

## The homoeopathic treatment of otitis media in children – comparisons with conventional therapy

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**Abstract.** In a prospective observational study carried out by 1 homoeopathic and 4 conventional ENT practitioners, the 2 methods of treating acute pediatric otitis media were compared. Group A received treatment with homoeopathic single remedies (*Aconitum napellus*, *Apis mellifica*, *Belladonna*, *Capsicum*, *Chamomilla*, *Kalium bichromicum*, *Lachesis*, *Lycopodium*, *Mercurius solubilis*, *Okoubaka*, *Pulsatilla*, *Silicea*), whereas group B received nasal drops, antibiotics, secretolytics and/or antipyretics. The main outcome measures were duration of pain, duration of fever, and the number of recurrences after 1 year, whereby  $\alpha < 0.05$  was taken as significance level. The secondary measures were improvement after 3 hours, results of audiometry and tympanometry, and necessity for additional therapy. These parameters were only considered descriptively. The study involved 103 children in group A and 28 children in group B, aged between 6 months and 11 years in both groups. For duration of pain, the median was 2 days in group A and 3 days in group B. For duration of therapy, the median was 4 days in group A and 10 days in group B: this is due to the fact that antibiotics are usually administered over a period of 8–10 days, whereas homoeopathics can be discontinued at an earlier stage once healing has started. Of the children treated, 70.7% were free of recurrence within a year in group A and 29.3% were found to have a maximum of 3 recurrences. In group B, 56.5% were free of recurrence, and 43.5% had a maximum of 6 recurrences. Out of the 103 children in group A, 5 subsequently received antibiotics, though homoeopathic treatment was carried through to the healing stage in the remaining 98. No permanent sequelae were observed in either group.

**Key words:** acute otitis media – homoeopathy – comparative study – antibiotic therapy – clinical trial

### Introduction

In medical literature [Arola et al. 1990, Boenninghaus 1996, van Buchem et al. 1981, Federspil 1984a,b, 1991a,b, Hendrickse et al. 1988, Luckhaupt 1991, Mandel et al. 1987, Zenner 1993] we find a relatively clear therapy regimen for acute otitis media using antibiotics, decongestant nasal drops, antipyretics, and secretolytics where considered necessary. Amazingly enough, this regimen is scarcely ever questioned, especially as it is not without adverse drug reactions. Antibiotics are capable of producing a large number of adverse effects, particularly allergies, a weakness of the immunoresistant system, and intestinal colonization by pathogenic and/or mycotic organisms etc. [Stammberger and Jaske 1987].

The application of decongestant nasal drops dries up the nasal mucosa, and a habituation effect (pruivism, naphazoline rebound) may be produced. It is also known

that various types of antipyretics may have severe adverse drug reactions [Forth et al. 1996, Fülgraff and Palm 1995]. Furthermore, we also know that acute otitis media in children heals spontaneously without therapy in a large number of cases [Boenninghaus 1996]. Naturally, although the 1-time treatment of an otitis media in accordance with the above schedule is without problems, it becomes burdensome after frequent recurrences. Thus, not infrequently we find children in our practices that have been given antibiotics up to 10 times per year for their otitis media. Banz et al. [1994] found that within 6 months children susceptible to infections on average receive 5 antibacterial treatments of 7 infections. In addition, an increasing number of parents refuse antibiotics for their children.

Treatment of otitis media with homoeopathics is much older than the method termed conventional. This can be seen from the extensive homoeopathic literature dealing with otitis media [Carlston 1992, Cunningham 1933, Fowler 1880, Friese 1994a, Gabr 1988, Ghestin 1987, Kent 1993, Messer 1987, Mezger 1995, Neustaedter 1986a,b, Stäger 1899]. In fact, some of these references are over 100 years old.

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Table 1 Selecting the right homoeopathic single remedy: a short rationalization

