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The Improvement Rate of Otitis Media with Effusion in Children under Gastroesophageal Reflux Therapy

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Abstract

Background: Otitis media with effusion (OME) is one of the most common causes of hearing impairment in children and if not treated, can result in many complications. It seems that gastroesophageal reflux disease (GERD) plays an important role in OME.

Aim: to determine the improvement rate of otitis media with effusion in children under gastroesophageal reflux therapy.

Methods: The study was conducted as a retrospective study. Medical records of forty children with OME were reviewed. Some patients were treated with antibiotic and anti-reflux. The others were managed only with antibiotic. All patients were treated for 2 weeks. Two weeks after treatment complement, the response rates of patients were determined by clinical examination and tympanometry. Type A, C, and B tympanometry were interpreted as a good, moderate, and no response respectively. Pre-and post-treatment conditions were compared.

Results: Overall 78 ears (40 in in the anti-reflux therapy group and 38 in the other group) were enrolled in the survey. The overall good, moderate, and no responses to medical treatment were 35.9%, 35.9%, and 28.2%, respectively. Among 40 ears in the anti-reflux therapy group, the rates of good, moderate, and no response were 50%, 37.5%, and 12.5%, respectively. These rates in 38 other ears were 21%, 34.2%, and 44.8% respectively. The differences between two groups were statistically significant (p-value <0.05).

Conclusion: Anti-reflux therapy should be considered as an essential component of medical management in the children with OME.

Conflicts of Interest: The Authors declare no conflicts of interest.
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Introduction

Eustachian tube dysfunction causes negative middle ear pressure and leads to accumulation of fluid within the middle ear, consequently otitis media with effusion (OME) occurs (1). OME is one of the most common causes of hearing impairment in children. Also, it is one of the most common causes of hospitalization and surgery in children. So, effective OME management prevents children from hearing loss, speech impairment, and possible developmental delay (2). Gastroesophageal reflux is a physiological condition. When it is accompanied by some troublesome features, is called gastroesophageal reflux disease (GERD) (3). There is some evidence of direct relationship between OME and GERD (4). More than 80% of patients with OME have been involved by laryngopharyngeal reflux

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(LPR) (5). This study has been designed to determine the improvement rate of otitis media with effusion in children under gastroesophageal reflux therapy.

Methods

The present study has been approved in Ethical Committee of Shahid Beheshti University of Medical Sciences. It was conducted as a retrospective study at Taleghani Hospital in Tehran. Medical records of children with OME were reviewed in a 5-year period untill 2019. From 170 files, only the complete ones considering the needed data were selected. Three to ten year-old patients with type B of tympanometry -constantly for at least 3 months- entered the study. They had undergone ear examination and tympanometry before and two weeks after complement of a 14-day period of medical therapy. The patients under medical treatment had the following criteria. Amoxicillin-clavulanate (Co-amoxiclav; Cosar Company, Tehran, Iran) suspension was ordered for all patients (amoxicillin 90 mg/kg/day in 3 divided doses). Some patients were received Omeprazole (Merazole; Abidi Company, Tehran, Iran), too (1.5 mg/kg/day in 2 divided dose). Patients with positive history of the conditions that predispose them to OME or GERD, such as Down syndrome, cleft palate, asthma, laryngomalacia, and subglottic stenosis didn't enter. The post-treatment records of patients, including the reports of otoscopic examination and tympanometry were analyzed.

Type A, C, and B tympanometry were interpreted as a good, moderate, and no response, respectively.

Statistical analysis

The results were analyzed by independent t-test and chi square test using SPSS software version 24 (IBM Corp. Released 2016. IBM SPSS Statistics for Windows; Version 24.0. Armonk, NY, USA). p-value less than 0.05 was considered as a significant level.

Results

In this study, finally 40 patients -out of the primary 170 ones- had the necessary criteria to enter the study. 20 patients (8 males and 12 females) were treated with antibiotic and anti-reflux (so-called as antireflux group) and 20 patients (7 males and 13 females) only received antibiotic (so-called as antibiotic group). The mean ages in the antireflux and antibiotic groups were 5.20±1.79 and 5.35±.03 years, respectively. There was no statistically significant difference between two groups considering the mean age ($p > 0.05$). Otoscopic examination in the antireflux group showed that both ears were affected in all cases, whereas in the antibiotic group, all except two patients had bilateral involvement. The difference between tympanometry results before treatment was not statistically significant, ($p > 0.005$). The post- treatment reports revealed the following results among all patients. The overall good, moderate, and no responses to medical therapy were 35.9%, 35.9%, and 28.2%, respectively. The general responses were better in the antireflux group (Table 1). The overall moderate to good response in this group was 87.5%, while nearly half of the patients in the antibiotic group unchanged. The difference between the antireflux and antibiotic groups was statistically significant (Table 1).

