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A Randomized Control Study Comparing Efficacy and Safety of Daily Oral Corticosteroids and Minipulse Therapy in Treatment of Rapidly Progressive Non Segmental Vitiligo

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ABSTRACT

Rapidly progressive non-segmental vitiligo (NSV) is a challenging autoimmune condition characterized by widespread depigmentation. Oral corticosteroids and minipulse therapy are commonly used immunosuppressive treatments, but their comparative efficacy and safety remain unclear. This randomized controlled study included 50 patients with rapidly progressive NSV. Patients were randomly assigned into two groups: Group A (n=25) received daily oral corticosteroids and Group B (n=25) underwent oral corticosteroid minipulse therapy. The primary outcome was the reduction in the Vitiligo Area Scoring Index (VASI) at 12 weeks. Secondary outcomes included disease stabilization, safety profile, and patient satisfaction. Statistical analysis was performed using Student's t-test and chi-square tests. Both groups showed significant improvement in VASI scores at 12 weeks. Group A demonstrated greater reduction (mean VASI: 4.2±1.6) compared to Group B (mean VASI: 6.3±1.9, p=0.001). Disease stabilization was achieved in 88% of Group A and 76% of Group B (p=0.23). Adverse events such as weight gain (56% vs. 24%, p=0.02) and mood changes (40% vs. 12%, p=0.01) were more frequent in Group A. Patient satisfaction was higher in Group A (72%) than Group B (64%, p=0.48), though not statistically significant. Daily oral corticosteroids were more effective in reducing VASI scores and stabilizing disease activity but were associated with a higher incidence of adverse events. Minipulse therapy offers a safer alternative with moderate efficacy, making it suitable for long-term management.

INTRODUCTION

The loss of functioning melanocytes in the skin causes vitiligo, an acquired depigmenting condition that manifests as hypopigmented or depigmented patches and macules. The most prevalent variety, non-segmental vitiligo (NSV), is characterized by symmetrical and bilateral lesions[1]. Rapidly progressive NSV is a challenging variant that involves the rapid extension of depigmentation, often necessitating early and effective intervention to halt disease progression and stabilize pigmentation[2]. Vitiligo has a global prevalence of approximately 0.5%-2%, with no significant gender predilection. It can occur at any age but most commonly manifests before the age of 30 years. The psychological and social impact of vitiligo, particularly in rapidly progressive cases, is substantial due to its visible nature and chronic course[3]. This highlights the need for prompt and effective treatment to stabilize disease activity and improve quality of life. Corticosteroids, administered orally or as minipulse therapy, have been widely studied for their efficacy in controlling vitiligo. Daily oral corticosteroids have been shown to stabilize disease activity, particularly in rapidly progressive cases, by suppressing the autoimmune destruction of melanocytes. However, their prolonged use is associated with significant adverse effects, including weight gain, hyperglycemia and mood disturbances. Minipulse therapy, involving the intermittent administration of high-dose corticosteroids (e.g., oral dexamethasone), has emerged as an alternative with a potentially better safety profile. Studies suggest that minipulse therapy may achieve comparable stabilization with fewer side effects. Despite these findings, limited direct comparisons of these two regimens exist, particularly in rapidly progressive NSV[4-6]. Given the lack of consensus on the optimal corticosteroid regimen for rapidly progressive NSV, this study aims to directly compare the efficacy and safety of daily oral corticosteroids and minipulse therapy. Understanding their relative benefits and risks will aid in formulating evidence-based treatment protocols to optimize patient outcomes and minimize adverse effects. This research is particularly relevant in settings where access to advanced therapies such as phototherapy may be limited, making corticosteroid-based regimens a primary treatment option.

Aims and Objectives:

Aim: The study aims to compare the effectiveness and safety of daily oral corticosteroids and minipulse therapy in managing rapidly progressive non-segmental vitiligo.

Objectives:

- To evaluate the clinical improvement in vitiligo area scoring index (VASI) between daily oral corticosteroids and minipulse therapy over 12 weeks.
- To assess the safety profile of both treatment modalities in terms of adverse events.

MATERIALS AND METHODS

Study Design: A 12-month study comparing daily oral corticosteroids and minipulse therapy for rapidly progressive non-segmental vitiligo was conducted at a tertiary care center's Department of Dermatology. The study involved patients diagnosed with vitiligo who had new or enlarged lesions within the past six months. The research aimed to compare the efficacy and safety of these treatments.

Inclusion Criteria:

- Patients aged 18-50 years with clinically confirmed non-segmental vitiligo.
- Rapid progression of vitiligo within the last 6 months.
- VASI score $\geq$10 at baseline.
- Willingness to provide informed consent and adhere to study procedures.

Exclusion Criteria:

- Segmental or localized vitiligo.
- History of systemic corticosteroid use in the past 3 months.
- Presence of uncontrolled comorbidities (e.g., diabetes mellitus, hypertension).
- Pregnant or lactating women.
- Known hypersensitivity to corticosteroids.

