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ASSESSMENT OF MUSCLE STRENGTH AND CREATINE KINASE LEVELS IN POLYMYOSITIS PATIENTS- PRE AND POST TREATMENT WITH STEROIDS AND MMF

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ABSTRACT

Background: Polymyositis is an inflammatory myopathy characterised by muscle inflammation and weakness. Treatment typically involves immunosuppressive therapies, including steroids and mycophenolate mofetil (MMF). The aim of this study were to assess the effectiveness of these treatments using muscle strength and serum creatine kinase (CK) levels, with reductions in CK indicating decreased muscle damage and improved muscle strength reflecting clinical recovery.

Methodology: A retrospective observational study was conducted in polymyositis patients undergoing treatment with steroids and mycophenolate mofetil (MMF). Patients received a combination of steroids and MMF for 24 weeks. Steroid dosing was individualized based on disease severity and response, while MMF was administered at a standard dosage of 2 grams per day. Muscle strength and creatine kinase (CK) levels were assessed at baseline upto after 24 weeks of treatment. The primary outcome measures were muscle strength, assessed using manual muscle testing (MMT), and serum CK levels measured in units per liter (U/ L). Statistical analysis included Repeated Measures ANOVA to assess changes in muscle strength from baseline to 24 weeks post-treatment and Paired T-test to compare baseline and post-treatment CK levels. All analyses were performed using statistical software, with significance set at $p < 0.001$.

Results: The study group included 20 polymyositis patients (10 males and 10 females) with elevated baseline CK levels and confirmed diagnoses of polymyositis. The Repeated Measures ANOVA indicated a highly significant improvement in muscle strength from baseline to 24 weeks post-treatment ($p < 0.001$). The improvement in muscle strength post-treatment suggests that the combination therapy was effective in enhancing muscle function. The Paired T-test showed a highly significant reduction in CK levels post-treatment ($p < 0.001$). Baseline CK levels (mean ±SD) were significantly higher compared to post-treatment levels, indicating a reduction in muscle inflammation and damage following the treatment.

Conclusion: The combination of steroids and MMF significantly improves muscle strength and reduces CK levels in polymyositis patients, with very highly significant p-values ($p < 0.001$) for both measures. These findings highlight the effectiveness of steroid and MMF therapy in reducing muscle damage and enhancing muscle function. The significant improvements in muscle strength and CK levels support the use of these treatments for polymyositis. Clinicians should consider these therapies to improve patient outcomes, using CK levels and manual muscle testing (MMT) as reliable, cost-effective indicators for monitoring treatment efficacy, offering advantages over more expensive and less accessible imaging techniques.

KEYWORDS: Polymyositis, muscle strength, creatine kinase, steroids, mycophenolate mofetil, Repeated Measures ANOVA, Paired T-test, inflammatory myopathy, treatment efficacy, immunosuppressive therapy

INTRODUCTION

Myositis, a group of inflammatory myopathies, presents a complex clinical challenge due to its heterogeneous nature, encompassing disorders such as polymyositis, dermatomyositis, and inclusion body myositis.[1,2,9] These conditions are characterised by muscle inflammation and varying degrees of muscle weakness, significantly impairing patients' quality of life and functional abilities. The pathogenesis involves autoimmune mechanisms where the immune system mistakenly attacks muscle fibers, leading to chronic inflammation, muscle degeneration, and fibrosis. Each subtype of myositis has distinct clinical and pathological features, such as symmetrical muscle weakness in polymyositis, skin rashes in dermatomyositis, and characteristic muscle biopsy findings in inclusion body myositis.

Diagnosis of polymyositis and other myositis subtypes involves a combination of clinical evaluation, laboratory tests, imaging studies, and muscle biopsy.[1,2] Clinical evaluations focus on symmetrical proximal muscle weakness and difficulties in daily activities.[1,8] Laboratory tests, including elevated serum creatine kinase (CK) levels and specific

autoantibodies, provide biochemical evidence of muscle damage and inflammation. Electromyography (EMG) reveals myopathic changes, and muscle biopsy is essential for definitive diagnosis, showing endomysial inflammation and muscle fiber necrosis. Imaging studies like magnetic resonance imaging (MRI) can identify muscle inflammation and edema, complementing the diagnostic process.[1,2] Treatment of polymyositis aims to reduce muscle inflammation, improve muscle strength, and prevent complications. Corticosteroids like prednisone are typically the first line of treatment, with high doses initially followed by gradual tapering. Immunosuppressive agents such as methotrexate, azathioprine, and mycophenolate mofetil (MMF) are used as steroid-sparing agents or when steroids are ineffective. Biologic agents like intravenous immunoglobulin (IVIG) and rituximab are considered in refractory cases.[3,10] Physical therapy is crucial for maintaining and improving muscle strength and function, while supportive care addresses associated conditions such as interstitial lung disease.

