Original Article

Effects of Vitamin D Supplementation on Asthma Control and Severity

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Abstract

Background: *Asthma is a major global health problem and one of the leading causes of childhood emergency visits. Management is often challenging because of comorbidities, poor adherence, improper inhaler technique, environmental factors, and severe therapy-resistant asthma.*

Objective: *To determine the effects of vitamin D supplementation on asthma control and severity.*

Materials and Methods: *This randomized clinical trial was conducted in the Department of Pediatric Respiratory Medicine at Bangladesh Shishu Hospital and Institute from January 2019 to December 2020 among children aged 6–15 years diagnosed with asthma. Eligible participants were randomly assigned into Group A and Group B with blinding. Group A received oral vitamin D3 (cholecalciferol) 400 IU daily for 4 months along with standard treatment, while Group B received standard treatment only. After 4 months, asthma severity, level of control, peak expiratory flow rate (PEFR), acute exacerbations, and emergency visits were assessed. A p-value <0.05 was considered significant.*

Results: *Asthma control improved significantly in Group A; 33 patients achieved well-controlled asthma compared to 21 in Group B (P=0.029). Moderate persistent asthma decreased from 42 to 20 patients in Group A versus 35 to 31 in Group B (P=0.033). PEFR <80% decreased significantly in Group A (P=0.014). Acute exacerbations and emergency visits were also significantly lower in Group A (P=0.031 and P=0.001, respectively).*

Conclusion: *Low-dose short-course vitamin D supplementation alongside standard therapy improved asthma control, reduced severity, decreased exacerbations, and lowered emergency hospital visits in children with asthma.*

Key words: *Vitamin D supplementation, Childhood asthma, Asthma control, Peak expiratory flow rate (PEFR).*

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Introduction

Asthma is one of the major health problems throughout the world. It is a serious global health problem affecting all age groups with increasing prevalence in many developing countries, rising up treatment costs and a rising burden for patient and the community.[1]

Asthma is a chronic disease causing considerable morbidity. In 2011 more than ten million children had been diagnosed with asthma with 70% of this group were current asthma. Childhood asthma is the most common causes of childhood emergency visits, hospitalizations and missed school days. Childhood asthma gradually increasing in prevalence.[2]

Asthma is a common respiratory disease affecting 1–18% of the population in countries. Asthma is characterized by wheeze, shortness of breath, chest tightness and/or cough, and by expiratory airflow limitation. Both clinical features and airflow limitation characteristically vary over the time and in intensity. These variations are triggered by factors such as allergen, exercise, or irritant exposure, viral respiratory infections or change in weather.[3]

Thirty percent of children with asthma had some limitation in activity, compared with 5% of children without asthma. Ten percent of children with asthma had severe disease; as measured

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by frequency of bother and limitations in function. These children accounted for 35% of hospitalizations and 77% of the missed school days in a year. Measures of the impact of disease on health become important tools to evaluate the effectiveness of treatment and prevention.[4] Asthma accounts for large number of costs with health care utilization. Children living in poverty have higher prevalence rates and suffering from significant disparities with increased mortality and morbidity. Complex social and environmental factors that shape these health disparities are referred to as SDH (Social Determinants of Health); and powerfully impact on asthma. Poor hygiene disproportionately exposes children to indoor allergens and outdoor pollutants that can exacerbate asthma. Asthma is difficult to treat because of comorbidities, improper inhaler technique, poor therapeutic adherence, environmental factors and true severe therapy-resistant asthma. Dedicated asthma programs have shown efficacy in reducing asthma burden in the literatures. Successful asthma programs like Community Asthma Initiative in target high-risk patients, coordinate community, provide education and home environment assessment public health and social services.[5]

Bangladesh National Asthma Prevalence Study (1999) states that seven million people including four million children are suffering from asthma and prevalence is more in rural areas than in metropolitan areas of Bangladesh. The prevalence of asthma: wheeze in the last 12 months was 6.9%. The prevalence of other asthma definitions were: lifetime wheeze 8.0%, perception of having asthma (perceived asthma) 7.6%, diagnosis of asthma by any category of doctor either qualified or unqualified doctor (diagnosed asthma) 4.4%. The prevalence of asthma in children was higher than in adults (7.3% versus 5.3%). Asthma in children was found significantly higher in households with ≤ 3 people than in larger households. The low-income group and illiterate group were more vulnerable to asthma than the high-income group and more educated group, respectively. Asthma is the most common chronic disease of childhood. In developed countries it affects 11-20% of all school age group children. Childhood asthma not only is very common but also it seems that it is becoming even more common in children. The incidence and new cases of asthma in children is 2-5 times than in young adults.[6]

