The Journal of Laryngology and Otology
July 1997, Vol. **111**, pp. 611–613

Review Article

Trends in randomized controlled trials in ENT: a 30-year review

K. W. Ah-See, M.D., F.R.C.S., N. C. Molony, B.Sc., F.R.C.S., A. G. D. Maran, M.D., F.R.C.S., F.A.C.S., F.R.C.P., F.D.S.(Hon), F.C.S.(S.A.) (Hon)

Abstract
There is a growth in the demand for clinical practice to be evidence based. Recent years have seen a rise in the number of randomized controlled clinical trials (RCTS). Such trials while acknowledged as the gold standard for evidence can be difficult to perform in surgical specialities. We have recently identified a low proportion of RCTS in the otolaryngology literature. Our aim was to identify any trend in the number of published RCTS within the ENT literature over a 30-year period and to identify which areas of our speciality lend themselves to this form of study design. A Medline search of 10 prominent journals published between 1966 and 1995 was performed. Two hundred and ninety-six RCTS were identified. Only five were published before 1980. Two hundred (71 per cent) of RCTS were in the areas of otology and rhinology. An encouraging trend is seen in RCTS within ENT literature.

Key words: Medicine, evidence based; Randomized controlled trials; Otolaryngology; Medline

Introduction

There is currently a high demand by purchaser, politician and patient (Sackett *et al.*, 1996) for the practice of evidence based medicine (EBM). This in turn requires the existence of a robust body of evidence, published or not (Chalmers *et al.*, 1992). The gold standard for EBM remains the randomized controlled trial (RCT). This study design when correctly executed permits an accurate comparison between the effectiveness of different interventions (Altman, 1996). While the RCT does not provide the only source of evidence it is recognized as providing the highest quality of evidence (Scottish Intercollegiate Guidelines Network (SIGN), Edinburgh).

An initial assessment of the evidence base in otolaryngology has revealed a paucity of RCTs and an abundance of descriptive literature (Maran *et al.*, 1997). The aim of this study was to identify the areas within otolaryngology for which RCTs exist and to document any pattern of change in the literature in favour of such research.

Materials and methods

A 30-year Medline search (1966–1995) was performed using a search strategy designed to identify all randomized controlled trials. The textwords, randomised, randomized, control, controlled, trial, study, prospective, RCT, clinical trial, were used in the search.

A broad range of 10 otolaryngology journals were chosen for the search. These included both general and specialty as well as European and American journals.

TABLE I
ENT JOURNALS SEARCHED

• *Acta Otolaryngologica*	• *Clinical Otolaryngology*
• *Annals of Otology, Rhinology and Laryngology*	• *Journal of Laryngology and Otology*
• *Archives of Otolaryngology–Head and Neck Surgery*	• *Laryngoscope*
• *Audiology*	• *Otolaryngology–Head and Neck Surgery*
• *British Journal of Audiology*	• *Rhinology*

These journals were chosen because of their high citation index and circulation numbers (Science Citation Index, 1992).

Using methodology previously described (Maran *et al.*, 1997) the abstracts of all references obtained were read to confirm the study was an RCT.

From the Department of Otolaryngology, The Royal Infirmary of Edinburgh, Edinburgh, UK.
Accepted for publication: 5 June 1997.

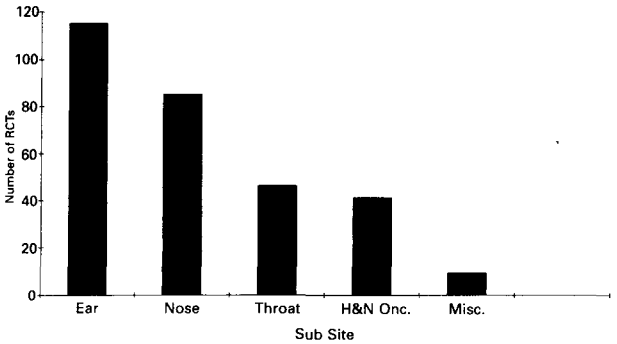

FIG. 1
The number of RCTs published for the general ENT subsites (1966–1995).

