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Sana Ghous
Chandka Medical College Hospital, Larkana

Anjlee Shankar
Chandka Medical College Hospital, Larkana

Abdul Rahman Soomro
Chandka Medical College Hospital, Larkana

Abdul Qadir Baloch
Chandka Medical College Hospital, Larkana

Asif Ali
Chandka Medical College Hospital, Larkana

See next page for additional authors

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Authors

Sana Ghous, Anjlee Shankar, Abdul Rahman Soomro, Abdul Qadir Baloch, Asif Ali, and Alam Ibrahim Siddiqui

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ANALYZING THE IMPACT OF PULSE STEROID THERAPY ON RELAPSE RATES AND DISEASE PROGRESSION IN RELAPSING-REMITTING MULTIPLE SCLEROSIS: A COMPREHENSIVE RETROSPECTIVE STUDY

Sana Ghous[1], Anjlee Shankar[1], Abdul Rahman Soomro[1], Abdul Qadir Baloch[1], Asif Ali[1], Alam Ibrahim Siddiqui[1]
[1].Department of Neurology, Chandka Medical College Hospital, Larkana

Corresponding author:* Sana Ghous** *Department of Neurology, Chandka Medical College Hospital, Larkana* ***Email: *sana_shk13@yahoo.com*

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ABSTRACT

Background and Objective:

Relapsing remitting MS (RRMS) is characterized by recurrent relapses with remissions. Over an extended time-frame, high-dose steroid administration has primarily centered on the treatment of acute relapses, rather than relapse prevention. The objective of this retrospective study is to assess the long-term impact of administering three monthly pulse steroid therapy for three days on relapse rates and the Expanded Disability Status Scale (EDSS) scores in patients with RRMS.

Methods:

This study was conducted at Neurology ward of Chandka Medical College Hospital in Larkana from January 2021 to January 2023. A retrospective analysis of historical patient data, focusing on individuals with RRMS who received three monthly pulse steroid therapy over a specified period. Data was collected through patient records, including details of treatment, relapse history, and EDSS scores.

Results:

Thirty MS patients including 25 females and five males received one gram methylprednisolone intravenously every three months for three days. The mean age range was 18-50 years. Among them, three experienced no relapses, 11 had one relapse, 13 encountered two relapses, and three had three relapses over next consecutive two years. The severity of relapses varied, with 20 classified as moderate and seven as severe. A reduction in relapse rates and notable improvements in EDSS scores were observed.

Conclusion:

The initial findings from this retrospective analysis suggest that three monthly pulse steroid therapy is associated with positive outcomes in RRMS patients. These results support the need for further investigation into the potential benefits of continuous steroid therapy in managing RRMS.

Keywords: Relapsing-remitting multiple sclerosis, Pulse steroid therapy, Relapse rates, Expanded Disability Status Scale, Disease activity, Disease progression

INTRODUCTION

Multiple sclerosis (MS) is a chronic, debilitating immune-mediated demyelinating disease leading to a range of manifestations resulting from the destruction of myelin and to some extent axons, within the central nervous system. MS is categorized into four distinct subtypes: relapsing-remitting MS, secondary progressive MS, primary progressive MS, and progressive-relapsing MS.[1] Among these, the most prevalent subtype, relapsing-remitting MS, is typically characterized by a pattern of recurrent relapses (marked by periods of disease manifestations), interspersed with remissions, (marked by periods of recovery). Over time, these relapses contribute to cumulative disability.[2]

In clinical practice, the universally acknowledged treatment for acute multiple sclerosis relapses consists of daily one-gram intravenous Methylprednisolone over [3] to 10 days.[3] This approach targets neural inflammation reduction, resulting in decreased edema, restoration of the blood-brain barrier, and swift brain homeostasis recovery, post- IV methylprednisolone administration.[4] Although not recommended but when used in long term, high dose intravenous steroids have shown good outcomes in improving EDSS and reducing relapse rates.[5] The level of evidence in supporting this method is notably lower than other drugs approved by FDA. The study explores the outcomes of an Immunomodulatory approach utilizing one gram intravenous methylprednisolone for three days administered every three months.