Asthma with vitamin D deficiency recognizes multiple risk factors such as industrialization, winter season, poor diet and obesity. There is a hypothesis; based on these evidences that vitamin D deficiency is to blame for asthma epidemic. A good number of literature supports the concepts that vitamin D is involved in pathogenesis of asthma, allergic rhinitis and sinusitis. Vitamin D regulates a range of immune, non-immune cells of body and modulates innate and adaptive immune response. Asthma exacerbations are favoured by vitamin D deficiency and decrease after long-term vitamin D supplementations.[7] Many researches have reported causal association between vitamin D level and asthma exacerbations including its probable protective mechanism. So it is imperative to realize the protective mechanism of vitamin D against asthma. Vitamin D is of particular interest in asthma due to its immune modulatory effects with a wide range of pulmonary disease including bacterial, viral respiratory infections and cancer. [8]

Over last few decades, vitamin D deficiency and insufficiency are increasingly being recognized in general population and have been attributed to lifestyle, behavioural and dietary change. A large number of studies have concluded that low 25 hydroxy vitamin D in mild to moderate asthma is correlated with poor asthma control, reduced lung functions, reduced glucocorticoid response, increased corticosteroid use and more frequent exacerbations.[9] Anti-inflammatory with inhaled glucocorticoids effectively manages childhood asthma by improving symptoms and lung functions. Inhaled treatment associated with adverse effects on growth and bone turn over. The catabolic effect of corticosteroids on bone turnover is well documented. So, vitamin D to children with asthma treated with inhaled glucocorticoids affects growth or markers of bone turnover.[10] Lower vitamin D levels in children with severe therapy-resistant asthma (STRA) were associated with increased airway smooth muscle mass (ASM) and worse asthma control and lung functions. The link between vitamin D and airway structure with function suggests vitamin D supplementation may be useful in Paediatric severe therapy -resistant asthma.[11]

Hypovitaminosis D is highly prevalent in the whole population in addition to a highly significant increase in several markers of allergy and asthma severity among asthmatic children as compared with healthy control children.[9] High prevalence of vitamin D deficiency and insufficiency were found in asthmatic children; however, there was no significant relationship between vitamin D status and the level of asthma control or other asthma parameters; study in Thailand.[12]

Associations between polymorphisms in the vitamin D receptor (VDR) gene with asthma were reported. Recently, it is found that genetic variation in genes, other than VDR, involved in vitamin D metabolic and signaling pathways were transmitted to asthmatic children. Co-administration of 1α,25(OH)2D3 with allergen immunotherapy significantly inhibited airway hyper-responsiveness and potentiated the reduction of airway eosinophilia, and Th2 cytokines.[13] As vitamin D is a potent immune modulator; capable of dampening inflammatory signals in several cell types involved in the asthmatic response. Its deficiency has been associated with increased inflammation, exacerbations and overall worse outcomes in asthma patients. Given the increase in the prevalence of asthma over the last few decades, there has been more interest in the use of vitamin D supplementation as a therapeutic option.[14] The discovery that many cells express VDR and the recognition of widespread vitamin D insufficiency has stimulated interest in the more beneficial effects of vitamin D in asthma.

Asthmatic children should be assessed to ensure adequate intake or supplementation with at least the minimum daily recommended doses of vitamin D. The simple intervention of vitamin D supplementation provide significant clinical improvement in atopic disease, like asthma.[15] In a study showed that, urban African American youth with persistent asthma were vitamin D deficient. Given the emerging associations between low vitamin D levels and asthma, strong consideration should be given to routine vitamin D levels testing in urban African American.[16] Vitamin D reduce the risk of certain infections and chronic diseases. Physicians should choose the appropriate

vitamin D supplement for their children.[17] Some studies have reported a possible relationship between asthma and vitamin D deficiency. Many cross-sectional studies have shown that serum vitamin D levels in asthmatic children are lower than in healthy children.

