

Effect of Vitamin D on Otitis Media with Effusion in Children

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ABSTRACT

Introduction: This study aimed to investigate the effect of vitamin D on the treatment of otitis media with effusion in children.

Materials and methods: In this clinical trial study, 90 children aged >2 years old with OME (otitis media with effusion) were involved. All children were treated with standard otitis media treatment (antibiotics, Mometasone nasal spray and Montelukast). In the case group, in addition to the standard treatment, vitamin D was administered monthly up to three months. In the control group, patients received placebo. The results of the treatment were evaluated at the end of the first and the third months by Tympanometric examination.

Results: In both groups, changes in left and right ear pressure were significant after one month of treatment ($p < 0.05$). But the improvement in the case group was greater than the control. At the end of the third month, similar results were observed. At the end of first month, the complete recovery rates of the left and right ears in the case group was 11.1% and 13.3%, respectively, while in the control group it was 4.4% and 11.1%, respectively. After three months of treatment, the complete recovery rate in the case group rose to 37.8% for the left and to 31.1%, for right ears, while in the control group complete recovery rate was 33.3% and 31.1% for the left and right ear respectively.

Conclusion: According to the results, it seems that vitamin D supplementation with routine antibiotic therapy for OME can be used.

KEYWORDS

Vitamin D, Otitis Media with Effusion, Treatment.

Introduction

Otitis media is one of the main causes of hearing loss in children and one of the most common diseases in children less than three years old (80%). Children over the age of seven have at least one occurrence of otitis media (1). Otitis media is divided into four types of acute otitis media, recurrent media otitis media, chronic otitis media, and otitis media with effusion (OME). The pathophysiology of otitis media with effusion is associated with dysfunction of the Eustachian tube and infection (2, 3). OME is characterized by a non-specific inflammation of the middle ear mucosa and secretory changes that causes fluid accumulation in the middle ear (4). The most common cause of otitis media with effusion is obstruction due to adenoid hypertrophy. The submucosal cleft palate, allergy, upper airway infection, tumors, sinusitis, acute otitis media, radiation, and obstruction of the Eustachian tube can cause fluid accumulation in the middle ear (5). In children with OME, prolonged contact of leukotrienes and prostaglandin with round window can cause sensory neural hearing loss (SNHL). In children between the ages of two and four, hearing impairment following the fluid effusion in the middle ear, which lasted 3 months or more, is 5% (2, 6). Also, one of the causes of middle ear infections is immune system disorders. In recent years, several studies have been conducted on risk factors associated with low levels of immunity and the role of vitamin D in improving immune status (7). Despite active treatment with antibiotics and ventilation tubes, OME has a marked tendency to recur. Therefore, strategic therapy is needed to reduce the frequency of recurrences. Vitamin D is an anti-inflammatory agent that reduces interleukin and interferon gamma activity, thereby reducing inflammation (8-10). In several studies, the roles of vitamin D deficiency in respiratory tract infections and middle ear have been observed. Vitamin D has receptor in all immune system cells, especially in B and T lymphocytes, monocytes and macrophages. Vitamin D increases peptide-cathelicidin activity. This peptide plays an antimicrobial role. In addition, calprotectin and S100 regulator are affected by vitamin D, which are also antimicrobial factors. As a result of increasing levels of vitamin D, the strength of monocytes and macrophages is multiplied, that all of which is effective in boosting the immune system (11). Considering the effect of vitamin D as an anti-inflammatory agent and the findings of studies on the efficacy of vitamin A in respiratory infections such as AOM (Acute otitis media) and its antimicrobial activity, in this study we aimed to investigate the effect of vitamin D on the treatment of OME.

Materials and Methods

After approval by the local Ethics Committee and obtaining written informed consent, in this clinical trial study 90 children aged >2 years old with OME (Type B or C tympanogram and negative pressure >150 in the middle ear) were involved. Patients with history of OME, chronic kidney disease, granulomatous and sarcoidosis disease, chronic liver disease and history of taking vitamin D supplements were excluded from the study. Also, children with common cold, fever, otalgia and acute tympanic perforation were excluded too. Patients were randomly divided into two groups (each group=45) using random number table. Both groups were treated with standard treatment of otitis media (antibiotic: Co- amoxiclave for 14 days, mometasone spray and montelukast: one tablet daily) for three months. In the case group, in addition to the standard treatment, 50,000 units of vitamin D (pearl vit D) (preventive dose) were prescribed monthly up to three months and the placebo group received placebo. In each group the Tympanometric and ear examination were performed one and three months after the treatment and the results were recorded. Tympanogram findings were classified based on the Jerger classification (Table.1) (4). On Tympanometric curve, changes from each of the type B, C1 and C2 to type A, have been considered as a complete recovery and changes from type B to C2 and type C2 to C1 have been considered as an improve recovery (Table.2). The obtained data was entered into SPSS software version 21 and analyzed using descriptive statistics and Chi-Square tests. P. value <0.05 was considered significant.