METHODS

This retrospective cross-sectional study was conducted at the Neurology Department of Chandka Medical College Hospital in Larkana from January 2021 to January 2023 over two years, in a real-world clinical context. Data of 30 patients was studied for this study. The study protocol received approval from Shaheed Mohtarma Benazir Bhutto Medical University (SMBBMU) Larkana institutional ethical review board.

Inclusion Criteria:

1. Confirmed MS diagnosis, with relapsing-remitting variety as per McDonald diagnostic criteria.6
2. Receiving one-gram intravenous methylprednisolone for three days every three months.
3. Age range between 18-50 years.

Exclusion Criteria:

1. Previous contraindications to steroid therapy.
2. Patients with chronic illnesses like hypertension, diabetes mellitus, chronic kidney disease, peptic ulcer, psychiatric disorders, and those taking warfarin.
3. Patients taking immune-modulatory drugs (like interferons, glatiramer, or monoclonal antibodies).

The rationale for administering pulse steroid therapy stemmed from the socioeconomic constraints faced by patients within a remote healthcare setting, where individuals of low socioeconomic status lacked the financial means to access standard care. Consequently, pulse steroid therapy emerged as a viable treatment option, particularly as it was exclusively accessible within government-operated healthcare facilities.

Data Collection: A comprehensive review of patient records captured demographic details, treatment specifics, relapse patterns, severity, symptoms, concomitant medication, and adverse effects.
Statistical Analysis: Descriptive statistics using SPSS version 23 provided insights into symptomatology, relapse patterns, EDSS scores, and adverse effects.

RESULTS

Thirty MS patients including 25 females and five males received one gram methylprednisolone intravenously every three months for three days. Their ages ranged between 18-50 years (mean 32). Among them, three experienced no relapses, 11 had one relapse, 13 encountered two relapses, and three had three relapses over consecutive two years. The severity of relapses varied, with 20 classified as moderate and seven as severe. Relapses were managed with a second round of intravenous steroids in most of the cases. Few were referred for plasmapheresis.

