive allocated interventions. Information on follow-up includes the number of participants lost to follow-up and the number of patients who stopped interventions along with the reasons why this occurred. The bottom tier of boxes includes the number of patients included in the main analysis and, if applicable, the reasons why some patients were excluded. We trust that this template could be improved further and would appreciate comments from readers through the CONSORT Web site.

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**Table 2. Association of Presence of a Flow Diagram With Completeness of Reporting**

<table>
<thead>
<tr>
<th>Reporting on No. of Participants</th>
<th>Crude OR (95% CI)</th>
<th>Adjusted for Journal OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessed for eligibility (overall)</td>
<td>1.79 (1.10-2.91)</td>
<td>1.90 (0.93-3.87)</td>
</tr>
<tr>
<td>Found to be eligible (overall)</td>
<td>3.28 (1.97-5.48)</td>
<td>3.19 (1.47-6.92)</td>
</tr>
<tr>
<td>Randomized (per group)</td>
<td>3.31 (1.42-7.72)</td>
<td>1.87 (0.53-6.52)</td>
</tr>
<tr>
<td>Received allocated intervention (per group)</td>
<td>2.79 (1.70-4.58)</td>
<td>1.75 (0.85-3.60)</td>
</tr>
<tr>
<td>Lost to follow-up (per group)</td>
<td>5.49 (3.24-9.28)</td>
<td>5.01 (2.33-11.1)</td>
</tr>
<tr>
<td>Excluded from analysis (per group)</td>
<td>3.27 (1.75-6.12)</td>
<td>3.10 (1.22-7.86)</td>
</tr>
<tr>
<td>Included in main analysis (per group)</td>
<td>2.45 (1.07-5.63)</td>
<td>4.96 (1.51-16.3)</td>
</tr>
</tbody>
</table>

*Results from univariate and bivariate logistic regression analyses. Odds ratios (ORs) >1 indicate that articles with flow diagrams are more likely to report the number of participants than articles without flow diagrams. CI indicates confidence interval.
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Acquisition of data: Egger, Juni, Bartlett.
Analysis and interpretation of data: Egger, Juni.
Drafting of the manuscript: Egger.
Critical revision of the manuscript for important intellectual content: Egger, Juni, Bartlett.
Statistical expertise: Egger, Juni.
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REFERENCES

Scientific activity is the only one which is obviously and undoubtedly cumulative and progressive.
—George Sarton (1884-1956)