TREATMENT OF ACUTE OTITIS MEDIA IN CHILDREN (SYSTEMIC ANTIBIOTIC AND TOPICAL NASAL DECONGESTANT VERSUS SYSTEMIC ANTIBIOTIC ALONE)

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ABSTRACT

Background: decongestants whether systemic or topical nasal are widely used in the treatment of acute otitis media but there is still controversy about their effectiveness. The aim of this study is to evaluate the effectiveness of topical nasal decongestants in the treatment of acute otitis media and their role in the resolution of middle ear effusion after acute otitis media attack.

Subject and Methods: The current study involved 100 children ranging from 4-12 years of both sexes with acute otitis media that need antibiotics in treatment and the study done in Rizgary teaching hospital in Erbil during the period of 2015-2017. Patients subsequently divided into two groups for treatment. Group A treated with oral co-amoxiclav, oral paracetamol, and topical nasal xylometazoline drop. Group B treated with the same antibiotic but without topical nasal xylometazoline drop. The children are followed up three months by 5 visits; in the first and second follow up visits the children are examined clinically for the improvement in the signs and symptoms of acute infection. In the last three visits the children are followed up for the resolution of middle ear effusion by otoscopic examination and tympanometry test. Pure Tone Audiometry (PTA) test done for children in the first and fifth visits, to know the hearing gain between the two visits and the difference between group A and group B.

Results: The mean age $\pm$ SD of the children were 7.26 $\pm$ 2.4 years, ranging from 4 to 12 years. The median was 7 years. 58% of the patients were boys and 42% were girls.

In the first visit, we found better results in group A that was near significant for pain relief (p=0.067). During subsequent visits we found good resolution in both groups with non significant better results in group A.

Conclusions: there is no significant benefit from the use of topical nasal decongestant in the treatment of AOM.

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Keywords: Acute otitis media, treatment, nasal decongestant, middle ear effusion.

Acute otitis media (AOM) is a common presenting illness encountering general practitioners, pediatricians, and otolaryngologists. Predominantly acute otitis media is a childhood disease, but also occurs in adults. Most of the children suffer from at least one attack of AOM during their life[1,2]. Acute otitis media can be defined as sudden onset of signs and symptoms of inflammation in the middle ear cleft mucosa associated with middle ear

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effusion[2].

The physiological importance of Eustachian tube (ET) for middle ear is pressure regulation, protection, and drainage. The Eustachian tube is shorter, wider, and more horizontal in children, which is one of the reasons that AOM is more common in children [2, 3]. AOM is common in cold seasons (especially in autumn and winter) and commonly is following an attack of Upper Respiratory Infections (URTI)[2,4].URTI causes congestion of the nasal and nasopharyngeal mucosa and around the nasopharyngeal orifice of the ET, this leads to a poorly functional tube and the dysfunctional ET plays a role in the development of the AOM [4,5], so decongestants are commonly used because of their effects on nasal congestion, and their role in the function of the ET [3, 6],and that is the aim of the study to evaluate the effect of topical nasal decongestant in the treatment of AOM and whether they have a role in the resolution of middle ear effusion.

Topical nasal decongestants are fast-acting drugs which are potently effective for the reduction of nasal congestion. Xylometazoline (Imidazolines group) achieve their decongestive effect via activation of α-adrenergic receptors, resulting in vasoconstriction of the blood vessels and, consequently, resumption of nasal airflow [7, 8].The diagnosis of AOM is usually difficult; there are no standard criteria and no specific laboratory tests [9]. The clinical signs of highest predictive value are bulging eardrum, clouding of the eardrum, reduced eardrum mobility, and hearing loss these signs indicate middle ear inflammation and effusion [5, 9]. Pneumatic otoscope and tympanometry can be used to confirm middle ear effusion [5, 9, 10].

Usually, AOM is a self-limited disease, in most instances it resolves spontaneously; however, some cases need antibiotics. Decongestants and antihistamines can be prescribed in the treatment of AOM, although, they are not proven to be effective[2, 4,5].

