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A COMPARATIVE STUDY OF SAFETY AND EFFICACY OF BETAMETHASONE ORAL MINI PULSE (BOMP) AND WEEKLY AZATHIOPRINE PULSE (WAP) IN THE TREATMENT OF ALOPECIA AREATA

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INTRODUCTION

Alopecia areata is an autoimmune disease, characterized by non-scarring hair loss on the scalp or any hair bearing surface.[1] Alopecia areata is common disease.[2] The lifetime risk of developing this condition is reported to be 1.7%.[3] Men and women are equally affected with same prevalence in all ethnic groups.[4,5] AA can occur at any age, but the peak incidence appears to be between 15 and 29 years of age.[6] Pediatric AA constitutes approximately 20% of AA cases.[7] A very few studies are conducted in this area focusing specially on children with alopecia areata.[8,9] 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.[10] However, it is rarely reported in infancy.[11,12] and even less so in the neonatal period.[13,14]

Arious therapeutic agents have been described for the treatment of 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. 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 promising 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 Parthenium dermatitis.

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 Langerhan cells and suppressing cell mediated immune reactions. 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.

Present study was carried out in a tertiary hospital to compare the efficacy of weekly azathioprine pulse (WAP) and betamethasone oral mini pulse (BOMP) in the treatment of alopecia areata and to compare the safety of weekly azathioprine pulse (WAP) and betamethasone oral mini pulse (BOMP) in the treatment of alopecia areata.

MATERIAL AND METHOD

Study design: A single centre, prospective, comparative clinical study.
Study location: Department of Dermatology, Venereology and Leprology,
Sample size: Total 60 patients, 30 in each group
Study duration: 1 year

Sixty patients of clinically diagnosed alopecia areata attending the skin clinic from November 2015 to October 2016 were included in the study.

Inclusion criteria

- Patients with confirmed diagnosis of alopecia areata.
- Patients between the age of 5 to 60 years.
- Patients willing for treatment, investigations and regular follow up.

Exclusion criteria

- Pregnant and lactating women.
- Patients with deranged CBC, LFT, RFT and random blood sugar.
- Patients unsure about attending treatment schedule regularly.

- Immunocompromised/ immunosupressed individual.
- Any psychiatric illness.

Baseline Evaluation

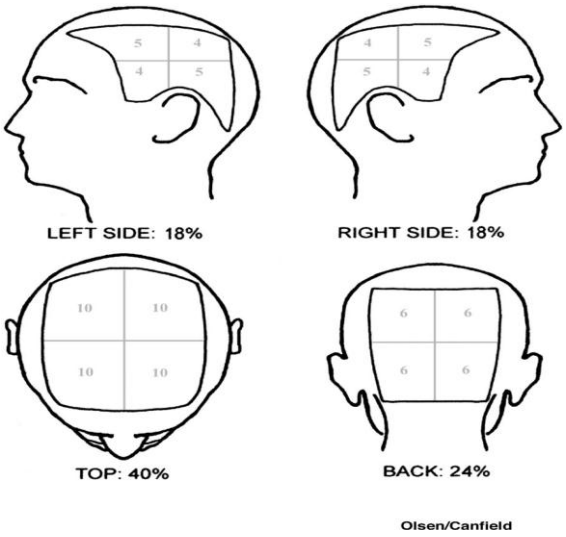
Initially a detailed history regarding the age of onset, the duration of illness, past modalities of treatment, family history of the disease, triggering factors, occupation and history of associated disease were taken. A detailed cutaneous and systemic examination was done in all the patients. Complete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

After a detailed clinical and laboratory evaluation, patients were assigned to azathioprine 5mg/kg once a week (WAP) in divided dose after meal or 1mg/10kg betamethasone on two consecutive days every week (BOMP) orally for 6 months and were followed up for 6 months. Severity of Alopecia Tool (SALT) score was used to determine disease severity.

Assesssment 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)[17]. The SALT score is computed by measuring the percentage of hair loss in each of 4 areas of the scalp (40% vertex, 18% right profile, 18% left profile, 24% posterior) and adding the total to achieve a composite score.



