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Original Research Article

Adverse effects of baricitinib in comparison to methotrexate in the treatment of severe alopecia areata

Pranam Swapan Dash[1], Lubna Khondker[1]*, Mostaque Mahmud[1], Marufa Shahrin[1], Wasi Deen Ahmed[1], Saikat Das Rony[2]

[1]Department of Dermatology and Venereology, Bangladesh Medical University, Dhaka, Bangladesh
[2]Department of ENT, Narayanganj Sadar (Victoria) Hospital, Narayanganj, Bangladesh

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***Correspondence:**
Dr. Lubna Khondker,
E-mail: lubnaderma@gmail.com

ABSTRACT

Background: Existing therapies for alopecia areata often yield suboptimal results and have some associated side effects. Janus kinase (JAK) inhibitors are a recent advancement in the treatment of alopecia areata which are treatment resistant or severe.
Methods: This analytical observational study was conducted in the department of Dermatology and Venereology of Bangladesh Medical University to compare the adverse effects of baricitinib and methotrexate in the treatment of severe alopecia areata. About 84 patients of alopecia areata were divided into two groups. Patients of group A were treated with oral baricitinib and group B were treated with oral methotrexate for 6 months.
Results: The most common adverse effects noted in baricitinib group was upper respiratory tract infection 14.3% and hyperlipidaemia was 11.9% of patients and in methotrexate group was nausea 28.6%, and elevated liver transaminase was 16.7 % patients. Serum transaminase (ALT) elevation was significantly raised from baseline to after 6 months (40.21±19.29, $p<0.001$) in methotrexate group, whereas there was no significant change (33.53±19.86, $p=0.506$) in baricitinib group. There was statistically significant change before and after treatment in serum creatinine (0.88±0.12, $p=0.004$) in baricitinib group, compared to no significant change in methotrexate group ($p=0.222$). There was significant rise in total cholesterol, triglyceride and LDL after 6 months of treatment with baricitinib and these results were statistically significant ($p<0.001$).
Conclusions: After 6 months of treatment, baricitinib has proven its superiority over methotrexate in terms of safety in the treatment of severe alopecia areata.

Keywords: Adverse effects of baricitinib, Adverse effects of methotrexate, Alopecia areata, SALT score

INTRODUCTION

Alopecia areata is a disorder in hair loss ranging from patches of hair loss to complete hair loss. It affects 2% of general population, is increasing over time and differs significantly by region.[1] It may appear suddenly and progresses circumferentially. The most common involved site is scalp, though any body part can be affected.[2] Alopecia areata is caused by a complex pathomechanism that includes close interactions between genetic, immunologic, and environmental factors.[3] The hair follicle is an immune privileged site. In healthy hair follicle epithelium, major histocompatibility complex (MHC) class I and II molecules are not expressed and TGF- β, IGF-1, and α-MSH are more expressed.[4,5] This immune privilege is collapsed in alopecia areata by the presence of increased MHC I and II complexes, decreased immunosuppressive molecules, and higher expression of adhesion molecules (ICAM-2 and ELAM-1) in the

perivascular and peribulbar hair follicular epithelium, leading to perifollicular inflammation.[6,7] This peribulbar inflammation adversely affects hair follicle activity, resulting in thin dystrophic hair with miniaturization.[8,9] Thus, alopecia areata is considered as hair follicle-specific autoimmune disease, triggered by environmental factors in genetically susceptible individuals.[10]

No specific treatment for alopecia areata has been established to date. Methotrexate is an immunosuppressive agent classified as a folic acid antagonist, shows promise as a well-tolerated and cost-effective treatment for severe alopecia areata, whether used alone or in conjunction with corticosteroids.[5] Janus kinase (JAK) inhibitors are a class of immunomodulatory drugs that have been extensively researched for their efficacy in treating various inflammatory conditions. Baricitinib, a recent addition to the first-generation JAK inhibitors, selectively targets JAK1 and JAK2, with a lesser effect on JAK3. In June 2022, the Food and Drug Administration (FDA) have approved baricitinib as a systemic treatment for adult patients with severe alopecia areata.[11,12]

Relapse is prevalent in alopecia areata, with studies indicating that the incidence rate of relapses among patients observed over 10-20 years ranges from 85-100%.[3] Baricitinib as monotherapy exhibited enhanced efficacy and acceptable safety relative to methotrexate monotherapy as initial treatment for patients with active rheumatoid arthritis.[13,14] There are no absolute contraindications to the use of baricitinib. The efficacy of baricitinib has been seen in some studies in alopecia areata in other countries, though there is scarcity of studies with adverse effects regarding this drug in our population.