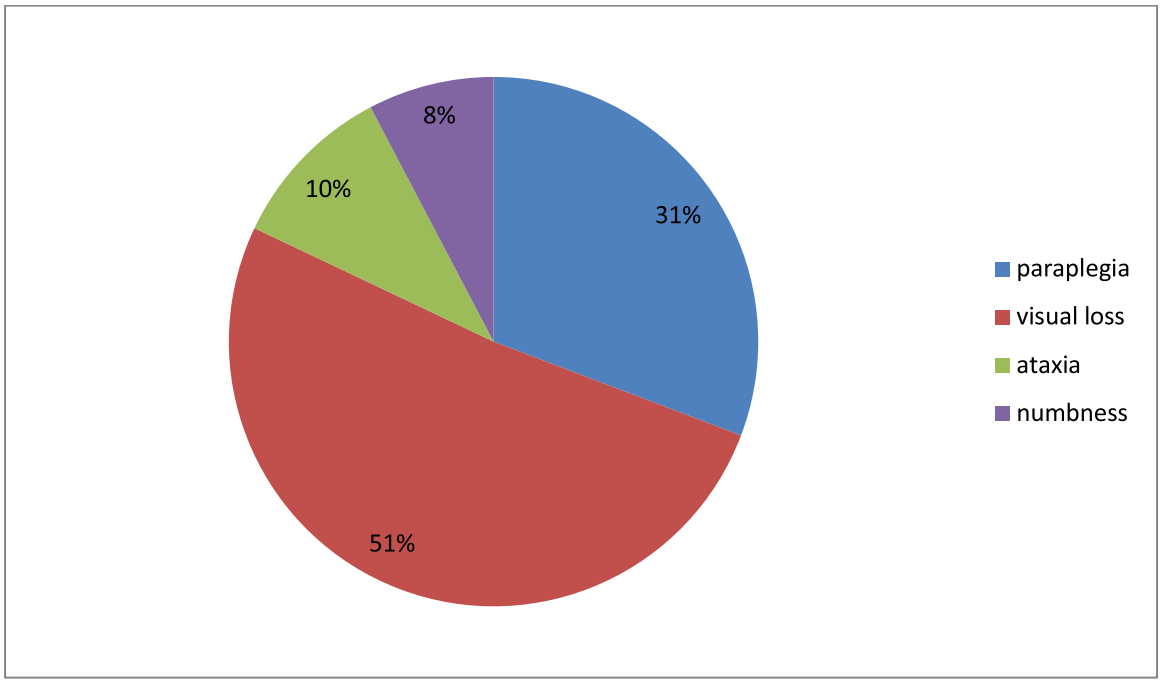

Figure 1: Frequency of symptomology of relapses

Diverse symptoms manifested during relapses, including unilateral visual loss, paraplegia, numbness and ataxia. Concomitant azathioprine orally (50mg BD) was administered to seven patients.

At presentation, EDSS scores were predominantly in the range of 5-8, with a majority at 7 and 8. The initial and final EDSS scores and the improvement over time are demonstrated in Figures 2, 3 and 4.

