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Under-reporting of socioeconomic status of patients in stroke trials: adherence to CONSORT principles.

Authors:

Parker Magin, PhD
Newbolds Building
University of Newcastle
Callaghan. 2308
NSW, Australia
parker.magin@newcastle.edu.au
61 249686793
Fax 61 249686737

Anousha Victoire, BA(Hons)
Newbolds Building
University of Newcastle
Callaghan.2308
NSW.
Australia

Xi May Zhen
Discipline of General Practice
University of Queensland
Brisbane. 4029
QLD.
Australia

John Furler, PhD
Department of General Practice
University of Melbourne
Carlton. 3065
Victoria.
Australia

Marie Pirotta, PhD

Department of General Practice
University of Melbourne
Carlton. 3065
Victoria.
Australia

Daniel Lasserson, MD
Primary Care Health Sciences
University of Oxford
New Radcliffe House
Woodstock Road, Oxford OX26GG
UK

Christopher Levi. MBBS
Centre for Translational Neuroscience & Mental Health Research
University of Newcastle
Callaghan.2305
NSW.
Australia

Amanda Tapley BBiomed(Hons)
General Practice Training Valley to Coast
Newbolds Bulding
Mayfield. 2304
NSW.
Australia

Mieke van Driel, PhD
Discipline of General Practice
University of Queensland
Brisbane. 4029
QLD
Australia

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SES reporting in stroke RCTs

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Abstract

Background and Purpose

The 2001 Revised CONSORT statement requires reporting of 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) post-stroke. We aimed to document the reporting of baseline SES in reports of RCTs of stroke and TIA.

Methods

Measures of SES were extracted from papers reporting trials of stroke or TIA published in twelve major journals (General Medicine, General Neurology, Cerebrovascular Disease, or Rehabilitation) subsequent to revised-CONSORT. Percentages of papers reporting SES measures were calculated. Differences in reporting between journal categories, and temporal trends in reporting, were tested.

Results

12% of papers reported any SES measure. Journal categories did not differ in rate of SES reporting. SES reporting didn't increase over time.

Conclusions

Improving reporting of SES could enhance clinicians' ability to evaluate RCT findings and apply them to their patients.

Introduction

Although the 2001 Revision of the Consolidated Standards of Reporting of Trials (CONSORT) statement,¹ requires that reports of RCTs provide ‘Baseline demographic and clinical characteristics’¹ 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 TIA, socioeconomic status (SES) is an important demographic characteristic owing to its relationships with stroke risk and outcome.

We previously reported that RCTs in four major general medical journals infrequently reported measures of socioeconomic status (SES).² Reporting of baseline SES in trials involving stroke is particularly important as 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.³ Furthermore, low SES increases mortality post-stroke,⁴ recurrent stroke risk,⁴ post-stroke hospital readmission,⁵ and is associated with lower functional independence⁶ and reduced motor recovery.⁷

Given the potential confounding between baseline SES and clinical outcomes in RCTs aiming to reduce the impact of stroke, 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 ten consecutive eligible papers from each journal, published since 2002 (i.e. after the revised-CONSORT), until a total of 100 papers was included.

Paper selection

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

- 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.
- RCTs with clinical (not biochemical or surrogate) outcomes were included
- Included studies had follow-up of at least 30 days post-intervention
- Studies with in-patient interventions were included if follow-up was undertaken in the community. RCTs recruiting, performing interventions and following-up with purely in-patient populations were excluded, as 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 (e.g. Carstairs Index) and summary occupation-based measures of SES (e.g. 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 two investigators. Disagreements were adjudicated by a third reviewer.

Analyses.

Percentages of papers reporting a) each of the extracted SES measures), b) any SES measure, and c) any SES measure or ethnicity or language were calculated.

Differences in proportion of papers reporting a) any SES measure, and b) any SES measure or ethnicity or language, by i) category of journal and ii) year of publication, were tested using Chi-square or Fishers exact test as appropriate. Changes in reporting over time was assessed with Chi-Square test for trend by forming four successive time periods (2002-2008, 2009-2010, 2011 and 2012) with approximately equal RCT numbers.

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Results

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

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

There were no significant differences in reporting between time-periods ($p = .53$ for SES measures, and $p = .063$ for SES or language or ethnicity). For the trend analysis, chi-square for trend was non-significant.

There were no significant differences in reporting between journal categories.

Discussion

We found SES measures were infrequently reported in stroke RCTs post-2001; despite the intent of the CONSORT statement, only 12% of papers presented any measure of SES and only one paper 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 fully 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

Whilst 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 post-2001 will have commenced prior to revised-CONSORT, but we found no trend to improved reporting 2002-2012. Whilst 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 vary between different geographic regions within the same RCT. But the very low level of reporting in our study suggests a robust finding.

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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:

Nil

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Table 1: Included journals, by classification.

General Medical journals	<i>British Medical Journal</i> <i>New England Journal of Medicine</i> <i>Lancet</i>
General Neurology journals	<i>Lancet Neurology</i> <i>Brain</i> <i>Annals of Neurology</i>
Cerebrovascular Disease journals	<i>Stroke</i> <i>International Journal of Stroke</i> <i>Cerebrovascular Diseases</i>
Rehabilitation journals	<i>Neurorehabilitation and Neural Repair</i> <i>Physical Therapy</i> <i>Archives of Physical Medicine and Rehabilitation</i>

Table 2: Measures of SES and associated factors reported in 100 papers

Measure of SES	% of papers
Occupational group	0
Income	0
Employment status	1
Educational attainment	12
Specific area based SES measures	0
Specific occupation based SES measure	0
<i>Any SES measure</i>	12
<i>SES-associated factors</i>	
Ethnicity	20
Language	1
<i>Any measure of SES, Ethnicity or Language</i>	31