METHODS

This analytical observational study was conducted in the Department of Dermatology and Venereology, Bangladesh Medical University, Dhaka from January 2023 to September 2024. Patients with alopecia areata attending the Department of Dermatology and Venereology, Bangladesh Medical University (BMU), Dhaka was the study population. Patients were divided equally into two groups, Group A (Baricitinib) and Group B (Methotrexate). Consecutive type of sampling technique was applied to collect the sample within the study period. Outcome variables were degree of hair regrowth by Severity of Alopecia Tool (SALT) score. Each of the adult alopecia areata patient fulfilling the inclusion criteria, was randomly allocated to either group using lottery method.

Inclusion criteria

Inclusion criteria were patients with alopecia areata involving >50% scalp hair loss, alopecia totalis, alopecia universalis; age between 18 and 65 years; disease duration more than 6 months and less than 5 years and patients with all systemic and/or topical treatments has been stopped for at least 8 weeks before inclusion in the study.

Exclusion criteria

Exclusion criteria were pregnant women and lactating mother; patients with active infection, patients with preexisting diabetes, hypertension, dyslipidemia, obesity; Impaired hepatic (ALT> 1.5 times upper limit of normal) and renal functions; patients with Hb% <8g/dl, absolute lymphocyte count < 500/cu mm, absolute neutrophil count < 1000/cu mm; clinically suspected or known case of tuberculosis; taking immunosuppressive drugs like prednisolone, cyclosporine, mycophenolate mofetil; known hypersensitivity to baricitinib or methotrexate; patient who refuses to enrol in this study and previously treated with JAK inhibitor within last 8 weeks with inadequate response.

Data collection procedure

Prior to data collection, both verbal as well as written consent was taken from the respondents. Data was collected using a preformed data collection sheet (questionnaire). Patients were randomly allocated in two groups of 42 patients each using lottery method. A proper diagnostic work up was made by taking detailed history and clinical examination. History included duration of disease, course of disease, treatment history, concomitant illness, any active infection and family history of alopecia areata. All patients were thoroughly examined and the extent of disease, involvement of area other than scalp and the presence of nail involvement was noted. Diagnosis of alopecia areata was made clinically by the presence of some criteria that includes: Oval or round shaped well circumscribed bald patches with a smooth surface, absence of inflammation and scaling in involved areas, presence of follicular ostia. Dermoscopic confirmation of diagnosis was done. Those who fulfilled the inclusion criteria were selected for the study. In this way 84 patients with alopecia areata were selected. Initial assessment of hair loss was assessed using SALT score.

SALT score

A SALT score is a tool used to measure the severity and extent of alopecia areata. National Alopecia Areata Foundation working committee has devised “Severity of Alopecia Tool score” (SALT score). According to SALT score the scalp was divided into four areas, namely: Vertex: 40% (0.4) of scalp surface area, Right profile of scalp: 18% (0.18) of scalp surface area, Left profile of scalp: 18% (0.18) of scalp surface area, Posterior aspect of scalp: 24% (0.24) of scalp surface area.

Percentage of hair loss in any of these areas was multiplied by percentage surface area of the scalp in that area. SALT score is the sum of percentage of hair loss in all the above-mentioned areas. Sub-grouping of patients into SALT sub-classes was done as follows: Scalp (S) includes S0 (no hair loss), S1 (<25% hair loss), S2 (25-49% hair loss), S3 (50-74% hair loss), S4 (75-99% hair loss), and S5 (100% hair loss).[9]

Body (B) hair loss was assessed as: B0: no body hair loss; B1: some body hair loss; and B2: 100% body (excluding scalp) hair loss. For example, if the percentage of hair loss in vertex, right profile, left profile and posterior aspect is 20%, 30%, 40% and 50% respectively, then, SALT score =(20x0.4)+(30x0.18)+(40x0.18)+(50x0.24) =8+5.4+7.2+12=32.6.

Group A

Before initiating therapy with baricitinib, proper history was taken regarding active infection and some baseline investigations were done to fulfil exclusion criteria. Baseline investigations included complete blood count with differentials, SGPT, serum creatinine, HBsAg, fasting lipid profile, CXR (P/A view), QuantiFERON TB Gold test. Patients were treated with Baricitinib 4mg (Baricent) tablet at night for 6 months. After starting the treatment, follow up was done after one month and after three months and at the end of the treatment (after six months). Patients came to follow up for reviewing their laboratory reports and for taking supplied drugs. In each follow up hair regrowth was assessed by SALT score. Laboratory investigations during follow up visit included complete blood count with differentials, SGPT, serum creatinine and fasting lipid profile. After stopping treatment, follow up was done for further one month to see relapse of the disease process.