Table 1. Overall responses to the medical treatment in the antireflux and antibiotic groups

Response	Antireflux Group (40 ears)	Antibiotic Group (38 ears)	Total (78 ears)	p-value*
Good	50% (20 ears)	21 % (8 ears)	35.9% (28 ears)	<0.003
Moderate	37.5% (15 ears)	34.2% (13 ears)	35.9% (28 ears)	<0.005
Nil	12.5% (5 ears)	44.8% (17 ears)	28.2% (22 ears)	<0.003

*The significant level was less than 0.05

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Discussion

The most common form of otitis media is OME (6). It is described as an asymptomatic collection of fluid in the middle ear without active infection (2, 7). It can lead to hearing loss, cognitive or behavioral problems, vestibular disturbance, and damage to ear drum (8). OME is a multifactorial disorder (2). Nowadays, GERD is considered as an important issue in the pathogenesis of OME (9). There is no precise definition for GERD. Despite improved technology, the objective diagnosis of GERD is still difficult. Especially objective PH monitoring testing has not been correlated with extra esophageal manifestation of GERD in children (10). Response to proton pump inhibitors (PPIs) is a practical way to confirm the diagnosis (3). The current study was conducted as a retrospective study considering the rate of response to treatment with PPIs as a way to diagnose GERD in children with OME. Although, the patients had not been examined for GERD, empiric anti-reflux treatment was significantly effective. Only one-eighth of the patients in the antireflux group did not change. If the treatment period had been long enough, the response rate might have been complete. Anyway, the treatment success in the antireflux group was apparent in a short 14-day course of anti-reflux therapy. This finding confirms the hypothesis of contributory role of GERD in OME pathogenesis. A cause -and -effect relationship has been suggested to exist between OME and GERD (11). Animal studies have shown that reflux causes eustachian tube dysfunction (7). Repeated exposure of middle ear mucosa to pepsin in rats has led to mucociliary impairment (9, 11). Nasopharyngeal mucosal inflammation and damage occur due to persistent exposure to refluxed acid, pepsin, and bile (9, 12). It further causes eustachian tube dysfunction.

In the pediatric population, the eustachian tube is undeveloped with a wide angle. So, the gastric contents easily reach the middle ear (7, 12, 13); particularly, when inflammatory dysfunction of eustachian tube has occurred.

Multiple studies have been done to evaluate the various aspects of this issue. The presence of pepsin in the fluid of inflamed middle ear in some patients with OME, has been reported (10, 11, 14, 15). These patients may get involved with a more sever disease (16). The concentration of pepsin/pepsinogen in the middle ear of patients with OME has been reported to be 4-540 times higher than plasma (17). The highest pepsinogen level has been detected in purulent effusions (18).

There was no evidence of pepsin production in the pathologic examination of middle ear mucosa (9). So, the source of these high concentration of pepsin should be somewhere out of the ear. Analysis of pepsin/pepsinogen in the middle ear fluid has been used as a reliable biochemical marker for evaluation of LPR (17, 19). The level of pepsinogen in the hypertrophied adenoid tissue has been significantly higher in patients with OME, comparing to those with adenoid hypertrophy and normal ear (15). Although pepsin is active merely in the acidic environment (18); it is active in higher PH in the throat. The rational may be the stimulation of cytokines and receptors (20).

There are some studies that have evaluated the relationship between the presence of Helicobacter Pylori (H. Pylori) in the middle ear and OME. Although, the results are inconsistent, most of them support the possible effect of GERD in the OME pathogenesis (7, 21, 22).

Some other studies have assessed the presence of GERD in children with ear problem and vice versa. Higher rate of middle ear dysfunction in GERD patients and higher nasopharyngeal reflux in OME cases were detected, though, none of them were statistically significant (23, 24). These results may be because of small sample size.

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There are a few reports about the effect of GERD treatment on OME. Some authors have enrolled adult patients with eustachian tube dysfunction with or without chronic secretory otitis media. Empiric prolonged anti-reflux therapy (for 2-16 weeks) caused positive response in all cases (18). Another study, which is more comparable to the present study, has addressed children with OME and GERD before and after anti-reflux therapy. They concluded that anti-reflux treatment not only was effective on the OME treatment and prevention from surgery, but also improved the patients' quality of life (11). These findings are compatible with the present study.

Conclusion

According to current survey, GERD should be considered as an etiology for OME. So, anti-reflux agent should be considered as an essential component of medical management in the children with OME. In this way, many unnecessary surgical interventions in OME can be avoided.

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Conflicts of Interest

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Ethics

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