



Original Article



Comparing the Efficacy of Weekly Azathioprine Pulse versus Betamethasone Oral Mini-Pulse in the Treatment of Moderate to Severe Alopecia Areata

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ABSTRACT

Alopecia Areata (AA) is a disease that leads to unpredictable hair loss. **Objective:** To assess and compare the efficacy of Weekly Azathioprine Pulse (WAP) versus Betamethasone Oral Mini-Pulse (BOMP) therapy in Alopecia areata. **Methods:** Sixty patients with $\geq 15\%$ scalp involvement were divided into two groups. The WAP group given azathioprine (300 mg) once weekly; the BOMP group received betamethasone (5 mg) on two consecutive days weekly. A randomized controlled trial was performed at the Dermatology Department of Sheikh Zayed Hospital, Rahim Yar Khan, over a 6-month (March–September 2023). Both treatments continued for 12 weeks. At baseline, 12 weeks, and 12 weeks post-treatment SALT scores were recorded. Efficacy was defined as $\geq 75\%$ hair regrowth. **Results:** The male-to-female ratio was 1.9:1 with 39 (65%) males and 21 (35%) females. WAP group baseline SALT score of 42.60 ± 13.75 decreased to 13.97 ± 11.79 after a follow-up period of 12 weeks post-treatment, compared to BOMP group reduction from 38.67 ± 10.76 to 21.63 ± 10.96 ; regrowth percentage was higher in WAP (68.62%) vs. BOMP (44.28%), $p=0.001$. In the WAP group, 13 (43.3%) of patients achieved efficacy with $\geq 76\%$ hair regrowth, compared to 3 (10%) in the BOMP group, showcasing a significant disparity (p -value=0.009). Relapse at three months occurred in 1 (3.3%) participant in the WAP group and 2 (6.7%) participants in the BOMP group (p -value of 0.500). **Conclusion:** This study demonstrated that WAP therapy was superior to BOMP in moderate to severe AA with notable hair regrowth.

INTRODUCTION

Alopecia Areata (AA) is a chronic autoimmune condition that results in non-scarring hair loss, typically presenting as solitary or multiple round or oval areas of baldness on the scalp or other parts of the body with hair. These regions often exhibit "exclamation mark" hairs near their borders. The condition affects individuals across all ages, genders, and ethnicities. Clinically, alopecia areata manifests in various patterns based on the extent of hair loss, including localized patchy involvement, total scalp hair loss (alopecia totalis), complete loss of scalp and body hair (alopecia universalis), or, less frequently, a linear pattern of hair loss affecting specific scalp regions [1, 2]. The spectrum of AA severity is associated with profound psychological impact,

emotional distress, and social phobia [3, 4]. The reported incidence of alopecia areata varies substantially across the globe, with higher rates generally observed in individuals aged 19–50 years. One extensive systematic review, comprising 88 studies from 28 countries, determined that the lifetime prevalence of alopecia areata is 0.10% in the overall population, 0.12% among adults, and 0.03% in children. The review further noted that Asian populations displayed the highest observed prevalence, whereas African regions reported the lowest [5]. This variability underscores the importance of considering geographical and demographic factors when evaluating the burden of alopecia areata worldwide [5]. The etiopathogenesis of AA



is not completely revealed yet, it is hypothesized that immune system loses its ability to distinguish hair follicle cells as "self," resulting in autoimmune-mediated damage. This damage is mediated by CD8+ T cells, which release interferon- γ , disrupt immune tolerance in hair follicles, and expose self-antigens [6, 7]. Etiological factors that have been linked with alopecia areata include psychological stress, genetics, and environmental influences, with approximately 20% of patients having a positive family history [8]. Due to its variable course and extent of alopecia, the disease outcome is unpredictable. Not all patients require treatment, as spontaneous regrowth is well documented, especially in cases with < 25% of scalp involvement. While extensive loss (>50%) for over a year typically does not see substantial regrowth without medical intervention [9]. Multiple management strategies for AA have been explored with no consensus, ranging from topical, intralesional to systemic therapies. For mild to moderate disease, anthralin, minoxidil, topical and intralesional corticosteroid have shown variable treatment efficacies. Systemic medications, such as oral corticosteroids, immunosuppressants (methotrexate or Azathioprine), or Janus Kinase (JAK) inhibitors (Baricitinib), are often required for Alopecia Totalis or Alopecia Universalis [9, 10]. Oral corticosteroids remain a preferred treatment for alopecia areata due to their affordability and widespread availability. However, most studies have highlighted numerous potential side effects of high dose oral steroids, including weight gain, impaired glucose regulation, fatigue, hormonal disturbances, hypertension, osteoporosis, and an elevated risk of infections. To decrease the adverse effects of systemic corticosteroids, Oral Mini-Pulse (OMP) therapy with various steroids, has been applied in immune-mediated dermatological disorders including lichen planus, vitiligo, and alopecia areata. This approach has demonstrated favorable outcomes, better safety, and improved patient adherence [11]. Azathioprine, targets autoimmune diseases by disrupting the purine pathways and impairing T-cell functions. Tested across various autoimmune dermatologic conditions, including pemphigus vulgaris and alopecia areata, it offers a steroid-sparing alternative for moderate to severe cases. Its weekly dosing regimen has shown promising results, attributed to its advantage in promoting higher compliance rates. However, monitoring for adverse effects is essential [12]. Given the uncertain pathogenesis and course of the illness, the effectiveness of treatment modalities remains unpredictable. While various treatment options exist, no consensus has been established for moderate to severe cases. Systemic corticosteroids, particularly Oral Mini-Pulse (OMP) therapy with betamethasone, are commonly used but are associated with adverse effects. Azathioprine, an