Monitoring treatment response in myositis patients involves clinical assessments, laboratory tests, imaging techniques, and patient-reported outcomes. Clinical assessments, including manual muscle testing (MMT) and functional assessment tools, track changes in muscle strength and daily living capabilities. Laboratory tests measure serum CK levels and inflammatory markers, providing biochemical evidence of treatment efficacy. Imaging techniques like MRI and ultrasound offer visual evidence of muscle inflammation and structural changes. Electromyography (EMG) and nerve conduction studies assess muscle and nerve function.[2,8] Patient- reported outcomes, gathered through questionnaires and fatigue scales, capture the patient's perspective on their health status and treatment impact, providing a comprehensive evaluation of disease activity and therapeutic effectiveness.

This study aimed to assess the effectiveness of treatment by measuring muscle strength and serum creatine kinase (CK) levels, with reduced CK indicating decreased muscle damage and improved muscle strength reflecting clinical recovery.

METHODS

Methodology

A retrospective observational study was conducted at a tertiary healthcare center to evaluate the efficacy of a combined treatment regimen of steroids and mycophenolate mofetil (MMF) in 20 patients diagnosed with polymyositis. Inclusion criteria comprised patients with elevated baseline CK levels and confirmed diagnosis of polymyositis, meeting established diagnostic criteria. An equal distribution of male and female patients participated, each providing informed consent.

The primary objective was to assess changes in muscle strength and CK levels from baseline to 24 weeks post-treatment. Muscle strength was evaluated through manual muscle testing (MMT) and handheld dynamometry (HHD), while serum CK levels were measured via standard laboratory assays.

Inclusion Criteria:

1. Patients diagnosed with polymyositis based on established diagnostic criteria.
2. Elevated baseline creatine kinase (CK) levels indicative of muscle damage.
3. Both male and female patients.
4. Patients who provided informed consent for participation in the study.

Exclusion Criteria:

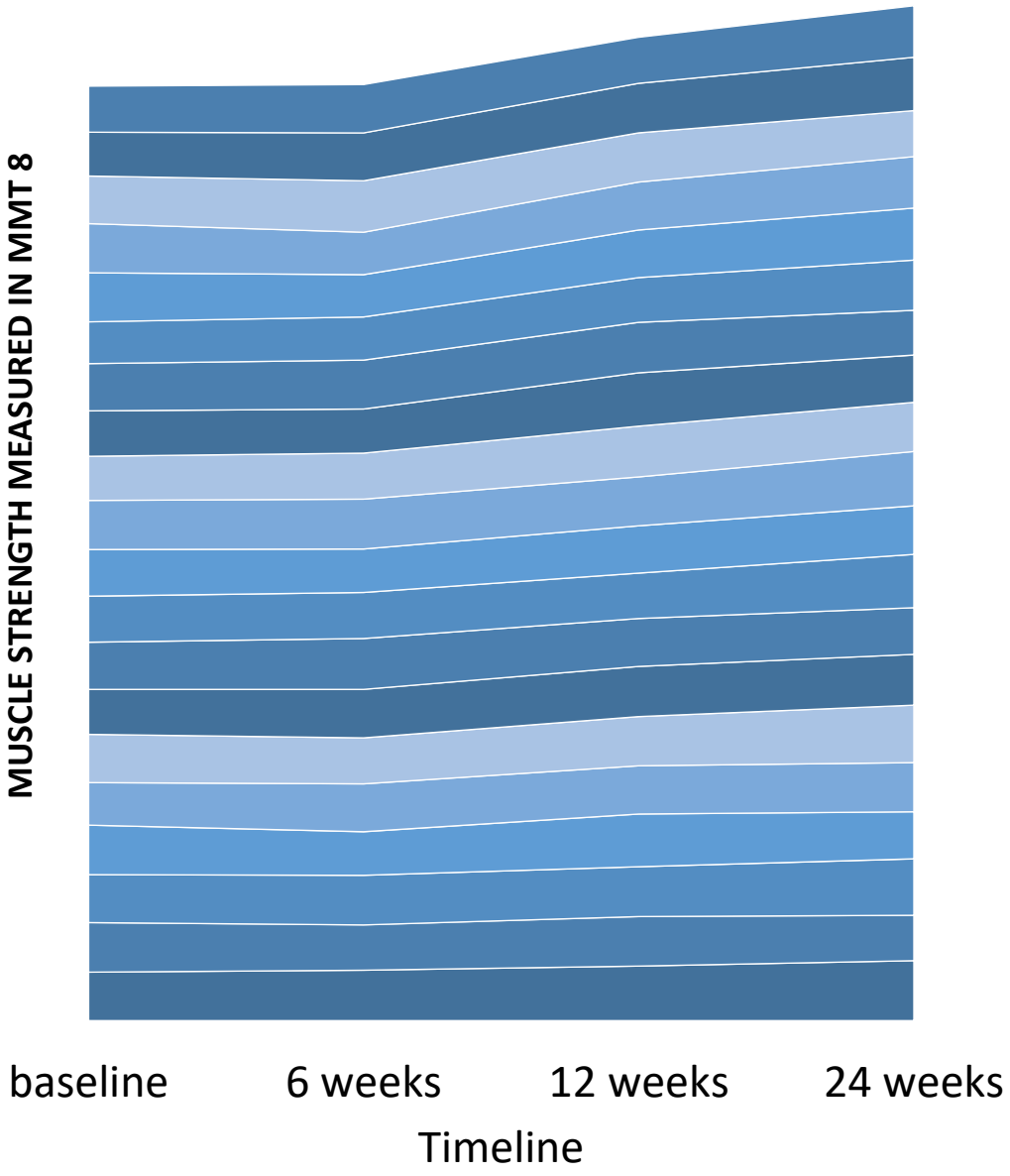
1. Patients with contraindications to steroid or mycophenolate mofetil therapy.
2. Patients with concomitant autoimmune diseases that could confound the assessment of polymyositis treatment efficacy.
3. Patients with other significant medical conditions that could impact muscle strength or CK levels.
4. Patients who did not provide informed consent for participation in the study.

