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Original Article

A Comparative Study of Efficacy of Vitamin D Replacement Therapy versus Intralesional Triamcinolone in the Treatment of Alopecia Areata

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ABSTRACT

Background: Alopecia areata (AA) is a chronic, relapsing immune-mediated inflammatory disorder affecting hair follicles which leads to a sudden loss of hair in patches on the scalp and sometimes other parts of the body. Our study aim was to determine the degree of response to Vitamin D replacement therapy in comparison with intra-lesional triamcinolone in patients of alopecia areata.
Methodology: A randomized control trial conducted over 12 months from January 1, 2022 to December 31, 2022, at skin center of a tertiary care hospital among 56 confirmed cases of alopecia areata who were randomly allocated to two groups of 28 each. In the first group, Vitamin D was given orally at a dose of vitamin D 60000 IU / weekly for period of 12 weeks and then monthly for 3 months. In second group, Inj. triamcinolone acetonide 5 mg/ml was given intradermally over area of hair loss on intervals of 21 days each, over a total period of three months. Visual analog scale (VAS) and tricoscan were used to assess the result at the end of 6 months and 1 year after enrollment.
Results: The mean hair density and percentage of increase in hair density at the end of 6 and 12 months of treatment was found to be significantly high among the patients in triamcinolone acetonide group as compared to those in Vitamin D group. Potential hair regrowth was also observed with Vitamin D administration among alopecia areata patients with deficient serum vitamin D levels.
Conclusions: Conventional Intralesional Triamcinolone acetonide is effective than Vitamin D administration in alopecia areata patients. However, significant improvement was noted in patients who are administered with Vitamin D also.

Keywords: *Alopecia areata, hair follicles, Triamcinolone acetonide, Vitamin D replacement therapy.*

INTRODUCTION

Alopecia areata(AA) is a type of non scarring alopecia. It is chronic, relapsing immune-mediated inflammatory disorder affecting hair follicles which leads to a sudden loss of hair in patches on the scalp and sometimes other parts of the body also, which includes body hair, eyebrow, eyelash, etc. Approximately half of all the affected people with mild alopecia areata recover within a year.[1] It was estimated that the prevalence of alopecia areata is nearly 1 in 1000 people, with a lifetime risk of approximately 2%.[2] In most of the patients the onset is usually before age 30; although, the disorder is reported to occur at any age. Also, irrespective of gender men and women are equally affected.[2] It is believed to result from an autoimmune-mediated hair follicle destruction consequent to a loss of immune privilege in the Hair follicle which leads to early and premature transition from anagen to non-proliferative catagen and telogen phases [3-5] .Approximately 20% of people were found to have a family member who is also affected with the same suggestive of genetic predisposition to the disease. A various autoimmune conditions are associated with alopecia areata like vitiligo,

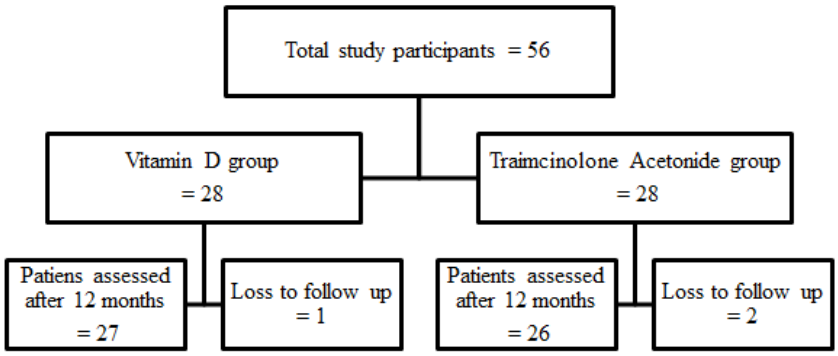
thyroiditis and pernicious anemia and atopic dermatitis. However, the pathogenesis of AA remains incompletely understood and AA remains incurable.