immunosuppressant, offers a potential steroid-sparing alternative with promising efficacy. Effective treatment must address both the clinical efficacy and safety. Previous studies have reported variable safety profiles, remission, and relapse rates for weekly Azathioprine therapy versus BOMP, particularly when compared to placebo. Moreover, data specific to the Pakistani population is notably lacking. Therefore, this study aimed to link the existing gap in literature by offering a comparative evaluation of these therapies in the management of alopecia areata.

METHODS

A randomized controlled trial with a parallel-group design (NCT06786689) was carried out in the Dermatology Department of Sheikh Zayed Hospital, Rahim Yar Khan, over a six-month period from March to September 2023. Ethical clearance was granted by the Institutional Review Board (IRB: 657/IRB/SZMC/SZH). All participants provided informed consent after being fully briefed on potential benefits and risks. Consecutive sampling identified adults with moderate-to-severe alopecia areata, who were enrolled until the target sample size was reached. Participants were subsequently randomized in a 1:1 allocation ratio into two intervention groups using a computer-generated sequence, with group assignments concealed in sealed envelopes maintained by an independent investigator. Given the nature of the interventions, neither patients nor treating physicians could be blinded, though outcome assessors remained unaware of group allocations. A sample size of 60 was estimated using a WHO calculator, presuming 96.67% efficacy for azathioprine pulse therapy versus 67.67% for corticosteroids (95% confidence, 80% power) [13]. Baseline complete laboratory investigations were performed. Female participants received counseling regarding contraception throughout the study. Sixty patients were enrolled through non-probability consecutive sampling technique. Patients were equally divided into two groups using lottery method. Patients in Group WAP received a single dose of Tab. Azathioprine 300 mg once weekly, while patients in Group BOMP received Tab. Betamethasone 5mg for 2 consecutive days weekly for 12 weeks [14]. This study includes patients aged 16-60 years with scalp area involvement of $\geq 15\%$ by Alopecia Areata. The diagnosis of AA was based on history and clinical examination performed by two consultant dermatologists. Patients having spontaneous terminal hair regrowth, used topical and intralesional treatment within last 1 month, received systemic therapy or phototherapy within last three months, anemia, leukocytosis, leukopenia, thrombocytopenia, deranged renal and liver function test, having active infection, and pregnancy were excluded. Additionally, patients with contraindications to corticosteroids or Azathioprine, as well as individuals with alopecia universalis, were also excluded. Standardized

scalp photographs were obtained at baseline and during follow-up using a 50-megapixel camera from four predefined views under consistent lighting conditions. The Severity of Alopecia Tool (SALT) scoring system was employed to assess hair loss, wherein the scalp was divided into anatomical zones: vertex (40%), occipital (24%), left parietal (18%), and right parietal (18%). The overall SALT score reflected the cumulative percentage of hair loss across these regions. Assessments were conducted at three time points: at study initiation, at the completion of 12 weeks of therapy, and at 12 weeks after cessation of treatment. Hair regrowth was quantified using the formula: Hair regrowth (%) = [(Baseline SALT- Follow-up SALT) / Baseline SALT] × 100 [15]. Based on the percentage of improvement, treatment response was classified into four categories: Poor response: <25% improvement from baseline; Moderate response: 26–50% improvement; Good response: 51–75% improvement; Excellent response: ≥75% improvement [14]. The primary efficacy endpoint was defined as achieving an excellent response at the 12-week post-treatment assessment. Relapse was operationally defined as either the shedding of newly regrown hair or the development of fresh alopecia patches during the follow-up interval. Safety monitoring included periodic laboratory testing (complete blood count, hepatic and renal function panels) performed every four weeks during the initial 12-week treatment period. Data were analyzed using SPSS version 23.0. Categorical variables, including gender, treatment efficacy, and relapse, were presented as frequencies and percentages. Continuous variables, such as age, duration of illness, and SALT scores, were expressed as mean ± SD. The Chi-square test was used for comparisons of categorical variables such as gender between groups. The Fisher's exact test was utilized for categorical outcomes with expected cell counts less than five, including treatment efficacy and relapse rates. Continuous variables, including baseline SALT scores, follow-up SALT scores, and percentage hair regrowth, were compared between the treatment groups using the independent t-test. Repeated measures analysis of variance (ANOVA) was used to measure the changes in SALT scores over time within each group across three evaluation points (baseline, 12 weeks, and 12 weeks post-treatment). A p-value of ≤ 0.05 was set to test statistical significance.