Additional data were collected on the principal topic of the research, the journal source and the year of publication.

Results

The initial yield from the Medline search highlighted 370 articles in the 10 journals from 1966–1996. Further analysis of the journal abstracts, however, revealed 74 articles which were clearly not RCTs. For example the search strategy would highlight an article with the words: '. . . the need for an RCT. . .' in the abstract while the article *per se* was a descriptive paper.

Two hundred and ninety-six articles were therefore available for further assessment. A general subdivision into ear, nose, throat, head and neck oncology, and miscellaneous is shown in Figure 1. This reveals a much higher number of RCTs involving the ear and nose compared with the latter groups. For RCTs involving ear disease this is largely due to the 'control limb' being the patients second ear. The miscellaneous group included studies on facial palsy and salivary gland disease.

A breakdown of the source journals for the RCTs is shown in Figure 2. Interestingly more RCTs appear in the general than in the specialized journals. This is presumably due to the wider readership of the general journals and hence the desire by authors to reach more clinicians with their results.

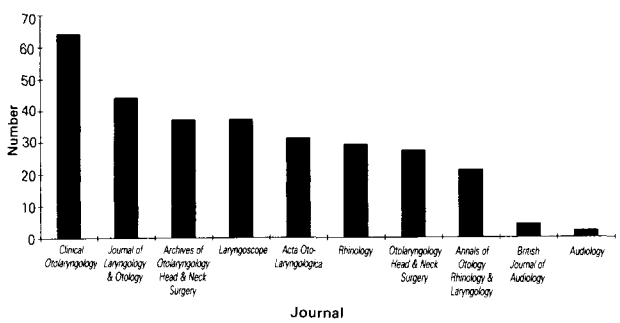

FIG. 2
The number of RCTs published per journal analysed (1966–1995).

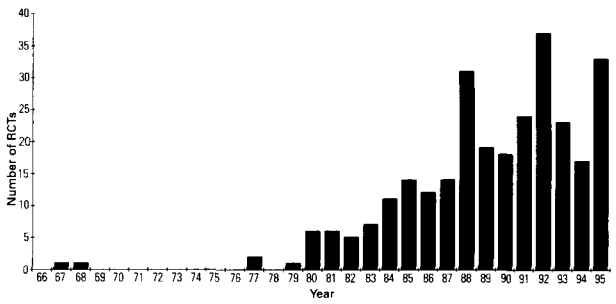

FIG. 3
The trend for the number of RCTs published per year from 1966 to 1995.

The British journals *Clinical Otolaryngology* and The *Journal of Laryngology and Otology* score the highest in terms of numbers of RCTs published compared with the rest of the literature. It should be noted however that not all the journals have been running for 30 years, in particular *Clinical Otolaryngology* and the *British Journal of Audiology*. Similarly, while some journals are published monthly others, notably *Clinical Otolaryngology*, appear once every two months.

Since 1966 there has been a significant rise in the number of RCTs published in the ENT literature (Figure 3). Several specific conditions were highlighted as the subjects of RCTs on a more frequent basis (Figure 4).

Discussion

It is worth noting that the first ever randomized controlled trial was published only 50 years ago (Medical Research Council, 1948). Clearly the first 10 years of this survey were barren years for otolaryngology. In recent years, however, there has been a noticeable increase in the number of published RCTs. We accept that such a search restricted to only Medline references will not necessarily pick up all RCTs, as bias against negative results has in the past prevented some trials from being published. Nonetheless within a speciality like otolaryngology we feel that this search is at least representative of a general trend.

