

Adenoidectomy versus chemoprophylaxis and placebo for recurrent acute otitis media in children aged under 2 years: randomised controlled trial

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Abstract

Objective To evaluate the efficacy of adenoidectomy compared with long term chemoprophylaxis and placebo in the prevention of recurrent acute otitis media in children aged between 10 months and 2 years.

Design Randomised, double blind, controlled trial.

Setting Oulu University Hospital, a tertiary centre in Finland.

Participants 180 children aged 10 months to 2 years with recurrent acute otitis media.

Intervention Adenoidectomy, sulfafurazole (sulphisoxazole) 50 mg/kg body weight, given once a day for six months or placebo. Follow up lasted for two years, during which time all symptoms and episodes of acute otitis media were recorded.

Main outcome measures Intervention failure (two episodes in two months or three in six months or persistent effusion) during follow up, number of episodes of acute otitis media, number of visits to a doctor because of any infection, and antibiotic prescriptions. Number of prescriptions, and days with symptoms of respiratory infection.

Results Compared with placebo, interventions failed during both the first six months and the rest of the follow up period of 24 months, similarly in the adenoidectomy and chemoprophylaxis groups (at six months the differences in risk were 10% (95% confidence interval -9% to 29%) and 18% (-2% to 38%), respectively). No significant differences were observed between the groups in the numbers of episodes of acute otitis media, visits to a doctor, antibiotic prescriptions, and days with symptoms of respiratory infection.

Conclusions Adenoidectomy, as the first surgical treatment of children aged 10 to 24 months with recurrent acute otitis media, is not effective in preventing further episodes. It cannot be recommended as the primary method of prophylaxis.

Introduction

About one third of all children experience recurrent episodes of acute otitis media.¹⁻⁴ Although there are many preventive strategies, none seem to be indisputably effective.⁵⁻⁸ Adenoidectomy may benefit the

middle ear by removing a source of infection from the nasopharynx⁵ and has been shown to be helpful in children over 4 years of age with chronic otitis media with effusion.⁹⁻¹⁰ In contrast, the evidence of the efficacy of adenoidectomy in preventing recurrent episodes of acute otitis media is conflicting.¹¹⁻¹² There is no evidence on the effectiveness of adenoidectomy as the first surgical treatment in preventing recurrent acute otitis media in children aged under 2 years, who are clearly at the highest risk.

We assessed the effectiveness of adenoidectomy in preventing further acute episodes, relieving acute symptoms, and reducing the numbers of visits to a doctor for infection and antibiotic prescriptions compared with chemoprophylaxis and placebo in children aged under 2 years with recurrent acute otitis media.

Methods

Enrolment and assignment

We selected participants from all children aged 10-24 months who were referred to the department of otolaryngology at Oulu University Hospital for recurrent acute otitis media from 1 April 1994 to 17 April 1997. To be eligible, the child had to have experienced at least three acute episodes during the previous six months. Exclusion criteria were a previously performed adenoidectomy or tympanostomy, cranial anomalies, documented immunological disorders, and ongoing antimicrobial chemoprophylaxis.

Intervention

The adenoidectomy operation was performed as daycare surgery. Chemoprophylaxis comprised sulfafurazole (sulphisoxazole) suspension 50 mg/kg of body weight, given once a day for six months. The placebo suspension had the same colour and taste and was given at a similar frequency and volume.

Follow up

The children were followed up for two years by means of symptom diaries and clinical examinations from the

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Table 1 Baseline characteristics of 180 children with recurrent acute otitis media randomised to receive adenoideotomy, sulfafurazole prophylaxis, or placebo. Figures are numbers of children unless stated otherwise

Characteristic	Adenoideotomy (n=60)	Sulfafurazole (n=60)	Placebo (n=60)
Mean (SD) age (years)	1.2 (0.3)	1.3 (0.3)	1.3 (0.3)
Boys/girls	32/28	32/28	30/30
Breast fed for <6 months	24	26	32
Mean (SD) age at first episode (months)	6.6 (3.1)	7.1 (3.7)	8.2 (4.2)
History of acute otitis media:			
3-5 episodes	27	23	25
>5 episodes	33	37	35
Mean (SD) No of episodes	6.1 (2.4)	6.3 (2.2)	5.8 (2.1)
Smoking in household	30	28	25
Attending daycare	29	29	31
Middle ear fluid at assignment	15	24	14

first day without effusion. We recorded all acute symptoms, episodes of acute otitis media, and visits to a doctor. Control visits were scheduled at least every four months with an assessment of ear status and compliance and collection of the symptom diaries.