Recently, in patients of Alopecia Areata, Vitamin D deficiency has been detected. Vitamin D has been associated with various autoimmune diseases.[6] Moreover, topical calcipotriol has shown good results in patients with alopecia areata[7] These findings confirm that there is a definite relationship between vitamin D and AA. The aim of this research is to establish the role of of vitamin D in the treatment of AA and to discuss the potential implication of vitamin D in the treatment of AA.

Typically, the lesions are characterized by smooth, circular, discrete areas of complete hair loss. It mainly involves the scalp but may be found on any hair-bearing area. Short hairs broken off a few millimeters from the skin surface (also known as exclamation point hairs) may be found at the edges of expanding patches.A band-like area of alopecia extending across the occipital scalp (ophiasis pattern) may occur in some patients.[8] The rare sisaipho pattern presents with alopecia involving the frontal, temporal, and parietal scalp but spares hair along the scalp periphery.[8] In few patients, the disease may progress to complete loss of scalp hair (alopecia totalis) or all scalp and body hair (alopecia universalis). In 7-66% of the patient nail involvement is there in the form of trachyonychia, onychorrhexis, onycholysis and onychomadesis.[9] Spontaneous regrowth of hair is noted in most of the patients. Around 50% of the cases will recover within a year.[8] However, alopecia areata may persist for several years and in some cases hair growth never recovers. Approximately 10% of patients progress to alopecia totalis or alopecia universalis.[2]The diagnosis of alopecia areata is mostly clinical. Biopsy and trichoscopy should be considered in cases where the diagnosis is uncertain.

The management of alopecia areata is challenging. It involves a variety of topical, intralesional, and systemic agents, but the response to treatment varies widely.[9] The first line treatments for patients include intralesional or topical corticosteroids along with topical immunotherapy formulations. For extensive disease, systemic steroids are the treatment of choice. Other treatment options available are topical sensitizers like Squaric acid dibutyl ester (SADBE), topical minoxidil, photochemotherapy and immunosppressants like, cyclosporine, methotrexate and azathioprine.[9] It is an immune-mediated disorder, hence attempts with biologic agents like tumor necrosis factor (TNF)-alpha inhibitors, Alefacept, Adalimumab, Infliximab, or Etanercept have been made to alter T cell function but have not shown any effectiveness while treating.[10] Othertherapies which were tried and showed different results are, Vitamin D ,Botulinum toxin , Hydroxychloroquine, Topical bexarotene, Excimer laser, Platelet-rich plasma, Recombinant interleukin 2, Janus kinase inhibitors, Simvastatin/ezetimibe. [11-14]

MATERIALS AND METHODS



A randomized intervention trial was done in the Department of dermatology and venereology among the patients in a tertiary care hospital in Delhi, between January 1, 2022 to December 3, 2022 after obtaining approval from the Institutional Ethical Committee. The sample size calculated was 56 patients. It consists of 10-60 years old patients of both genders presenting with clinically diagnosed alopecia areata. All those patients who have taken any kind of treatment for the same, any previous scalp disease,normal vitamin D levels, active infection at local site or patients with other autoimmune disorder were excluded from the study. Patients were randomly divided into two groups each of 28 by using random sampling number table. Informed consent from the patients was obtained. Patients who gave consent for participation and found eligible for the study were evaluated with history and clinical examination. Serum Vitamin D (25 (OH)D concentrations) level were measured for all the participants on the day of enrolment. A value < 20 ng/ml was said to be vitamin D deficiency.

In group 1,Vitamin D group: Vitamin D replacement therapy was given orally at a dose of vitamin D 60000 IU / weeklyfor period of three months and then monthly for 3 months. In group 2,Triamcinolone Group: Inj triamcinolone acetonide, 5 mg/ml, 0.1 ml was given intradermally in one sq cm area of affected scalp on intervals of 21 days each, over a total period of six months.