Materials and Methods

After obtaining ethical approval, a randomized clinical trial was conducted in the Department of Pediatric Respiratory Medicine, Bangladesh Shishu (Children) Hospital and Institute, Dhaka, Bangladesh, from January 2019 to December 2020. Children aged 6–15 years with mild persistent or moderate persistent asthma were enrolled. Patients using home oxygen, receiving vitamin D supplementation or active vitamin D, recently hospitalized for asthma, or having urinary tract stones, calcium- or bone-related disorders, or other chronic illnesses were excluded.

A total of 125 eligible patients were recruited after obtaining written informed consent from their parents or guardians. Baseline demographic and clinical information, including age, disease duration, symptoms, aggravating factors, treatment history, asthma control, and severity, was recorded using a structured questionnaire and case report form. Asthma diagnosis and classification were based on history, clinical examination, and Global Initiative for Asthma (GINA) guidelines.

Participants were randomly allocated into Group A or Group B using the sealed opaque envelope method. Blinding was maintained by labeling the treatment groups as A and B. The intervention group received oral vitamin D_3 (cholecalciferol) 400 IU daily for 4 months, while both groups received standard asthma management.

Participants were evaluated at baseline and after 4 months. Asthma control, disease severity, and peak expiratory flow rate (PEFR) were assessed according to GINA guidelines through clinical examination, interviews, asthma diaries, and peak flow measurements. Adherence to supplementation was assessed by interview, and parents were contacted regularly by telephone to encourage follow-up and report any asthma exacerbations or illnesses. Data were collected by the researcher and analyzed using Statistical Package for the Social Sciences (SPSS) version 23. A p-value <0.05 was considered statistically significant.

Results

The mean age of the study population was 9 years in Group A and 8 years in Group B. Boys were predominant over girls. There is no statistically significant difference in symptoms and aggravating factors between two groups. There is no statistically significant difference between severity, level of control and treatment technique in the two group.

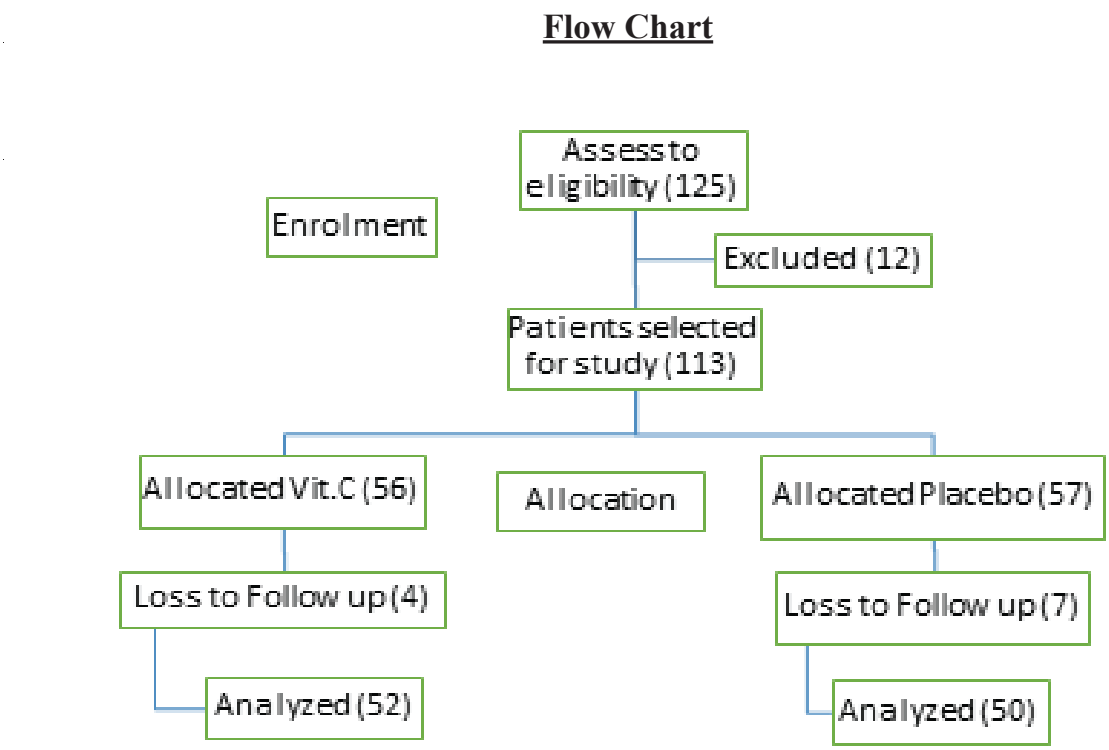

Figure 1: Flow diagram of study profile

Table I: Base line characteristics of the study patients in two groups (n=102)

