meetings also provide motivation for regular data collection, opportunities for staff to meet, and for other health problems to be discussed by the group. The implementation of perinatal audit has been shown to be associated with a reduction in the perinatal mortality rate, especially from labour-related asphyxia.[1] Provinces should place priority on instituting audit meetings at all delivery units. In our experience, South African midwives are resistant to involvement in perinatal audit, and research is required to identify barriers to the establishment of perinatal audit meetings in midwifery settings.

Conclusion

Perinatal death from asphyxia and trauma is tragic and preventable. The data in this report will provide useful information for health planners and politicians involved in health care provision. The Medical Research Council (MRC) Unit for Maternal and Infant Health Care Strategies will now supervise the implementation of detailed confidential enquiries of all deaths caused by intrapartum-related birth asphyxia at hospitals that perform PPIP-based perinatal audit. This supervision will give more precise information on the weaknesses in perinatal services in South Africa, so that specific recommendations for improvement can be made.

The authors are very grateful to all the PPIP users who submitted their perinatal mortality data. Funding was provided by the MRC Unit for Maternal and Infant Health Care Strategies, and by the National Department of Health.

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Accepted 15 May 2002.

Randomised trials in the *South African Medical Journal*, 1948 - 1997

E D Pienaar, J Volmink, M Zwarenstein, G H Swingler

Objective. To describe randomised controlled trials (RCTs) published in the *South African Medical Journal* (*SAMJ*) over a 50-year period from 1948 to 1997 with regard to number, topic and quality.

Methods. We hand searched all issues of the *SAMJ* published during the study period to identify all published RCTs.

Outcome measures. Number, topic and quality of RCTs published from 1948 to 1997.

Results. Eight hundred and fifty-eight clinical trials were published during the period reviewed. Eighty-four per cent of RCTs were published as full articles. During the 1980s the number of RCTs published increased rapidly, with a peak of 35 in 1985, but then declined to only 5 in 1997. The majority (92%) of RCTs were conducted in a hospital setting. A varied range of subjects was covered, with gastroenterology taking the lead and no trials in public health. The sample size in more than 50% of RCTs was smaller than 50 patients. Fifty-one per cent (435 trials) used random allocation and 49% (423) quasi-random methods of allocation. Concealment of treatment allocation was judged to be adequate in 46% of studies (N = 200), blinding of observers assessing outcomes was adequate in 28% (123), and all the allocated test subjects were included in the primary analysis in 28% (123). The follow-up period was more than 1 year in 4% (17) and less than 6 days in 16% (71).

Conclusions. Compared with other international journals the *SAMJ* is highly regarded in terms of the number of trials published. There are, however, a number of deficiencies in the quality of the trials.

S Afr Med J 2002; **92:** 901-903.

South African Cochrane Centre, Medical Research Council, Tygerberg, W Cape
E D Pienaar, BSc Hons (Med Biochem)
J Volmink, MD, PhD, MPH (Present address: Director of Research and Analysis, Global Health Council, 1701 K Street, Suite 600, Washington, DC, 20006, USA)
G H Swingler, MB, ChB, PhD, FCP (SA), DCH (SA) (Present address: School of Child and Adolescent Health, University of Cape Town and Red Cross Children's Hospital, Rondebosch)

Health Systems Research Division, Medical Research Council, Tygerberg, W Cape
M Zwarenstein, MB BCh, MSc (Community Health), MSc (Med)

Randomised controlled trials (RCTs) have become widely accepted as the best means, when feasible and ethically acceptable, of measuring the effects of health care interventions.[1] This is because random allocation minimises biases arising from known and unknown imbalances between study groups that can overwhelm modest treatment effects.[2]

The South African Cochrane Centre, based at the Medical Research Council, is assembling a register of controlled trials performed in Africa[3] as a resource for researchers preparing systematic literature reviews of RCTs. Because electronic searches of databases such as MEDLINE and EMBASE miss many RCTs[4,5] the process of identifying trials has also involved hand searching of a range of African journals, including the *South African Medical Journal* (*SAMJ*). The African Trials Register provides an opportunity to study patterns of research into health care interventions published in the *SAMJ*.

