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To Compare The Efficacy of Weekly Azathioprine Pulse (WAP) And Betamethasone Oral Mini Pulse (BOMP) in The Treatment of Alopecia Areata.

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Abstract:

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

Result: According to table at 12th week of treatment In group I, 6.67% patients showed poor response, 13.33% of patients showed moderate response, 13.33% of patients showed good response and 66.67% of patients showed excellent response to the treatment. In group II, none of the patients showed poor response and moderate response, 3.33% of patients showed good response and 96.67% of patients showed excellent response to the treatment. Test of significance showed p value <0.05 it meant that there was significant difference in the groups regarding response to therapy; group II response was better than group I.

Conclusion: In the present study, the peak age of onset was seen in the young adult age group between 15-30 years (53.3%). 15. SALT response was statistically significant at 18th week and 24th week which means that there was significant difference between the decreases in SALT score to reduce to its 75% of the original value in both the groups. Group II showed significant improvement during 18th week and 24th week.

Keywords:efficacy, weekly azathioprine pulse (WAP) and betamethasone oral mini pulse (BOMP) & alopecia areata.

Study Designed:prospective& comparative clinical study.

1. INTRODUCTION

Alopecia areata is an autoimmune disease, characterized by non-scarring hair loss of the scalp or any hair bearing surface. The life time risk of developing this condition is reported to be 1.7%. Pediatric AA constitutes approximately 20% of AA cases[1]. Family history is positive in 10 to 20% of cases. AA is considered to be an autoimmune disease with a definite evidence for the role of T-lymphocytes. Associated auto immune diseases include-vitiligo,

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thyroid disorder, lichen planus, collagen vascular diseases, diabetes mellitus, and pemphigus foliacious[2].

Various therapeutic agents have been described for the treatment of alopecia areata (AA), but none are curative or preventive. The aim of AA treatment is to suppress the activity of the disease. The high rate of spontaneous remission and the paucity of randomized, double-blind, placebo-controlled studies make the evidence-based assessment of these therapies difficult[3]. Treatment of moderate to severe AA remains a challenge. Corticosteroids are usually effective, though their long-term use may result in serious side effects. Azathioprine has shown promisin results in the management of various disorders in comparison to oral corticosteroid pulse therapy. Weekly azathioprine pulse (WAP) has shown good efficacy, better compliance, and reduce costs in Partheniumdermatitis[4&5].

As relapse mostly occurs with steroid therapy and long term steroid may cause many adverse effects, steroids can be given in a pulse form to reduce the side effects. Azathioprine is a potent immunosuppressant and its action results from inhibition of purine synthesis, thus blocking DNA replication in T-cells and Langerhancells and suppressing cell mediated immune reactions[6]. Full-dose azathioprine can work for alopecia areata, but the low-dose option makes azathioprine more attractive with a predictably lower side-effect profile in recalcitrant disease. A comparision of Weekly azathioprine pulse (WAP) and Betamethasone Oral Mini Pulse(BOMP) for the treatment of alopecia areata has not been attempted yet. This study is the first of its kind as it will open avenues in the management of alopecia areata.

2. MATERIAL & METHOD

A single centre, 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.

Sixty 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.

BASELINE EVALUATION

Initially a detailed history regarding the age of onset, the duration of illness, past modalities of treatment, family history of the disease, triggering factors, occupation and history of associated disease were taken. A detailed cutaneous and systemic examination was done in

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all the patients. Complete haemogram, urine routine and microscopy, skin biopsy, blood sugar, liver function test, renal function test, thyroid function test were done in all the patients before initiation of therapy.

The patients were explained regarding the duration of treatment, the need for regular follow up to therapy, and probable side effects that could be encountered during treatment. Complete haemogram, urine routine and microscopic, blood sugar, liver function test, renal function test were done periodically to observe for any systemic involvement or any derangement due to therapy. The response to treatment was evaluated six weekly by SALT score and the patients were observed clinically for any cutaneous or systemic side effects.