The percentage of hair loss in any one of the four views (areas) of the scalp = the percentage hair loss X percent surface area of the scalp in that area. The SALT score then equals the sum of the scalp hair loss in each area.

Investigations

Selected investigations were done only in doubtful cases of AA,

- KOH preparation and fungal culture
- Hair microscopy
- Skin biopsy
- Serology for lupus erythematosus
- Serology for syphilis
- Psychiatric evaluation for trichotilimania

Group A: Betamethasone oral mini pulse (BOMP): In this group Oral Tab. Betamethasone consisting of 1mg/10 kg as a single oral dose with breakfast on two consecutive days per week.

Group B: Weekly Azathioprine Pulse: Thirty patients of the second group were given oral Azathioprine 5mg/kg weekly as a divided dose of 6 tablets of 50 mg each, half an hour after meals. Forty- eight hours before giving this large dose, an initial test dose of 50 mg orally was given to look for any idiosyncrasy and gastric intolerance.

Patients were clinically evaluated and routine laboratory investigations repeated every month to determine response and adverse effects of the therapy.

In both the groups duration of therapy was 24 weeks or till the patients achieved SALT 75 (75% reduction in the base line SALT Score), whichever was earlier, subsequently patients were either tapered or put on maintenance therapy and monitored accordingly.

All patients in both groups were examined at each visit up to six months. SALT scoring was carried before initiation of therapy then at 6 weeks, 12 weeks, 18 week and 24 weeks of therapy. The patient was considered in remission when there was 75% reduction in the baseline SALT score.

Outcome measures

1. SALT score at each visit.
2. SALT 75 (it means 75% reduction in original SALT)

- Response was graded as
- Poor(<25% reduction)
- Moderate (26-50%)
- Good(51-75%)
- Excellent (>75%)

3. Assessment of side effects of each modality/ group.
4. Clinical photograph

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.

RESULTS

Table 1: Age distribution in each groups.

Age (in years)	1-15	16-30	31-45	46-60	Total	Mean	SD	F	P value
Group-I	5	15	9	1	30	25.46	9.68		
Group-II	4	17	8	1	30	27.23	10.48	0.671	0.544
Total	9	32	17	2	60				

Out of 60 patients, 30 patients of group-I had mean age and standard deviation 25.46±9.68year. In group-II mean and standard deviation was 27.23±10.48 year. The P value was 0.544 which showed no significant difference in the age of both groups.

Table 2: 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 3: 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%)

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 4: 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).

Table 5: Episode number.

EPISODE	GROUP I	GROUP II	TOTAL	P VALUE
1ST	25	26	51(85%)	0.9553 (NS)
2ND	4	3	7(11.67%)	
3RD	1	0	1(1.67%)	
>3	0	1	1(1.67%)	

85% of the patients were facing the first episode. 11.67% had 2nd episode, 1.67 % had 3rd episode and 1.67% had faced > 3 episodes.

As the test statistics indicated that p >0.05 it meant that the patients were comparable in both groups.

Table 6: Nail involvements 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 7: 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.

Table 8: Results at 1st follow up (6 weeks).

STUDY GROUP	GROUP I (N=30)	GROUP II (N=30)	TOTAL (N=60)	UNPAIRED T TEST	INTERPRETATION
POOR (<25%)	7(23.33%)	7(23.33%)	14(23.33%)	P >0.99	NOT SIGNIFICANT
MODERATE (26-50%)	18(60%)	18(60%)	36(60%)		
GOOD (51-75%)	4(13.33%)	4(13.33%)	8(13.33%)		
EXCELLENT (>75%)	1(3.33%)	1(3.33%)	2(3.33%)		

At 6th week of treatment

In group I 23.33% patients showed poor response, 60% of patients showed moderate response, 13.33% of patients showed good response and 3.33% of patients showed excellent response to the treatment according to SALT score.

In group II 23.33% patients showed poor response, 60% of patients showed moderate response, 13.33% of

patients showed good response and 3.33% of patients showed excellent response to the treatment. There was no significant relation in the groups regarding response to therapy.

