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ORIGINAL ARTICLE

Improving levels of evidence in studies published in spinal journals from 1983 to 2011

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Abstract

Introduction. **The evidence basis for spinal surgical practice is closely related to the quality of clinical studies published. In the hierarchy of study designs, the quality of evidence from a randomised controlled trial (RCT) and meta-analysis are considered better than other types of prospective and retrospective study designs. We assessed the level of evidence in studies published from 1983 to 2011 in 4 journals, publishing predominantly on spine related topics.** ***Methods.*** **Computerised search of the Medline database was undertaken to evaluate the articles published in 4 'spinal' journals (Spine, European Spine Journal, Journal of Spinal Disorders and Techniques and Spinal Cord) from 1983 to 2011. The numbers of RCTs, meta-analyses and other clinical trials (non-RCT) over the time periods 1983-7, 1988-92, 1993-7, 1998–2002, 2003-7 and 2008-11 were compared.** ***Results.*** **From a total number of 21775 articles evaluated, there were 888 (4.1%) RCTs, 93 (0.4%) meta-analyses and 1355 (6.2%) other clinical trials. Overall, comparing the time periods 1983-7 with 2008-11, there were increases in the proportion of RCTs (1.6% to 5.1%), meta-analysis (0% to 0.6%) and other clinical trials (0.9% to 6.3%) and a decrease in the proportion of other articles published (97.6% to 88.1%). These changes appear to have plateaued after 2003-7.** ***Conclusions.*** **Although RCTs, meta-analysis and other clinical trials form a small proportion of the studies published in leading 'spinal' journals, there have been an encouraging increase in their proportion over the years. This is comparable with other larger surgical specialities and provides a better evidence basis for clinical practice in spinal disorders.**

Keywords: levels of evidence, spine journals and change over time

Introduction

Assessing the type of clinical studies published in medical journals can be useful to both monitor current research trends and to assess the evidence basis for clinical practice. In the hierarchy of evidence-based medicine, the highest quality of evidence is provided by randomised controlled trials (RCT) and meta-analysis of such studies. Here, the use of comparable control groups and the process of randomisation can provide robust clinical evidence.[1–4] Other less well-designed prospective and retrospective comparative study types (e.g. cohort, case-control and cross-sectional) are more prone to biases and provide a lower quality of clinical evidence. Individual case reports and case series are a useful format for describing rare clinical findings but provide low levels of evidence in clinical medicine.[1–4]

There has been limited research into the type of publications that appear in clinical journals, and the trends in levels of evidence over time. Previous studies in this area have highlighted a relatively low percentage of RCT in medical (General Medicine, Primary care, Paediatrics) and, to a greater extent, surgical specialties.[5–12] However, the proportion of RCT study designs has increased over the decades.[5–12] On the other hand, the proportion of different study types in the 'spinal literature' and changes over time are unclear. We assessed the levels of evidence of clinical studies appearing in peer-reviewed journals publishing predominantly on spine-related topics between 1983 and 2011.

Methods

An online electronic literature search was undertaken for 4 'spinal journals', chosen on the basis of their relatively high impact factors (IF) among journals publishing almost exclusively on spine-related disorders and because of their inclusion in the Medline database.[13] These included: Spine (IF-2.1), European Spine Journal (IF-2.4), Journal of Spine Disorders and Techniques (IF-1.5) and Spinal Cord (IF-1.8).

For each journal, all articles published between 1983 and 2011 were studied utilising the National Library of Medicine, Medline database, on the Ovid platform.[14] The exceptions to these were Journal of Spine Disorders and Techniques which was first published in 1988 and the European Spine Journal which commenced publication in 1992. Spinal Cord and Journal of Spine Disorders and Techniques were formerly

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published as Paraplegia (prior to 1996) and Journal of Spine Disorders (prior to 2002), respectively. Their publication data are included but described by the contemporary title.

For each journal issue, all articles listed in the Ovid Medline database, with the exception of letters of correspondence (Medical Subject Heading - MESH term, 'letter') were included in the study.[12] Medline database-specific limits (under 'Publication types') were set to identify: the total number of articles published; the number of RCTs (MESH term, 'randomised controlled trial'); meta-analysis (MESH term, 'meta analysis') and 'other clinical trials' (includes MESH terms, 'clinical trials', 'clinical trial phase I to IV', 'controlled clinical trial' and 'multi-centre trial') in the years 1983 to 2011. It should be noted that RCTs are also classified as clinical trials and would appear within a search for MESH term 'clinical trial phase I to IV'. This was accounted for. The remaining articles were grouped as 'Other articles'.[12] These search specifics were chosen in part to enable direct comparison with a similar study undertaken looking at quality of publications in other medical and surgical specialities over a similar time period. [12]

To compensate for fluctuations in the proportion of publication types when assessed on a yearly basis, averages were calculated over the following time periods; 1983-7, 1988-92, 1993-7, 1998–2002, 2003-7 and 2008-11.