Data Collection: A study involving 50 patients was conducted to compare the effectiveness of daily oral corticosteroids and minipulse therapy in treating Vitiligo. The patients were divided into two groups: Group A (25 patients) received daily corticosteroids, followed by a gradual taper over two weeks and Group B (25 patients) received minipulse therapy. The study was single-blinded, with patients unaware of their treatment group assignment. The primary outcome measures included changes in Vitiligo Area Scoring Index (VASI) at 4, 8 and 12 weeks, stabilization of disease activity at 12 weeks, incidence of adverse events, patient satisfaction and long-term remission rate evaluated three months post-treatment. Clinical assessments were conducted at baseline, four weeks, eight weeks and 12 weeks, with patient-reported outcomes and adverse events recorded at each visit. Laboratory investigations were also conducted at baseline and after 12 weeks.

RESULTS AND DISCUSSIONS

Table 1: Baseline Characteristics of Study Participants (n=50)

Parameter	Daily Oral Corticosteroids (n=25)	Minipulse Therapy (n=25)	P-value
Age (years, mean±SD)	28.4±6.7	29.1±7.3	0.62
Gender (M:F)	12:13	11:14	0.78
Duration of vitiligo (months)	10.5±3.2	11.1±4.1	0.54
Baseline VASI score	12.7±2.4	13.1±2.5	0.68

Table 2: Change in VASI Score Over 12 Weeks

Time Point	Daily Oral Corticosteroids (Mean±SD)	Minipulse Therapy (Mean±SD)	P-value
Baseline	12.7±2.4	13.1±2.5	0.68
Week 4	9.4±2.1	10.2±2.3	0.18
Week 8	6.5±1.8	7.8±2.0	0.04
Week 12	4.2±1.6	6.3±1.9	0.001

Table 3: Stabilization of Disease Activity at Week 12

Parameter	Daily Oral Corticosteroids (%)	Minipulse Therapy (%)	P-value
Stabilization of disease (%)	88	76	0.23
Patients achieving ≥50% VASI reduction	84	68	0.12

Table 4: Safety Profile (Incidence of Adverse Events)

Adverse Event	Daily Oral Corticosteroids (%)	Minipulse Therapy (%)	P-value
Weight gain	56	24	0.02
Mood changes	40	12	0.01
Hyperglycemia	28	8	0.04
Skin atrophy	8	4	0.45

Table 5: Patient Satisfaction and Long-Term Remission

Parameter	Daily Oral Corticosteroids (%)	Minipulse Therapy (%)	P-value
Patient-reported satisfaction (High/ Very High)	72	64	0.48
Long-term remission at 3 months post-therapy (%)	68	52	0.21

The current study aimed to compare the efficacy and safety of daily oral corticosteroids (DOC) and minipulse therapy (MPT) in the management of rapidly progressive non-segmental vitiligo. Our findings indicate that both treatments were effective in reducing disease activity, with DOC demonstrating a greater reduction in the Vitiligo Area Scoring Index (VASI) at 12 weeks compared to MPT (4.2±1.6 vs. 6.3±1.9, p=0.001). These results align with earlier reports highlighting the potent anti-inflammatory effects of corticosteroids in halting disease progression. In a study by Sinha[7], systemic corticosteroids given as MPT were found to stabilize disease activity in 76% of patients, which is consistent with our observation of 76% stabilization in the MPT group. However, the higher efficacy observed in the DOC group in our study (88% stabilization) suggests that daily dosing may provide a more consistent anti-inflammatory effect, albeit with a higher risk of side effects. Shaffrali[8] previously reported that daily corticosteroid therapy leads to significant repigmentation but is associated with a higher incidence of adverse events such as weight gain and hyperglycemia. Our findings echo these concerns, with 56% of DOC-treated patients experiencing weight gain compared to 24% in the MPT group. This suggests that while DOC may be more effective in controlling disease activity, its safety profile warrants careful consideration. The remission rates observed in our study three months post-therapy (68% for DOC and 52% for MPT) are comparable to those reported by Pasricha and Khaitan[9], who demonstrated long-term stabilization in approximately 60% of patients treated with MPT. This consistency across studies underscores the role of corticosteroid therapy in preventing disease progression and achieving sustained control. Adverse events were significantly more common in the DOC group, particularly systemic side effects like weight gain (p=0.02) and mood changes (p=0.01). These findings align with the work of Alireza[10], who noted that systemic corticosteroids pose a higher risk of metabolic and psychological side effects when used continuously. The lower incidence of side effects in the MPT group in our study reinforces the view that intermittent dosing schedules can mitigate some of the risks associated with corticosteroid therapy. Patient satisfaction was higher in the DOC group (72% vs. 64%), possibly due to the more rapid and pronounced improvement in VASI scores. Similar results were reported by Oakley[11], who found that rapid stabilization of vitiligo led to better patient-reported outcomes, even when associated with mild to moderate side effects. The strengths of our study include a randomized design and comprehensive evaluation of both efficacy and safety parameters. However, the relatively short follow-up period is a limitation, as vitiligo is a chronic condition requiring long-term management. Future studies with extended follow-up are needed to confirm the long-term benefits and risks of both treatment modalities.

CONCLUSION

In conclusion, daily oral corticosteroids were more effective than minipulse therapy in reducing disease activity in rapidly progressive non-segmental vitiligo, but this was at the cost of a higher incidence of adverse events. Minipulse therapy offers a safer alternative with reasonable efficacy, making it a preferable option for patients where safety is a primary concern. Further large-scale studies are recommended to optimize dosing regimens and minimize side effects.

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