Table 9: Response at 2nd follow up (12 weeks).

STUDY GROUP	GROUP I (N=30)	GROUP II (N=30)	TOTAL	UNPAIRED T TEST	INTERPRETATION
POOR (<25%)	11(36.67%)	3(10%)	14(23.33%)	P=0.387	NOT SIGNIFICANT
MODERATE (26-50)	11(36.67%)	14(46.67%)	25(41.66%)		
GOOD (51-75)	5(16.67%)	6(20%)	11(18.33%)		
EXCELLENT (>75)	3(10%)	7(23.33%)	10(16.67%)		

At 12th week of treatment

In group I 36.67% patients showed poor response, 36.67% of patients showed moderate response, 16.67% of patients showed good response and 10% of patients showed excellent response to the treatment according to SALT score.

In group II 10% patients showed poor response, 41.66% of patients showed moderate response, 18.33% of patients showed good response and 16.67% of patients showed excellent response to the treatment.

Table 10: Response at 3rd follow up (18 weeks).

STUDY GROUP	GROUP I (N=30)	GROUP II (N=30)	TOTAL	UNPAIRED T TEST	INTERPRETATION
POOR (<25%)	5(16.67%)	1(3.33%)	6(10%)	P= 0.065	NOT SIGNIFICANT
MODERATE (26-50)	11(36.67%)	1(3.33%)	12(20%)		
GOOD (51-75)	7(23.33%)	8(26.67%)	15(25%)		
EXCELLENT (>75)	7(23.33%)	20(66.67%)	27(45%)		

At 18th week of treatment

In group I 16.67% patients showed poor response, 36.67% of patients showed moderate response, 23.33% of patients showed good response and 23.33% of patients showed excellent response to the treatment according to SALT score.

In group II 3.333% patients showed poor response, 3.33% of patients showed moderate response, 26.67% of patients showed good response and 66.67% of patients showed excellent response to the treatment.

Table 11: 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.

Table 12: 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%)	
ACNEFORM ERRUPTION	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.

Table 13: Salt measurement.

Groups		Baseline salt	Salt at 6week	Salt at 12 week	Salt at 18 week	Salt at 24 week
I	MEAN±SD	34.37±25.53	23.2±18.63	15.36±14.58	9±10.94	4.01±8.24
II	MEAN±SD	27.85±23.47	19.25±20.04	11.43±15.94	4.47±11.48	0.9±3.85
ANOVA	F*	.704	.759	.737	.740	.857
	P	.824	.768	.791	.788	.658
Difference Between Groups ** (A VS B)	P	0.3544	0.4649	.3275	.0265	.0143

*One Way ANOVA
** Unpaired t – test

Mean SALT score of group I was 34.37±25.53 and group II was 27.85±23.47 and there was significant reduction in mean SALT score in each follow up visit with quicker response in group-II.

In both groups there was gradual reduction in mean SALT score at each follow up visits. The baseline SALT score in both the groups was almost equal and it showed significant reduction (P <0.05, Significant) at the end of 18 weeks and 24 weeks in group II (WAP). There was 67% and 70% reduction in mean SALT score respectively in group I and II at 6 week and this was the quickest response to therapy in both the groups.

Table 14: patient having $salt_{75}$ response of therapy every followup visit.

Duration	Group	$Salt_{75}$		CHI-Square Test
		Yes	No	
6 Week	I	1(3.33%)	29	P= 1.00(NS)
	II	1(3.33%)	29	
12 Week	I	3(10%)	27	P= 0.299(NS)
	II	7(23.3%)	23	
18 Week	I	7(23.3%)	23	P= 0.0016(S)
	II	20(66.6%)	10	
24 Week	I	20(66.6%)	10	P= 0.0056(S)
	II	29(96.7%)	1	

$SALT_{75}$ response was stastically significant at 18th week and 24th week which means that there was significant difference between the decrease 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.