Group B

Before initiating therapy with methotrexate, proper history was taken regarding active infection and some baseline investigations were done to fulfil the exclusion criteria. Baseline investigations included complete blood count with differentials, ALT and serum creatinine. Patients were treated with Methotrexate 15mg once weekly at night after meal, with folic acid 5mg tablet the day after taking methotrexate. Follow up was done after one month and after three months and at the end of the treatment (after six months). Patient's hair regrowth was assessed using SALT score at each follow up visit, and monitoring of side effects were done clinically and by laboratory investigations. Laboratory investigations during follow up visit included Complete blood count with differentials, ALT and S. creatinine. After stopping treatment, follow up was done for further one month to see relapse of the disease process.

Data processing and analysis

Data was collected on proposed data sheets and was also recorded in digital formats for security and convenience for analysis. Continuous variables were expressed as mean and standard deviation whereas categorical variables were summarized using numbers and percentages. Students T tests were used to compare continuous variables. Differences in the distribution of categorical variables were assessed by Chi-Square tests. A p value <0.05 was considered as statistically significant. Statistical analysis was conducted by expert statistician of the institute by using SPSS 23 software.

Ethical consideration

All patients were informed that they have the right to refuse or accept to participate in the study and they have the right to refuse during study period, if he/she desires and it will not hamper the treatment protocol. They were also informed that, during the study period if the patient experiences any hamper in physical health, it is the responsibility of the principal investigator. Patients were included in the trial after taking their written consent. All the information collected from each patient including photographs and results of any laboratory tests were kept confidential under the responsibility of the principal investigator.

RESULTS

In this study a total of 84 patients with alopecia areata were selected for the study. The majority of the patients were in the 4th decade with mean age 29.9±8.39. In group A most of the participants were male (59.5%), whereas in group B both were equal. All of these results were not statistically significant. In both groups, the most common type was patchy alopecia areata (69.0% and 54.8%), followed by alopecia totalis (26.2% and 19.0%) and alopecia universalis (19.0% and 11.9%) in group A and group B respectively, (p=0.395). The study demonstrates that, before treatment SALT score in baricitinib group was 71.1±19.62, after 6 months which reduced to 13.16±22.6. Whereas, in methotrexate group before treatment SALT score was 65.4±18.6, after 6 months which reduced to 51.3±31.1 and the findings were statistically significant (p<0.001).

Table 1: Demographic characteristics of the study patients with alopecia areata (n=84).

Variables	Group A (Baricitinib) (n=42), N (%)	Group B (Methotrexate) (n=42), N (%)	P value
Age group (years)			
<20	9 (21.4)	7 (16.7)	
21-30	12 (28.6)	15 (35.7)	
31-40	17 (40.5)	18 (42.9)	
41-50	4 (9.5)	2 (4.8)	
Mean±SD	29.9±8.39	29.8±7.95	0.979[a]
Gender			
Male	25 (59.5)	21 (50.0)	0.381[b]
Female	17 (40.5)	21 (50.0)	

P value obtained by Unpaired t-test (a) and Chi-square test (b), p<0.05 was considered as a level of significant

Table 4 shows that ALT was significantly raised from baseline to after 6 months (40.21±19.29, p<0.001) in methotrexate group, whereas there was no significant change (33.53±19.86, p=0.506) in baricitinib group. There

was statistically significant change before and after treatment in serum creatinine (0.88±0.12, p=0.004) in baricitinib group, compared to no significant change in methotrexate group (p=0.222).

Table 2: Different types of alopecia areata in Group A and Group B (n=84).

Type of Alopecia areata	Group A (Baricitinib) (n=42), N (%)	Group B (Methotrexate) (n=42), N (%)	P value
Patchy alopecia areata	23 (54.8)	29 (69.0)	0.395
Alopecia totalis	11 (26.2)	8 (19.0)	
Alopecia universalis	8 (19.0)	5 (11.9)	
Total	42 (100.0)	42 (100.0)	

P value obtained by Chi-square test, p<0.05 was considered as a level of significant

Table 3: Distribution of patients based on absolute changes in SALT score from baseline between Group A and Group B (n=84).

	Before treatment (n=42), Mean±SD	After 6 months (n=42), Mean±SD	P value
Group A (Baricitinib)	71.1±19.62	13.16±22.6	<0.001
Group B (Methotrexate)	65.4±18.6	51.3±31.1	<0.001

P value obtained by Paired t-test, p<0.05 was considered as a level of significant

Table 4: Comparison of investigations findings between Group A and Group B (n=84).

