

## Comparison of oral prednisolone pulse therapy with intravenous methyl prednisolone pulse therapy in severe Alopecia Areata

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### Abstract

#### Background and aim:

Alopecia Areata is an autoimmune hair follicle's disease that causes hair loss in scalp, eyebrows, eyelashes and other hairy areas of the body. There is no approved therapy for this condition but several methods have been introduced. In this paper, we assessed oral prednisolone pulse therapy in comparison to the intravenous methyl prednisolone pulse therapy in treatment of severe Alopecia Areata.

#### Materials and methods:

In this clinical-based study, all patients with Alopecia Areata registered during 2006-2009 in dermatologic department of 5-Azar hospital, Gorgan, Northeast of Iran were included. Including criteria was as followings: at least 30% involvement of scalp or more than 10 patch of alopecia in scalp and body. Forty patients with severe Alopecia Areata were enrolled and divided into 2 groups. Group A was treated with 200 mg oral prednisolone in one dose, every week for 3 months and group B were treated with 500 mg intravenous methyl prednisolone in 3 continuous days each month for 6 months. Data were entered into SPSS-16 statistical software and analyzed using non parametric Mann-Whitney and Chi-square tests. Repeated-measure was used to compare the trend of recovery in two groups. P-value of less than 0.05 was considered significant.

#### Results:

Recovery rate after 1, 3, 6 and 12th months after treatment was significantly higher in group B compared to group A. Side effects were included: Acne (5 in A and 7 in B), heartburn (4 in A and 5 in B), stria (4 in A and 6 in B) and were more seen in group B but it was not significant statistically. The recovery rate was not significantly different between two sex.

#### Conclusions:

In this study, 500 mg intravenous methyl prednisolone in 3 continuous days each month for 6 months showed a better recovery rate in severe Alopecia Areata. Patients must be warned about the side effects and outcomes.

**Key word:** oral prednisolone, methyl prednisolone , Alopecia Areata

#### Introduction:

Alopecia Areata is an autoimmune hair follicle's disease that causes hair loss in scalp, eyebrows, eyelashes and

other hairy areas of the body. (1)

Approximately, 2% of population would experience this disease lifelong. The difficulties in reviewing the diseases of hair follicles lay in the long list of different etiologic factors (infectious, autoimmune, inflammatory, neoplastic, physical, chemical, congenital) and a still missing classification system according to etiopathogenetic principles (2,3). The origin of disease is not fully understood. This disease has a variable clinical course, Although spontaneous remission is possible in these cases, it occurs rarely and treatment is difficult and it may develop to Alopecia totalis or Alopecia universalis (4).

Alopecia affects social life and mental health of the patient. There are some reports of suicide. It is more common in 3-5th decades (5).

There is no approved therapy for this condition but several methods have been introduced like systemic steroids that may induce hair growth in Alopecia Areata (6,7,8) but have their side effects.

Long term corticosteroids daily or one another day has certain side effects. Reports suggest fewer side effects with pulse therapy (9,10,11).

In this paper, we assessed oral prednisolone pulse therapy in comparison to the intravenous methyl prednisolone pulse therapy in treatment of severe Alopecia Areata.

### **Methods:**

This was a clinical-based study, all patients with Alopecia Areata registered during 2006-2009 in dermatologic department of 5-Azar hospital, Gorgan, Northeast of Iran were included.

Including criteria was as followings: at least 30% involvement of scalp or more than 10 patch of alopecia in scalp and body. Forty patients with severe Alopecia Areata were enrolled and divided into 2 groups. Group A was treated with 200 mg oral prednisolone in one dose, every week for 3 months and group B were treated with 500 mg intravenous methyl prednisolone in 3 continuous day each months for 6 months.

Effectiveness of therapy and side effects were assessed in each group. Data were entered into SPSS-16 statistical software and analyzed using non parametric Mann-Whitney and Chi-square tests. Repeated-measure was used to compare the trend of recovery in two groups. P-value of less than 0.05 was considered significant.

### **Results:**

Five cases were excluded from the study because they did not come for follow-up (3 from group A and 2 from group B), and three were excluded due to the side effects like headache, hypertension and gastrointestinal complications. Totally, 35 cases (18 in group A and 17 in group B) were followed up to the end of the study. (Demographic data are given in Table 1 and 2 and 3.)

The rate of less than 30% recovery after one month in group A was 61.1% (N=11), and 30-60% recovery was 38.9% (N=7). But in group B, 30-60% recovery was 64.7% (N=11), and 60-99% was 53.3% (N=6); which shows a significant higher rate of recovery in group B (P-value< 0.05). (table 4- Figure 1,2)

The rate of recovery after 3 months was as followings:

In group A: less than 30% recovery in 33.3% (N=6), 30-60% in 38.9% (N=7), 60-90% in 27.8% (N=5). In group B: 23.5% (N=4) had 30-60% recovery, 64.7% (N=11) had 60-99% and 11.8% (N=2) showed 100% recovery, respectively. Recovery rate was significantly higher in group B compared to group A. (table 4- Figure 1,2)

Six months and 12 months after the beginning of treatment, recovery rate was yet higher in group B significantly.