PATIENTS AND METHODS

This study involved 100 children ranging from 4-12 years diagnosed to have acute otitis media that need antibiotics in treatment according to American Academy of Pediatrics (AAP) and American Academy of Family Physician (AAFP) guidelines 2013 (Antibiotics should be prescribed for bilateral or unilateral AOM in children aged at least 6 months with severe signs or symptoms of moderate or severe otalgia or otalgia for 48 hours or longer or temperature 39°C or higher).

All the cases have been taken in ENT and head and neck surgery department at Rizgary teaching hospital in Erbil city/Iraq. The children included in this study were taken during the duration of 1ST November 2015 to 1st April 2017 in cold seasons in order to have the same environmental effect. Patients then divided into two groups for treatment and the first child is randomly chosen for the group A.

Group A; treated with oral amoxicillin-clavulanate (amoxiclav)(80-90 mg/kg/day of amoxicillin component and 6.4 mg/kg/day of clavulanate component, in two divided doses),oral paracetamol 10mg/kg/day in three divided doses, and topical nasal xylometazoline drop 0.05% 2 drops in each nostril 2 two times per day for 7 days duration.

Group B; treated with the same antibiotic regime and paracetamol analgesia but without topical nasal xylometazoline drop. Both groups treated for 10 days duration[2].

Diagnosis of the AOM made by signs and symptoms of acute infection (otalgia, fever, irritability) and according to the otoscopic examination (erythema, bulging tympanic membrane TM and middle ear effusion). Children with AOM and otorrhia excluded from the study.

The children are followed up three months by 5 visits; in the first and second follow up visits (after3 days and 1 week of treatment respectively) the children are examined clinically for the improvement in the signs and symptoms of acute infection(pain/irritability, fever, congestion of tympanic membrane and middle ear effusion). In the 3rd, 4th, and 5th visits (2 weeks, 1month, and 3 months respectively) the children are followed up for the resolution of middle ear effusion by otoscopic examination and tympanometry test. Type B and type C tympanogram considered persistence of middle ear effusion[11].

Pure tone audiometry (PTA) test done for children in the 1st and 5thvisits, to know the hearing gain between the two visits and the difference between group A and group B.

Inclusion criteria: children 4-12 years old with unilateral or bilateral AOM that need systemic antibiotics.

Exclusion criteria: Acute otitis media that does not need antibiotics, age less than 4 years and more than 12 years**,** recurrent otitis media, syndromic child, immunocompromised patients**,** children allergic to penicillin**,** and patients received amoxiclav in the last month.

STATISTICAL ANALYSIS

Data were analyzed using the Statistical Package for Social Sciences (SPSS, version 22).Chi square test of association was used to compare proportions. Fisher's exact test was used when the expected count of more than 20% of the cells of the table was less than 5. A p value of ≤ 0.05 was considered statistically significant.

RESULTS

Two groups of children participated in the study, 50 children in each group. Group A was given an antibiotic (AB) and a topical nasal decongestant (xylometazoline), and Group B was given antibiotic only. The mean age $\pm$ SD of the children were 7.26 $\pm$ 2.4 years, ranging from 4 to 12 years. The median was 7 years. The mean age $\pm$ SD of group A was 7.44 $\pm$ 2.54, and that of Group B was 7.08 $\pm$ 2.27 years (p= 0.457).

Table 1, shows that around half (45%) of the whole sample aged 4-6 years, with no significant difference in the age distribution of the two groups (p = 0.730). The table shows also that 58% of each group were males (p =1).

Table 2, shows that in the first visit, there is improvement in all children, but 41% of the whole sample had mild pain or irritability, 50% of group Bcompared with 32% of group A. The difference was close to the significance level (p = 0.067). Regarding fever, 20% of group B still havelow grade fever(less than 39^0C) compared with 10% of group A (p = 0.161). The table shows also that 94% of group Bhave tympanic membrane congestion compared with 92% of group A (p = 1). All the patients have middle ear effusion.

Table 1: Difference in clinical and serological parameters in anti-CCP2 seropositive versus anti-CCP2 seronegative patients Age and gender distribution of the study groups.