Participants characteristics	Group A (n=52)	Group B (n=50)	p-value
Age (years)			
6-10	36(69.2%)	37(74.0%)	
10-15	16(30.8%)	13(26.0%)	0.372[ns]
Total	52(100%)	50(100%)	
Mean±SD	9.1±2.7	8.6±2.8	
Range	6-15	6-14	
Gender			
Male	30(57.7%)	26(52.0%)	0.564[ns]
Female	22(42.3%)	24(48.0%)	
Mean age at onset (years)	7.71±2.35	7.18±2.44	0.266[ns]
Mean age at diagnosis (years)	8.52±1.61	8.32±1.24	0.485[ns]
Mean frequency of episode (per week)	3.35±0.68	3.34±0.66	0.963[ns]
Mean frequency of SABA (per week)	3.10±0.75	3.10±0.79	0.980[ns]
Mean number of exacerbations in past year	1.71±0.67	1.60±0.70	0.412[ns]
Mean nocturnal awakening (per month)	1.44±0.50	1.44±0.50	0.982[ns]
Co-morbidity present	35(57.7%)	29(50.0)	0.436[ns]
Peak excitatory flow rate % predicted	100.2±10.9	110.4±11.8	0.001[s]
Daily dose of Inhaled Corticosteroid(ICS)	400 (200-400)	400 (200-400)	

Unpaired t-test for quantitative variables and Chi-square test for qualitative variables were done to analys the data, ns= not significant, s=significant

Participants' characteristics were described in Table I. There is no statistically significant difference in symptoms and aggravating factors between two groups.

Figure 2 shows the sex distribution of the study participants in the Vitamin D and placebo groups. Among the total 102 participants, 56 (54.9%) were male and 46 (45.1%) were female. In the Vitamin D group (n=52), 30 (57.7%) participants were male and 22 (42.3%) were female. In the placebo group (n=50), 26 (52.0%) participants were male and 24 (48.0%) were female. The distribution of male and female participants was nearly similar between the two groups.

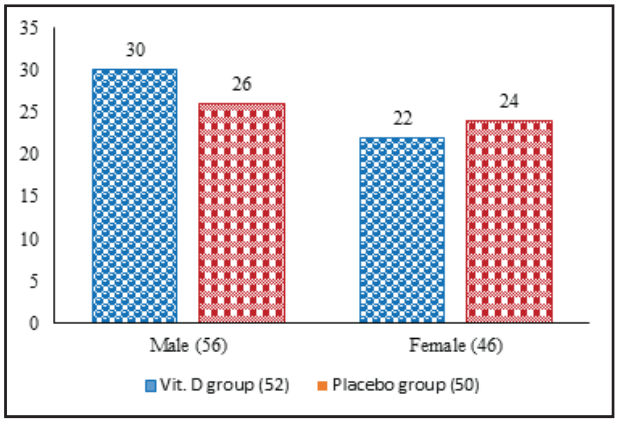

Figure 2: Distribution of the subjects by gender and study group.

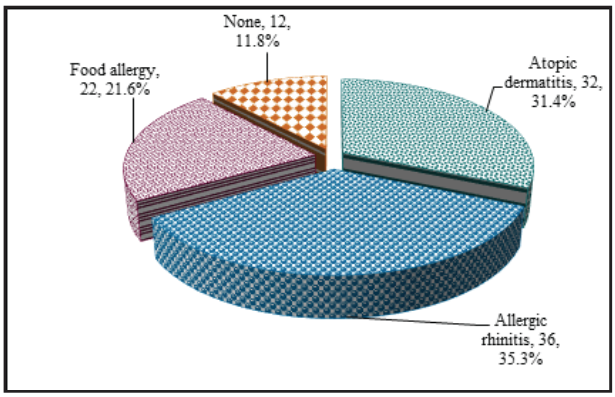

Figure 3: Distribution of the patients by comorbidities in study group

Figure 3 showing presence of co morbidity. Food allergy present in 21.6% of study population. Allergic rhinitis was present in 35.3% of patient. Atopic dermatitis was present in 31.4% of patient, 11.8 % patient did not have any comorbidity.