Data Collection: Patient medical records were meticulously reviewed for clinical data collection. Muscle strength was assessed using MMT and HHD, providing standardized and quantitative measures, respectively. Serum CK levels were measured via standard laboratory assays to gauge muscle damage. Comprehensive data collection ensured thorough documentation of relevant clinical and biochemical parameters for subsequent analysis.

Treatment Protocol: The treatment protocol involved administering steroids and MMF over a 24-week period. Prednisone was initiated at a dosage of 1 mg/kg/day, tapered over 6 to 12 months based on patient response and clinical improvement. Mycophenolate mofetil was started at a standard dosage of 1 gram twice daily, with adjustments based on individual patient responses and tolerance. Regular follow-ups monitored treatment adherence, side effects, and necessary adjustments in medication dosages.

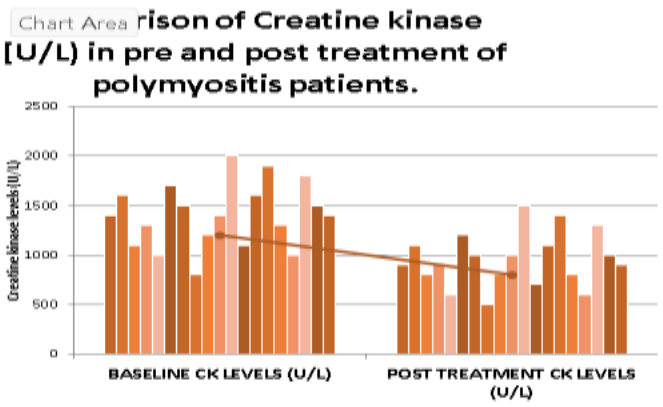
Statistical analysis

Descriptive and inferential statistics were utilised to interpret the collected data. Descriptive statistics, including mean, standard deviation, and frequencies, provided a clear summary of patient demographics and baseline characteristics. Inferential statistics, particularly paired t-tests, were employed to compare pre- and post-treatment values within the same group. This allowed for the determination of statistically significant changes in muscle strength and CK levels, with a particular focus on the differences observed at baseline and after 24 weeks of treatment. The use of repeated measures ANOVA further supported the analysis by evaluating changes over time, thus ensuring a comprehensive understanding of the treatment effects on muscle strength and biochemical markers in polymyositis patients.