	Group A		Group B		Total		
Age	No. of examined	(%)	No. of examined	(%)	No. of examined	(%)	P
4-6	21	(42)	24	(48)	45	(45)	
7-9	17	(34)	17.0	(34)	34	(34)	0.730
10-12	12	(24)	9	(18)	21	(21)	
Gender							
Male	29	(58)	29	(58)	58	(58)	1.000
Female	21	(42)	21	(42)	42	(42)	
Total	50	100	50	100	100	100	

***p*- Value ≤ 0.05 was considered significant by unpaired t-test (*) and z-test of one proportion (**), NS=non-significant**

Table 2: Symptoms and signs during first follow up visit after treatment each group

	Group A N = 50		Group B N = 50		Total N = 100		
Signs & symptoms	No.	(%)	No.	(%)	No.	(%)	p
Mild Pain	16	(32)	25	(50)	41	(41)	0.067
Low grade Fever	5	(10)	10	(20)	15	(15)	0.161
Tympanic membrane congestion	46	(92)	47	(94)	93	(93)	1†
Middle ear effusion	50	(100)	50	(100)	100	(100)	NA

Note: The first visit is on the third day after treatment.NA: Not applicable.
†By Fisher's exact test.

During the second visit (Table 3) the pain and fever disappeared, but 32% of each of the groups had tympanic membrane congestion, and middle ear effusion. In group A 19 patients were free of effusion (recovery rate 38%) and group B 13 patients had type Atympanometry (recovery rate 26%). The correlation between them is not significant p-value= 0.198 and the recovery rate of the whole sample during the second follow up visit is 32%.

Table 3: SymptomsandSigns during secondfollow up visit after treatment by group (recovery rate)

	Group A N = 50		Group B N = 50		Total N = 100		
Signs & symptoms	No.	(%)	No.	(%)	No.	(%)	P
No Pain	50	100	50	100	100	100	NA
No Fever	50	100	50	100	100	100	NA
No Tympanic membrane congestion	19	(38)	13	(26)	32	(32)	0.198
No Middle ear effusion	19	38	13	26	32	32	0.198

Note: The second visit is one week after treatment. NA non applicable

Table 4, shows that the recovery rates (resolution of middle ear effusion by otoscopic examination and tympanometry) of the whole sample during the third, fourth, and fifth visits were 75%, 86%, and 94% respectively. No significant differences were detected in the recovery rates between the two study groups during the third visit (p = 0.488), fourth visit (p = 0.564), and fifth visit (p = 0.678).

Table 4: Resolution of the middle ear effusion (Recovery rates) of the two study groups.

	Recovery rate Group A N = 50		Recovery rate Group B N = 50		Total N = 100		
Visits	No.	%	No.	%	No.	%	p
Third	39	78	36	72	75	75	0.488
Fourth	44	88	42	84	86	86	0.564
Fifth	48	96	42	92	94	94	0.678*

*By Fisher's exact test

Table 5, shows that the mean hearing gain (difference between the PTA done during the 1st follow up visitand PTA of the 5th follow up visit) in group A was 11.1 dB, and that of group B was 10.9 dB (p = 0.840).

Table 5: Hearing gain of the two study groups by pure tone audiometry

Group	N	Mean hearing gain dB	(SD)	p
Group A	50	11.100	(5.080)	0.840
Group B	50	10.900	(4.812)	

DISCUSSION

In this study examined 100 children (16 bilateral) with AOM, age ranging from 4-12 years old. All the cases were with the same severity of AOM, all have been taken in the same season (cold seasons), and all of them treated with the same antibiotic, this is first study in Erbil city. The mean age ± SD of the children were 7.26 ± 2.4 years. The median was 7 years. 58% of the children were boys and 42% girls. According to the previous studies done by Sipilä *et al*, 1987 and Teele *et al*, 1989 there is significant higher incidence of AOM in boys and are more prone to persistent middle ear effusion[12,13], in this study we found no significant difference between the two genders and similar results were found by Eyibilen *et al*, 2009[4].