Remedy/Potency/Form	Indications
Aconitum 30x, globules	sudden onset of condition; fever, sequel of exposure to wind
Apis mellifica 6x, globules	if the child likes ice on the ear
Belladonna 30, globules	inflamed red ear drum, often combined with reddened throat, cold extremities, high fever, throbbing pains in the ear(s)
Capsicum 6x, tablets	high fever, very pronounced pains in the ear(s)
Chamomilla 3x, globules	otitis media as a sequel to teething problems
Kalium bichromicum 4x tablets	increased temperature, yellow nasal secretion, moderate pains in the ear(s), diffuse headache
Lachesis 12x, globules	high, continuous fever, otitis media starts on the left side first, then on the right
Lycopodium 6x tablets	otitis media starts on the right side first, then on the left
Mercurius solubilis 12x tablets	pronounced sensitivity to cold (freezing sensation), otitis media combined with purulent tonsillitis, pronounced soreness in the throat, and fever
Okoubaka 3x, globules	following an unsuccessful therapy with antibiotics, intermediate administration for approximately 2 days
Pulsatilla 2x, globules	fever, pronounced pains in the ear(s), generally administered after Aconitum (see above)
Silicea 6x, tablets	if progress is protracted, if purulent otorrhea occurs, mild pains in the ear(s), generally no fever

For years now, at the ear-, nose-, and throat practice of the first author of this paper, pediatric otitis media has received as good as no antibiotic treatment and, if at all, only in cases with an extremely protracted or severe history. This is less than once a year in relation to all other patients. It was our aim to test how the results of homoeopathic treatment compare with those of conventional therapy.

Agreement of the Ethical Commission was not necessary in our case as the patients were treated in their respective practices as if no study were being carried out. So we are dealing here with a surveillance study in accordance with § 67.6 of the German Drugs Law (Arzneimittelgesetz, AMG). The children's parents received full clarification on the type, extent, and purpose of this study.

## Methods

The trial was conducted as an open nonrandomized observational study. The progress of acute otitis media in children as treated in a homoeopathic ear-, nose-, and throat practice was prospectively compared with that observed in the practices of 4 other ENT practitioners applying conventional methods. Patients were not selected on a random basis. Rather, the parents of the children concerned sought the practice of their choice for consultation (i.e. either conventional or homoeopathic).

The study involved a total of 131 children: of these, 103 (group A) attended the homoeopathic practice, compared with 28 seeking conventional therapy (group B).

Inclusion criteria were:

- at least 2 signs of an acute otitis media,
- obligatory typical tympanon,
- facultatively: ear-aches

- reduced hearing,
- fever,
- reduced general feeling,
- typical history,
- no treatment before,
- age between 6 months and 11 years,
- agreement of parents.

Exclusion criteria were:

- severe concomitant disease (immune deficiency),
- long-term therapy with steroids and other immunosuppressors,
- long-term therapy with antibiotics as prophylaxis,
- first contact in emergency service,
- living more than 30 km away from practice.

To guarantee the comparability of these children, all 5 ENT practices are situated in the outskirts of Stuttgart, i.e. outside the major urban area. All practices concerned were large (over 1,600 cases treated quarterly). As the potentialities of microscopic ear examinations, tympanometry, and audiometry are limited at established pediatricians, no pediatricians were included into the present study. Moreover, we did not find any pediatrician who was willing to participate.

The doctors were free in their choice of therapy. In other words, no influence of any kind was exerted on the conventional ENT therapists, so that they were not expected to apply antibiotics or antipyretics in every case.

Otoscopic findings and anamnestic information on fever, duration, and frequency of pain were used to describe the initial conditions.

Regular follow-up examinations after 2 weeks were carried out on the children after termination of their otitis media, these consisting, insofar as possible, of a microscopic otological examination, tympanography and sound threshold audiography (for details consult [Kruse 1997]).

The study was set to start on 15th November 1991 and to finish when a total of 100 patients had been reached in 1 of the groups. The last patient was included on 11th May 1992.

Duration of pain, duration of therapy, and the number of recurrences after 1 year were taken as the main outcome measures. Treatment differences were statistically tested with log rank tests and the Poisson test, respectively ( $\alpha = 0.05$ ). Secondary measures were improvement after 3 hours, audiometric and/or tympanometric findings, and additional therapy. These parameters only were analyzed descriptively. All analyses were done with the statistical analysis system SAS.

## Results

In group A, treatment was with various homoeopathic single remedies (Aconitum napellus 30x globules, Apis mellifica 6x globules, Belladonna 30x globules, Capsicum 6x tablets, Chamomilla 3x globules, Kalium bichromicum 4x tablets, Lachesis 12x globules, Lycopodium 6x tablets, Mercurius solubilis 12x tablets, Okoubaka 3x globules, Pulsatilla 2x globules, Silicea 6x tablets). Dosage depended in each case on the acuteness of the child's symptoms and was administered individually, for the most part every 2 hours or 3 times per day. The choice of homoeopathic remedies has been described in greater detail elsewhere [Frieze 1994a], see also Table 1. No additional medication was prescribed in this group (A). The parents were instructed not to treat their children with additional drug or non-drug treatments. This item was inquired at the follow-up examination.