Results

In this clinical trial study 90 children aged >2 years old with OME were involved. The case group included 45 patients (25 males and 20 females) and the control group included 45 patients (26 males and 19 females). The mean age of the case group was 4.7 ± 1.5 years, while the mean age of the control group was 4.7 ± 1.7 years. There was no significant difference between the two groups regarding age and sex ($p < 0.05$). The number of cases and controls who underwent Tympanometric evaluation is shown in (Table.3).

In both groups, changes in left and right ear pressure were significant after one month of treatment ($p < 0.05$). But the improvement in the case group was greater than the control. At the end of the third month, similar results were observed. At the end of first month, the complete recovery rates of the left and right ears in the case group was 11.1% and 13.3%, respectively, while in the control group it was 4.4% and 11.1%, respectively. After three months of treatment, the complete recovery rate in the case group rose to 37.8% for the left and to 31.1%, for right ears, while in the control group complete recovery rate was 33.3% and 31.1% for the left and right ear respectively. After one month, the improve recovery rate in the case group was 11.1% in both ears and 11.3% for both ears in the control group while after three months of treatment, improvement of recovery in the case group was 24.4% for both ears and in the control group, was 26.7% for the left ear and 20% for the right ear (Table.4).

Discussion

Otitis media with effusion (OME) does not have many symptoms, and patients complain of hearing loss and hearing loss is conductive. One of the possible causes of OME is a disfunction of the immune system. In recent years, various studies have been conducted to evaluate the risk factors associated with weakening of the immune system, that the role of vitamin D is mentioned in their study. Also the role of vitamin D on the incidence and severity of bacterial and viral infections, have been identified in various studies in patients with TB, respiratory infection and acute otitis media (12-14). Recent studies showed that medical treatments for OME such as antibiotics, steroids, antihistamines, decongestants and mucolytics have no long-term benefits. In the present study, the results of treatment were significant in both groups before and one month after treatment and the frequency of different types of middle ear pressure in the two groups was improved, but the improvement was higher in the case group. There was also a significant difference between the two groups in the third months after treatment, and this was also higher in the case group. Also, the results of the study showed that the rate of complete recovery after one month and three months of treatment in the case group in both ears was more than the control group (one month after treatment in the case group was 24.4% compared with 15.6% in both ears) but the difference was not statistically significant and seems to be due to a lack of sample size. Cayir et al, investigated the role of vitamin D in the treatment of children with recurrent otitis media, and their results showed that prescribing vitamin D, along with routine therapy (antibiotics, steroids, antihistamines, decongestants and mucolytics), is an appropriate option for the treatment of upper respiratory infections such as otitis media(13). In another study by Cayir et al, vitamin D levels in children with otitis media

were measured and their results indicated that vitamin D deficiency plays an important role in increasing the incidence of middle ear infections (14). Marchisio et al, investigated the role of vitamin D in reducing the risk of recurrent infection of the middle ear and their results showed that in children with acute recurrent otitis media, vitamin D levels should be checked and in children with vitamin D deficiency, vitamin D supplementation with routine therapy for children can be effective in improving their illness (11). Sabetta et al, also found that vitamin D levels above 38 ng/ml, effectively reduced the risk of respiratory infections (15). In a study by Khajavi et al, the results showed that vitamin D levels were 26.1 ng/ml in case group and 29.5 ng/ml in the control group. Although vitamin D levels were lower in the study group, but this difference was not significant in the study. They concluded that evaluation of vitamin D levels in children with OME is essential and vitamin D deficiency should be treated (16). Cayir et al showed that prescribing vitamin D reduced otitis media recurrence, and their results showed that vitamin D was a major immuno-modulator, and its deficiency increased upper respiratory infections such as otitis media. They believed that administration of vitamin D supplementation with conventional therapy in controlling upper respiratory infections, such as recurrent otitis media, is beneficial (13). The effect of N-Acetylcysteine on the treatment of otitis media with effusion was investigated in Boztepe et al. The results of their study showed that at the end of the first month, the recovery rates of the left and right ears in the case and control group were 66% and 72%, vs 13% and 22%, respectively (4). whereas in the present study, the recovery after one month in the case and control group was 11.1% and 13.3% vs 4.4% and 11.1% respectively for the left and right ear. The results of their study showed that recovery rate after 3 months in the case group was 84% and 87% for the left and right ears; while in the control group it was 10% and 39%, respectively. however, it should be noted, that this difference with the present study is probably due to considering any changes to better pressure as recovery in the Boztepe study(4).

Conclusion

According to the results, it seems that vitamin D supplementation with routine antibiotic therapy for OME can be used.

Recommendation

Extensive studies with a larger sample size are needed to determine the long-term effects of vitamin D on the treatment of OME.

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