This report describes RCTs published in the *SAMJ* over a 50-year period from 1948 to 1997 with regard to number, topic and quality.

Materials and methods

The *SAMJ*, including supplements and conference proceedings, was hand searched for controlled trials from 1948 (the year of publication of the first RCT internationally)[6] to 1997 by three trained assistants. Articles were included if they met all of the following criteria: (*i*) two or more interventions in humans were compared with each other; (*ii*) the report stated that the study was prospective; and (*iii*) assignment to a particular intervention was done using a random or quasi-random method (such as birth date or folder number).

Two authors (EDP, JV) independently extracted the following data from the eligible studies using a structured pre-piloted data capture sheet: year of publication, nature of the report (full article, abstract or letter), trial setting, subject area, sample size, whether participants were patients or healthy volunteers, unit of allocation (individual or cluster), trial design (parallel, crossover or factorial), nature of the control intervention, duration of follow-up, and elements of quality of design and reporting. Quality criteria were based on the quality assessment scale developed by Jadad:[7]

1. Randomisation, i.e. study described as randomised, and allocation adequately concealed.

2. Blinding, i.e. participant, investigator or outcome assessor blinded, and placebo used.

3. Patient attrition, i.e. attrition described for each group (including the number of patients lost or excluded, along with reasons).

Disagreements between observers in the selection of studies and the extraction of data were resolved by discussion.

Results

We identified 858 trials, 51% (435) of which used random allocation and 49% (423) a quasi-random method of allocation (such as date of birth or folder number). The 435 RCTs are further described in this report. Eighty-four per cent (366) were published as full articles, 14% (59) as abstracts from conference proceedings and 2% as letters. The number of RCTs published per decade is shown in Fig. 1. There was a rapid increase during the 1970s and early 1980s, peaking in 1985 with 35 reports. Thereafter the number declined steadily to 5 trials in 1997.

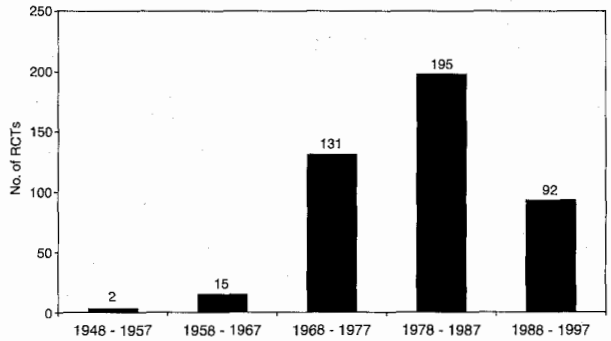

Fig. 1. Number of randomised controlled trials in the SAMJ *per decade.*

Ninety-two per cent (394) of RCTs were conducted in a hospital setting. Of these, 350 were in a clinical setting and 44 were done in a hospital laboratory. The subject areas covered by the RCTs are varied. The greatest number of trials were performed in the fields of gastroenterology, pharmacology, obstetrics and gynaecology, paediatrics and anaesthesiology. No trials of intervention in the fields of public and community health were identified.

The sample sizes of the RCTs are shown in Fig. 2. There were fewer than 50 participants in 54% (218) of the 406 RCTs in which sample size was reported. The unit of allocation was the individual in all of the RCTs, i.e. there was no cluster randomisation. Healthy volunteers participated in 15% of

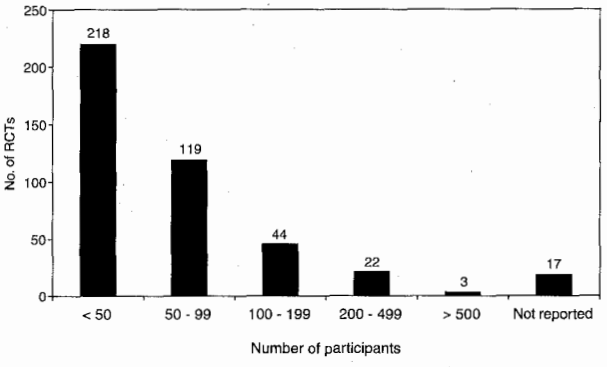

Fig. 2. Sample size of RCTs in the SAMJ.

