

The effectiveness of nasal decongestants, oral decongestants and oral decongestant-antihistamines in the treatment of acute otitis media in children

Çocuklarda akut otit media tedavisinde nazal dekonjestan, oral dekonjestan ve oral dekonjestan-antihistaminiklerin etkinliği

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Objectives: The aim of this study was to evaluate the effectiveness of nasal decongestants, oral decongestants and oral decongestant-antihistamines in the treatment of acute otitis media and resolution of the middle ear effusion in children.

Patients and Methods: 355 ears of 318 children [160 boys (179 ears) and 158 girls (176 ears)] who were diagnosed to have acute otitis media and treated for it with different drug regimens were evaluated retrospectively regarding resolution of the middle ear fluid. 151 ears were treated with antibiotics and analgesics (group 1), 64 with antibiotics, nasal decongestants and analgesics (group 2), 81 with antibiotics, oral decongestants and analgesics (group 3), and 59 with antibiotics, oral decongestant-antihistamine combinations and analgesics (group 4). The children with middle ear effusion were followed up for three months.

Results: Group 1, 2, 3 and 4 had persistent middle ear effusion and the presence of middle ear effusion was 27.2%, 18.8%, 25.9%, 28.8% at the 1st month and 5.8%, 0%, 0% and 5.9% at the end of the 3rd month, respectively. At the end of the third month, there was no significant difference between the groups regarding the resolution rates of the middle ear fluids in the antibiotic group and decongestants groups ($p>0.05$).

Conclusion: We do not recommend the use of decongestants and antihistamines in the treatment of acute otitis media as they do not change the natural course of the disease.

Key Words: Decongestants, nasal; middle ear, fluid/inflammation; respiratory tract infection.

Amaç: Bu çalışmada çocuklarda akut otit media tedavisinde ve orta kulak efüzyonunun çözülmesinde nazal dekonjestan, oral dekonjestan ve oral dekonjestan-antihistaminik kombinasyonu içeren ilaçların etkinliği değerlendirildi.

Hastalar ve Yöntemler: Akut otit media tanısı konan ve farklı ilaç uygulanarak tedavi edilen 318 çocuğun [160 erkek (179 kulağı) and 158 kız (176 kulağı)] toplam 355 kulağı orta kulak sıvısının çözülmesine göre geriye dönük olarak incelendi. Kulakların 151'i yalnızca antibiyotik ve analjezik (grup 1), 64'ü antibiyotik analjezik ve nazal dekonjestanla (grup 2) 81'i antibiyotik, analjezik ve oral dekonjestanla (grup 3), 59'u ise antibiyotik, analjezik ve oral dekonjestan-antihistaminik kombinasyonu (grup 4) içeren ilaçlarla tedavi edilmişlerdi. Orta kulak sıvısı olan çocuklar üç ay takip edildi.

Bulgular: Grup 1, 2, 3 ve 4'de inatçı orta kulak sıvısı vardı ve orta kulak sıvısının varlığı birinci ayın sonunda gruplara göre sırasıyla %27.2, %18.8, %25.9 ve %28.8, üçüncü ayın sonunda ise sırasıyla %5.8, %0, %0 ve %5.9 idi. Üçüncü ayın sonunda orta kulak sıvısının çözülmesi açısından yalnızca antibiyotik kullanan ve ilaveten dekonjestanların verildiği gruplar arasında anlamlı bir fark yoktu ($p>0.05$).

Sonuç: Akut otit media tedavisinde hastalığın doğal seyrinde herhangi bir değişikliğe neden olmadıkları için dekonjestan ve antihistaminik içeren ilaçların kullanılmasını önermiyoruz.

Anahtar Sözcükler: Dekonjestan, nazal; orta kulak, sıvısı/enflamasyonu; solunum yolu enfeksiyonu.

Acute otitis media (AOM) continues to be a widespread health problem in childhood, although most cases resolve spontaneously.^[1-4] Acute otitis media usually occurs secondary to an upper respiratory tract infection (URTI), and its incidence increases during the winter.^[1,4] An AOM attack usually begins a few days after the onset of the URTI.^[5,6] There are often signs of rhinitis such as nasal obstruction and discharge, and cough caused by the URTI.^[1] Decongestants and antihistamines can be recommended in the treatment of the AOM and URTI,^[3,7,8] despite the fact that they are not proven to be effective in AOM.^[3,7,9-11] In this study, we aimed to retrospectively analyze the effects of decongestants and antihistamines on recovery from AOM.

PATIENTS AND METHODS

Medical records of 487 children who were treated for AOM between February 2003 and March 2008 in the tertiary referral center were evaluated retrospectively. Of these children, 179 had purulent otorrhea and perforation of the tympanic membrane, and they were therefore excluded from the study. Thus, 355 ears of the remaining 318 children [160 boys (179 ears) and 158 girls (176 ears)] who had AOM without a tympanic membrane perforation.

