

Systematic review of autoinflation for treatment of glue ear in children

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Autoinflation refers to the opening of the eustachian tube by blowing up a balloon with the nose, which raises intranasal pressure. Although autoinflation has been proposed for the treatment of glue ear in children it has been researched far less than surgical or pharmacological interventions, and research that has been conducted has not been reviewed systematically.

Methods and results

We searched Medline and the Cochrane Library using "otitis media," "autoinflation," "auto-inflation," "Valsalva," and "poltizer" as headings. This provided 35 potential studies, five of which were randomised controlled trials (see table on website).¹⁻⁵ A further unpublished trial was obtained from a pharmaceutical company (J Suonpää and R Grénman, unpublished data). All the subjects in that trial underwent myringotomy.

Each of the trials used a mechanical aid to assist autoinflation of the middle ear; one trial used a modified anaesthetic mask,¹ two used toy balloons,^{4,5} and three used manufactured nasal balloons^{2,3} (unpublished data).

Unfortunately, no two studies were comparable in several respects: method of autoinflation, selection criteria for subjects, presence of unilateral or bilateral glue ear, length of treatment (range 2-12 weeks), and level of data analysis (patient versus ear). Two studies used poorly defined outcome measures such as "recovery" (unpublished data) and "absence of effusion,"¹ two studies used tympanograms,^{2,3} and two studies measured improvement in hearing.^{4,5} One study did not provide direct data on the number of patients who improved in the treatment and control groups.⁴ Instead, improvement was estimated from the sample sizes, the standard error of the mean difference between the groups, and an increased audibility of 10 dB as measured on an audiogram.

None of the studies used blinding to outcome measures.

We recreated an intention to treat analysis of two of the studies, which reported results from "low compliance" and "high compliance" patients separately. The figure shows the odds ratios and 95% confidence intervals for all the studies.

The study using the modified anaesthetics mask¹ and one of the toy balloon studies⁵ showed no significant difference between the treatment and the controls, although the trend was towards treatment having an adverse effect on outcome. The other toy balloon study showed no significant difference between the treatment group and controls (odds ratio almost one).⁴ All the nasal balloon studies^{2,3} (unpublished data) showed a trend towards a benefit of treatment, although only two of these studies showed a significant benefit² (unpublished data).

For all studies combined, the odds ratio for improvement with autoinflation was 1.85 (95% confidence interval 1.22 to 2.8; $P=0.0038$) suggesting a benefit. There

was, however, significant heterogeneity in the observed effects between the six studies ($Q=16.44$, $df=5$, $P=0.006$); that is, there was evidence that the studies were not measuring a common treatment effect.

Because the nasal balloon studies provided a potentially homogeneous group ($Q=0.52$, $df=2$, $P=0.76$), we retrospectively calculated the Mantel-Haenszel statistic for the three studies. This indicated that children receiving autoinflation were around 3.5 times more likely to improve than controls (odds ratio 3.53, 2.03 to 6.14); however, two of these studies were of low quality³ (unpublished data).

Comment

Evidence for the use of autoinflation in the treatment of glue ear in children is conflicting but suggests that it may be of clinical benefit. Unfortunately, the studies are of variable and low quality. None used blinded outcome assessors, and all were short term studies. We cannot recommend autoinflation for clinical practice, as a better designed and larger trial is warranted.

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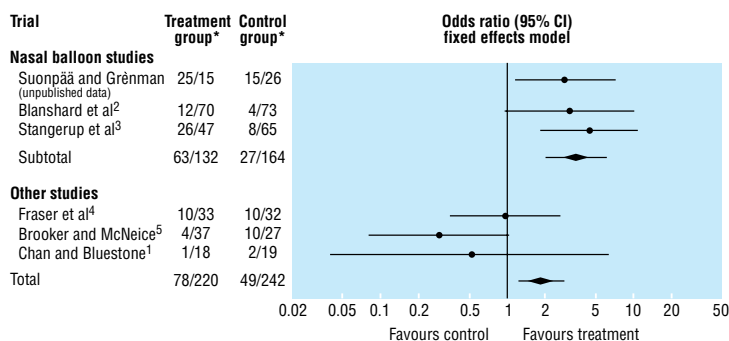
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website
extra

Details of the trials appear on the BMJ's website

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* No of cases cured/No of cases not cured

Meta-analysis (Mantel-Haenszel fixed effects model) of autoinflation as treatment for glue ear

Commentary: Plausible candidates for treatment of glue ear—is one issue really three?

