ORIGINAL ARTICLE

A 30 year perspective of the quality of evidence published in 25 clinical journals: Signs of change?

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Methods: The quality of clinical studies published in five different specialties, over three decades was evaluated. Computerised search of the Medline database was undertaken to evaluate the articles published in 25 clinical journals in 1983, 1993, and 2003 from five different specialties (medicine, surgery, paediatrics, anaesthesia, and psychiatry). The number of randomised controlled trials (RCTs), meta-analyses, and other clinical trials (non-RCT) were noted.

Results: From the 27 030 articles evaluated, there were 2283 (8.4%) RCTs, 166 (0.6%) meta-analyses, and 4153 (15.4%) other clinical trials. For the proportion of RCTs, the rank order of the specialties was; anaesthesia (503; 18%), psychiatry (294; 9.6%), medicine (899; 8.1%), paediatrics (326; 6.4%), and surgery (261; 5.3%) ($p < 0.001$). For the proportion of meta-analysis, the rank order of the specialties was; psychiatry (36; 1.2%), medicine (105; 0.9%), paediatrics (15; 0.3%), anaesthesia (6; 0.2%), and surgery (4; 0.1%) ($p < 0.001$). Overall, from 1983 to 2003, there were increases in the proportion of RCTs (449, 5.9% to 1027, 9.6%), meta-analysis (0, 0% to 127, 1.2%), and other clinical trials (897, 12% to 1983, 19%) ($p < 0.001$). This trend was apparent in each clinical specialty ($p < 0.001$).

Conclusions: Over the three decades evaluated, clinical trials, notably RCTs and meta-analysis form only a small proportion of articles published in prominent journals from five clinical specialties. This is notwithstanding the modest increases in the proportions of RCTs and meta-analysis over the same period.

Much of the information for “evidence based” clinical practice originates from publications in clinical journals. Assessing the quality of this evidence, however can be challenging.^{1–4} In the hierarchy of research study designs, prospective randomised controlled trials (RCT) and meta-analysis of several RCTs or other clinical trials are considered to provide the highest quality of evidence.^{3–4} Other clinical trial designs such as cohort and case-control studies are more prone to bias and confounding factors. Weaker study designs include case series and case reports.

Over the past few decades, there has been a proliferation in the number of clinical journals and articles published. However, whether this has led to an improvement in the quality of articles published in journals is questionable.^{2–5–9} To evaluate this further we assessed the quality of articles published in prominent peer reviewed clinical journals listed in the Medline database from five different specialties, between 1983, 1993, and 2003.

METHODS

An online electronic literature search of five clinical journals each from five different clinical specialties (medicine, surgery, paediatrics, anaesthesia, and psychiatry) was undertaken. For these 25 journals, all articles published in 1983, 1993, and 2003 were studied using the National Library of Medicine, Medline database, on the Ovid platform.¹⁰ These journals were chosen on the basis of their relatively high impact factors (IF)¹¹ in the respective subspecialty, inclusion in the Medline database, and for their online availability.

The following 25 clinical journals, from the five specialties were identified: medicine (*New England Journal of Medicine* IF-35, *Lancet* IF-18, *Journal of the American Medical Association* IF-22, *Annals of Internal Medicine* IF-12, and *Archives of Internal Medicine* IF-7); surgery (*Annals of Surgery* IF-6, *British Journal of Surgery* IF-4, *Surgery* IF-3, *Transplantation* and *Archives of Surgery* IF-4); paediatrics (*Pediatrics* IF-4, *Journal of Pediatrics* IF-3, *Archives of Disease in Childhood* IF-2, *Pediatric Research* and

Journal of Pediatric Gastroenterology and Nutrition IF-1); anaesthesia (*Anaesthesia* IF-2, *British Journal of Anaesthesia* IF-2, *Pain* IF-5, *Anaesthetist* IF-1, and *Anaesthetic Intensive Care* IF-1); and psychiatry (*American Journal of Psychiatry* IF-7, *Archives of General Psychiatry* IF-11, *Journal of Clinical Psychiatry* IF-5, *British Journal of Psychiatry* IF-4, and *Psychosomatic Medicine* IF-4).¹¹

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.¹⁰ For each journal, 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 trial phase I to IV, controlled clinical trial, and multi centre trial) in years 1983, 1993, and 2003.¹⁰

All data were entered and analysed on the SPSS statistical package (Statistical Programs for the Social Sciences, Chicago, USA) and statistical analysis was carried out using the χ^2 test (with Yates's correction).