At 6 week both the groups had 3.33% patient with $SALT_{75.}$ At 12th week group II had 23.3% patients achieving $SALT_{75}$ as compared to 10% in group I. At 18th week $SALT_{75}$ was 23.3% and 66.6% respectively in group I and II, this was stastically significant and comparable. At 24th week $SALT_{75}$ was 66.6% and 96.7% respectively in group I and II, this was stastically significant and comparable.

DISCUSSION

The present study included 60 cases of alopecia areata patients who were allocated into three groups of 30 each, Group I treated with Betamethasone Oral Mini Pulse (BOMP), Group II treated with Weekly Azathioprine Pulse (WAP).

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.

The male to female ratio was found to be 3.23:1. It is also comparable to the study by Sharma VK et al which found it as 2.3:1.

In our study, 5% of patients had a positive family history of AA. It is comparable to a study by Sharma VK et al[8] which found 5.9% with a family history of AA.

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 by Sharma VK et al[8] where a definite evidence of atopy was obtained in 35 (17.5%) children

Majority of the patients presented between 1 to 6 months after the onset. The earliest presentation was at one week after the onset. Boys presented early compared to girls. It can be attributed to the short hair in the boys due to which AA becomes more noticeable early in its course. There was no such difference in patients presented after 6 months.

13 patients (21.66%) presented with one patch where as 37 patients (61.6%) had multiple patches. The mean number of patches was 3.2 at the time of presentation.

The common patterns of alopecia areata observed in our study were patchy (81.67%). Rarer types included reticulate pattern, Alopecia totalis and universalis, ophiasis, sisaphio, diffuse alopecia areata was also present in our study.

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.

Sharma VK et al[8] 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.

A characteristic finding that is frequently seen in (or at the border of) the patches is "exclamation mark hairs." These are short hairs that are tapered proximally and wider distally.

In the present study, 9 patients (15%) had exclamatory mark hairs with equal sex incidence.

This study also included cases resistant to various other modalities of treatment. The patients had tried topical and oral medications like steroids, emollients, and ayurvedic preparations. 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%).

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.

In our study mean SALT score of group I was 34.37±25.53 and group II was 27.85±23.47 and there was significant reduction in mean SALT score in each follow up visit with quicker response in group-II. The baseline SALT score in both the groups was almost equal and it showed significant reduction (P <0.05, Significant) at the end of 18 weeks and 24 weeks in group II (WAP).

SALT $_{75}$ response was stastically significant at 18th week and 24th week which means that there was significant difference between the decrease 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. At 18th week $SALT_{75}$ was 23.3% and 66.6% respectively in group I and II, this was stastically significant and comparable. At 24th week $SALT_{75}$ was 66.6% and 96.7% respectively in group I and II, this was stastically significant and comparable.

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. In the per-protocol analysis of the outcome, 40% (8/20) patients in the WAP group and 2% (13/21) in the BOMP group achieved SALT50. The difference was not significant and hair regrowth was cosmetically acceptable. The median percentage hair regrowth was 44.52 (0 – 75.43) in the WAP group and 71.43 (11.11 – 100) in the BOMP group (P = 0.001), which was also statistically highly significant and comparable.

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 diarrhea, nausea vomiting, epigastric pain and headache/ drowsiness which was seen in 3.33% of patients. Overall side effects were seen in 16.67% cases of 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). One of patient of group I had started developing cushingoid features for which he had transferred to group II after which he had showed excellent response.

Verma et al (2015) reported seven (35%) patients in the WAP group had transient nausea, whereas 16 (76%) patients in the BOMP group had corticosteroid-induced adverse effects. Side effects did not warrant treatment discontinuation, however. No significant changes in biochemical parameters were noted in either group.

Patients were given treatment for six months after which they were followed up for the next six months. In group-I 8.3% patients showed relapse while none of the patient in group II showed relapse.
Verma et al. showed one patient in each group relapsed after complete regrowth of hair during the follow-up period.

CONCLUSION

Weekly azathioprine pulse may be considered as effective as oral betamethasone pulse with lesser side effects. BOMP is also considered safe. However a large group study should be performed to confirm these findings.

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