In the other practices forming group B, patients received treatment with antibiotics, secretolytics, antipyretics and/or decongestant nasal drops (see Table 2). The antibiotics were dosed according to body weight as given in the instructions. This therapy went on between 6 days (minimum) and 20 days (maximum).

Table 3 provides the relevant data of the children according to group. Table 4 gives the background data of the children prior to their otitis media. The history of otitis media as observed during the study is shown in Table 5. Table 6 compares the improvements of the symptoms after consultation.

Although no analgesics were administered in group A, a median pain duration of 2 days was reported, compared with a median of 3 days in group B, whereby parents were also asked as to the presence of mild pains. This duration of pain showed no significant differences according to the log rank test. Duration of therapy in group A had a median of 4 days, this being considerably less than the 10 days in group B. This is significant in the log rank test. According to the patient histories, a total of 70.7% of the children in group A were free of recurrences, this

Table 2 Pharmaceuticals used in group B

Form	Name	
Nasal drops (= sympathicomimetic)	Xylometazoline Tramazoline	
Antibiotics	Amoxicillin Erythromycin Penicillin Trimethoprim + Sulfamethoxazol	4 children 8 children 3 children 8 children
Secretolytics	Ambroxol Acetylcysteine	
Antipyretics	Paracetamol Sodium salicylate + Paracetamol + codeine phosphate	

Table 3 Distribution data of the children investigated

		Group A (homoeopathic)	Group B (conventional)
Number		103	28
Age	median	5 years	6 years
	25th percentile	4 years	4 years
	75th percentile	6 years	8 years
Weight	median	19 kg	24 kg
	25th percentile	15 kg	19 kg
	75th percentile	21 kg	32 kg
Height	median	111 cm	118.5 cm
	25th percentile	102 cm	109 cm
	75th percentile	120 cm	134 cm
Sex	males	65 (= 63.1%)	14 (= 50%)
	females	38 (= 36.9%)	14 (= 50%)

amounting to 56.5% in group B. This is not significant in the Poisson test. Five of the children in group A changed practices and were given antibiotics, and 1 child in group B changed to a homoeopathic physician.

Whereas in group A the otitis media changed sides in 11.7% of the cases, this did not occur at all in group B. In group A, 0.41 recurrences were found per child after 1 year on average, this comparing with 0.70 in group B, at which recurrences were included.

It was found that the symptoms improve considerably more quickly under homoeopathic than under conventional therapy.

The parents were asked to assess the disease progress 3 hours after initial therapy, particularly as regards pain subsidence and the reduction of fever in their children. 30.2% reported a noticeable improvement in group A and

11.5% in group B, here meaning that, 3 hours after starting therapy, the relevant children had clearly improved in the context of freedom from pain and fever.

Table 7 shows the results from tympanometry and audiometry. Both groups do not show relevant differences in audiometric and tympanometric results. Because of age, compliance, and technical reasons tympanometry and audiometry was not possible to perform in all patients.

Serious adverse effects were not recorded neither in group A nor in group B. In group B some slight adverse effects as diarrhea or stomach-aches occurred.

Table 4 Previous history of otitis media

		Group A (homoeopathic)	Group B (conventional)
No. of times otitis media had previously occurred	median	2	2
	25th percentile	1	1
	75th percentile	6	6
Chronic aeration difficulties via the Eustachian tube		13.6%	7.1%
Previous adenotomy		15.5%	32.1%

## Discussion

For theoretical reasons, the performance of a double-blind study ought to have been aimed at here. But this is not possible for ethical reasons. It would also not have been feasible, technically, to prepare placebo forms for the antibiotics, decongestant nasal drops, analgesics, and homoeopathics without a layperson immediately recognizing the difference. The difficulties in planning this study have already been discussed [Friese 1994b].

The current type of study raises some methodological problems: due to its nonrandomized patient recruitment the results may be superimposed by some selection bias. Moreover, we cannot provide standardized measurements of blood parameters as this study was conducted in several practices of established ENT surgeons.

Nevertheless, there exist randomized clinical trials in homeopathy. Kleinen et al. [1991] provide a survey. Most of those trials studied a single remedy, but not the homeopathic therapeutic regimen as a whole. There is, for example, a series of 7 randomized placebo-controlled studies to evaluate the efficacy of *Galphimia glauca* in the treatment of pollinosis [Wiesenauer and Lüdtke 1996]. Here the therapeutic success appeared to be statistically significant reproducible.