The criteria for acute otitis media were acute symptoms together with signs of middle ear inflammation (hyperaemic, opaque, or bulging ear drum) and middle ear effusion obtained in pneumatic otoscopy or otorrhoea. Each acute episode was managed with an antibiotic, usually amoxicillin for one week, and a control visit was scheduled with the study otolaryngologist within two weeks. In the case of a prolonged episode, another antibiotic was prescribed and control visits were scheduled every two weeks until the middle ear was found to be free from effusion.

Outcome measures

The primary outcome measure was intervention failure during the first six months of follow up. Intervention was deemed to have failed whenever the child experienced two acute episodes in two months or three episodes in six months, or if the child had middle ear effusion for at least two months. The secondary outcome measures were mean numbers of episodes of acute otitis media, visits to a doctor, antibiotic prescriptions, days of symptoms (rhinitis, earache, fever), and adverse effects as recorded in the diary.

Sample size and data analysis

Our primary aim was to compare the adenoideotomy and placebo groups. We expected a 50% failure rate in the placebo group. A 25 percentage point decrease in this rate in the adenoideotomy group was considered clinically relevant. Based on two tailed testing with $\alpha=0.05$ and $\beta=0.20$ we recruited 60 children in each group.

We regarded those children who did not get the allocated prophylaxis or whose prophylaxis was changed before defined failure as protocol violations. The fact that there were protocol violations in the non-surgical arms made the interpretation of the data more difficult. We analysed the data by regarding the protocol violations as both drop outs and failures.

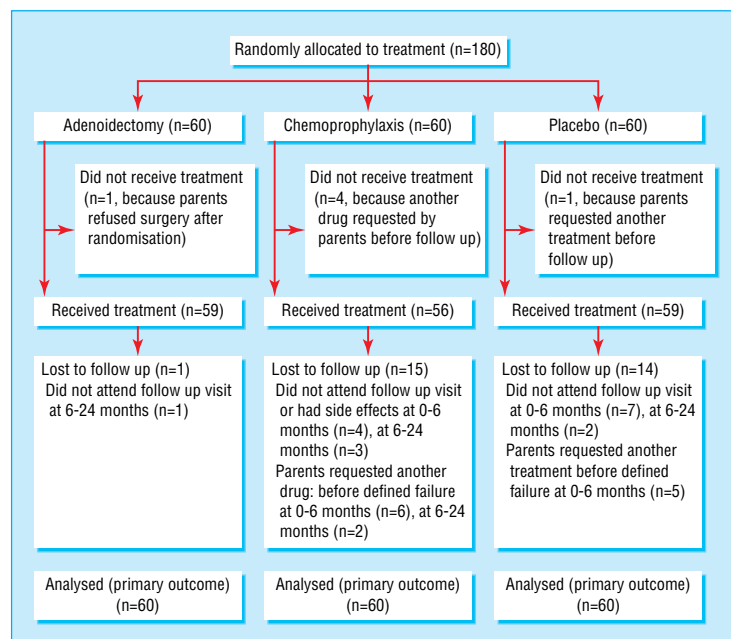
Results

Follow up of participants—Altogether 180 children were randomly allocated to one of the treatment groups (table 1). Twelve children in the adenoideotomy group underwent concurrent tympanostomy because secretory middle ear fluid was found at the operation.

Outcome at six months—Intervention failed in 25 children in the adenoideotomy group (one drop out) and in 26 in the placebo group (13 drop outs) (difference in percentage failure 10%, 95% confidence interval -9% to 29%; protocol violations regarded as drop outs) (table 2). The difference was 15% (-3% to 33%) when we counted protocol violation as failure (table 2). Intervention failed in 17 children in the sulfafurazole group (14 drop outs), showing a 18% (-2% to 38%) decrease in risk compared with the placebo group. There were no significant differences between the groups in the time to intervention failure (figure). There were no significant differences between the groups in the numbers of episodes of acute otitis media, visits to a doctor, antibiotic prescriptions, and days with symptoms of respiratory infection.

