Under-Reporting of Socioeconomic Status of Patients in Stroke Trials
Adherence to Consort Principles

Parker Magin, PhD; Anousha Victoire, BA (Hons); Xi May Zhen; John Furler, PhD; Marie Pirotta, PhD; Daniel S. Lasserson, MD; Christopher Levi, MBBS; Amanda Tapley, BBiomed (Hons); Mieke van Driel, PhD

Background and Purpose—The 2001 Revised Consolidated Standards of Reporting of Trials (CONSORT) statement requires reporting of Randomized Controlled Trials (RCTs) to include participants’ baseline demographics. This enables comparison of intervention and control groups on potential confounding variables as well as assessment of study generalizability. Socioeconomic status (SES) is associated with access to care and outcomes (mortality, functional outcome, recurrent stroke, and hospital readmission) poststroke. We aimed to document the reporting of baseline SES in reports of RCTs of stroke and transient ischemic attack.

Methods—Measures of SES were extracted from studies reporting trials of stroke or transient ischemic attack published in 12 major journals in the disciplines of general medicine, general neurology, cerebrovascular disease, and rehabilitation subsequent to revised CONSORT. Percentages of studies reporting SES measures were calculated. Differences in reporting between journal categories, and temporal trends in reporting, were tested.

Results—Only 12% of studies reported any SES measure. Journal categories did not differ in rate of SES reporting. SES reporting did not increase over time.

Conclusions—Improving reporting of SES could enhance clinicians’ ability to evaluate RCT findings and apply them to their patients. (Stroke. 2013;44:2920-2922.)

Key Words: ischemic attack, transient ■ randomized controlled trials ■ socioeconomic factors ■ stroke

Although the 2001 Revision of the Consolidated Standards of Reporting of Trials (CONSORT) statement requires that reports of Randomized Controlled Trials (RCTs) provide baseline demographic and clinical characteristics to allow comparison of intervention and control groups and to aid assessment of generalizability of findings, these characteristics are not specified in CONSORT. In trials of stroke and transient ischemic attack (TIA), socioeconomic status (SES) is an important demographic characteristic due to its relationships with stroke risk and outcome.

We previously reported that RCTs in 4 major general medical journals infrequently reported measures of SES. Reporting of baseline SES in trials involving stroke is particularly important because exposure to low-SES environments (measured using income, occupation, education, or geographically based summary statistics) in childhood or adulthood is associated with stroke risk, even after adjusting for the effects of traditional vascular risk factors. Furthermore, low SES increases mortality poststroke, recurrent stroke risk, and poststroke hospital readmission, and is associated with lower functional independence and reduced motor recovery.

Given the potential confounding between baseline SES and clinical outcomes in RCTs, we documented the reporting of baseline SES in major journals’ reports of RCTs recruiting patients with stroke and TIA or with clinical stroke outcomes.

Methods

Journal Selection
High-impact clinically oriented journals across the disciplines of general medicine, general neurology, cerebrovascular disease, and rehabilitation were selected. We aimed to include up to 10 consecutive eligible studies from each journal, published since 2002 (ie, after the revised CONSORT), until a total of 100 studies was included.
Study Selection

Studiees were initially identified using a Medline search for RCTs with stroke or TIA defining recruitment or outcome, with the following inclusion and exclusion criteria:

1. RCTs recruiting patients after stroke or TIA, or prevention studies with stroke or TIA as the primary outcome. Studies in which stroke was both part of a primary composite outcome and a secondary outcome were also included.
2. RCTs with clinical (not biochemical or surrogate) outcomes were included.
3. Included studies had follow-up of at least 30 days postintervention.
4. Studies with inpatient interventions were included if follow-up was undertaken in the community. RCTs recruiting, performing interventions, and following up with purely inpatient populations were excluded, because SES is less likely to be relevant to outcomes.