In the first visit we found better results with the group A especially for pain. The difference between the two groups was near significant level (p = 0.067) for pain but far from significance for other signs and symptoms and the recovery rate was very low in both group. The study done by 4foundsignificant better outcome for group A during first visit, but also concluded that in long term duration there is no difference from the use of decongestants and antihistamines in the treatment of AOM. There is an old study done by Schnore *et al*, 1986[14], they found no difference in relief of pain between the two groups. In the 2nd follow up visit pain and fever disappeared from both groups but congestion and effusion persist in some children and no statistical benefit found from decongestant although the results were better in decongestant group, and the recovery rate in this visit was 32% (38% in group **A)** and 26% in group **B)** in contrast

to the study done by Eyibilen *et al,* 2009[4], which they found significant decrease in the recovery rate of the decongestant group during 2nd visit (7.81% group A and 39.7% group B) that may be due to their retrospective results of different antibiotic use and different severity of AOM.

In the 3rd, 4th, and 5thfollow up visits we followed the cases for the resolution of middle ear effusion and we found little benefit in the group A, but were not significant statistically. The study done by Eyibilen *et al,* 2009[4] found better results in group B during 3rd visit but after that in the 4th and 5th visits the results become better in group A. Heerbeek *et al,* 2002 reported that topical decongestants had no effect on the ET function in children[3]. They did not notice any improvement in the ET function with the use of topical decongestants in children with ventilation tube. Flynn *et al,* 2004 revealed that the use of decongestants and antihistamines had no benefit in the recovery rates and prevention of surgery or complications in AOM[15]. Moreover, there was a 5-8 fold increased risk of side effects for those receiving an intervention. The results of Coleman *et al,* concluded that decongestant and antihistamines if added to the treatment of AOM do not improve the recovery[16]. While the study done by Johnson *et al,* 2008 did not observe any effect of intranasal phenylephrine-surfactant therapy on otitis media with effusion[17]. Griffin and Flynn, 2011 emphasized that there is no benefit and some harm from the use of antihistamines or decongestants alone or in combination in the management of otitis media with effusion[18]. We also discovered that there is no significant difference from the use of topical nasal decongestant in the treatment of AOM.

In the present study we also did PTA for the children in the 1st and 5th follow up visits to know the mean hearing gain of each group after 3 months and to support our results. We didn't find any difference between the two groups mean hearing gain in group A was 11.1 dB, and that of group B was 10.9 dB (p = 0.840), and this is not done in any study previously.

Rosenfeld and Kay, 2003 reported that an untreated AOM had a 59% resolution by one month and 74% resolution by three months[19]. The authors found that most children without risk factors for AOM and above two years old will recover without antibiotic therapy. Renko *et al,* 2006 reported better results with antibiotherapy, they showed that 69% of children with AOM treated with different antibiotics were free of middle ear effusion within 2 weeks[20], in our study after 2 weeks 75% of children were free of middle ear effusion(78% in group A and 72% in group B) and after one month 86% of the patients had type A tympanogram (88% group A and 84% group B), so we found better resolution with antibiotics in compares to Renko *et al,* 2006 results although almost all our cases were sever AOM.

In conclusion there is no long term benefit from the use of topical nasal decongestant in the treatment of AOM.

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پوختە

چارەسەریا هەودانا گوهێ ناڤەکی ل زارۆکان (ئەنتیبایوتیک و دەرمانێت دژی ئێڤیتینێ یێن دڤنێ بەرامبەر ئەنتیبایوتیک بتێ).

پێشەکی و ئارمانج: دەرمانێت دژی ئێڤیتینێ چ ب رێکا دەڤی یان دفنێ بشێوەیەکی بەربەلاڤ دهێتە ب کار ئینان بو چارەسەریا هەودانا گوهێ ناڤەکی، لێ تا نها گوتوبێژ هەیە ل سەر گرنگیا رولێ وان.
بو هەلسەنگاندنا رولێ دەرمانێن دژی ئێڤیتینێ یێن دڤنێ بو چارەسەریا هەودانا گوهێ ناڤەکی و نەمانا ئاڤا گوهێ ناڤەکی پشتی هەودانێ.