Outcome at 24 months—At 24 months treatment failure was similar in the three groups (table 2). The number of children who needed tympanostomy tubes because of persistent middle ear fluid was somewhat lower in the adenoideotomy and sulfafurazole groups than in the placebo group (6, 6, and 11 children, respectively).

Adverse effects—There were no complications in the adenoideotomy procedures (no serious haemorrhage, fever, or persistent emesis). Five children in the sulfafurazole group (two had diarrhoea, two had skin rashes, one unknown) and two children in the placebo group (one had diarrhoea, one unknown) were reported to have adverse effects.



Cumulative occurrence of failures during two year follow up in 180 children, by treatment groups (adenoideotomy, chemoprophylaxis, placebo). Failure recorded if child had two episodes of acute otitis media within two months or three episodes within six months or middle ear effusion that persisted for two months. Protocol violations regarded as drop outs. No significant differences in time to failure between groups ($P=0.22$ at 6 months; $P=0.28$ at 24 months, log rank test)

Table 2 Main outcome measures in children with recurrent acute otitis media randomised to receive adenoidectomy, sulfafurazole prophylaxis, or placebo

Time	Adenoidectomy			Sulfafurazole			Placebo	
	No*	No (%) of failures†	Difference‡ (95% CI)	No*	No (%) of failures†	Difference‡ (95% CI)	No*	No (%) of failures†
Analysis where protocol violations were regarded as drop outs								
At 6 months	59/60	25 (42)	10 (-9 to 29)	46/60	17 (34)	18 (-2 to 38)	47/60	26 (52)
At 24 months	58/60	42 (76)	0 (-17 to 17)	41/60	27 (60)	15 (-4 to 35)	45/60	35 (76)
Analysis where protocol violations were regarded as failures								
At 6 months	60/60	26 (43)	15 (-3 to 33)	56/60	27 (47)	12 (-7 to 30)	53/60	32 (58)
At 24 months	59/60	43 (76)	3 (-13 to 19)	53/60	39 (71)	7 (-9 to 24)	51/60	41 (79)

*Effective sample size (total minus drop outs)/total sample size.

†Defined as having two episodes of acute otitis media in two months or three in six months or middle ear effusion for two months.

‡Compared with placebo.

Discussion

Adenoidectomy as the primary treatment for recurrent acute otitis media in children aged under 2 years slightly diminished the risk of further acute recurrences and of persistent middle ear effusion, but the beneficial effect, if any, seems to be so small that we cannot recommend it as the primary prophylactic method in this age group. The number of children who did not receive the allocated intervention was quite small, but still some of the children in the chemoprophylaxis and placebo groups were given another prophylaxis in response to parental request or did not attend the follow up visits. The results did not change essentially even when we interpreted the protocol violations as failures. However, there were children in the placebo and sulfafurazole groups who discontinued the allocated intervention without clinically defined failure. As these children may have had more severe otitis media, this could have caused some bias by weakening the true effect of adenoidectomy. Twelve children in the adenoidectomy group received tympanostomy tubes because of secretory middle ear effusion, but we would expect the tubes to have improved the outcome rather than impaired it.

We failed to show any significant effect of long term prophylaxis with sulfafurazole in recurrent otitis media. We do not know whether this lack of effect was due to the antibiotic used because the evidence of differences in efficacy between antibiotics is controversial.⁸ The worldwide problem of multiple resistance and the poor compliance with non-surgical treatments further limit the usefulness of chemoprophylaxis.

There are two other important sources of bias that may have diminished the true effect of the treatments: firstly, the use of symptom diaries to collect the outcome, and, secondly, the possibility of misdiagnoses. We reminded the parents about the importance of recording the events, and the symptom diaries were colourful leaflets, which were collected every four months. Most of the diagnoses of otitis were made by general practitioners working in the health centres of one city and four surrounding communities who have been trained to use a pneumatic otoscope. In addition, follow up visits with the investigating otolaryngologists were scheduled after the acute episodes and regularly every four months. The number of treatment failures in our study was high, which reflects the young age of the children and success in the enrolment of children at a high risk of otitis media. In view of the baseline characteristics, our results are generalisable to the population seen in primary care in Finland.¹³