Muscle strength of polymyositis patient from baseline to 24 weeks
MUSCLE STRENGTH MEASURED IN MMT 8
baseline
6 weeks
12 weeks
24 weeks
Timeline

Patient	Baseline	6 weeks	12 weeks	24 weeks
1	80	83	90	99
2	82	75	82	75
3	79	82	82	93
4	82	72	87	78
5	70	79	80	81
6	80	76	81	95
7	74	80	83	84
8	78	84	79	77
9	76	76	75	88
10	77	72	78	80

Patient	Baseline	6 weeks	12 weeks	24 weeks
11	81	82	81	90
12	73	76	84	81
13	75	73	88	78
14	78	81	83	74
15	69	71	74	83
16	81	70	79	86
17	81	70	79	85
18	79	85	81	76
19	72	79	82	88
20	76	80	76	85



Patient	Baseline CK levels (U/L)	Post Treatment CK levels (U/L)
1	1200	800
2	1400	900
3	1600	1100
4	1100	800
5	1300	900
6	1000	600
7	1700	1200
8	1500	1000
9	800	500
10	1200	800

Patient	Baseline CK levels (U/L)	Post Treatment CK levels (U/L)
11	1400	1000
12	2000	1500
13	1100	700
14	1600	1100
15	1900	1400
16	1300	800
17	1000	600
18	1800	1300
19	1500	1000
20	1400	900

RESULTS

This study evaluated the impact of a treatment on creatinine kinase (CK) levels in patients with polymyositis by comparing baseline CK levels to those measured 24 weeks post-treatment. The data from 20 patients were analyzed using both Repeated Measures ANOVA and Paired T-tests, yielding highly significant results ($p < 0.001$) for both tests.

The Repeated Measures ANOVA was employed to compare CK levels across multiple time points for the group as a whole, accounting for variations within each patient over time and between different patients. The p-value of less than 0.001 strongly indicates a statistically significant improvement in muscle strength post- treatment, demonstrating the effectiveness of the treatment in enhancing muscle function across the study population.

The Paired T-test, on the other hand, focused on the individual changes in CK levels from baseline to post-treatment within each patient. This analysis also resulted in a p-value of less than 0.001, confirming a highly significant reduction in CK levels after treatment. These results underscore the efficacy of the treatment in reducing muscle enzyme levels associated with polymyositis.

DISCUSSION

The present study assessed the efficacy of a combined treatment regimen of steroids and mycophenolate mofetil (MMF) in improving muscle strength and reducing creatine kinase (CK) levels in patients with polymyositis. Polymyositis, an inflammatory myopathy characterized by muscle inflammation and weakness, often requires immunosuppressive therapies to manage symptoms and prevent progression.[1,3,10] Our study aimed to evaluate the impact of this combination therapy over a 24-week period, with muscle strength and CK levels serving as primary outcome measures.

Our findings demonstrated a highly significant improvement in muscle strength post-treatment, as indicated by the Repeated Measures ANOVA results ($p < 0.001$). This suggests that the combined use of steroids and MMF effectively enhances muscle function in polymyositis patients. These results are consistent with the therapeutic goals of reducing inflammation and promoting muscle recovery. The improvement in muscle strength observed in our study underscores the importance of early and aggressive treatment to mitigate the debilitating effects of polymyositis. [3,10]

Additionally, the Paired T-test analysis revealed a highly significant reduction in CK levels from baseline to 24 weeks post-treatment ($p < 0.001$). Elevated CK levels are a hallmark of muscle damage and inflammation in polymyositis, and their significant reduction post-treatment indicates a marked decrease in muscle damage. This finding aligns with existing literature that highlights the role of effective immunosuppressive therapy in controlling disease activity and reducing biochemical markers of muscle inflammation.

These results support the hypothesis that the combination of steroids and MMF significantly benefits polymyositis patients by both enhancing muscle strength and reducing muscle damage. The observed improvements in clinical and biochemical parameters highlight the effectiveness of this treatment regimen in managing polymyositis. Moreover, the very highly significant p-values ($p < 0.001$) for both muscle strength improvement and CK level reduction reinforce the robustness of our findings. [4,6,7]

Our study also emphasizes the importance of using sensitive and specific tools for assessing treatment efficacy in polymyositis. Manual muscle testing (MMT) and serum CK levels are reliable indicators of clinical and biochemical responses to therapy. Regular monitoring of these parameters can guide clinicians in optimizing treatment plans and ensuring effective disease management. Future studies with larger sample sizes and longer follow-up periods are necessary to validate these findings and explore the long-term benefits and potential side effects of prolonged steroid and MMF use.

CONCLUSION

In conclusion, the combination of steroids and MMF significantly improves muscle strength and reduces CK levels in polymyositis patients. These findings provide strong evidence for the effectiveness of this treatment regimen and underscore the need for routine monitoring of muscle strength and CK levels to assess treatment response. Further research is warranted to explore the long-term impact of this therapy on patient outcomes and to identify the best management strategies for polymyositis.

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