All data were analysed on the SPSS statistical package (Statistical Programs for the Social Sciences, Chicago, USA) and statistical analysis was carried out using the Chi-square test (with Yates's correction).

Results

A total number of 21775 articles from the 4 journals, Spine (N = 12996), European Spine Journal (N = 3359), Journal of Spinal Disorders and Techniques (N = 2122) and Spinal Cord (N = 3298) were analysed (Table I).

Overall, there were 888 (4.1%) RCTs, 93 (0.4%) meta-analysis and 1355 (6.2%) other clinical trials (Table I). There were differences in the study types between the journals (Table I; $p < 0.0001$; $X^2 = 412$; Chi-square test). For the proportion of meta-analysis, the rank order of the journals was: European Spine Journal (0.6%); Spine (0.5%); Spinal Cord (0.3%) and Journal of Spine Disorders and Techniques (0.2%). For the proportion of RCTs, the rank order of the journals was: Spine (4.7%); European Spine Journal (4.0%), Journal of Spine Disorders and Techniques (2.8%); Spinal Cord (2.6%). For the proportion of other clinical trials, the rank order of the journals was: Spinal Cord (13.6%); Journal of Spine Disorders and Techniques (7.0%); European Spine Journal (5.1%) and Spine (4.5%, Table I).

When articles from all four journals were considered together, there were changes in the study types, between the time periods 1983-7 and 2008-11 (Fig. 1; $p < 0.0001$; $X^2 = 307$; Chi-square test). From the period 1983-7 to 2008-11 the proportions of RCTs (1.6% to 5.1%), meta-analysis (0% to 0.6%) and other clinical trials (0.9% to 6.3%) increased, with a corresponding decrease in the proportions of other articles published (97.6% to 88.1%). These trends were not linear. The proportion of RCTs appears to have plateaued since 2003, whilst the proportion of other clinical trials peaked in 2002 (Fig. 1)

These trends were apparent in all 4 journals between 1983-7 and 2008-11; Spine ($p < 0.0001$; $\chi^2 = 213$), Journal of Spine Disorders and Techniques ($p < 0.0001$; $\chi^2 = 112$), Spinal Cord ($p < 0.0001$; $\chi^2 = 279$) and the European Spine Journal ($p < 0.01$; $\chi^2 = 29$; Chi-square test; Fig. 2). When considering the proportion of other clinical trials published in Spinal Cord, there was a transient peak between the time periods 1993-7 which was out of keeping with the general trend (Fig. 2b).

Discussion

Evidence-based practice has become an important concept in medicine that is also dependant on the quality of evidence published in medical literature.[1–4] Furthermore, the type of study design itself has a great influence on the quality and robustness of clinical evidence. This equally applies to spinal disorders, and we evaluated the temporal changes in the quality of studies published in prominent journals dedicated to spinal medicine.

From the outset, it is important to recognise the limitations of the present study. Only four journals publishing predominantly clinical research were considered in this study. A detailed review of each article with respect to the study design, statistical methodology, sample numbers or impact in the clinical setting was beyond the scope of this study. We have also presumed on the accuracy of study categorisation in the Medline database. There are other clinical and basic science journals publishing on spinal research that were not considered and studies in this field may also appear in other general surgical and medical journals. However, the four journals included in the present study are prominent within spinal medicine, widely read and carry relatively high impact factors.[13] Accepting these limitations, the main findings of the present study were that between 1983 and 2011, RCTs (4.1%), meta-analysis (0.4%) and 'other clinical trials' (6.2%) contributed to only a minority of publications. 'Other articles', which included the case report format, formed the largest study type (89.3%). We noted an increase in the

Table I. Comparison of the clinical study types between the 4 Spinal journals from 1983 to 2011 (N = 21775). Overall, there were significant differences between the journals ($p < 0.0001$; Chi-squared test).