A similar design is not appropriate in the context of our study. The parents' preference given to one of the treatment strategies will lead to a self selection of patients. Therefore, nearly no one will be willing to accept randomization between a homeopathical and an antibacterial therapy.

A difference in the number of patients was inevitable. In the course of a pretrial examination we had, in fact, found that a large number of children come to a homoeopathic ENT practice for treatment of their otitis media, compared with few coming to standard ENT practices. This is due to the fact that conventional pediatricians are generally far more likely to treat children with this condition than ENT specialists.

Parents attending a homeopath expect to be efficaciously treated without any adverse effects.

A total of 20 ENT practitioners were asked whether they would be prepared to participate in this trial, of which

Table 5 History of otitis media as observed before starting therapy

		Group A (homoeopathic)	Group B (conventional)
Duration of fever	median	0 days	0 days
	25th percentile	0 days	0 days
	75th percentile	1 day	0.6 days
Duration of pain	median	0.5 days	1.0 day
	25th percentile	0.3 days	0.2 days
	75th percentile	1.0 day	1.0 day
Side	both sides	13.6%	28.0%
	left	48.5%	36.0%
	right	37.9%	36.0%

6 finally cooperated. One of these ENT practices could not be included in the study as no child with otitis media came to it during the set time. It was extremely difficult to motivate colleagues in conventional therapy to cooperate with a homoeopathic physician, a fact which is generally known in the case of such studies [Haidvogel 1993].

Both patient populations were only partly comparable. In addition to the fact that there were fewer of them, the children in the conventionally treated group were somewhat older in total than those in the homoeopathic group. This is because more children than adults are treated in the homoeopathic ENT practice, and the total of patients is on the whole younger. There is no great difference in the otitis media found in a 4-year-old and that in a 6-year-old child. The authors were unable to find any statements in literature as to differences in progress of otitis media within this age range.

Parents of sick children expect prescribed remedies to be efficacious, irrespective of their homeopathic or allopathic nature. Therefore, a high placebo effect can be assumed in both groups. Presumably this effect is higher in the conventional group B. First of all, the number of prescribed remedies is greater (secretolytics + antipyretics + antibiotics vs. a single homeopathic remedy), the drugs are more

Table 6 Development of otitis media observed during and after therapy

		Group A (homoeopathic)	Number	Group B (conventional)	Number	p value	Test
<i>Main outcome measures</i>							
Duration of pain	median	2 days	99	3 days	28	p = 0.1186	log rank
	25th percentile	1 day		1 day			
	75th percentile	3 days		4 days			
Duration of therapy	median	4 days	98	10 days	27	p = 0.0001	log rank
	25th percentile	3 days		7 days			
	75th percentile	7 days		10 days			
Total recurrences per patient after 1 year	mean value	0.41	99	0.70	27	p = 0.3887	Poisson
<i>Secondary measures</i>							
Clear subjective improvement after 3 hours (protocol)		30.2%		11.5%			
Change of side during therapy		11.7%		0%			
No recurrence after 1 year		70.7%		56.5%			

expensive, and they often are colored and well-tasting. In contrast, homeopathic remedies are small and simply sweet. Second, conventional remedies show immediate effects like subsiding nasal mucosae, and often result in minor adverse drug reactions like diarrhea. Homeopathic remedies do show slow effects that mostly are not followed by adverse drug reactions. Third, the information that is given in the package circular of conventional remedies may raise the placebo effect in group B. In Germany, homeopathic remedies are not supplemented by similar package circulars.

With this study, however, we are able to demonstrate that homeopathy may provide a good alternative to the conventional treatment of otitis media. This can be seen from the fact that there were no statistical differences between the 2 groups in any of the outcome measures considered. This naturally does not mean that homeopathy is always able to heal every single case of otitis media. But homeopathy can be successfully applied in most cases at least, thus avoiding those forms of medication which have a large number of known adverse drug reactions.

Under homeopathic treatment, therapy was shorter and improvement was slightly more favorable. As no reliable information can be obtained from children of these ages all these data base on subjective parents' assessments. This contrasts with the popular concept that homeopathics are particularly slow in acting.