Side effects were included: Acne (5 in A and 7 in B), heartburn (4 in A and 5 in B), stria (4 in A and 6 in B) and were more seen in group B but it was not significant statistically. (P>0.1%)

The recovery rate was not significantly different between two sex.

Table 1 :Demographic groups

group B (n=17)	group A (n=18)	Characteristics
34/2±6/2	29/3±7/3	Mean age in years
6	7	male
1	11	female
25/7±9/1	24/2±7/2	The average age of onset in years
2/9±2/2	3/3±2/3	The mean duration of disease
2	3	Family history of atopy
4	4	Personal history of atopy
7	5	Nail changes
3	5	The first episode

Table 2 : Profile of clinical response to pulse therapy than those without response (group A)

Non response	response	Characteristics
28/6±6/21	26/8±7/7	Mean age in years
25/3±6/2	19/9±7/6	The average age of onset in years
2	1	Family history of atopy
4	-	Personal history of atopy
4	1	Nail changes
1	4	The first episode

Table 3 : Profile of clinical response to pulse therapy than those without response (group B)

Non response	response	Characteristics
28/6±6/21	26/8±7/7	Mean age in years
25/3±6/2	19/9±7/6	The average age of onset in years
2	-	Family history of atopy
4	-	Personal history of atopy
5	2	Nail changes
1	2	The first episode

Table 4: Recovery rate (growing hair) in groups A and B at the end of the first month, third, sixth and twelfth month \* result \* group Crosstabulation

Total	result				group		
	improvement <30%	improvement =100%	60% < improvement <99%	30% < improvement <60%	improvement <30%		
18	0	0	7	11	Count	1.00	month A
100.0%	.0%	.0%	38.9%	61.1%	% within month		
18	0	5	7	6	Count	3.00	
100.0%	.0%	27.8%	38.9%	33.3%	% within month		
18	5	4	7	2	Count	6.00	
100.0%	27.8%	22.2%	38.9%	11.1%	% within month		
18	4	3	5	6	Count	12.00	
100.0%	22.2%	16.7%	27.8%	33.3%	% within month		
72	9	12	26	25	Count	Total	
100.0%	12.5%	16.7%	36.1%	34.7%	% within month		
17	0	6	11		Count	1.00	month B
100.0%	.0%	35.3%	64.7%		% within month		
17	2	11	4		Count	3.00	
100.0%	11.8%	64.7%	23.5%		% within month		
17	7	10	0		Count	6.00	
100.0%	41.2%	58.8%	.0%		% within month		
17	7	6	4		Count	12.00	
100.0%	41.2%	35.3%	23.5%		% within month		
68	16	33	19		Count	Total	
100.0%	23.5%	48.5%	27.9%		% within month		

**Bar Chart**

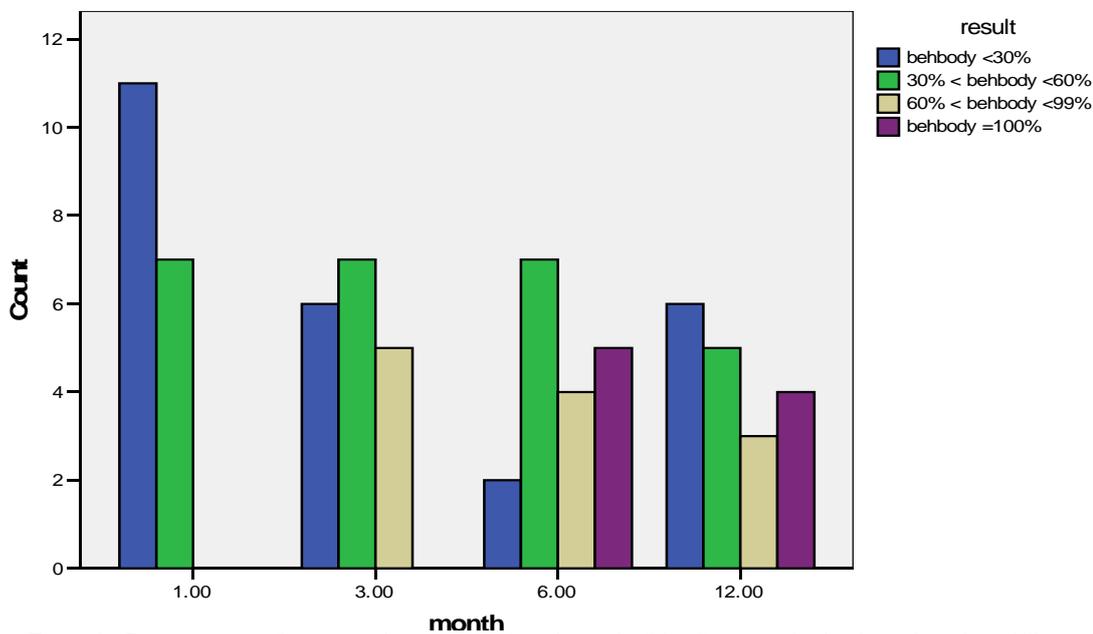


Figure1: Recovery rate (hair growth) in group A at the end of the first month, third, sixth and twelfth