RESULTS

Changes in study types

A total of 27 030 articles from the 25 journals, over three decades were analysed. Overall, there were 2283 (8.4%) RCTs, 166 (0.6%) meta-analysis, and 4153 (15.4%) other clinical trials.

Overall, there were differences in the study types, between the different clinical specialties (table 1; $p < 0.0001$; $\chi^2 = 1693$). For the proportion of RCTs, the rank order of the specialties was; anaesthesia (18%), psychiatry (9.6%), medicine (8.1%), paediatrics (6.4%), and surgery (5.3%). For the proportion of meta-analysis, the rank order of the specialties was; psychiatry (1.2%), medicine (0.9%), paediatrics (0.3%), anaesthesia (0.2%), and surgery (0.1%). For the

Table 1 Comparison of the study types between different clinical specialties ($p < 0.0001$; χ^2)

Study type	Medicine	Surgery	Paediatrics	Anaesthesia	Psychiatry
RCT (%)	899 (8.1)	261 (5.3)	326 (6.4)	503 (18)	294 (9.6)
Meta-analysis (%)	105 (0.9)	4 (0.1)	15 (0.3)	6 (0.2)	36 (1.2)
Other clinical trials (%)	1788 (16)	496 (10)	661 (13)	640 (23)	568 (19)
Other articles (%)	8340 (75)	4198 (85)	4105 (80)	1632 (59)	2153 (71)
Totals (%)	11132 (100)	4959 (100)	5107 (100)	2781 (100)	3051 (100)

proportion of other clinical trials, the rank order of the specialties was; anaesthesia (23%), psychiatry (19%), medicine (16%), paediatrics (13%), and surgery (10%) (table 1).

When articles from all 25 journals were considered together there were changes in the study types, over the three decades (table 2; $p < 0.0001$; $\chi^2 = 805$). From 1983 to 2003, there were increases in the proportion of RCTs (5.9% to 9.6%), meta-analysis (0% to 1.2%) and other clinical trials (12% to 19%) (table 2). These changes were also apparent when each clinical specialty was analysed separately (fig 1; $p < 0.001$, in each specialty; χ^2 test).

DISCUSSION

The type of study design greatly influences the quality of evidence available for evidence based practice in clinical medicine. In this respect, we found that, RCTs (8.4%), meta-analysis (0.6%), and other clinical trials (15.4%) contributed to a comparatively small proportion of articles published in 25 clinical journals from five different specialties. Nevertheless, there were inter-specialty differences and in all specialties, modest increases in the proportion of these study types over the three decades studied were noted.

In the hierarchy of study designs, a RCT is thought to be the best way to control known and unknown confounding variables and to reduce bias.¹⁻⁴ Meta-analysis of several RCTs is a more powerful statistical technique of pooling together data from similar studies.²⁻⁴ Other clinical trial designs such as cross sectional, cohort, and case-control studies, whether prospective or retrospective, suffer from the lack of randomisation, blindness, and the inclusion of control groups. Thus, these study designs are more prone to confounding influences. On the other hand, case series and single case reports, while useful to describe rare diseases and unusual observations, provide the weakest evidence (if any) for testing the benefit of one treatment over another.²⁻⁴ Thus, in any clinical specialty research primarily based on clinical trials, notably RCTs and meta-analysis is likely to provide the best quality of evidence.

