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Chronic otitis media with effusion (glue ear) and adenotonsillectomy: prospective randomised controlled study

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Abstract

A prospective study was conducted of the effects of adenoidectomy and adenotonsillectomy on established otitis media with effusion unresponsive to medical treatment. The operations were performed at random with a controlled no surgery group on a cohort of 103 children with the condition and the results assessed six weeks, three months, six months, nine months, and one year later. After adenoidectomy the rate of resolution of the condition increased from 39% at six weeks to 72% at one year; and after adenotonsillectomy the rate increased from 59% at six weeks to 62% at one year. In the no surgery group the rate increased from 16% at six weeks to 26% at one year. Compared with the no surgery group the effect of adenoidectomy alone at one year was highly significant ($p < 0.001$), and similarly the effect of adenotonsillectomy was significant ($p < 0.01$). There was, however, no increased benefit from the addition of tonsillectomy compared with adenoidectomy alone. Thus there was resolution of 36-46% of chronic effusions as a result of adenoidectomy.

Introduction

Otitis media with effusion, a term synonymous with chronic non-suppurative otitis media, secretory otitis media, serous otitis media, and glue ear, is one of the commonest chronic otological conditions of childhood. It results from alteration of the mucociliary system within the middle ear cleft and is frequently caused by malfunction of the eustachian tube. Serous or mucoid fluid accumulates within the cleft where there is a negative pres-

sure. It is especially prevalent in children with cleft palate and frequently occurs in association with upper respiratory tract infection and generalised disorders such as allergic rhinitis, fibrocystic disease, and ultrastructural ciliary abnormalities of the mucosa of the respiratory tract. The condition presents in children as hearing loss, which may be overt or covert, presenting as educational or behavioural problems. Often, however, the hearing loss is first detected on routine screening examinations. Occasionally attention is drawn to it by frequent episodes of otalgia, which signify an acute episode of suppurative otitis media superadded to a middle ear effusion, and very occasionally presentation is with complications such as continuous otorrhoea secondary to perforation.

Treatment varies widely and is directed to the ears in the form of myringotomy and aspiration with or without insertion of a grommet; to the nose and sinuses by eradication of infection and control of allergy; and to the postnasal space and oropharynx in the form of adenoidectomy and tonsillectomy. It is removal of the adenoids and tonsils which is mainly responsible for the morbidity and mortality attached to the treatment of chronic otitis media with effusion. The main reasons postulated for adenoidectomy as a means of treatment and prevention of recurrence have centred on the size of the adenoids and their role as a focus for ascending eustachian tube infection. In addition, they are thought to alter nasopharyngeal pressure relations. The potential source of infection from the tonsils is similarly implicated. Removal of the tonsils, however, is often additionally advised with adenoidectomy on grounds which on their own merit might not prove valid for tonsillectomy.

Arguments for¹⁻³ and against⁴⁻⁸ adenoidectomy and adenotonsillectomy for all types of disease of the middle ear have been discussed and reported at length in papers and symposia world wide.⁹⁻¹² Nevertheless, given the large numbers of these operations performed for this condition, it is remarkable that so few studies have been carried out to substantiate their efficacy. Evidently the long held belief that adenoidectomy relieves recurrent acute suppurative otitis media has been extrapolated, as yet without convincing supportive evidence as grounds for the management of otitis media with effusion. The present study began prospectively in September 1979 with the specific object to evaluate randomly the effect of adenoidectomy and adeno-

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tonsillectomy together with no treatment on established otitis media with effusion unresponsive to medical treatment in children aged 2 to 11 years.

Patients and methods

The study was approved by the district ethical committee and was performed in two parts. A preliminary pilot study was undertaken to assess interobserver agreement and to validate my specificity (75%), sensitivity (90%), and accuracy of diagnosis of otitis media with effusion. That study has been reported.^{13 14}

The definitive study was conducted during July 1979 to March 1982. At regular intervals throughout the period children suffering with bilateral otitis media with effusion were examined. There were 103 children aged between 2 and 11 years (mean 5.25 years), of whom 62 were boys and 41 girls. Diagnosis was confirmed by otoscopy using Siegle's pneumatic speculum together with compliance studies, tympanometry, acoustic reflex stimulation, and pure tone audiometry. On the first appointment the condition and trial were explained and an antihistamine-sympathomimetic amine mixture (Dimotapp elixir) in appropriate dosage for age prescribed until the second appointment six weeks later. Repeat examination and investigations were then performed to confirm the presence of *bilateral* otitis media with effusion. For the next six weeks no treatment was prescribed, and a final, identical review was made at 12 weeks.