Data Extraction

We manually extracted reporting of SES-relevant baseline data: occupational group, income (individual or household), employment status, educational attainment, summary composite area–based SES measures (eg, Carstairs Index), and summary occupation–based measures of SES (eg, Goldthorpe Class Schema). We also extracted measures of ethnicity and language of study participants, given their association with SES health outcomes.8 Only data presented in tabular form was extracted (revised CONSORT specifies that baseline information be presented in a table).9

Data were independently extracted by 2 investigators. Disagreements were adjudicated by a third reviewer.

Analyses

Percentages of studies reporting (1) each of the extracted SES measures, (2) any SES measure, and (3) any SES measure or ethnicity or language were calculated.

Differences in proportion of studies reporting (1) any SES measure and (2) any SES measure or ethnicity or language, by (a) category of journal and (b) year of publication, were tested using $\chi^2$ or Fisher exact test as appropriate. Changes in reporting over time were assessed with $\chi^2$ test for trend by forming 4 successive time periods (2002–2008, 2009–2010, 2011 and 2012) with approximately equal RCT numbers.

Results

Studies were selected from 12 journals (Table 1). Twenty-eight studies were from general medical, 20 from general neurological, 24 from cerebrovascular, and 28 from rehabilitation journals.

Percentages of studies reporting any measure of SES, ethnicity, and language are presented in Table 2. Only 12% of studies reported an SES measure, and 31% of studies reported a measure of SES, ethnicity or language.

There were no significant differences in reporting between time periods ($P=0.53$ for SES measures and $P=0.063$ for SES or language or ethnicity). For the trend analysis, $\chi^2$ for trend was nonsignificant. There were no significant differences in reporting between journal categories.

Discussion

We found SES measures were infrequently reported in stroke RCTs after 2001; despite the intent of the CONSORT statement, only 12% of studies presented any measure of SES and only 1 study reported an SES measure other than educational attainment.

This under-reporting of SES in stroke RCTs impairs readers’ ability to assess the comparability of randomized intervention and control groups regarding an important potential confounder. It also limits clinicians’ ability to assess the generalizability of results to their patients.

General medical journals have been found to implement CONSORT more completely than specialist journals,10 but we found no difference in SES reporting between classifications of journals. Furthermore, the under-reporting of SES contrasts with findings of improved reporting of other CONSORT-mandated parameters.11

Study Limitations

Although our search was not systematic, we focussed on the major journals that have published trial evidence influencing stroke guidelines and subsequent clinical practice.

The time-course of an RCT means that some of RCTs reported after 2001 will have commenced before revised CONSORT, but we found no trend to improved reporting 2002–2012. Although our methodology of time-grouping was data driven, it would, if anything, have strengthened the effect of very recent changes in reporting of SES.

Another caveat is that confounding by SES may be more plausible in some RCTs populations than in others, and may

<table>
<thead>
<tr>
<th>Measure of SES</th>
<th>% of Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupational group</td>
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</tr>
<tr>
<td>Income</td>
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</tr>
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<td>Employment status</td>
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</tr>
<tr>
<td>Educational attainment</td>
<td>12</td>
</tr>
<tr>
<td>Specific area–based SES measures</td>
<td>0</td>
</tr>
<tr>
<td>Specific occupation–based SES measure</td>
<td>0</td>
</tr>
<tr>
<td>Any SES measure</td>
<td>12</td>
</tr>
<tr>
<td>SES-associated factors</td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td>20</td>
</tr>
<tr>
<td>Language</td>
<td>1</td>
</tr>
<tr>
<td>Any measure of SES, ethnicity, or language</td>
<td>31</td>
</tr>
</tbody>
</table>

SES indicates socioeconomic status.
vary between different geographic regions within the same RCT. But the very low level of reporting in our study suggests a robust finding.

**Means to Improve SES Reporting in RCTs of Stroke**
We suggest that a policy of major stroke journals encouraging reporting of baseline SES measures in reports of RCTs could improve the ability of clinicians to apply RCT findings to their individual patients.

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**Disclosures**
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**References**


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