Patients were observed and followed up for next 6 months without any treatment. Patients were instructed not to alter their hair style or dye their hair during the study period. Trichoscan record (Measurement of hair density with scalp analysis system), Photographic record and visual analogue scale (VAS) were maintained at the start of the study and at reassessment was done at the end of 6 months and 12 months for the extent of regrowth of hair, complications and recurrence.

Data were maintained prospectively in a computerized data base. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 23.0. Student t test and Mann Whitney U test was done to check for statistical significant difference between two means in normally distributed and non-normally distributed data, respectively. Spearman correlation coefficient was calculated to check for linear correlation between two non-normal continuous variables. Chi square test was applied to test statistically significant difference in proportions. A p values <0.05 was considered statistically significant.

RESULTS

Most of the study participants were in the age group of less than 30 years (51.8%), followed by 31-45 years who represented 42.9% of the study population. The mean age of the study participants was observed to be 30.13±10.5 years. Majority of the study participants were females, who represented 53.6% and males represented 46.4% of all study participants. The duration of symptoms was less than 3 months for majority of the study participants (51.8%), while it was 4-6 months for 33.9% of the participants.

Both the study groups were distributed equally in terms of age, gender, duration of illness, initial hair density and baseline vitamin D levels. No statistically significant difference was observed between the study groups. Thereby it implied both the study groups are comparable on demographic characteristics. **(Table 1)**

Table 1. Distribution of study groups based on baseline characteristics

Age (in years)	**Study Group**				**Total n (%)**	**p value**
	Vitamin D (n = 28)		**Triamcinolone Acetonide (n = 28)**			
<30	12(42.9)		17(60.7)		29(51.8)	0.394
31-45	14(50.0)		10(35.7)		24(42.9)	
46-60	2(7.1)		1(3.6)		3(5.4)	
Gender						
Male	13(46.4)		13(46.4)		26(46.4)	1.0
Female	15(53.6)		15(53.6)		30(53.6)	
Duration of illness						
0-3 months	13(46.4)		16(57.1)		29(51.8)	0.65
4-6 months	10(35.7)		9(32.1)		19(33.9)	
7-9 months	5(17.9)		3(10.7)		8(14.3)	
Initial Hair Density on Visual analogue score						
0	5(17.9)		12(42.9)		17(30.4)	0.089
1	22(78.6)		16(57.1)		38(67.9)	
2	1(3.6)		0(0.0)		1(1.8)	
Total	**28(100.0)**		**28(100.0)**		**56(100.0)**	
	Mean	SD (IQR)	Mean	SD (IQR)	**95% CI**	**p value**
Vitamin D (in ng/ml)	15.24	3.6 (12.9-18.4)	15.02	3.2 (12.1-17.7)	-0.21 (-2.04 – 1.6)	0.812*
Initial hair density	1.3	3.6 (0-10)	5.5	4.3 (0-5)	4.1(2.0-6.3)	<0.001#

** Independent sample t test was applied; #Mann Whitney U test was applied*

Significantly higher levels of hair density and higher percentage of increase in hair density was observed in triamcinolone acetate group as compared to that of the patients in vitamin D study group. Also, this difference in hair density levels and percentage of increase in hair density was found to be statistically significant. **(Table 2)**