Study types	Spine (%)	European spine journal (%)	J spine dis & techniques (%)	Spinal cord (%)	Totals (%)
Meta-analysis	59 (0.5)	20 (0.6)	5 (0.2)	9 (0.3)	**93 (0.4)**
RCTs	610 (4.7)	133 (4.0)	59 (2.8)	86 (2.6)	**888 (4.1)**
Other clinical trials	589 (4.5)	171 (5.1)	148 (7.0)	447 (13.6)	**1355 (6.2)**
Other articles	11738 (90.3)	3035 (90.4)	1910 (90.0)	2756 (83.6)	**19439 (89.3)**
Totals	**12996 (100)**	**3359 (100)**	**2122 (100)**	**3298 (100)**	**21775 (100)**

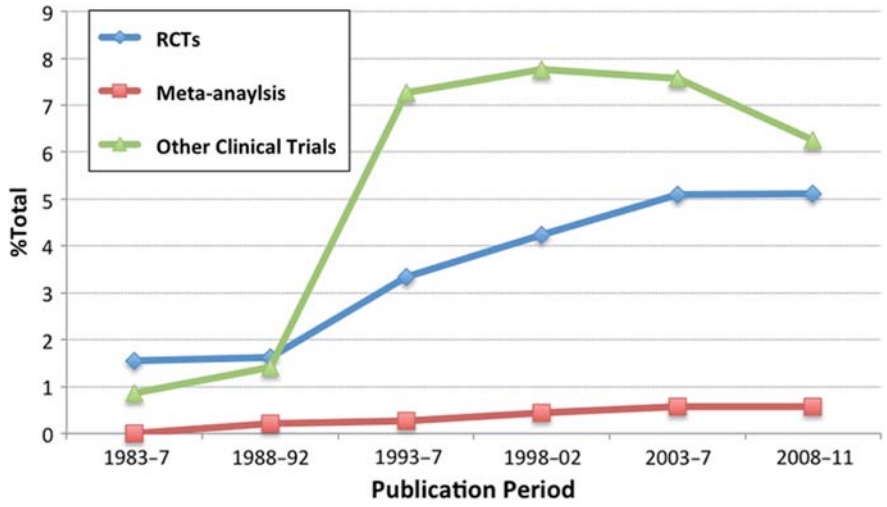

Fig. 1. The change in proportion of study type between 1983 and 2011 in the 4 'Spinal' journals. The data are expressed as a percentage of total articles studied in each journal within each time period. For the time periods 1983-87, 1988-92, 1993-97, 1998–2002, 2003-7 and 2008-11, the respective numbers of total articles published were 1160, 2333, 3717, 4101, 5239 and 5225. Overall there were significant changes in the study types over the study period ($p < 0.0001$; Chi-squared test).

proportion of RCT, Meta-Analysis and other clinical trials over the study period in all four 'spinal' journals, but this trend seems to have plateaued since 2003.

Significant variability existed between the journals and in general those journals with the higher IF published a higher proportion of meta-analysis and RCTs. Spinal cord had the largest proportion of 'other clinical trials', but fewest RCTs, which may reflect its larger basic science content. The transient rise in the proportion of 'other clinical trials' published in Spinal Cord between 1993-7 was also an odd finding. Reasons for this are unclear but may relate to the change in journal name, and perhaps editorial direction, in 1996.

In all study types, the level of evidence produced is determined by the likelihood of the study design to control bias.[2,3,15] In assembling an effective RCT, one employs all known bias-controlling techniques and, importantly attempt to account for bias from unknown sources by including the process of randomisation when allocating patients to study groups.[2,3,15] The essential requirements of an RCT are detailed in the recently published CONSORT statement.[15] Thus, RCTs usually require greater degree of pre-planning, follow-up, large patient numbers, and collaboration between investigators. As a result RCTs can be more demanding in terms of time, finance and resources and require greater commitment from all participants, both clinicians and patients. By comparison, other non-randomised prospective and more especially retrospective study designs (eg case control and cross sectional studies) require less rigorous planning and are thus easier to conduct, but this is also likely to introduce greater bias.[3,12,15] Study designs such as case reports and case series are a useful format for reporting rare and novel findings. However, they are very prone to confounding influences and provide relatively weak evidence (if any) for testing the benefit of one treatment over another.[2,3,15] Thus, the relatively small percentage of clinical trials, both of RCT and other types in prominent spinal journals observed in the present study is of concern.