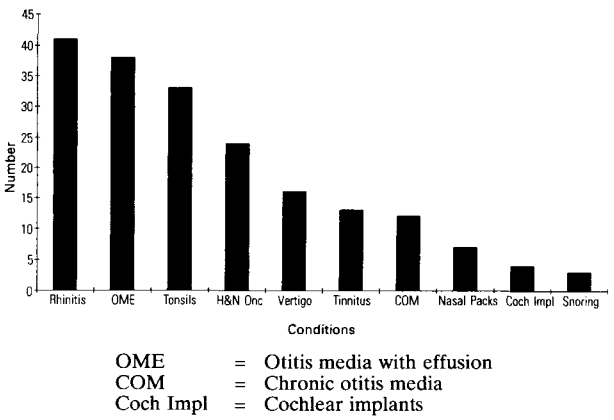

FIG. 4
The number of RCTs published on certain specific topics.

https://doi.org/10.1017/S0022215100138101 Published online by Cambridge University Press

We have noted before (Maran *et al.*, 1997) that the British literature tends to fare more favourably than other countries when it comes to RCTs and levels of evidence. This perhaps reflects a tradition in this country, as already mentioned, dating back to 1948. It is perhaps not surprising that otology and rhinology topics figure most highly for published RCTs, particularly since conditions of the ear or nose affect the largest proportion of our cases (ISD, 1997). In addition the need for adequate numbers in a trial means that studies for head and neck cancer patients tend to require multicentre collaboration or lengthy periods of study to recruit patients. Certain specific conditions appear to lend themselves to study in the form of an RCT, such as otitis media with effusion (OME) (Figure 4). It is perhaps a reflection on the quality of some of these trials that OME in particular still remains a controversial management issue. Studies including patients as their own control are the most robust in terms of outcome assessment, again this is facilitated by the trial of a bilateral condition. In addition, trials involving medical management of ENT conditions are more amenable to RCTs than those requiring a surgical procedure.

This study does not reflect the overall quality of the RCTs highlighted although we are currently evaluating a process for scoring trial quality.

We conclude that an encouraging trend is visible in the number of RCTs appearing in the otolaryngology literature. This should in the future result in a more substantial base of evidence from which clinical guidelines may be derived. It is important, however, that the standard of published RCTs should be high if valid conclusions are to be drawn. Indeed a recent report warns us that strict criteria will be demanded of RCTs in the future if they are to be published at all (Altman, 1996). In view of this recent advice we are currently assessing RCT quality in the ENT literature based on the CONSORT recommendations (Begg *et al.*, 1996). The results of this analysis will be available shortly.

We would encourage the speciality to ensure that prospective researchers are encouraged to produce good quality trials as a prerequisite to establishing robust clinical guidelines within otolaryngology.

References

Altman, D. G. (1996) Better reporting of randomised controlled trials: the CONSORT statement. *British Medical Journal* **313:** 570–571.

Begg, C., Cho, M., Eastwood, S., Horton, R., Moher, D., Olkin, I., Pitkin, R., Rennie, D., Schulz, K. F., Simel, D., Stroup, D. F. (1996) Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *Journal of the American Medical Association* **276:** 637–639.

Chalmers, I., Dickersin, K., Chalmers, T. C. (1992) Getting to grips with Archie Cochrane's agenda (editorial). *British Medical Journal* **305:** 786–788.

Information and Statistics Division (ISD), Section 6 Outpatient Activity. In *Scottish Health Statistics* 1997, Information and Statistics Division, The NHS in Scotland (in press).

Journal Citation Reports (1992) Subject Category Listing, Otorhinolaryngology. In *Science Citation Index*, Institute for Scientific Information Inc., Philadelphia, USA, p 108.

Maran, A. G. D., Molony, N., Armstrong, M., Ah-See, K. W. (1997) Is there an evidence base for the practice of ENT surgery? *Clinical Otolaryngology* **22(2):** 152–157.

Medical Research Council (1948) Streptomycin treatment in pulmonary tuberculosis: a Medical Research Council investigation. *British Medical Journal* **2:** 769–782.

Sackett, D. L., Rosenberg, W. M. C., Gray, J. A. M., Haynes, R. B., Richardson, W. S. (1996) Evidence based medicine: what it is and what it isn't. *British Medical Journal* **312:** 71–72.

Scottish Intercollegiate Guidelines Network (SIGN). (1995) Royal College of Physicians, Edinburgh.

Address for correspondence:
K. W. Ah-See M.D., F.R.C.S.,
Department of Otolaryngology,
The Royal Infirmary of Edinburgh,
Lauriston Place,
Edinburgh EH3 9YW.

Fax: 0131-536 6167