Whether it was necessary for those 5 children who received antibiotics after a homeopathic treatment to do so at all beyond the scope of this article. At any rate, it was

Table 7 Post-treatment tympanometry and audiometry after 2 weeks

	Group A (homoeopathic)	Group B (conventional)
Tympanogram in	73 children	19 children
of which tympanogram normal	77%	63%
tympanogram restricted	18%	26%
tympanogram flat	5%	11%
Audiogram in	38 children	12 children
of which audiogram w/o findings	79%	75%
audiogram pathological	21%	25%

found that 95% of the patients with acute otitis media could be treated without antibiotics. Thus, among the data obtained, this rate of spontaneous healing was highly interesting. Unfortunately, due to the fact that considerable complications are possible if no or inadequate therapy is applied [Pospiech et al. 1990], the authors were not able to test this on a practical basis for just such methodical and ethical reasons. However, on the basis of our present experience with otitis media, a spontaneous healing rate far below 95% may be assumed.

## Conclusion

It must always be the highest maxim for a physician not to apply any form of treatment which might endanger

his or her patient. This objective can only be met when the physician concerned is not only thoroughly familiar with the methods applied, but also fully aware of the risks involved. Under these premises, the homoeopathic treatment of young otitis media patients seems to be unproblematic, because the type of therapy applied here is relatively easy to learn.

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#### REFERENCES

- Arvola M, Ruuskanen O, Ziegler T, Nantö-Salonen K, Putto-Laurila A, Viljanen MK, Halonen P 1990 Clinical role of respiratory virus infection in acute otitis media. *Pediatrics* 86: 848-855
- Banz K, Schwicker D, Thomas AM 1994 Economic evaluation of immunoprophylaxis in children with recurrent ear, nose and throat infections. *Pharm Eco* 6: 464-477
- Boenninghaus H-G 1996 Hals-Nasen-Ohrenheilkunde. Springer, Berlin
- Buchem van FL, Dunk JH, van't Hof M 1981 Therapy of acute otitis media; myringotomy, antibiotics, or neither? A double-blind study in children. *Lancet* 2: 883-887
- Carlston M 1992 Belladonna. *J Am Inst Homeopath* 85: 132-137
- Friese K-H, Kruse S, Moeller H 1996 Otitis media acuta bei Kindern – Vergleich zwischen konventioneller und homöopathischer Therapie. *HNO* 44: 462-466
- Fülgraff G, Palm D 1995 Pharmakotherapie, Klinische Pharmakologie. Fischer, Stuttgart
- Gabr M 1988 Managing the child with ear infections. *Otitis media. Hahnemann Homoeopath Sand* 12: 45-46
- Ghestin F 1987 Le traitement homéopathique des otites séreuses. *Homéopathie* 4: 9-27
- Haidvogel M 1993 Klinische Studien zum Wirksamkeitsnachweis der Homöopathie. *Dtsch Apotheker Z* 133: 1697-1705
- Harsten G, Prellner K, Heldrup J, Kalm O, Kornfält R 1989a Recurrent acute otitis media. *Acta Otolaryngol* 107: 111-119
- Harsten G, Prellner K, Heldrup J, Kalm O, Kornfält R 1989b Treatment failure in acute otitis media. *Acta Otolaryngol* 108: 253-258
- Hendrickse WA, Kusmiesz H, Shelton Sh, Nelson JD 1988 Five vs. ten days of therapy for acute otitis media. *Pediatr Infect Dis J* 7: 14-23
- Kent JT 1993 Repertorium der homöopathischen Arzneimittel, Vol I-III. Haug, Heidelberg
- Kleijnen J, Knipschild P, ter Riet G 1991 Clinical trials of homeopathy. *BMJ* 302: 316-323
- Kruse S 1997 Otitis media bei Kindern – Homöopathie versus konventionelle Therapie. Inaugural-Dissertation an der Universität Tübingen. Hippokrates, Stuttgart
- Luckhaupt H 1991 Aktuelle antibiotische Behandlung der HNO-Infektionen des Kindes. *HNO* 39: 419-423
- Mandel EM, Rockette HE, Bluestone CHD, Paradise JL, Nozza RJ 1987 Efficacy of amoxicillin with and without decongestant-antihistamine for otitis media with effusion in children. *N Engl J Med* 8: 432-437
- Messer SN 1987 Homeopathic treatment of pediatric otitis media. *J Am Inst Homeopathy* 80: 15-21
- Mezger J 1995 Gesichtete Homöopathische Arzneimittellehre. Hahnemann, Stuttgart