trials (N = 64) and patients in 85% (371). Eighty-four per cent (365) of the RCTs were of parallel design, 16% (69) crossover, and 0.2% (1) factorial. A placebo was used as a control in 193 trials. In the other trials the control was either an alternative treatment or no treatment. Four per cent (17) of RCTs had a follow-up of more than 1 year, 16% (71) follow-up of less than 6 days and in 30% (130) the follow-up period was not clearly stated. Concealment of treatment allocation was judged as adequate in 46% of cases (200), blinding of observers assessing outcomes was adequate in 28% (123) and all the allocated test subjects were included in the primary analysis in 28% (123).

Discussion

This report describes only those trials published in the *SAMJ* and not all South African trials published during the period of study. A more comprehensive description of South African trials will be possible once hand searching of other local and international journals is completed.

Given the importance of interventions to the provision of health care and the unique place of randomised trials in the evaluation of interventions, the relatively large number of trials published in the *SAMJ* is encouraging.[8] There has, however, been a marked decrease in the number since 1985. This is partially explained by the reduction in frequency of the *Journal* from weekly to fortnightly in July 1985, and monthly from 1992. This decrease in the number of trials is not unique to the *SAMJ*, but has been found to be the pattern in all of the major general medical journals.[5]

The small proportion of studies in a primary care or community setting and the absence of any trials in public health are striking, and appear out of keeping with South African health needs. The absence of trials in public health may be partly explained by difficulties in performing them. This is because randomisation usually needs to be done by cluster rather than individual. It is also not possible from this survey to assess whether this pattern reflects the pattern of manuscript submissions to the *Journal* or of acceptance by the *Journal* for publication.

The trials were generally small. More than half had fewer than 50 participants and more than three-quarters had fewer than 100 subjects. To detect a reduction in risk from 50% to 25% or to detect a difference between means of half a standard deviation (with the conventional 95% confidence and 80% power) would require approximately 130 participants. It therefore appears that the majority of trials were too small to detect clinically meaningful effects.

There were other important deficiencies in the design and reporting of many studies. Allocation concealment was not clearly reported in half the studies and was judged to be adequate in only 46%. The unique benefit of random allocation may be lost if the person enrolling a participant is aware of the treatment allocation. The effect of interventions has been shown to be on average empirically exaggerated by 40% if allocation concealment is inadequate, and by 30% if the reporting of concealment is unclear. The use and/or reporting of assessor blinding was slightly lower. The absence of double blinding has also been found empirically to exaggerate effects by 17%.[9]

The CONSORT statement (Consolidated Standards of Reporting Trials)[9,10] is an attempt to improve RCT reporting and has been adopted by many major medical journals as the standard for reporting of RCTs. We suggest that South African researchers review the CONSORT statement when planning RCTs and when preparing manuscripts for publication. Adoption of the CONSORT guidelines by the *SAMJ* would also greatly contribute to the quality of trial design and reporting in South Africa.

The tendency to publish trials as abstracts only is of concern. There is, however, the possibility that these trials may have been published elsewhere as full articles. It has been found that approximately half of abstracts are later published as full reports.[11]

Conclusions

The *SAMJ* ranks high among hand-searched journals in terms of the number of trials identified.[5,8] Although the quality of trials has improved, there remains room for further improvement. South Africa appears to have a substantial foundation on which to build a culture of effective research and evidence-based care.

The valuable assistance of Andre and Jeanine Hopley in identifying all randomised controlled trials is acknowledged. We also thank the South African Medical Research Council and the Department of Arts, Culture, Science and Technology for continued support and the University of Stellenbosch Medical Library for assistance.

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Accepted 19 July 2002.