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For a long time there has been clinical acknowledgment of some need for temporising management in glue ear but a failure in medical literature to consistently distinguish proposals for temporising management and definitive management.¹ Although rarely used in the United Kingdom for glue ear, antibiotics have been seen, internationally at least, as one temporising management. Under the growing threat from resistant bacteria consideration of alternatives is particularly timely. Reidpath and colleagues usefully summarise the evidence base for autoinflation—blowing up a balloon with the nose. Although the therapeutic hypothesis is based on a somewhat dated emphasis on anatomical rather than microbiological risk factors, the two sets of factors probably interact and the evidence for efficacy is suggestive. Effectiveness trials can now be considered in which generalisation issues and some of the methodological shortcomings in existing work would be addressed.

The larger pragmatic trials of effectiveness required to define a wise treatment policy are not as simple as the simplicity of the treatment might suggest. Before protocols are investigated, a further question must be posed: “What sort of child can most sensibly be viewed as a candidate for autoinflation?” This is a matter partly of staging in a disease that fluctuates and evolves, and partly a matter of adherence. A longstanding issue is whether children aged 4-6 years really can be trained to use autoinflation effectively. Adherence will be indirectly reflected in the outcome of any pragmatic trial, but development work on the best way to train and encourage adherence needs logically to precede a trial of effectiveness. Autoinflation could be seen as a secondary prevention and temporising management for very large numbers of cases in primary care or, alternatively, as a criterion (via “non-response”) for proceeding to surgery in smaller numbers of patients in secondary care with more serious or persistent glue ear. The lore growing up around one such use could confuse the other. Any trial needs to address the costs, risks, and outcomes specific to the assigned role, within a public health perspective. Adherence data on deprived children and those from ethnic minorities would be

required for generalisation of any resulting treatment policy. The treatment could also have a special niche for the comparatively rare older child who has continuing ear problems but reasonable age related prospects of remission, with probably good adherence after receiving two or more sets of ventilation tubes (grommets) in a clinical history of several years. Although a multicentre trial is needed for large numbers of subjects, a simple provider based trial would suffice here.

Thus, the staging issue for autoinflation suggests three trials on rather different sorts of question. Because of the differing requirements for data it is probably not efficient to address them in one trial. For example, with the first trial in primary care, ethics committees would probably require as a prerequisite a fail safe system ensuring reassessments after a period of watchful waiting with a view to referral to paediatric otolaryngology. Extensive safety data could be required before dropping that safeguard for routine practice. Under the current constraints on UK primary care, watchful waiting by doctors in cases of glue ear is a euphemism for demand suppression. This context suggests that reassessment could become a genuine policy issue if availability of a treatment in primary care reduced the referral rate to otolaryngology. The assumptions for costing the treatment in primary care should include this.

After the first question of whether autoinflation can work is answered, the fuller effectiveness evaluation of treatment policies can raise a wide range of possibilities and questions, as well as formidable demands for research investment. Is the probably small benefit from the treatment worth such investment? Formal “pay-back analysis” is currently restricted to major research on major treatments,² but may need to be extended to the prioritisation of trial questions even for treatments of low cost and risk.

1 Haggard MP, Hughes EA. *Screening children's hearing*. London: HMSO, 1991.

2 Buxton M, Hanney S. How can payback from health services research be assessed? *J Health Serv Res Policy* 1996;1:35-43.

One hundred years ago Motor cars for medical men

Sir,—Any medical man who visited, as I did, the motor car exhibition at Richmond during the past week could not help noticing the recent improvements in these vehicles.

To a medical man the motor car will be of the utmost utility. Long journeys can be undertaken and no questions will be asked as to whether the horse will be too tired to undertake more work; all that is necessary is a supply of petrol, a very elementary knowledge of the mechanism, and an efficient car.

In a car with a long wheel base, pneumatic or solid rubber tyres, a well upholstered seat, and a carriage properly hung so as to distribute weight equally, there is the greatest comfort in riding twelve or fourteen miles an hour, and the actual cost of such running should not exceed one halfpenny a mile. Comparing this with a horse and carriage there must be considerable economy. I have never estimated the cost per mile travelled by a horse and trap, but I am told on good authority that it cannot be done for less than sixpence. Edward Phillips, Coventry. (*BMJ* 1899;ii:57)