To our knowledge, there have not been similar studies assessing the trends in the publication type in spine-related journals over time. A previous study of the published Cochrane Reviews was only able to identify 130 RCTs in the spinal literature between 1974–2008.[16] Although, these RCTs were of variable quality, a yearly increase in the published numbers of RCTs over the study period was noted.[16] The authors concluded that with careful design, better funding and effort, increasing numbers of RCTs seemed feasible in spinal medicine.[16] We noted a far higher number of RCTs ($N = 888$) between 1983 and 2011, but this may largely reflect differences in the criteria used to select RCTs between the Medline and Cochrane databases. Other studies similar to the present, undertaken in a variety of medical and surgical disciplines have reported a variable proportion of RCTs ranging from 1 to 26% of all publications.[5–12,17] Such variability between specialities may mostly reflect the differences in the relative size of the specialities, with a greater number of RCTs expected in the larger medial and surgical sub-specialities. Moreover, the differences in the methodology used to classify study types and the time point at which the study was undertaken can influence the results.[13] As apparent in our study, the proportion of RCTs increase over the years.[16] However, by utilising similar methodology and time points to an earlier study by our group, we observed that the proportion of RCTs in Spinal journals (4.1%) was comparable to General surgery (5.3%), but lower than that observed for General Medicine (8.1%), Paediatrics (6.4%), Psychiatry (9.6%) and Anaesthesia (18%).[12]

The lower proportion of RCTs in spinal surgery may in part reflect some of the recognised difficulties in undertaking RCTs in surgical specialities compared with medical specialities.[12,18,19] Notably, randomising between two surgical procedures can be a dilemma for surgeons especially when they may have greater surgical expertise or personal preference for one of the treatment types.[18,19] Nevertheless, there were encouraging increases in the proportions

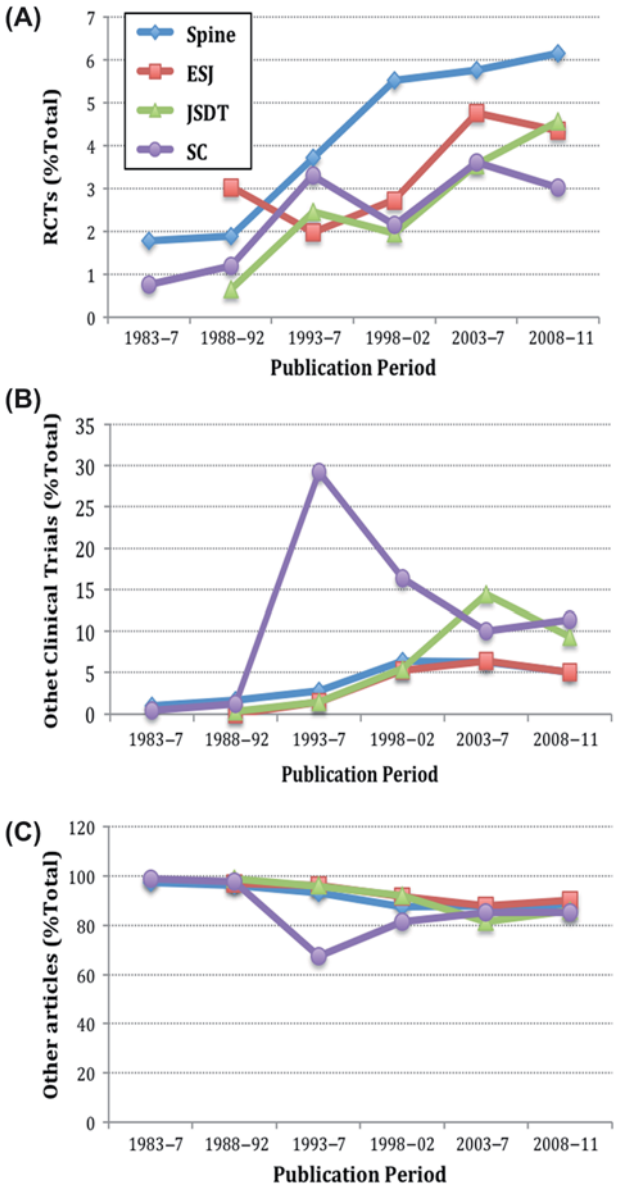

Fig. 2. Figure showing the changes in the proportion of RCT (A), 'Other clinical trials' (B) and 'Other articles (C), from 1983 to 2011 between the different 'Spine journals'. The data are expressed as a percentage of total articles studied in each journal within each time period. For the time periods 1983-87, 1988-92, 1993-97, 1998–2002, 2003-7 and 2008-11, the respective numbers of total articles published in each journal were as follows: Spine (898, 1579, 2289, 2480, 3087, 2663); Spinal Cord, SC (262, 416, 667, 648, 609, 696); Journal of Spinal Disorders and Techniques, JSDT (0, 305, 407, 460, 534, 416); European Spine Journal, ESJ (0, 33, 354, 513, 1009, 1450).