The patients were divided into four groups according to the applied treatment regimen: Of 355 ears, 151 were treated with oral antibiotics and analgesics (group 1); 64 were treated with oral antibiotics, analgesics and topical decongestants (group 2); 81 were treated with oral antibiotics, analgesics and oral decongestants (group 3); and 59 were treated with oral antibiotics, decongestants, antihistamines and analgesics (group 4; Table 1).

Diagnosis of the AOM was made according to the otoscopic examination (hyperemic and bulging tympanic membrane) and occurrence of acute signs of infection (otalgia, fever, irritability). The children were followed up by otoscopic examination and were examined on the 3rd day (2nd visit), the 5-7th day (3rd visit), and on the 10th day (4th visit). If the middle ear effusion persisted, then the children were followed up over three months and examined between the 25th day-1st month (5th visit); in the 2nd (6th visit) and 3rd months (7th visit). Otoscopic and tympanometric examinations were performed in the long term follow-up to assess the presence of effusion in the middle ear. Type B and C2 tympanograms were accepted as the presence of the middle ear effusion on the tympanometry.^[2,4]

Statistical analysis

Statistical Package for the Social Sciences 15.0 for Windows (SPSS Inc., Chicago, Illinois, USA) and GW-BASIC 3.22 programs were used for the statistical comparisons. A Chi-square test was used to compare the recovery rates of the groups from the AOM.

RESULTS

The ages ranged from 1 to 13 years (mean 6.04 years; 6.19 years for boys and 5.88 years for girls). The mean ages in group 1 through 4 were 5.4 years (5.7 for boys, 5.0 for girls), 7.1 years (7.3 for boys, 6.7 for girls), 7.4 years (6.4 for boys, 8.2 for girls) and 5.1 years (6.1 for boys, 4.3 for girls), respectively. There was no significant difference between the ages of the children in four groups ($p>0.05$).

Table 2 shows the healing ratios according to the resolution of the middle ear effusion for all groups. Also, Table 3 presents the percentages of healing in the AOM according to the gender.

There was a statistically significant difference between the 1st visit and the visits 2, 3, 6 and 7, as the recovery rates from AOM increased in the follow-up in all groups ($p<0.001$). For boys, there was a statistically significant recovery at visits 2, 5, 6 and 7 both in groups 1 and 2 ($p<0.001$). In addition, boys had a statistically significant improvement between the 1st visit and the visits 5, 6 and 7 in group 3; and visits 2, 3, 6 and 7 in group 4. Girls had a statistically significant increase in the recovery rates at visits 2, 6 and 7 in group 1, and at visits 2, 3, 6 and 7 in the other groups ($p<0.001$).

There was a significant increase in the recovery from AOM in group 3 ($p<0.001$) at the 2nd visit, without a significant difference between the boys and girls.

In comparison to the other groups, there was a significant recovery in group 1 at visit 3 ($p<0.001$); ($p<0.001$ for boys and $p<0.001$ for girls at visit 3).

There was a significant decrease in the resolution of effusion in group 2 ($p<0.001$) at visit 4. Also, this decrease was equal between the males ($p<0.05$) and the females ($p<0.001$).

None of the treatment groups showed a significant difference at visits 5, 6 and 7 regarding to healing of the AOM.

The healing rate of the AOM increased insignificantly at visits 4 and 5 for all patients. Also,

Table 1. The use of drugs according to groups

Drugs	Dosage	Group 1 (n)	Group 2 (n)	Group 3 (n)	Group 4 (n)
Amoxicillin/clavunate	45/6.4 mg/kg/day in two divided doses for 10 days	127	47	76	46
Azithromycin	10 mg/kg/day for 3 days	13	–	4	8
Cefuroxime-axetil	30 mg/kg/day in two divided doses for 10 days	16	17	–	7
Xylometasine HCl (5 mg/ml)	2 or 3 drops/day, only 3 days	–	34	–	–
Oxymethazolin 0.25 mg/ml	2 or 3 drops/day, only 3 days	–	30	–	–
Pseudoephedrine HCl 30 mg/5 ml	90 mg/day in three doses in over 6 age, 45 mg/day in three doses in under 6 age	–	–	81	–
Pyrilamine maleate 6.25 mg+phenylephrine HCl 5 mg+acetaminophen 120 mg/5 ml	30 ml/day in three doses in over 6 age, 15 ml/day in three doses in under 6 age	–	–	–	24
Chlorpheniramine maleate 1 mg+phenylephrine HCl 2.5 mg+acetaminophen 160 mg/5 ml	30 ml/day in three doses in over 6 age, 15 ml/day in three doses in under 6 age	–	–	–	31
Pseudoephedrine HCl 30 mg+triprolidine HCl 1.25 mg/5 ml	30 ml/day in three doses in over 6 age, 15 ml/day in three doses in under 6 age	–	–	–	4

n: Number of the ears; HCl: Hydrochloric acid.

there was a significant increase in respect to the improvement of the AOM at visits 6 and 7 in all groups.