Table 2. Distribution of study groups based on outcome

	Study Group				Total n (%)	p value
	Vitamin D n (%)		Triamcinolone Acetonide n (%)			
Hair Density on Visual analogue score after 6 months						
1	3(10.7)		0(0.0)		3(5.4)	<0.001
2	21(75.0)		4(14.3)		25(44.6)	
3	4(14.3)		19(67.9)		23(41.1)	
4	0(0.0)		5(17.9)		5(8.9)	
Hair Density on Visual analogue score after 12 months						
2	6(22.2)		0(0.0)		6(11.3)	0.001
3	13(48.1)		6(23.1)		19(35.8)	
4	8(29.6)		20(76.9)		28(52.8)	
	Mean	**SD (IQR)**	**Mean**	**SD (IQR)**	**95% CI**	**p value#**
Hair density after 6 months	42.32	10.67 (35-48)	64.46	10.99 (60-70)	22.14(16.3-27.9)	<0.001
Percentage of increase in Hair Density after 6 months	41.0	11.2 (35-45)	58.96	12.9 (50-70)	17.96(11.4-24.4)	<0.001
Hair Density after 12 months	68.89	13.1 (35-45)	84.42	7.39 (60-70)	15.53(9.6-21.4)	<0.001
Percentage of increase in Hair Density after 12 months	67.51	13.7 (60-80)	75.77	19.36 (70-85)	8.25(-0.9-17.4)	0.005

 # Mann Whitney U test was applied to test for statistical difference between the study group mean.

A significant negative correlation was observed between age and percentage of increase in hair density after 6 and 12 month in both the study groups. Similarly a significant negative correlation was observed between vitamin D levels and percentage of increase in hair density after 6 and 12 months in both the study groups.**(Table 3)**

Table 3. Correlation between baseline characteristics and outcome.

Study group	Vitamin D		Triamcinolone Acetonide	
Statistics	**Spearman Correlation Coefficient**	**p value**	**Spearman Correlation Coefficient**	**p value**
Age & Percentage of increase in hair density after 6 months	-0.417	0.027	-0.36	0.06
Age & Percentage of increase in hair density after 12 months	-0.195	0.330	-0.334	0.089
Duration of symptoms & Percentage of increase in hair density after 6 months	-0.229	0.241	0.037	0.851
Duration of symptoms & Percentage of increase in hair density after 12 months	-0.003	0.986	0.160	0.426
Vitamin D levels & Percentage of increase in hair density after 6 months	-0.417	0.027	-0.255	0.199
Vitamin D levels & Percentage of increase in hair density after 12 months	-0.195	0.330	-0.185	.355

DISCUSSION

The present study was carried out as a randomized intervention trial among patients with alopecia areata (AA). Alopecia areata(AA) is a common autoimmune skin disease characterized by loss of the hair on the scalp and elsewhere on the body, affecting approximately 2% of the general population at some point during their lifetime.[1] The hair loss in AA is believed to result from an autoimmune-mediated hair follicle (HF) destruction consequent to a loss of immune privilege (IP) in the HF. Auto reactive effector and regulatory T cells and mast cells, cytotoxic T cells, activators of transcriptional signaling (JAK/STAT) pathways, Janus kinase/signal transducers and oxidative stress (OS) all are involved in

pathogenesis of alopecia areata. [1,2].However, the exact pathogenesis still remains incompletely understood and hence treatment options also.Recently, in alopecia areata the deficiency of vitamin D has been reported. [15] Moreover, in alopecia areata, topical calcipotriol has shown satisfactory results.[7]

Allthese reports attracted the attention on the relationship between vitamin D and AA. The aim of this study is to compare the effect of Vitamin D replacement therapy with intra-lesional triamcinolone in terms of increase in density and diameter (thickness) of hair during the treatment and follow up period, over a total period of 12 months in patients with alopecia areata.

In our study, maximum of the study participants were in the age group of less than 30 years (51.8%) and mean age of the study participants was observed to be 30.13±10.5 years. Majority of the study participants were females, who represented 53.6% of the total participants. The duration of symptoms was less than 3 months for majority of the study participants (51.8%). The study groups were comparable in terms of age, gender and duration of illness. The mean hair density (64.46±10.99 vs 42.32±10.67) and the percentage of increase in hair density(58.96±12.9 vs 41.0±11.2) after 6 months of treatment was found to be significantly higher among the patients in triamcinolone acetonide group as compared to those in Vitamin D group. The mean hair density (84.42±7.39 vs 68.89±13.1) and percentage of increase in hair density (75.77±19.36 vs 67.51±13.7) was also seen high among the patients in triamcinolone acetonide group after 12 months of treatment. Visual analogue scale also showed more increase in hair density in triamcinolone acetonide group. A significant negative correlation was observed between age, duration of symptoms and percentage of increase in hair density after 6 and 12 months of treatment in both the study groups.