Investigations findings	Group A (Baricitinib) (n=42)	Group B (Methotrexate) (n=42)	P value
Hb			
Baseline	13.79±1.55	13.30±1.35	0.144
After 6 months	13.52±1.71	13.37±2.40	0.762
P value	0.05	0.831	
ALT			
Baseline	31.66±14.58	28.18±11.24	0.244
After 6 months	33.53±19.86	40.21±19.29	0.157
P value	0.506	<0.001*	
Serum creatinine			
Baseline	0.83±0.14	0.78±0.13	0.191
After 6 months	0.88±0.12	0.80±0.14	0.008*
P value	0.004*	0.222	

Abbreviation: Hb: Hemoglobin, SGPT-serum glutamic pyruvic transaminase, p value obtained by Unpaired t-test between two groups and Paired t-test within group, p<0.05 was considered as a level of significant

Table 5 demonstrates comparison of lipid profile from baseline to 6 months in baricitinib group. There was significant rise in total cholesterol, triglyceride and LDL after 6 months of treatment with baricitinib. These results were statistically significant (p<0.001).

Table 5: Comparison of lipid profile from baseline to 6 months in baricitinib group (n=84).

Lipid profile	Baseline (n=42), Mean±SD	After 6 months (n=42), Mean±SD	P value
Total cholesterol (mg/dl)	159.9±34.3	202.0±61.2	<0.001*
Triglyceride (mg/dl)	80.1±26.1	150.6±68.8	<0.001*
LDL (mg/dl)	89.8±32.1	128.2±50.0	<0.001*

Abbreviation: LDL: low density lipoprotein, p value obtained by Paired t-test, *p<0.05 was considered as a level of significant

Table 6 shows that the most common clinical adverse effects noted in baricitinib group was upper respiratory tract infection (14.3%), followed by acne vulgaris (7.1%) and headache (4.8%). Hyperlipidaemia was seen in 11.9% of patients.

Table 7 demonstrates that the most common clinical adverse effects noted in methotrexate group was nausea (28.6%), followed by fatigue (11.9%) and 2 (4.8%) patients experienced respiratory tract infection. Elevated liver transaminase was seen in 16.7 % patients.

Table 8 shows that about 54.8% of group A patients and 47.6% of group B patients experienced relapse of the condition after stopping treatment. Through this result was not statistically significant among both groups (p=0.512).

Table 6: Clinical and laboratory adverse effects after being treated with baricitinib among participants (n=42).

Adverse effects	Frequency	Percentage
Clinical		
Upper respiratory tract infection	6	14.3
Acne vulgaris	3	7.1
Headache	2	4.8
Skin infections (multiple boils)	1	2.4
Pruritus	1	2.4
Nausea	2	4.8
Laboratory		
Hyperlipidaemia	5	11.9
Elevated transaminases	0	0.0

Table 7: Clinical and laboratory adverse effects after being treated with methotrexate among participants (n=42).

Adverse effects	Frequency	Percentage
Clinical		
Nausea	12	28.6
Fatigue	5	11.9
Respiratory tract infection	2	4.8
Oral ulcer, erythematous skin rash	1	2.4
Laboratory		
Elevated transaminases	7	16.7
Anaemia	3	7.1

Table 8: Relapse after stopping treatment with baricitinib among participants (n=42).

Relapse after stopping treatment	Group A (Baricitinib) (n=42), N (%)	Group B (Methotrexate) (n=42), N (%)	P value
Yes	23 (54.8)	20 (47.6)	0.512
No	19 (45.2)	22 (52.4)	
Total	42 (100.0)	42 (100.0)	

P value obtained by Chi-square test, $p<0.05$ was considered as a level of significant