RESULTS

There were 39 (65%) males and 21 (35%) females. There were 18/39 (46.15%) males and 12/21 (57.1%) females in WAP group and 21/39 (53.8%) male and 9/21 (42.8%) females in BOMP group (p-value=0.417). Details of baseline characteristics are given in Table 1.

Table 1: Baseline Demographic and Clinical Characteristics of Patients in the WAP and BOMP Groups (n=60)

Baseline Characteristics	WAP Group Frequency (%) /Mean ± SD	BOMP Group Frequency (%) /Mean ± SD	p-Value
Gender			
Male	18 (60%)	21 (70%)	0.598
Female	12 (40%)	9 (30%)	
Age (Years)			
Mean Age	31.00 ± 9.94	32.37 ± 10.04	0.537
Duration of Illness (Years)	4.03 ± 1.75	3.77 ± 1.57	

The mean Baseline SALT score for the WAP group was 42.60±13.75, which decreased to 23.77±8.01 at the end of the 12-week treatment period, and further diminished to 13.97±11.79 after a follow-up period of 12 weeks post-treatment. In contrast, the BOMP group presented with a mean Baseline SALT score of 38.67±10.76, observed a reduction to 28.87±8.96 at treatment completion, and recorded a SALT score of 21.63±10.96 at the 12 weeks follow-up. The mean percentage hair regrowth at second follow-up of 12 weeks was significantly greater in the WAP group (68.62±25.83 %) compared to the BOMP group (44.28±27.39 %), with a p-value of 0.001 (Table 2).

Table 2: Comparison of SALT Scores and Hair Regrowth Percentage between WAP and BOMP Treatment Groups (n=60)

SALT Score	Treatment Group		p-Value
	WAP Group Mean ± SD	BOMP Group Mean ± SD	
Baseline SALT Score	42.60 ± 13.75	38.67 ± 10.76	0.222
SALT score at end of the 12-week treatment	23.77 ± 8.01	28.87 ± 8.96	0.024
SALT score 12 weeks post-treatment	13.97 ± 11.79	21.63 ± 10.96	0.012
Mean %age hair Regrowth at last 12 weeks follow up	68.62 ± 25.83	44.28 ± 27.39	0.001

Treatment response and Efficacy in terms of improvement in SALT score has been reported in "Figure 1" showing significant difference (p-value=0.009). Relapse at three months occurred in 1 (3.3%) participant in the WAP group and 2 (6.7%) participants in the BOMP group, with a Fisher's exact test p-value of 0.500. Within the BOMP group, a repeated measures ANOVA on SALT scores indicated a significant change over time ($F(2, 38.380) = 74.233, p < 0.001$), suggesting substantial improvement in patients' condition across the study duration. Similarly, for the WAP group, significant temporal changes in SALT scores were observed ($F(2, 46.838) = 129.049, p < 0.001$). During the study, the follow-up rate was 100% and no serious adverse effect was reported.

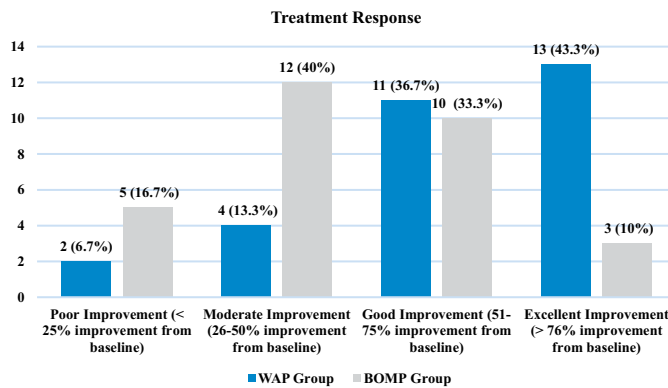


Figure 1: Comparison of Treatment Response and Efficacy between Treatment Groups (p-value=0.009)