رێکێن ڤەکولینێ : ئەڤ ڤەکولینە هاتە کرن ل دوو وەرزێن زڤستانێ یێن ساڵێن (٢٠١٥ و ٢٠١٦)،ئەڤە ڤەکولینەکا جیاوازیێ یە کو تێدا سەد زاروک هاتنە وەرگرتن یێن ژیێن وان (٤ تا ١٢) ساڵی کو هەودانا توند یا گوهێ ناڤەکی هەبوو و پێتڤی ئەنتیبایوتیکا بوون بو چارەسەریێ. ئەڤ نەخوشە هاتنە دەبەشکرن بو دوو گرووپا:گرووپێ (آ) هاتێنە چارەسەرکرن ب (ئەنتیبایوتیک دگەل دەرمانێن دژی ئێڤیتینێ یێن دڤنێ).گرووپێ (ب) هاتێنە چارەسەرکرن ب (ئەنتیبایوتیک) ب تنێ.دیڤچوونا ڤان نەخوشا هاتە کرن بو ماوێ سێ هەیڤا ب شێوێ پێنج سەرەدانادا ،د ڤان سەرەدانادا نەخووش هاتنە پشکنینکرن ژ بو هەبوون یان نەبوونا نیشانێن هەودانا گوهێ ناڤەکی، هەروەسا هەبوون یان نەبوونا ئاڤا گوهێ ناڤەکی .

ئەنجام: تێکرایێ ژیێ زاروکان(٧,٢٦ ±٢,٤)ساڵ،٥٨٪ کور بوون و ٤٢٪ کچ بوون.ژیێ ناڤنجی ٧ ساڵ بو. سەرەدانا ئێکێ یا دیڤچوونا گرووپێ (آ) دا دیاربوو ب شێوەکێ بەرچاڤ ئێشان نەمابوو (p=٠,٠٦٧). لێ د سەرەدانانێن دی دا چ جیاوازییەکا بەرچاڤ نەبوو دناڤ بەرا هەردوو گرووپادا.

دەرئەنجام: دەرمانێن دژی ئێڤیتینێ یێن دڤنێ چ رولەکێ گرنگ نەبوو بو چارەسەریا هەودانا گوهێ ناڤەکی یا توند.

الخلاصة

علاج التهاب الاذن الوسطى الحاد في الاطفال (استعمال المضادات الحيوية و مضادات الاحتقان الانفية مقابل المضادات الحيوية فقط)

الخلفية والأهداف: مضادات الاحتقان سواء" عن طريق الفم والانف تستعمل بشكل واسع في علاج الالتهاب اللأذن الوسطى لكن هناك جدال حول تأثيرها .
لتقيم تأثيرمضادات الاحتقان الانفية في علاج الالتهاب اللأذن الوسطى الحاد ودورها في ازالة تدفق الاذن الوسطى بعد الالتهاب.

طرق البحث: هذه الدراسة تضمنت اخذ 100 طفل ممن اعمارهم تتراوح بين (4-12)سنةومن كلتا الجنسينو يعانون من الالتهاب اللأذن الوسطى الحاد ويحتاجون للمضادات الحيوية لغرض العلاج.تمت هذه الدراسة في مستشفى الرزكاري في اربيل بين (2015-2017), ثم تم تقسيم هؤلاء المرضى الى مجموعتين لغرض العلاج , المجموعة (أ) تم معالجتهم بمضادات الحيوية عن طريق الفم و مضادات الاحتقان الانفية.المجموعة (ب) تم معالجتهم بنفس المضاد الحيوي باستثناء مضاد الاحتقان الانفي.ثم تابعنا المرضى في خمس زيارات لمدة ثلاثة أشهر، وخلال المتابعات فحصنا المرضى سريريا لمراقبة التحسن في اعراض وعلامات الالتهاب وكذلك لمراقبة تحسن في تدفق الاذن الوسطى باستخدام جهاز الاوتوسكوب وتخطيط السمع.

النتائج: معدل العمر كان (٧,٢٦± ٢,٤)سنة ،متوسط العمر كان سبع سنوات، ٥٨٪ ذكور و ٤٢٪ اناث. تبين في الزيارة الاولى من المجموعة(أ) تحسن كبير في الالم ولكن لم يكن مهما احصائي (p = ٠,٠٦٧). خلال الزيارات اللاحقة لم يكن هناك اختلاف ملحوض في التحسن بين المجموعتين.

الاستنتاجات: لم نلاحظ دور مهم لمضادات الاحتقان الانفية في علاج الالتهاب اللأذن الوسطى الحاد.