What is already known on this topic

Adenoidectomy may affect the middle ear beneficially by removing a source of infection from the nasopharynx and is often used to prevent recurrences of otitis media

Little is known about the effectiveness of adenoidectomy in preventing recurrent acute otitis media in children aged under 2 years, who are clearly at the highest risk

What this study adds

In this randomised controlled trial, compared with chemoprophylaxis and placebo, adenoidectomy as the primary treatment for recurrent acute otitis media in children aged under 2 years did not significantly diminish the risk of acute recurrences

Adenoidectomy cannot be recommended as the primary method of prophylaxis for children aged under 2 years

Conclusion

We cannot recommend adenoidectomy as the primary method of prophylaxis for recurrent acute otitis media in children aged under 2 years.

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Randomised controlled trial of effect of hands and knees posturing on incidence of occiput posterior position at birth

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Abstract

Objective To evaluate the efficacy of hands and knees position and pelvic rocking exercises on the incidence of fetal occiput posterior position at birth.

Design Multicentre randomised controlled trial.

Setting Seven maternity units in New South Wales, Australia, encompassing teaching hospitals and district general hospitals.

Participants 2547 pregnant women at 37 weeks' gestation; 1292 randomised to the intervention group and 1255 to the control group.

Intervention Hands and knees position and pelvic rocking exercises from 37 weeks' gestation until the onset of labour.

Main outcome measure Incidence of fetal occiput posterior position at birth.

Results 1046 women in the intervention group and 1209 women in the control group remained in the study until they went into labour. No significant difference existed between the groups for the incidence of occiput posterior position at birth: 105 (8.1%) women in the intervention group and 98 (7.8%) in the control group had a baby in a posterior position at delivery (difference in risk 0.3%, 95% confidence interval -1.8 to 2.4). The incidence of fetal transverse arrest was 3.4% (44 women) in the intervention group and 3.0% (38 women) in the control group (difference in risk 0.4, -1 to 1.7). No differences occurred between intervention and control groups for induction of labour, use of epidural, duration of labour, mode of delivery, use of episiotomy, or Apgar score.

Conclusion Hands and knees exercise with pelvic rocking from 37 weeks' gestation to the onset of labour did not reduce the incidence of persistent occiput posterior position at birth.

Introduction

Occiput posterior position is the most common malposition of the fetus with a vertex presentation. Persistent fetal occiput posterior position at delivery has been reported in up to 6% of all deliveries.^{1 2} It is associated with deflexion of the fetal head and an increased incidence of prolonged painful labour, operative delivery, postpartum haemorrhage, vaginal trauma, maternal infection, and neonatal morbidity.^{3 4}

Puddicombe first introduced the maternal hands and knees exercise as a way of facilitating fetal rotation antenatally in 1958.⁵ Subsequent authors have recommended the use of the hands and knees exercise as the optimal method of facilitating anterior fetal rotation.⁶⁻⁸ Evidence for this intervention is weak, however. A systematic review stressed that the hands and knees exercise cannot be recommended as an intervention until substantive evidence of its effect is available.⁹ The authors recommended that a randomised controlled trial should be conducted to guide clinical practice.

Despite limited evidence of a beneficial effect, the hands and knees exercise has been adopted in many maternity facilities in Australia. We sought to assess the efficacy of this intervention in decreasing the incidence of persistent fetal occiput posterior position at delivery.

Methods

This randomised controlled trial took place between 1999 and 2001 in seven hospitals in New South Wales, Australia, encompassing university and district hospitals. Women were eligible to participate in the study if they had a single fetus and were not booked for elective caesarean section. A midwife or research assistant approached eligible women at 36-37 weeks of gestation. All women who agreed to participate gave fully informed consent before randomisation. We calculated gestational age by using the best available data from the last menstrual period and early ultrasound scan. No ultrasonography was done specifically for the purposes of this study.

Sample size

We designed the study to have an 80% power to detect a clinically significant 50% reduction in fetal occiput posterior position at delivery from 5% to 2.5% by using a two sided method with α set at 0.05. The calculated sample size was 1968.

Participants were randomised into two groups at a remote trial centre, by a computer generated allocation sequence. Because of the nature of the intervention, participants were not blinded. Although midwives who



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