Treatment of acute otitis media: are children entered into clinical trials representative?

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SUMMARY

This study involved a meta-analysis of randomised control studies of the treatment of acute otitis media and judged the characteristics of these trials on the basis of methods, age groups, interventions, and outcomes. An investigation of the eight trials reported in the meta-analysis of clinical trials revealed that the number of children entered per doctor in all practices was low and that the recruitment rate was probably lower than 44%. Low recruitment rates indicate that the type of children entered into trials may only relate to those with mild to moderate symptoms and signs, which could explain why the results of these trials show that antibiotics are not essential in treating acute otitis media.

Keywords: *acute otitis media; meta-analysis; children; clinical trials.*

Introduction

ONE in four children will have an episode of acute otitis media at some time during the first 10 years of life and it is extremely common in pre-school children.[1] In terms of treatment, the current trend is to recommend watchful waiting[2,3] on the basis of the fact that controlled trials of antibiotic versus placebo have shown that, in the short term, there is only a marginal benefit in favour of antibiotics while long term outcomes do not seem to be effected by whether children receive an antibiotic or not. A meta-analysis of randomised control studies of the treatment of acute otitis media judged the characteristics of these trials on the basis of methods, age groups, interventions, and outcomes,[2] yet this review did not investigate whether children were representative of all those presenting with presumed middle ear infections.

Method and Results

The most recent study of antibiotic versus placebo[3] did not report on how representative the children entered to the trial were and this stimulated further investigation of the eight trials reported in the meta-analysis of clinical trials.[2] The latter showed that the number of children entered into these trials varied from 142 to 536 and the number of doctors participating varied from 2 to 53, with the largest study (563 children) not giving the number of doctors involved over a four-year period.

In the three general practice based studies[3-5] the average number of cases entered per doctor were 13, 14, and 4 respectively (Table 1). If one accepts that a typical general practitioner (GP) will see about 20 children with acute otitis media every year,[1] then a notable proportion of children will be excluded for one reason or another.

Reliable information about patients excluded from studies is not available in any of the published trials. In the only British-based trial of antibiotic versus placebo, there were 48 GPs from 17 practices.[5] One practice had a policy of systematically recording all eligible children with 84 being recruited and 105 excluded, although they met the entry criteria (inferred recruitment rate of 44%). In this study children with bulging drums were excluded which further reduces the range of ear infections. The average number of children entered per doctor in all practices was four, which suggests that the recruitment rate was even lower than 44%. The reasons for exclusion in the practice that recorded details of all eligible children was varied, 50% of exclusions were owing to the GPs' clinical judgement that an antibiotic was required.

Discussion

Low recruitment rates indicate that the type of children entered into trials may only relate to those with mild to moderate symptoms and signs which could explain why the results of these trials show that antibiotics are not essential in treating acute otitis media. While evidence-based medicine can be helpful in teasing out contrasting findings in clinical trials, the design of these trials is hampered by the way in which doctors recruit patients for research. A survey of

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Table 1. Children per participating GP entered into trial.

General practice studies	Number of children	Number of doctors	Trial patients per doctor per 12 months
Damioseaux *et al*	240	53	13
Van Buchem *et al*	171	12	14
Burke *et al*	232	48	4

HOW THIS FITS IN

What do we know?

The management of acute otitis media presents the general practitioner with a number of dilemmas. Traditionally, the use of antibiotics has been accepted as normal practice, but in recent years clinical trials have indicated that antibiotics are not essential.

What does this paper add?

This brief report points out that children entered into trials may not be representative and the non-use of antibiotics may only be justified in children with mild to moderate symptoms and signs.

general practitioners participating in clinical trials revealed forgetfulness and time pressures as the main factors inhibiting recruitment.[6] Patient refusal to enrol is seldom reported, but when investigation of recruitment of patients with lung cancer into a randomised clinical trial was carried out it was found that 73% of patients had refused to enter the study.[7]

It would be helpful for the practising doctor if systematic reviews indicated to what extent studies have shown how representative the trial sample actually is. In children with presumed middle ear infection, the GP is likely to adopt a 'wait and see' policy only when he or she is confident that the child has mild to moderate symptoms. Where a child presents with fever, irritability, and a bulging ear drum, and where doubts exist about whether follow-up in the short term can be assured, the GP is probably still justified in giving an antibiotic.

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