DISCUSSION

Our study was conducted with 84 patients suffering from severe alopecia areata. Among the patients, majority presented with a mean age of 29.9±8.39 and most of them were male (59.5%). A study by Kavak et al, involving 539 patients reported similar findings, with a mean age of 24.32±0.54 with a male predominance.[16] A retrospective study by Uzuncakmak et al, indicated that the mean age of patients with alopecia areata was 29.86±14.48 years, with the condition being most prevalent in the 30 to 39 years age group for men and the 20 to 29 years age group for women.[17] In the current study the most frequent type of alopecia areata was patchy alopecia areata found in 54.8% in group A and 69.0% in group B, followed by alopecia totalis found in 26.2% in group A and 19.0% in group B and alopecia universalis 19.0% in group A and 11.9% in group B. Likewise, Olamiju et al observed that patchy alopecia areata is the most prevalent form of alopecia areata.[18] Another study indicate that patchy alopecia areata is prevalent among the clinical types of alopecia areata, with scalp being the most frequent site of hair loss.[19] In our study, at the end of 6 months of treatment with baricitinib, showed that JAK inhibitor baricitinib confers a superior efficacy over a traditional systemic treatment methotrexate in the treatment of severe alopecia areata. Ahmed HE and Ahmed SH demonstrated that baricitinib and deuruxolitinib significantly enhance response rates, with baricitinib exhibiting the highest efficacy in patients with severe alopecia areata.[20] The study Freitas et al, involved phase 2 and phase 3 clinical trials, included the proportion of patients achieving a 20% improvement in SALT score ($SALT_{20}$) at week 36**.** Secondary endpoints included achieving a 30% improvement ($SALT_{30}$) at week 12 and a 50% improvement ($SALT_{50}$) at week 16.[12] According to Senna et al, in two phase 3 trials assessing baricitinib for severe alopecia areata, continuous monotherapy with baricitinib over 104 weeks showed sustained efficacy. At week 52, 90.7% of patients receiving 4 mg of baricitinib and 89.2% of those receiving 2 mg maintained a SALT score of ≤20, indicating continued clinical response at week 104. In week 52 responders, at least 50% improvements from baseline in SALT score were sustained in all patients receiving continuous treatment with baricitinib 2 mg, and 98.4% of those treated with baricitinib 4 mg. The findings indicate that prolonged treatment is essential to achieve optimal benefits.[21]

Regarding safety outcomes, the most frequent adverse event of baricitinib was upper respiratory tract infection (14.3%), followed by in decreasing order of frequency, hyperlipidaemia (11.9%), acne (7.1%), headache (4.8%) and nausea (4.8%). Laboratory abnormalities included lipid profile alteration which was managed using lipid lowering drugs. King et al, demonstrated the most frequently reported adverse effects in patients treated with baricitinib were upper respiratory tract infection, acne, and nausea, with no serious adverse event or death, though there was one case of grade 3 neutropenia and three cases of creatinine phosphokinase elevation. The study found that baricitinib is typically well tolerated, with mild adverse effects.[22]

In the methotrexate group in our study, the most frequent adverse effect experienced by the patients was nausea (28.6%) followed by elevation in transaminase (16.7%). After the end of 6 months treatment with baricitinib and methotrexate, patients were asked to stop the medications and followed up for further one month, to see the recurrence of hair fall among the patients. We found that about 55% of the patients who received baricitinib

reported restart of hair fall from different areas of the scalp, compared to 47.6% in methotrexate group. There was no statistically significant difference between both groups. The observation corresponds to King et al, who found that discontinuing therapy in a patient population with severe alopecia areata, after achieving significant hair regrowth following one year of treatment with baricitinib, led to a loss of benefits for nearly all patients. The group receiving 4mg baricitinib exhibited a recapture rate of 67% following ≥48 weeks of retreatment. Restarting baricitinib after withdrawal demonstrates reduced efficacy compared to initial treatment.[22]

Numata et al showed that baricitinib serves as an effective treatment for individuals with moderate to severe alopecia areata, with a notable percentage of patients achieving hair regrowth. The safety profile is acceptable, with manageable side effects that generally do not outweigh the treatment benefits for most patients.[2] The objective of the study by Alsufyani et al was to assess the efficacy and safety of methotrexate therapy in patients with severe alopecia areata, both as a standalone treatment and in conjunction with systemic or intralesional corticosteroids. A therapeutic response characterized by regrowth exceeding 50% of the scalp was noted in 67.9% (n=19) of patients. Among these, 25% (n=7) experienced 75-95% regrowth, while 19.3% (n=6) achieved complete regrowth (100%). Relapse was observed in 33.3% (n=7) of patients exhibiting >50% regrowth (n=21) and in 40% (n=6) of those with >75% regrowth (n=15).[23]

This study has few limitations. The present study was conducted within a short period of time, so response of patients with long follow up in assessing safety could not be evaluated; Scoring systems such as, Patient-Reported Outcome (PRO) and Clinician-Reported Outcome (ClinRO) for eyebrows and eyelashes were not used in the study.

CONCLUSION

In this study, after completion of 6 months of treatment, baricitinib was overall well tolerated, with mild adverse effects. In methotrexate group, along with some mild side effects, significant percentage of patients developed elevated transaminases. Considering all the facts, it can be concluded that, baricitinib is safer treatment option than methotrexate in the treatment of severe alopecia areata.

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