3. RESULTS

TABLE NO.01: AGE DISTRIBUTION IN EACH GROUPS

AGE (IN YEARS)	1-15	16-30	31-45	46-60	TOTAL	MEAN	SD	F	P VALUE
GROUP-I	05	15	09	01	30	25.46	09.68	0.671	0.544
GROUP-II	04	17	08	01	30	27.23	10.48		
TOTAL	09	32	17	02	60				

Out of 60 patients, 30 patients of group-I had mean age and standard deviation 25.46±9.68year. Maximum and minimum age is 55year and 5 year respectively. Most common age group involved was between 16 to 30 year of age. In group-II mean and standard deviation was 27.23±10.48 year. Maximum and minimum age was 60 year and 7 year respectively. Most common age group involved was between 16 to 30 year of age.The P value was 0.544 which showed no significant difference in the age of both groups.

TABLE NO. 02: PREVIOUS TREATMENTS TAKEN

PREVIOUS TREATMENT	**GROUP I**	**GROUP II**	**TOTAL**
TOPICAL STEROID	5	2	7(11.67%)
I/L STEROID	11	5	16(26.67%)
PULSE STEROID	0	1	1(1.66%)
MINOXIDIL	0	1	1(1.66%)
HOMEOPATHIC	0	2	2(3.34%)
BOP	0	1	1(1.66%)

Most of the patients in our study had taken steroid in some form, 26.67% of patients had already taken intralesional injection of steroid followed by topical application (11.67%).

One patient who had taken prednisolone pulse was allocated to group-II, another patient of group-I who was on BOMP was shifted to group-II due to steroid side effect (facial puffiness)

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TABLE NO. 03: RESPONSE AT 4TH FOLLOW UP (24TH WEEKS)

STUDY GROUP	GROUP I (N=25)	GROUP II (N=15)	TOTAL	UNPAIRED T TEST	INTERPRETATION
POOR (<25%)	2(6.67%)	0(0%)	2(3.33%)	P= 0.0025	SIGNIFICANT
MODERATE (26-50)	4(13.33%)	0(0%)	4(6.67%)		
GOOD (51-75)	4(13.33%)	1(3.33%)	5(8.33%)		
EXCELLENT (>75)	20(66.67%)	29(96.67%)	49(81.67%)		

According to table at 12th week of treatment In group I, 6.67% patients showed poor response, 13.33% of patients showed moderate response, 13.33% of patients showed good response and 66.67% of patients showed excellent response to the treatment. In group II, none of the patients showed poor response and moderate response, 3.33% of patients showed good response and 96.67% of patients showed excellent response to the treatment. Test of significance showed p value <0.05 it meant that there was significant difference in the groups regarding response to therapy; group II response was better than group I.

4. DISCUSSION

In the present study, the peak age of onset was 15-30 years (53.3%), it is comparable to study by Muller SA et al, (1963) which also showed the peak age of onset between 15-30 years.
This study also included cases resistant to various other modalities of treatment. The patients had tried topical and oral medications like steroids, emollients, and ayurvedicpreparations[7]. Our study, showed that 31.6% of cases had taken previous medications. Most of the patients in our study had taken steroid in some form, 26.67% of patients had taken it in intralesional injection followed by topical application (11.67%)[8].
One patient had taken prednisolone pulse who was included in group-II another patient of group-I who was on BOMP was shifted to group-II due to steroid side effect (facial puffiness). Being a referral hospital, most of the patients come after trying other modalities of treatment at peripheral level[9].
Verma et al. (2015) evaluated the effectiveness and side effect profile of WAP and betamethasone oral minipulse (BOMP) therapy in the treatment of moderate to severe AA. Fifty consecutive patients with at least 10% scalp area involvement with AA for at least 3 months were included. A total of 50 patients, 36 males and 14 females, between 18 and 46 years of age (mean age 26.6 ± 7.38 years) were included. There were 25 patients in each group of whom 20 patients in the WAP and 21 patients in the BOMP groups completed the study. Five patients in the WAP group and four patients in the OMP group were lost to follow-up[10].

5. CONCLUSION

In the present study, the peak age of onset was seen in the young adult age group between 15-30 years (53.3%). 15. SALT response was statistically significant at 18th week

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and 24th week which means that there was significant difference between the decreases in SALT score to reduce to its 75% of the original value in both the groups. Group II showed significant improvement during 18th week and 24th week.

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