Table II: Level of asthma control of the patients in the two groups (n=102)

Level of control	Group A (n=52)	Group B (n=50)	p-value
At baseline			
Well control	12(23.1%)	10(20.0%)	0.705 ns
Not well control	40(76.9%)	40(80.0%)	
3 months			
Well control	33(63.5%)	21(42.0%)	0.029 s
Not well control	19(36.5%)	29(58.0%)	

Chi-squared Test (x2) was done to analyses the data, ns=not significant, s=significant

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Table 2 show level of asthma control. Asthma control was achieved in more patients in Group A after 3 months. 33 patients in Group A had their asthma well controlled as compared to 21 patients in Group B (P = 0.029)

Table III: Effect of Vitamin D supplementation on C-ACT score.

Study outcome	At baseline Mean±SD	At 3 months Mean±SD	p-value
Group A			
C-ACT score	14.34±3.56	20.23±3.94	<0.001 s
Group B			
C-ACT score	13.43±2.48	15.80± 3.80	0.114 ns

Data were expressed as mean±SD, Paired t-test was done to analysis, s=significant, ns= not significant

Childhood asthma Control Test (C-ACT) findings are shown in Table 3. At baseline C-ACT score mean was 14.34 in Group A and 13.43 in Group B. At follow up the score was 20.23 in Group A and 15.80 in Group B. Significant differences found between two groups (P = 0.001).

Table IV: Effect of Vitamin D supplementation on ACT score.

Study outcome	At baseline Mean±SD	At 3 months Mean±SD	p-value
Group A			
ACT score	14.45±1.51	15.27±1.74	0.122 ns
Group B			
ACT score	13.56±1.33	14.22±2.49	0.493 ns

Paired t-test was done to analysis, ns= not significant

ACT finding are shown in table 4. At base line ACT score mean was 14.45 in Group A and 13.56 in Group B. No Significant differences found between two groups after 3 months.

Table V: Level of severity of the patients in the two groups (n=102)

Level of severity	Group A (n=52)	Group B (n=50)	p-value
At baseline			
Mild	10(19.2%)	15(30.0%)	0.206 ns
Moderate	42(80.8%)	35(70.0%)	
Severe	0(0.0%)	0(0.0%)	
3 months			
Mild	30(57.7%)	16(32.0%)	0.033 s
Moderate	20(38.5%)	31(62.0%)	
Severe	2(3.8%)	3(6.0%)	

Chi-squared Test ($\chi 2$) was done to analyses the data, ns =s=significant.

Table V shows level of asthma severity. At the beginning, there were 42 patients suffering from moderate persistent asthma in Group A and 35 patients in Group B. After 3 months supplementation, 20 patients with moderate persistent asthma in Group A whereas 31 patients with moderate asthma in Group B, which is statistically significant (p =0.033).

Table VI: Effects of Vitamin D on pulmonary function (N=102)

PEFR<80%	Group A (n=52)	Group B (n=50)	RR (95% CI)	p-value
PEFR< 80% at baseline	14(26.9%)	16(32.0%)	0.841(0.46-1.54)	
PEFR<80% at 3 months	7(13.5%)	17(34.0%)	0.396(0.18-0.87)	0.014[s]

Chi-squared Test (x2) was done to analyses the data; s = significant

Results of pulmonary function tests are shown in Table 6. At baseline, PEF < 80% was observed in 14 patients in Group A, after 3 months 7 patients having PEF < 80% which is statistically significant (P = 0.014).The value of RR < 1 so vitamin D is a protective factor for asthma.

