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To Compare the Safety of Weekly Azathioprine Pulse (WAP) and Betamethasone Oral Mini Pulse (BOMP) in the Treatment of Alopecia Areata.

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Abstract:

Background&Method: A prospective & comparative clinical study done with an aim to compare the safety of weekly azathioprine pulse (WAP) and betamethasone oral mini pulse (BOMP) in the treatment of alopecia areata in Department of Dermatology, Venereology &Leprology, MDM Hospital, Jodhpur. Sample size of total 60 patients, 30 in each group Study duration of 01 year at patients of clinically diagnosed alopecia areata attending the skin department of Dr. S. N. Medical College, Jodhpur.

Result: Nail involvement was seen in 28.34% of patients. 21.67% of the patients had less than 6 months of illness and 6.67% patients had greater than 6 month duration of illness. Odds ratio = 0.631 and P value = 0.729 which meant that there is no statistically significant association of nail involvement and duration of illness. Most common nail change was pitting in 10% of patients followed by ridging (6.67%), ridging and pitting (5%), leuconychia (3.3%), dystrophy (1.67%). One of our patient had twenty nail dystrophy.

Conclusion: The male to female ratio was found to be 3.23:1 which was comparable. Nail changes were noted in 28.4% of patients. Majority of the patients (71.6%) had no associated nail changes. Most common nail change was pitting followed by ridging. One of our patient had twenty nail dystrophy. Pitting was associated with severity and duration of illness.
Thus the conclusion for the treatment of alopecia areata, weekly azathioprine pulse may be considered as effective as oral betamethasone pulse with lesser side effects. Although BOMP is also considered safe. However a large group study should be performed to confirm these findings.

Keywords:efficacy, (WAP), (BOMP) & alopecia areata.

Study Designed:prospective, comparative clinical study.

1. INTRODUCTION

ANATOMY OF HAIR

The hair follicle can be divided into 3 regions: the lower segment (bulb and suprabulb), the middle segment (isthmus), and the upper segment (infundibulum). The lower segment extends from the base of the follicle to the insertion of the erector pili muscle. The

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middle segment is a short section that extends from the insertion of the erector pili muscle to the entrance of the sebaceous gland duct[1]. The upper segment extends from the entrance of the sebaceous gland duct to the follicular orifice.

Alopecia areata is common disease.6 The lifetime risk of developing this condition is reported to be 1.7%.[2] Men and women are equally affected with same prevalence in all ethnic groups.8,9 AA can occur at any age, but the peak incidence appears to be between 15 and 29 years of age. Pediatric AA constitutes approximately 20% of AA cases.10 A very few studies are conducted in this area focusing specially on children with alopecia areata.[3] AA is reported to occur before the age of 16 years in 11% to 23.9% of the affected population. Traditionally it has been classified as an acquired disorder. [4] However, it is rarely reported in infancy. [5]and even less so in the neonatal period.16,17 Walker and Rothman18 did a study of AA in 120 patients with average 14 years follow-up. They found that the onset before puberty correlated with severity, with 50% of prepubertal cases developing alopecia totalis as compared to 23% of post-pubertal onset cases.[6]

The exact etiology of AA is not known. Family history is positive in 10 to 20 % of cases.19 Family history of AA is more common in those with disease onset before the age of 30 years.20 The etiology and pathogenesis of alopecia areata is still uncertain but many factors have been described in its pathogenesis e.g. genetic, family history, the atopic state, non-specific immune and organ specific autoimmune reaction, possible emotional stress, infectious agents and neurological factors.[7]

2. MATERIAL & METHOD

A prospective& comparative clinical study, Department of Dermatology, Venereology &Leprology, MDM Hospital, Jodhpur. Sample size of total 60 patients, 30 in each group Study duration of 01 year at patients of clinically diagnosed alopecia areata attending the skin department of Dr. S. N. Medical College, Jodhpur from November 2015 to October 2016 were included in the study. These patients were selected and allocated according to the inclusion and exclusion criteria which are mentioned below.
Patients of alopecia areata were included adopting the following criteria.

Inclusion criteria:
1. Patients with confirmed diagnosis of alopecia areata.
2. Patients between the age of 05 to 60 years.
3. Patients willing for treatment, investigations and regular follow up.

Exclusion criteria:
1. Pregnant and lactating women.
2. Patients with deranged CBC, LFT, RFT and random blood sugar.
3. Patients unsure about attending treatment schedule regularly.
4. Immunocompromised/ immunosupressed individual.
5. Any psychiatric illness.

Assessment of the patients:
The severity of hair loss was assessed by measuring the percentage of the alopecic area on the scalp. Patients with AA were evaluated using Severity of Alopecia Tool (SALT). The SALT score is computed by measuring the percentage of hair loss in each of 4 areas of the scalp

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(40% vertex, 18% right profile, 18% left profile, 24% posterior) and adding the total to achieve a composite score.

STATISTICAL METHODS AND DATA ANALYSIS PROCEDURES

Statistical analysis was performed with the PRIMER and SPSS, Tril version 20 for Windows statistical software package (SPSS inc., Chicago, il, USA). Results were expressed as Mean±SD and number and percentages. The Categorical data were presented as numbers (percent) and were compared among groups using Chi square test. Groups were compared for demographic data were presented as mean and standard deviation and were compared using by students t-test. Probability P value <0.05 was considered statistically significant.