DISCUSSION

The Eustachian tube (ET) plays a very important role in the normal middle ear functions including the ventilation, protection, and clearance of the middle ear.^[7,12,13] The incidence of the AOM is at its highest in wintertime and lowest in the summertime, and it shows a parallelism with the occurrence of the viral URTI.^[1,4] The upper respiratory tract infection causes a congestion of the nasal and nasopharyngeal mucosa and around the nasopharyngeal orifice of the ET. This condition also leads to a dysfunction of the tube and the dysfunctional

ET plays a role in the development of the AOM. In fact, this is considered to be the most important factor in the development of the latter.^[1,12]

Decongestants are widely used because of their effects on nasal congestion^[3,14] as well as the improvement they provide in the function of the ET.^[7] However, the effectiveness of decongestants or decongestant-antihistamine combinations has not been proven in AOM.^[3,9-11,15]

In this study, there were differences between the groups regarding the recovery from AOM. Groups 2, 3 and 4 had higher recovery rates at visit 2, whereas the recovery rates in groups 2 and 3 remained same at visit 3 (Table 2). The recovery rate was relatively lower in groups 2, 3 and 4 at visits 3

Table 2. Recovery rates of the groups

	Group 1 (rr %)	Group 2 (rr %)	Group 3 (rr %)	Group 4 (rr %)
2 nd visit	3.31	7.81	18.51	8.47
3 rd visit	39.73	7.81	18.51	16.94
4 th visit	53.64	17.18	49.38	44.06
5 th visit	72.84	81.25	74.07	71.18
6 th visit	84.76	90.62	93.82	84.74
7 th visit	96.68	100	100	96.61

rr: Recovery rate.

Table 3. Gender specific recovery rates

	Group 1		Group 2		Group 3		Group 4	
	Males (%)	Females (%)	Males (%)	Females (%)	Males (%)	Females (%)	Males (%)	Females (%)
2 nd visit	–	9.2	–	17.4	30.3	10.4	–	14.7
3 rd visit	22	61.5	–	17.4	30.3	10.4	–	29.4
4 th visit	41.8	69.2	17.1	17.4	36.4	58.3	24	58.8
5 th visit	69.7	76.9	82.8	79.3	51.5	89.6	84	61.7
6 th visit	77.9	95.4	82.8	100	84.8	100	88	82.3
7 th visit	94.2	100	100	100	100	100	100	94.1

and 4, although that was not the case in the 2nd visit. Group 2 showed a significantly decreased recovery rate at visit 4 compared to the other groups; however, there was no difference in the recovery rates at visits 6 and 7 in any of the groups. Unlike the other groups, group 1 had a regular healing rate.

Flynn et al.^[3] emphasized that the use of decongestants and antihistamines had no benefit in the recovery rates and prevention of surgery or complications in AOM. Moreover, there was an increased risk of side effects in the patients who used oral decongestants. van Heerbeek et al.^[7] also reported that topical decongestants had no effect on the tubal function in children. The authors did not observe any improvement in the ET function with the use of topical decongestants. Schnore et al.,^[9] Bhambhani et al.^[10] and Thomsen et al.^[11] have also not found any therapeutic effect of decongestants and antihistamines on the recovery and prevention of the complications of AOM. Chonmaitree et al.^[15] reported that the use of antibiotics with antihistamines does not contribute to the outcome of AOM. Also, there was a prolonged duration of the middle ear effusion in their study. A recent study reported by Johnson et al.^[16] did not observe any effect of intranasal phenylephrine-surfactant therapy on otitis media with effusion in an animal model. In our study, we also found that these drugs have no effect on the recovery from AOM.

According to some previous studies, boys have a significantly higher incidence of AOM and are more prone to persistent middle ear effusion than girls.^[2,17,18] The present study showed that boys have a smaller resolution rate of the middle ear effusion compared to girls.

A meta-analysis by Rosenfeld and Kay^[19] showed that an untreated AOM had a 59% resolution by one month and 74% resolution by three months. The authors emphasized that most children without

risk factors for AOM and over two years of age will recover without antibiotherapy. In our study, the rate of persistent middle ear effusion in groups 1-4 were 27.2%, 18.8%, 25.9%, 28.8% at the 1st month and 5.8%, 0%, 0% and 5.9% at 3rd months, respectively. The results show a better resolution rate compared to the untreated cases of AOM in children.

In the present study, resolution of the middle ear effusion was considered as recovery from the AOM. The signs of infection almost improve in a few days,^[20,21] but the middle ear fluid may persist for months.^[2,19] Most of the previous studies related to the effectiveness of nasal decongestant drops, oral decongestants or oral decongestant-antihistamines did not evaluate the recovery from AOM based on the resolution of the middle ear fluid.^[9-11] Only, this last study evaluated the effectiveness of antihistamines in the resolution of the middle ear fluid.^[15]

In conclusion, decongestants and antihistamines are not beneficial in the treatment of AOM and they may even delay the resolution of the effusion in the middle ear. There is no difference between the groups regarding the resolution rates of the middle ear fluid during the three-month period. We do not recommend the use of decongestants and/or antihistamines in the treatment of AOM.

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