of RCTs and other clinical trials over the study period, although this may now have plateaued. Similar increases have also been observed in other specialities.[5,6,11,12,20] The reason for this trend is likely to be multifactorial, but is also likely to reflect the increased importance placed by journal editors upon original and well-designed research which enhances the journal's reputation, readership and citation rate. Evidence of this editorial approach can be seen in some journals which restrict case reports to online editions and generally discourage such submissions unless in exceptional circumstances.

Conclusions

The present study confirms that although clinical trials in general and notably RCT study type, contribute to only a small proportion of articles in journals publishing predominantly on spine-related topics, this has increased between 1983 and 2011. The proportion of RCTs in spinal journals appears comparable to other surgical but not medical subspecialities. Increasing the available level of evidence, will enhance the scientific basis on which to base patient care.

***Declaration of interest*:** The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

References

1. Evidence Based Medicine Working Group. Evidence based medicine. A new approach to teaching the practice of medicine. *JAMA* 1992;268:2420–5.
2. Haines SJ. Evidence based Neurosurgery. *Neurosurgery* 2003;52: 36–47.
3. Sackett DL. Rules of evidence and clinical recommendations on use of antithrombotic agents. *Chest* 1986;89:2S–3S.
4. Cochrane AL. *Effectiveness and Efficacy: Random Reflections on Health Services*. London: Nuffield Provisional Hospitals Trust, 1972.
5. Fletcher RH, Fletcher SW. Clinical research in general medical journals: a 30 year perspective. *New Eng J Med*. 1979;301:180–3.
6. McDermott MM, Lefevre F, Feinglass J, *et al*. Changes in study design, gender issues and other characteristics of clinical research published in three major medical journals from 1971 to 1991. *J Gen Intern Med* 1995;10:13–18.
7. Thomas T, Fahey T, Somerset M. The content and methodology of research papers published in three United Kingdom primary care journals. *Brit J General Pract* 1998;48:1229–32.
8. Hayden GF, Saulsbury FT. A review of the journal of paediatrics: the first 50 years. *J Paediatr* 1982;101:5–11.
9. Tompkins RK, Ko CY, Donovan AJ. Internationalisation of general surgical journals – origin and content of articles published in North America and Great Britain from 1983 to 1998. *Arch Surg* 2001;136:1345–52.
10. Kiter E, Karatosun V, Gunal I. Do orthopaedic journals provide high quality evidence for clinical practice? *Arch Orthop Trauma Surg* 2003;123:82–85.
11. Gnanalingham KK, Tysome J, Martinez-Canca J, Barazi SA. Quality of clinical studies in neurosurgical journals: signs of improvement over three decades? *J Neurosurg* 2005;103:439–43.
12. Gnanalingham GM, Robinson SG, Hawley DP, Gnanalingham KK. A 30 year perspective of the quality of evidence published in 25 clinical journals: signs of change? *Postgrad Med J* 2006;82:397–99.
13. Thomson Reuters Journal Citation Reports. Available at: http://thomsonreuters.com/products_services/science/science_products/a-z/journal_citation_reports. Accessed 22/08/2012.
14. The United States National Library of Medicine. Medline database—Ovid platform. Available at: http://ovidsp.tx.ovid.com/index.html. Accessed 22/08/2012.
15. Moher D, Shulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet 2001;357:1191–4.
16. Brox JI. The contribution of RCTs to quality management and their feasibility in practice. *Eur Spine J* 2009;18:279–93.
17. Reich J, Black DW, Jarjoua D. Architecture of research in psychiatry, 1953 to 1983. *Arch Gen Psychiat* 1987;44:311–3.
18. Horton R. Surgical research or comic opera: questions but few answers. *Lancet* 1996;347:984–5.
19. Devereaux PJ, Bhandari M, Clarke M, *et al*. Need for expertise based randomised controlled trials. *BMJ* 2005;330:88–92.
20. Pincus HA, Henderson B, Blackwood D, Dial T. Trends in research in two general psychiatry journals in 1969–1990: research on research. *Am J Psychiatry* 1993;150:135–142.