If fluid in the middle ear was still present on both sides the trial was further explained and the child admitted to hospital within two weeks for operation. During this time a lateral cephalometric radiograph of the nasopharynx was taken. All the surgery was performed by me. Surgery to the tonsils and adenoids was allocated at random, as follows: adenotonsillectomy 34 cases; adenoidectomy 36; no surgery 33. Additionally, in all cases on a randomly allocated basis *unilateral* myringotomy was performed. The middle ear fluid was aspirated and assessed for quantity and type. A Shepard Xomed grommet was inserted anteroinferiorly. The contralateral, *unoperated* ear was examined on this occasion with a Zeiss microscope using six times magnification to reconfirm clinically the presence of fluid in the middle ear but myringotomy was not performed. There was a similar distribution of each treatment group within the seasonal divisions of the year and there were no differences among the three groups in age, sex, and postnasal space airway measured on the lateral radiograph.

All 103 children entered the study. They were re-examined six weeks, three months, six months, nine months, and one year after surgery. I performed similar clinical examinations in all cases together with pure tone audiometry and impedance studies. The unoperated ear was assessed for fluid in the middle ear without prior examination of the pharynx or operation notes and a rate of improvement calculated for each follow up time based on the findings in the unoperated ear. The improvement rate represents the percentage of the unoperated ears in which fluid was no longer present as judged with a Siegle's pneumatic otoscope.

Results

Only one patient was lost to follow up (after three months). Some of the children failed to attend follow up appointments at the expected time; thus a comparison was made between the rate of resolution of otitis media with effusion observed at the precise time of follow up and an interpolated assessment at each selected follow up time based on the middle ear findings at the next appointment. Analysis by χ^2 test showed no difference in any of the cells between the observed and interpolated data, and therefore the larger numbers in the interpolated data were used for subsequent analysis (fig 1).

In the group treated by adenoidectomy alone the rate of improvement increased from 39% at six weeks to 56% at three months, 64% at six months, 58% at nine months, and 72% at one year. After adenotonsillectomy the rate changed from 59% at six weeks to 50% at three months, 59% at six months, and 62% at nine months and one year. In the no surgery, control group, however, the improvement rate increased from 16% at six weeks to 22% at three months, 26% at six months, 19% at nine months, and 26% at one year (fig 2). χ^2 analysis showed that compared with the no treatment group the effect of adenoidectomy alone was significant at three months ($p < 0.05$) and at six and nine months ($p < 0.01$) and one year ($p < 0.001$). Likewise, there was a significant effect after adenotonsillectomy at six weeks ($p < 0.001$), three and six months ($p < 0.05$), and at nine months and one

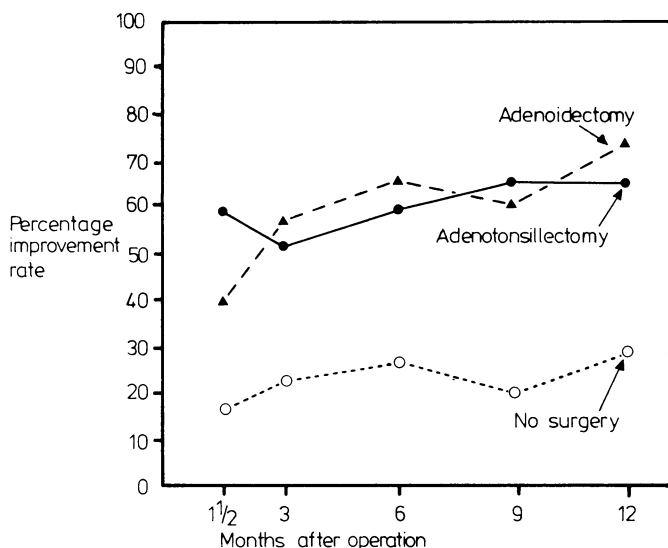


FIG 1—Comparison between observed and interpolated improvement rates. χ^2 analysis showed no differences in any cells.

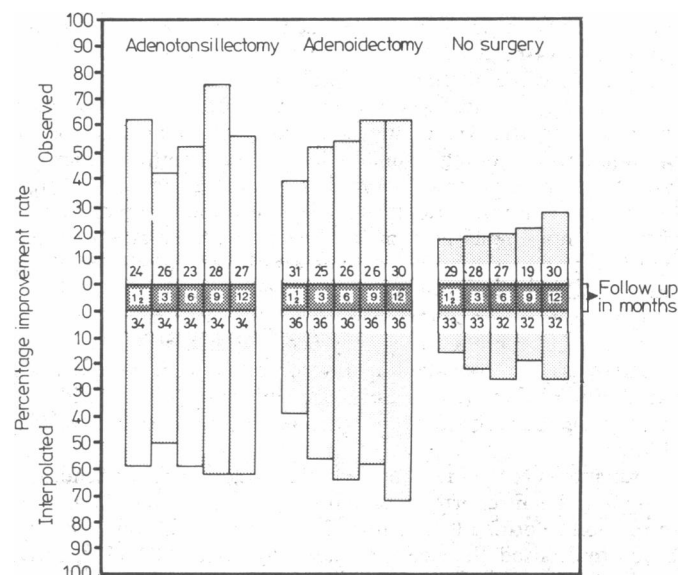


FIG 2—Percentage improvement rate of middle ear effusion after operation.