**Bar Chart**

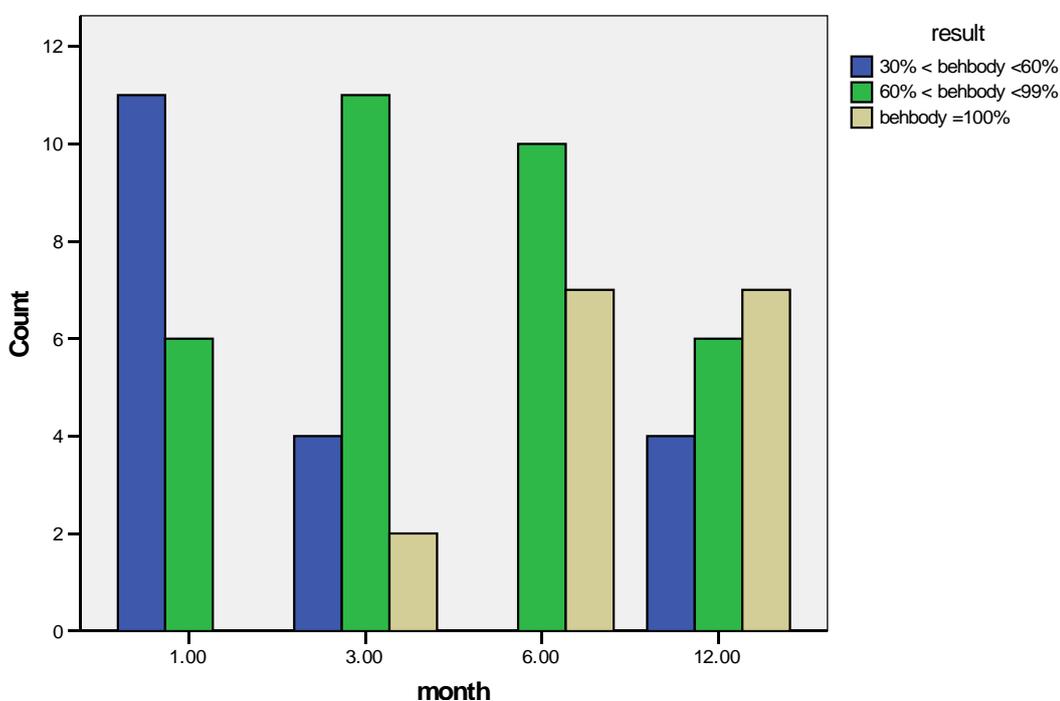


Figure2: Recovery rate (hair growth) in group B at the end of the first month, third, sixth and twelfth

## Discussion:

Alopecia areata is an autoimmune disorder with unpredictable and recurrent progression. It has been thought that T-cell lymphocytes have a role in this disease. Genetic and environmental factors may contribute in starting the disease, but the main cause is unknown (12-18). Local baldness in hairy places may cause mental problems (19-20).

Treatment of severe Alopecia Areata is difficult and several methods including local steroids and local sensitizing like squaric acid dibutylester, photochemotherapy, cryotherapy, minoxidile and immunomodulators have been used and revealed to different outcomes (12-18).

After the treatment, there is risk of recurrence (19). Sometimes regression of the disease makes the effect of the therapy difficult.

Long term treatment with corticosteroids daily or one day another has some side effects. It seems that different side effects with corticosteroids are fewer in pulse therapy (20,21).

Burton and Shuster introduced pulse therapy with corticosteroids in Alopecia Areata in 1975 (22). However, oral prednisolone pulse therapy in these patients is limited (23, 21). In Shaheedi-Dadras M study adequate" (i.e., hair regrowth on > or =70% of the affected area) response was observed in six (33%) patients: three with alopecia totalis and 3 with alopecia universalis. (9)

In one study, remission rate in group B (oral pulse therapy) in comparison with group A (intravenous pulse therapy) was significantly higher at the end of first, third, 6th and 12th months. This may suggest effectiveness of oral pulse therapy over the intravenous therapy.

Long lasting cases (more than 2 years), starting in childhood, Alopecia universalis, Alopecia totalis, Ophiasis. Atopy and nail involvement have fewer response (23). It has been reported that treatment in the first episode of the disease has better outcome (12-18).

In this study, both groups had less response in the terms of long lasting disease, atopy and nail involvement that was the same as other reports. Remission rate was significantly higher in group B (P-value< 0.05).

Side effects were 45% in group A and 55% in group B that was more than Sharma et al report (26.6%), even though these side effects did not stop the treatment. Because of different therapeutic protocols and selection of patients, it is not possible to compare the results of our study with others.

Weekly pulse therapy with 200 mg oral prednisolone is a therapeutic method for severe Alopecia Areata. Patients must be warned about the side effects and outcomes. In this study, side effects were not that severe that interrupts the treatment. Factors associated with poor prognosis are atopy, nail involvement, recurrent episodes and long lasting disease. Most of the studies suggest oral prednisolone pulse therapy for treatment to maintain the optimum time and effect.

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Hereby, We Convey Our Sincere Appreciation For Any Help Of university Staffs

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