DISCUSSION

Alopecia Areata (AA) significantly impacts patients' psychological and social well-being. Approximately 60% of individuals report their initial AA episode occurring before reaching their twenties [8]. Moderate to severe AA complicates treatment and poses a considerable challenge for dermatological management. This study aimed to evaluate the efficacy of WAP and BOMP in the treatment of moderate to severe AA. Demographically, this study reported that mean age of the patients was 31 years and male predominance. Khandpur S (2019) reported similar mean age of participants 26.6 ± 7.38 years and similar ratio of male compared to female participants 2.2:1 [16]. Current study's demographic findings align with those reported by Cua VC et al., in (2019), corroborating that alopecia areata frequently presents during the second and third decades of life, as supported by prior research [12]. This study compared weekly azathioprine pulse therapy with oral betamethasone mini-pulse in treating moderate-to-severe alopecia areata, finding both effective, with azathioprine showing a slightly better safety profile [17]. This open-label study assessed betamethasone oral mini-pulse therapy for extensive alopecia areata, reporting positive clinical outcomes, though without a control group for comparison [18]. In the present study, a profound improvement in alopecia areata treatment was observed, supported by the decrease in SALT scores within both the WAP and BOMP groups. The WAP group demonstrated a significant decline in SALT score from 42.60 to 13.97 at 12 weeks post-treatment follow-up, outperforming the BOMP group which reduced from 38.67 to 21.63. These findings are consistent with previous studies, such as Khandpur S et al., in (2019) who noted a substantial decrease in median scalp hair loss with Azathioprine and Betamethasone treatments, and Farshi S et al., in (2010) who reported a significant reduction in hair loss percentage from 72.7 to 33.5 after Azathioprine treatment [16, 19]. Moreover, Sánchez-Díaz M et al., in (2022) documented similar trends of improvement with mini pulse oral corticosteroids

therapy, demonstrating a decrease in baseline SALT scores from 71.35 to 52.93 [20]. This Summative evidence not only confirms the efficacy of both Azathioprine and corticosteroids but also highlights the resilience of the WAP group's response in this study, asserting its utility in managing moderate to severe AA. This study reported that WAP treatment demonstrated higher hair regrowth ($68.62 \pm 25.83\%$) compared to the BOMP treatment ($44.28 \pm 27.39\%$), achieving a statistical significance in outcomes (p-value=0.001). This differs from results in Khandpur S (2019), where the BOMP higher regrowth 71.43% compared to the WAP treatment 44.52% [16]. Similarly, Gupta P et al., in (2019) reported a higher median regrowth in the BOMP group compared to this study [17]. However, Farshi S et al., in (2010) reported a lower regrowth rate 52.3% compared to current study with weekly Azathioprine treatment [19]. These differences could be due to single arm studies or different treatment duration and follow-ups. Based on changes in the Severity of Alopecia Tool (SALT) score, the study highlights the superior efficacy of WAP therapy, with 43% of participants achieving excellent regrowth, compared to 10% in the BOMP group. Sonare D et al., in (2017) reported no patients in the WAP group showing poor or moderate responses, and a remarkable 96.67% displayed an excellent response [14]. Khaitan BK et al., in (2004) also confirmed the efficacy of BOMP, with a 43.7% rate of excellent response [18]. Sánchez-Díaz M et al., in (2022) noted a 51.8% good response (SALT-50) response at 9 months with mini-pulse corticosteroids treatment [20]. Thi PT et al., in (2019) demonstrated a good regrowth in over 82% of patients over six months, indicating a more gradual but substantial improvement with mini-pulse corticosteroid therapy [21]. Sharma VK et al., in (1999) in single arm study, reported slightly higher excellent regrowth (26.6%) with oral mini-pulse corticosteroids treatment [22]. WAP and BOMP therapies both demonstrated effectiveness in reducing SALT scores and promoting hair regrowth in patients with moderate to severe alopecia areata. Among these, WAP therapy exhibited greater clinical benefit and may be considered a more effective option in such cases. Nonetheless, this study is subject to certain limitations, including its single-institution design, use of non-probability consecutive sampling, and relatively limited sample size, which may restrict the broader applicability of its conclusions. However, strengths of the study include a comparatively larger sample than previous investigations, extended follow-up duration, and a direct comparative evaluation of weekly azathioprine pulse therapy versus oral mini-pulse betamethasone. These factors enhance the depth of insight into their respective efficacies. Further validation through multicenter randomized controlled trials with longer follow-up and focused safety assessments is

recommended to support the generalizability and clinical integration of these findings.

CONCLUSIONS

The study conclusively demonstrated the superior efficacy of WAP therapy over BOMP in increasing hair regrowth among patients with AA. Significantly, the WAP cohort was associated with considerable SALT scores improvement and higher percentage of hair regrowth. These findings promote for the consideration of weekly azathioprine pulse therapy in clinical practice, offering new hope to patients seeking effective management for moderate to severe alopecia areata.

Authors Contribution

Conceptualization: KU

Methodology: KU, TH, MN

Formal analysis: MIJ

Writing, review and editing: KU, MKS, TH, MIJ, MN

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors declare no conflict of interest.

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