year ($p < 0.01$). There was no significant difference between the adenoidectomy and adenotonsillectomy groups at any time after surgery.

Discussion

Tonsillectomy with adenoidectomy is less frequently recommended than adenoidectomy alone for otitis media with effusion, yet only two^{4 15} of the six reported prospective studies investigated adenoidectomy in isolation from the combined operation for the relief of middle ear disease. Moreover, these studies assessed the overall effect of surgery in relieving various aural and upper respiratory tract signs and symptoms and none specifically investigated the effect of the procedures on otitis media with effusion as a properly controlled randomised prospective study. Sade found no improvement in otitis media with effusion after adenoidectomy and insertion of a grommet compared with insertion of a grommet alone,⁶ and similar results were reported in a small study by Fiellau-Nikolajsen *et al.*¹⁶ A retrospective study by Marshak and Ben Neriah⁵ showed a statistically non-significant ($p < 0.3$) improvement rate in otitis media with

effusion after adenoidectomy and myringotomy (74%) compared with myringotomy alone (59%). Roydhouse found no difference in cure rate of effusion after adenoidectomy, though there was a 9% greater relapse rate in a similar non-adenoidectomy group independent of adenoid size.⁷ After adenoidectomy recurrent acute suppurative otitis media has been seen to improve by some investigators,¹⁷⁻¹⁹ though others^{4, 20} have found no improvement.

Little is known of the natural history of adenoid development and the growth of the nasopharynx. Jeans *et al* showed that growth of the soft tissue of the postnasal space outstrips growth of the nasopharynx from 3 to 5½ years of age with resultant reduction in the nasopharyngeal airway.²¹ Subsequently growth of the nasopharynx increases while the soft tissues remain relatively unchanged and thus the airway increases. Middle ear effusions have been detected where the adenoids either are not enlarged or have been removed.^{22, 23} Independently, Gerwat,²⁴ Hibbert,²⁵ and Maw *et al*²⁶ found no correlation between size of the adenoids radiologically or volumetrically and the presence or absence of otitis media with effusion. By contrast, however, we have shown a significant reduction in the postnasal space airway ($p < 0.05$) in children with the condition compared with age matched controls (A R Maw, W D Jeans, unpublished data). Bluestone *et al* in selected cases found improved function of the eustachian tube after adenoidectomy.²⁷ They also found in some cases worsened tubal function with more frequent and more serious otitis media after adenoid removal. Birck and Mravec reported a 27% failure rate for adenoidectomy alone, particularly when allergy was coexistent.²⁸

Other factors must be considered in relation to the evaluation of these operations for this condition. In many studies the material is not homogeneous²⁹; some cases of effusion are bilateral, others unilateral,⁷ numerical problems arise, and often for ethical reasons patients with severe middle ear disease or gross adenoid enlargement are excluded.⁴ Paradise *et al*²⁹ rightly stated that studies must assess the obvious variables of age, sex, degree of nasal obstruction, adenoid size, and allergy in addition to other factors such as seasonal variation and spontaneous improvement which may occur with time.³⁰

There is also considerable interobserver and intraobserver variability in the assessment of these children,^{13, 14} and validation of investigators' accuracy of clinical diagnosis must be considered.⁴

Statements recommending virtual abandonment of adenoidectomy have been reported³⁰ but still appear to be unsubstantiated in relation to otitis media with effusion. Almost all other studies have emphasised the need for carefully controlled prospective randomised trials to assess the place of adenoidectomy and tonsillectomy for otitis media with effusion. The work presented here is the first such study to be reported. It suggests that adenoidectomy has a significant therapeutic effect for up to 12 months in resolving the effusion in 36-46% of cases of established otitis media with effusion resistant to medical treatment. Moreover the effect is independent of age, sex, size of the adenoids, and the influence of any seasonal variation on the condition (A R Maw, unpublished data). It further suggests that combination of tonsillectomy with adenoidectomy does not confer any additional therapeutic benefit for this condition. Finally, it shows that without treatment 26% of cases resolve spontaneously during this time.

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