3. RESULTS

TABLE NO. 01: SEX DISTRIBUTIONS

Sex	**Group I**		**Group II**		**Total**
Male	19	63.34%	27	90%	46(76.67%)
Female	11	36.67%	3	10%	14(23.33%)
Total	30		30		

Out of 60 patients 46 (76.67%) were male and 14(23.33%) were female. In group-I there were 63.34% males and 36.67% female and in group-II there were 90% and 10% males and females respectively. The male to female ratio was found to be 3.23:1.

TABLE No. 02: ASSOCIATED DISEASE

ASSOCIATED DISEASE	**GROUP I**	**GROUP II**	**TOTAL**
ASTHMA	1	0	1(1.7%)
ATOPY	1	1	2(3.33%)
DM	3	1	4(6.67%)
HYPERTHYROIDISM	2	0	2(3.33%)
VITILIGO	1	0	1(1.7%)
INFECTION	0	1	1(1.7%)
IDIOPATHIC	22	27	49(81.6%)

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Majority of the patients (81.6%) had no associated dermatological or systemic disease. Diabetes was the commonest dermatological disease associated (6.67%). Atopy and thyroid dysfunction were seen in two patients each (3.33%). Vitiligo, asthma and infection were present in one patient each (1.7% each).

TABLE NO. 03: NAIL INVOLVEMENT WITH DURATION OF ILLNESS

NAIL INVOLVEMENT	**PRESENT**	**ABSENT**	**TOTAL**	**P VALUE**
< 6 MONTH	13(21.67%)	36(60%)	49(81.67%)	0.729
>6 MONTH	4(6.67%)	7(11.67%)	11(18.33%)	
TOTAL	17(28.34%)	43(71.67%)	60	

Nail involvement was seen in 28.34% of patients. 21.67% of the patients had less than 6 months of illness and 6.67% patients had greater than 6 month duration of illness.

Odds ratio = 0.631 and P value = 0.729 which meant that there is no statistically significant association of nail involvement and duration of illness.

TABLE NO. 04 NAIL CHANGES

NAIL CHANGES	**NO.**	**%**
PITTING	6	10.00
RIDGING	4	6.67
DYSTROPHY	1	1.67
LEUCONYCHIA	2	3.33
PITTING+RIDGING	3	5.00
NORMAL	44	73.33

Most common nail change was pitting in 10% of patients followed by ridging (6.67%), ridging and pitting (5%), leuconychia (3.3%), dystrophy (1.67%). One of our patient had twenty nail dystrophy.

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TABLE NO. 05 SIDE EFFECT OF BOTH THERAPY

SIDE EFFECTS (CLINICAL, INVESTIGATIONAL)	GROUP I (N=30)	GROUP II (N=30)	TOTAL (N=60)	P VALUE
ABNORMALITY IN HB, TLC,PLATELET COUNT	1 (3.33%)	1(3.33%)	2(3.33%)	P= 0.1143
ABNORMAL LFT	1(3.33%)	0(0%)	1(1.67%)	
ABNORMAL BLOOD SUGAR	2(6.67%)	0(0%)	2(3.33%)	
ABNORMAL KFT	0(0%)	0(0%)	0(0%)	
ABNORMALITY IN ECG, CHEST X RAY	0(0%)	0(0%)	0(0%)	
DIARRHEA	0(0%)	1(3.33%)	1(1.67%)	
NAUSEA, VOMITING	2(6.67%)	1(3.33%)	3(5%)	
EPIGASTRIC PAIN	0(0%)	1(3.33%)	1(1.67%)	
ACNEFORMERRUPTION	3 (10%)	0(0%)	3(5%)	
HEADACHE/ DROWSINESS	2(6.67%)	1(3.33%)	3(5%)	
OTHERS (DRY MOUTH, ACHES/PAINS)	0(0%)	0(0%)	0(0%)	
TOTAL	11(36.67%)	5(16.67%)	16(26.67%)	

The side effects in group I were acneform eruption in 10% of patients, followed by nausea 6.67% and headache in 6.67%, overall 36.6% patients encountered side effects.

In group II the most common side effect was abnormal hemogram, diarrhea, nausea vomiting, epigastric pain and headache/ drowsiness which was seen in 3.33% of patients, overall side effects were seen in 16.67% of cases in group II.

Side effects encountered were higher in group I patients (36.6%) as compared to group II (16.67%) and were not significantly significant (p= 0.1143) (P < 0.05, Significant) in patients.

4. DISCUSSION

Majority of the patients (81.6%) had no associated dermatological or systemic disease. Diabetes was the commonest dermatological disease associated (6.67%). Atopy and thyroid dysfunction were seen in two patients each(3.33%). Vitiligo, asthma and infection were present in one patient each (1.7%). It was comparable to the study, where a definite evidence of atopy was obtained in 35 (17.5%) children.[8]

Nail changes were noted in 28.4% of patients. Majority of the patients (71.6%) had no associated nail changes. Most common nail change was pitting in 10% of patients followed by ridging (6.67%), ridging and pitting (5%), leuconychia(3.3%), and dystrophy(1.67%). One of our patient had twenty nail dystrophy.[9]

Sharma VK et al11 reported 30% children had associated nail changes and these changes co-related with the severity of AA. However in our study, only nail pitting co-related with severity and duration of AA.

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5. CONCLUSION

The male to female ratio was found to be 3.23:1 which was comparable. Nail changes were noted in 28.4% of patients. Majority of the patients (71.6%) had no associated nail changes. Most common nail change was pitting followed by ridging. One of our patient had twenty nail dystrophy. Pitting was associated with severity and duration of illness.

Thus the conclusion for the treatment of alopecia areata, weekly azathioprine pulse may be considered as effective as oral betamethasone pulse with lesser side effects. Although BOMP is also considered safe. However a large group study should be performed to confirm these findings.

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