Table VII: Number of patient having exacerbations during treatment period (n=102)

Number of patient having exacerbations	GroupA (n=52)	GroupB (n=50)	p - value
At baseline	12(73.1%)	16(46.0%)	
3 months	5(9.6%)	13(26.0%)	0.031[s]

Chi-squared Test ($\chi 2$) was done to analyze the data, s=significant

Patients having episodes of acute exacerbations during the treatment period were significantly less in the Group A as compared to Group B (Table VII). The number of patient was 12 in Group A, who had history of exacerbation in previous months but it was 16 in Group B. After 3 months of vitamin D supplementation, the patient number was decreased in Group A in comparison to Group B. This is statistically significant (p=0.031).

Table VIII: Comparison of mean number of emergency visits between two groups (n=102).

Number of emergency visits	Group A(n=52) Mean±SD	Group B(n=50) Mean±SD	p - value
Atbaseline	0.55±0.30	0.65±0.40	0.155[ns]
At3 month	0.10±0.20	0.30±0.15	<0.001[s]

Unpaired t-test was done to analyses the data,
ns= not significant, s=significant

The patients in the Group A required less number of emergency visits after 3 months of treatment. Mean number of emergency visits showed a statistically significant difference in favour of Group A (P =0.001)

Discussion

In this childhood asthma randomized controlled trial study was carried out in department of Pediatric of Dhaka Shishu (Children) Hospital, Dhaka, where 113 patients with childhood asthma were included. The present study was showed that vitamin D supplementation reduce the clinical severity, exacerbation, emergency hospital visit and improve the clinical control, peak expiratory flow rate in asthma patient than does standard treatment. The two study groups in the present study were almost similar with respect to their demographic characteristics, baseline clinical characteristics.

In this study, 52 patients were randomly assigned to receive vitamin D supplements (n = 52; 400 IU/day for 3 months) or standard treatment (n = 50) in a single-blind setting for 2 years. All patients were followed up, although a few were missing some data. Four patients in the vitamin D group and seven in the placebo group did not comply with the supplement schedule. The mean age of the study population was 9 years in vitamin D group and 8 years in standard treatment group. Boys were predominant over girls. Both groups had a history of being admitted to the hospital, at least once, due to asthma attack. Both groups have the history of using either Inhaled Corticosteroid (ICS) alone, both Leukotriene Receptor Antagonists (LTRAs) and ICS or ICS and Short-Acting Beta-Agonists (SABAs). Patients' characteristics were similar in both groups. There is no statistically significant difference in symptoms and aggravating factors between two groups. There is no statistically significant difference between severity, level of control and treatment technique in the two groups.

In this childhood asthma RCT, daily supplementation with 400 IU of vitamin D for 3 months showed significant improvement in levels of asthma control defined by Global Initiative for Asthma (GINA) (P = 0.029)). Thus, the effect of vitamin D in addition to standard therapy was considered obvious in terms of improving asthma control levels. On the other hand, there were no clear adverse events associated with vitamin D supplements. We could not identify differential effects via stratification of subgroups by the use of ICS or initial levels of 25OHD. However, vitamin D supplementation may be a good option to improve control levels of childhood asthma because it significantly improves asthma effects, has few side effects, and inexpensive. By Tachimoto et al, 2016, recently a small-scale RCT was done where showed that the active form of vitamin D, 1a, 25-dihydroxyvitamin D (1,25OHD) improve asthma control, which is consistent with our findings.[18] The results of the interventional study agree with the main goal of this study, indicating that vitamin D supplementation to asthmatic patients was associated with a significant disease improvement, consisting in reduced number of exacerbations and increased values of PEFR. Similar effect found by Solidoro P.et al, 2017.7

The level of severity was less in vitamin D group as compared to placebo group. A delayed beneficial effect on asthma severity

may be found. Thus, monthly doses of vitamin D can reduce the level of severity of asthma patients. The decrease level of severity of asthma also found in a study,by Yadav et al, 2013 which is consistent with our study.[19] One systemic review and meta- analysis provides weak evidence to support vitamin D supplementation for the reduction of asthma symptom by Riverin et al, 2015.[20] A prospective and RCT study done by Baris et al, 2013; showed that vitamin D supplementation in asthmatic children decreased total asthma symptom score, total medication score, lower dose of ICS needed to control symptom, less acute attack and higher steroid discontinuation.[21] In this study C-ACT score are improved by vitamin D. C-ACT is a good diagnostic tool to assess asthma control. ACT score improvement is not significant between two groups.