Consequently, the overall paucity of meta-analysis and RCTs noted in this study is of concern. There are several possible explanations for this. RCTs require greater planning, potentially difficult patient recruitment, prospective clinical follow up, and painstaking collection and analysis of data. Thus, RCTs are more expensive, time consuming, and call for greater commitment and cooperation between researchers, frequently from multiple centres in the case of infrequent disease types. Difficulty securing funding is also likely to be a further barrier. In these respects, most non-RCT clinical trials tend to be easier to undertake and undoubtedly the retrospective reporting of case series or individual case reports are even less taxing, perhaps underlying their popularity.^{3 7 12}

Interestingly, there were sizeable variations in the proportion of RCTs and meta-analysis between the specialties. Thus, the highest proportion of RCTs and meta-analysis were noted in the anaesthetic (18%) and psychiatric journals (1.2%), respectively. In contrast, the lowest proportion of these study

types were seen in the surgical journals. Indeed, previous investigations considering individual clinical specialties have reported a wide variation in the proportion of RCTs (5%–26%)

Figure 1 Figure showing the changes in the proportion of meta-analysis (A), RCT (B), and other clinical trials (C), over three decades between the different clinical specialties ($p < 0.0001$; χ^2 test). The data are expressed as a percentage of total articles studied in each specialty (11 132, medicine; 4959, surgery; 5107, paediatrics; 2781, anaesthesia; 3051, psychiatry)

Table 2 Changes in study types over three decades in the 25 clinical journals investigated ($p < 0.0001$; χ^2 test)

Study type	1983	1993	2003
RCT (%)	449 (5.9)	807 (9.3)	1027 (9.6)
Meta-analysis (%)	0 (0)	39 (0.4)	127 (1.2)
Other clinical trials (%)	897 (12)	1273 (15)	1983 (19)
Other articles (%)	6320 (82)	6557 (76)	7551 (71)
Totals (%)	7666 (100)	8676 (100)	10688 (100)

between different specialties.^{5 6 8 9 13} But, this may have also reflected the differences in the methodology used between studies, notably discrepancies in the definitions used to classify the articles. However, in this study identical methodology and definitions were used to investigate the quality of published articles across several specialties, confirming that these inter-specialty differences in study types are indeed real. On the other hand, we did not consider all journals in each specialty or review each article to ascertain the appropriateness of study design, statistical methodology, or impact in the clinical setting. Such a detailed review was beyond the scope of this study.

The lower rate of RCTs and meta-analyses in surgical journals may in part reflect genuine difficulties in undertaking RCTs in this specialty.^{7 12 14} Thus, surgeons may be apprehensive about randomising between two treatments, when they may have greater expertise and/or belief in the efficacy of one surgical treatment modality. This has led to calls for expertise based RCTs in surgical trials.¹⁴ However, this is unlikely to explain, why the rate of RCTs in medicine (8.1%) should be less than half that of anaesthesia. This was a surprising finding considering the relative prominence and high impact factors of the medical journals involved. Could this perhaps reflect the relative ease with which data are obtainable in anaesthetised patients, who are also being continuously monitored? Not entirely, as a RCT is much more than a data collection exercise and not least requires readiness on the part of the physician to randomise the patient between treatments. Perhaps such disparity in the proportion these study types between specialties partly reflects diversity in the beliefs of the clinicians involved, with respect to the usefulness of RCTs. The willingness to question and change aspects of clinical practice is an important requisite for evidence based medicine. This may also call for a change in ideology for some clinicians.

CONCLUSIONS

In this study of 25 prominent clinical journals from five different clinical specialties, clinical trials, notably RCTs and meta-analysis form only a small proportion of articles published over the three decades evaluated. This is despite the modest increases in the proportions of RCTs and meta-analysis over the same period. Increasing proportions of RCTs and meta-analyses would improve the evidence basis for the clinical management of disease in that sub-speciality.

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AUTHOR CONTRIBUTIONS

MGG and KKG jointly contributed to the design of the study, analysis of the results, and writing of the paper. KKG will act as guarantor. SGR and DPH contributed to the collection of data, analysis of results, and writing of the paper.

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