On detailed review of the published literature and to the best of our knowledge there are very less studies which compared Vitamin D and Triamcinolone in the treatment of Alopecia areata patients. A study by d'Ovidio R was one of the pioneering research which suggested the association between vitamin D deficiency in patients with alopecia areata.[16] This study was followed by various other similar studies in the subsequent year which also demonstrated vitamin D deficiency among alopecia areata patients.[17,18]

Vitamin D is a secosteroid hormone that plays an important role in calcium homeostasis and bone health. The mechanism of action of topical vitamin D analogues in enhancing regrowth of hair in cases of alopecia areata is thought to be regulated by the differentiation of B cells, T cells, dendritic cells, and the expression of Toll-like receptors.[19] However the role of vitamin D among these alopecia areata patients with deficient levels of vitamin D was not clearly understood. Very few research works have explored the potential use of administering vitamin D in the treatment of alopecia areata. In a study done by Kim DH et al [20] a 7 year old child with alopecia areata who was noted to be resistant to conventional topical and intralesional steroid applications, stated that the patient responded to topical application of a vitamin D analog. Followed by the above stated research work, Cerman AA et al[7]evaluated the efficacy and safety of topical calcipotriol for the treatment of mild-to-moderate patchy alopecia areata. After 12 weeks of treatment and followup to the 48 patients studies it was observed that a regrowth score (RGS) ≥ 3 (hair regrowth of ≥ 50%) was observed in 75% of patients, whereas a RGS ≥ 4 (hair regrowth of ≥ 75%) was observed in 62.5% of patients and the complete regrowth rate (hair regrowth= 100%) was 27.1%. The result observed in the above discussed study was similar and comparable to vitamin D group of study participants that of our present study.

In a recent Indian study by Narang T et al [21]among 22 patients with alopecia areata efficacy of calcipotriol lotion 0.005% twice daily for three months was evaluated. It was observed by the authors that after 12 weeks of treatment, hair regrowth was seen in 13 (59.1%) patients. Similarly it was also found that response to treatment was better in patients with lower vitamin D levels ($p < 0.009$). A similar observation was noted in our study. Further, a negative correlation was observed between the vitamin D levels and the Vitamin D treatment group (**Error! Reference source not found.**) similar to our study. Thompson JM et al[22]reported that there was no significant association between dietary, supplemental, or total vitamin D intake and alopecia areata, which therefore does not support a preventive role for vitamin D in the risk of developing alopecia areata. These fact suggests the potential immune mediated role of vitamin D in the treatment of alopecia.

The findings of the above discussed studies support the results derived from our present study. Though not equivalent to that of the conventional steroid therapy, potential hair regrowth can be produced with Vitamin D administration among alopecia areata patients. This finding potentiates the additional role of using Vitamin D as an alternative treatment modality of alopecia areata.
The relatively smaller sample size restricted the use of parametric statistical tests. However, considering the study period and feasibility, adequate sample was taken appropriate to sample size calculation is one of the limitation of our study.

CONCLUSION

Studies have shown a substantial link between the levels of vitamin D and AA, even though the underlying mechanism is not well known. Our study revealed that although conventional intralesional Triamcinolone acetonide was more effective than Vitamin D in alopecia areata patients but those who were administered with Vitamin D also showed significant improvement. Higher percentage of increase in hair density correlates with lower Vitamin D levels among the patients treated with Vitamin D. Hence role of Vitamin D cannot be ignored. In the future, vitamin D analogs and corticosteroids combination treatment might provide potential benefit in the treatment of AA.

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