The association of vitamin deficiency with asthma exacerbations and severity has been reported by several trials in children and adults. In Puerto Rican children, Brehm et al found that the influence of low vitamin D on exacerbations was independent of atopy, racial ancestry, markers of disease severity, and asthma control.[22] Usalol et al, 2013 found that vitamin D levels were considerably lower in children with asthma than in healthy children.[23] They also found that a more severe asthmatic episodes, higher frequency of asthma attacks and greater difficulty in asthma control were observed in children with asthma with low vitamin D levels but few studies showed no such relationship. Turkeli et al found that low vitamin D levels were associated with increased asthma severity and poor asthma control.[9]

Vitamin D affects the adaptive immunity through Th1, Th2, and regulatory T cells. Vitamin D promotes induction of T cells providing the controlling of inhibitor cytokine secretion (IL-10 and TGF-β) and CD4+ T lymphocytes (Th1, Th2). Vitamin D was shown to inhibit the Th1 cytokine production related to asthma severity and low steroid response. Vitamin D can increase the glucocorticoid responsiveness in steroid resistant asthma. Vitamin D deficiency decreases glucocorticoid responsiveness, contributing to asthma attacks. By these mechanisms, vitamin D may have a therapeutic role in reducing asthma attacks.
In a placebo controlled trial of Liu et al, high dose vitamin D treatment was initiated for deficiency and sufficiency in asthmatic patients between the ages of 6-17 for one year.[24] There was no significant difference in, spirometric values, ACT levels, serum level of vitamin D in the placebo and treated groups at the end of the year. Rather, this study suggests that boosting a patient's serum vitamin D level may be beneficial irrespective of whether they are vitamin D deficient at baseline. The strength of the present study is that it is the randomized -controlled trial to examine whether low-dose, short-term vitamin D supplementation has an effect on asthma control levels in school ages children, most of them were using ICS and/or LTRA.

Patients treated with vitamin D had significantly less exacerbations during the treatment period. Similarly, a randomized double-blind, placebo-controlled trial by Solidoro P et al, compared the effect of vitamin D3 vs. placebo in school ages children.[7] vitamin D3 supplementation was associated with a reduced risk of exacerbations compared with placebo. In a more recent randomized, double-blind, clinical trial, parallel arm 6 months, conducted by Majak et al, children receiving supplemental 500 IU/day vitamin D had a decreased risk of asthma exacerbations triggered by acute respiratory viral infections.12 Improvement in mean PEFR was observed in both the treatment groups during follow up visits. But, the improvement in the PEFR in the vitamin D group was significantly higher as compared to placebo group showing the effect of vitamin D on airway narrowing. Low vitamin D levels have been associated with decreased lung function. Recently, a RCT study by S. Arshi et al. in concluded that 25(OH) D levels had direct and significant correlations with both predicted FEV1 and FEV1/FVC ratio. So, serum 25-hydroxy vitamin D levels were inversely associated with asthma and, direct and significant relationship between serum vitamin D levels and outcomes in childhood asthma.[25] Searing et al, in a cross-sectional study of 100 children of mean age 7 year of moderate to severe persistent asthma have founded increased corticosteroid requirement in children as a function of decreased 25(OH) D levels.[25]

Patients having asthma exacerbation is less in vitamin D group as compared to standard treatment group. So asthma patients are benefited by vitamin D supplementation. The mean number of emergency visits decreased till 3 month of treatment in both the groups. The treatment given according to severity of asthma was able to reduce visits to emergency as there was a significant fall in number of emergency visits at follow up in both the groups. However, the fall in the number of emergency visits in vitamin D group was statistically significant. So, monthly doses of vitamin D were effective in reducing the number of emergency visits in mild to moderate asthma patients. Similar findings were found by Brehm et al. that the risk of hospitalization and emergency visit was more common among the vitamin D deficient children.[22] The limitations of the study were sample size is too small, long term follow-up was not done and different regimens, including higher doses may lead to different findings.

Conclusion

Low dose, short course vitamin D supplementation in addition to standard treatment was found more effective in asthma patient in terms of reducing clinical severity, changing of peak expiratory flow rate, exacerbation and emergency hospital visit.

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