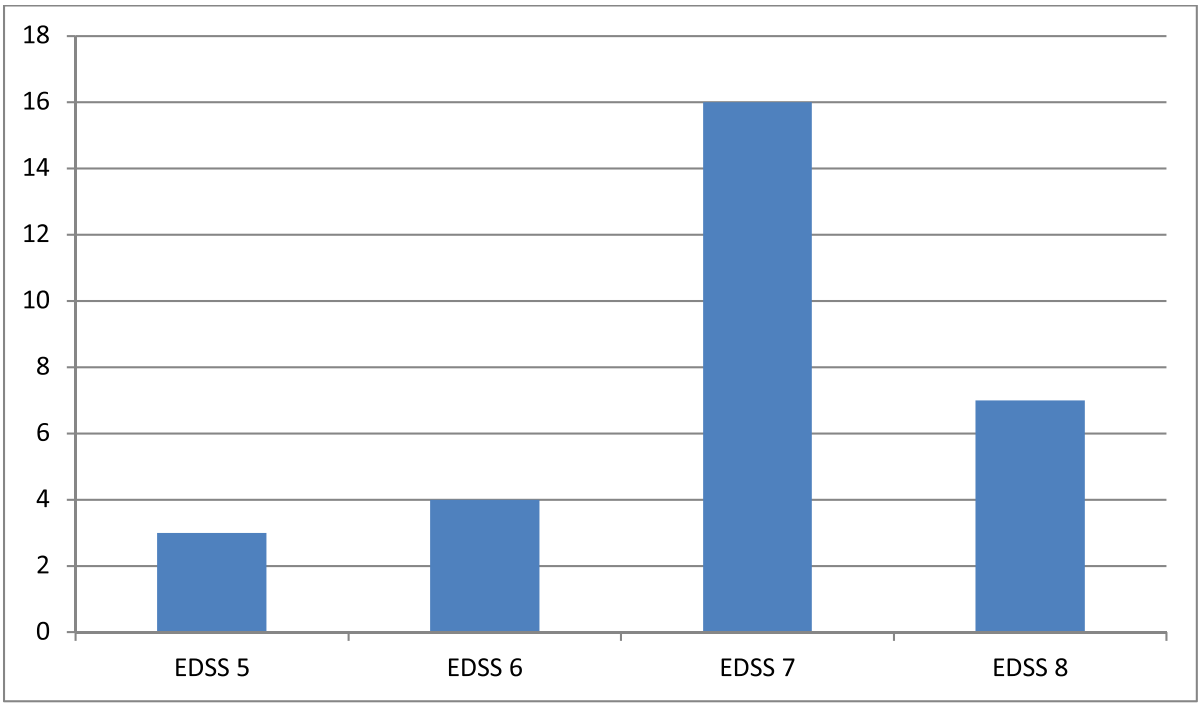

Figure 2: Initial EDSS in the patients

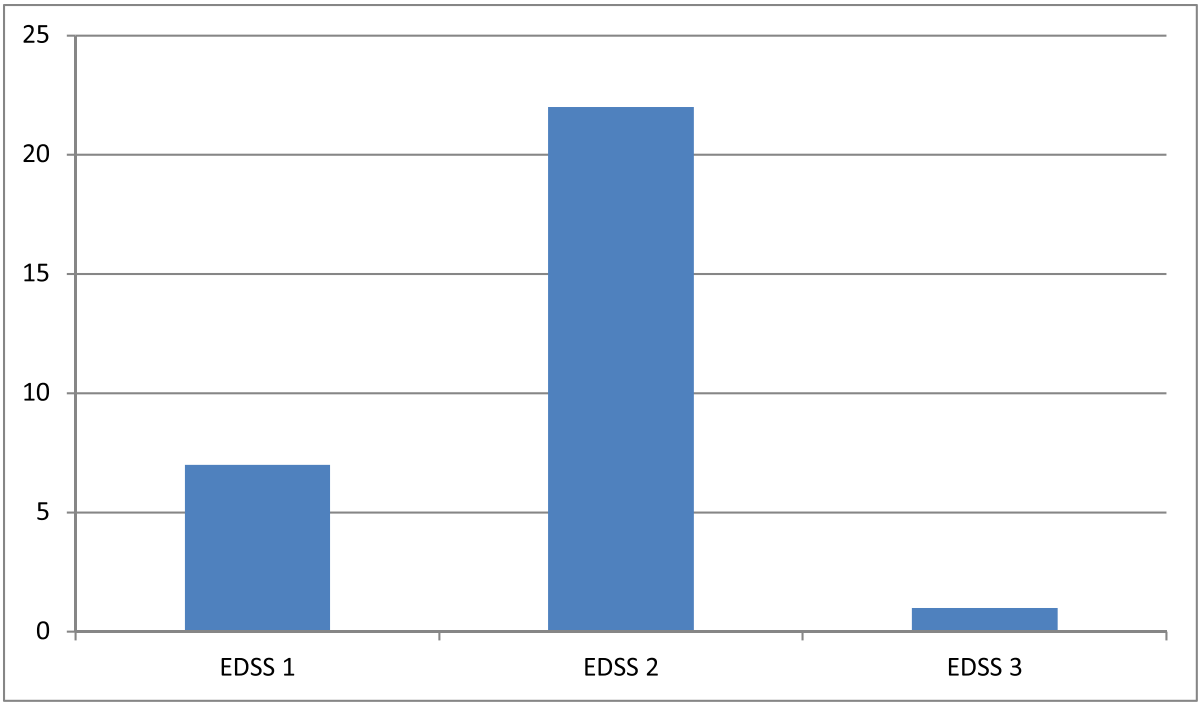

Figure 3: Final EDSS in the patients

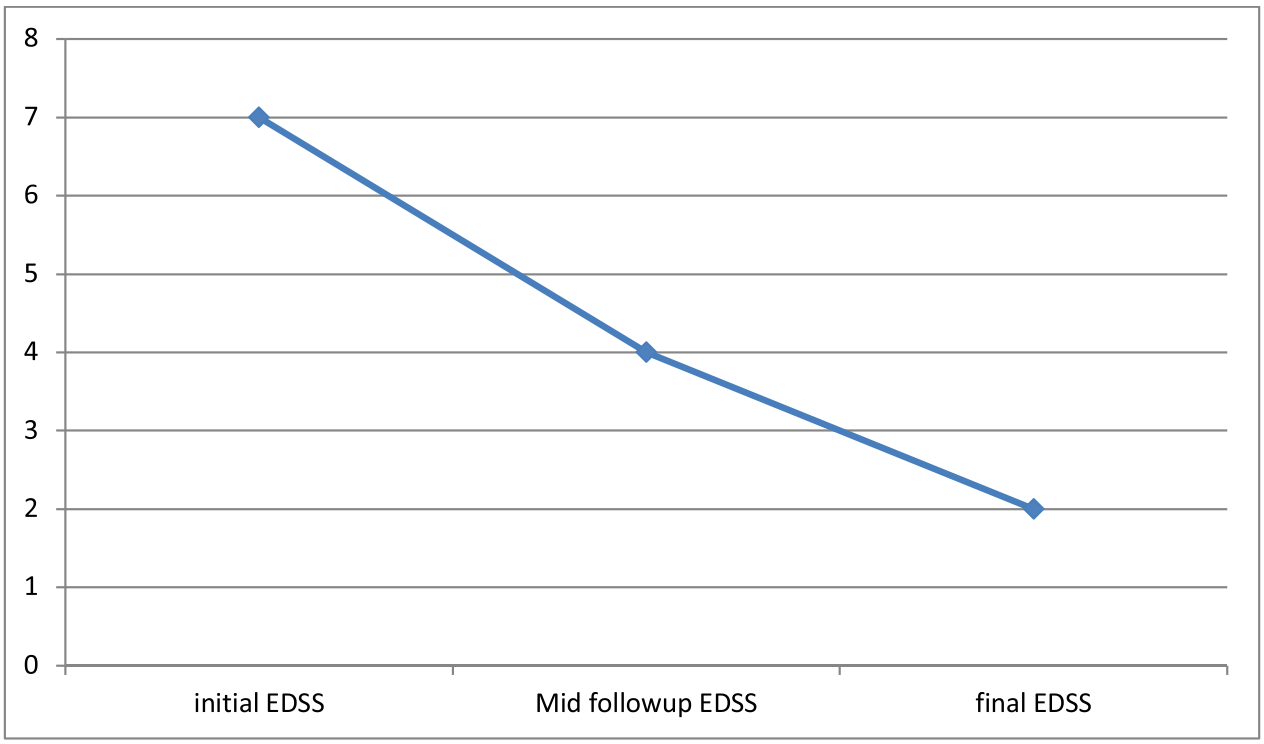

Figure 4: Improvement (reduction) in mean EDSS over time

A dramatic improvement in EDSS was noted that greatly improved the patient's quality of life. Adverse effects of steroids including hyperglycemia, mild psychiatric symptoms, transient facial flushing, bone pain, insomnia and heartburn were observed. Nine patients reported no adverse effects. These effects were generally mild in eight and moderate in 13 patients. No serious life-threatening adverse effects were reported that could not be managed.

DISCUSSION

Relapsing-Remitting Multiple Sclerosis (RRMS) is a form of multiple sclerosis, in which individuals experience distinct relapses, also known as exacerbations or flare-ups, due to inflammation and demyelination in the central nervous system. These relapses are typically separated by periods of remission, wherein symptoms stabilize or improve. This leads to the accumulation of disability, marked by a deterioration in EDSS scores and an escalation in the frequency of relapses.[7]

The observed reduction in relapse rates and improvement in EDSS scores in this study align with existing literature on the immunomodulatory effects of pulse steroid therapy.[8,9] The variety of symptoms observed during relapses highlights the diverse nature of presentations in individuals with MS. Consistently using pulse steroids could have positive long-term
effects for individuals with MS. This treatment approach may help achieve the goal of "no evidence of disease activity" (NEDA) and is generally easy for patients to tolerate.[10]

Symptomatology, ranging from unilateral visual loss to complex combinations, emphasizes the need for tailored interventions. The substantial improvement in EDSS scores signifies not only reduced disability but also hints at restored functionality. Adverse effects, varying in intensity, prompt an in-depth analysis of therapy tolerability.[11]

A few limitations of the study were there. First one is that the number of cases were inadequate for accurate estimation of efficacy of pulse steroid therapy as an immune-modulator regime. Secondly, all the cases were from a single healthcare facility. Also, the limited

accessibility to MRI resources further constrained the ability to integrate regular imaging for comprehensive disease monitoring. MRI was used exclusively for diagnosing MS). This oversight, while essential for initial diagnosis, failed to capture the dynamic nature of MS evolution. Last one is the concurrent use of azathioprine, which introduces complexity, necessitating exploration of synergistic effects and long-term safety. It is a necessity that its validation should be assessed in a large cohort.

CONCLUSION

This study highlights the promising efficacy of long-term immunomodulatory pulse steroid therapy in mitigating relapse rates and fostering notable enhancements in EDSS scores among individuals with MS. While acknowledging that EDSS improvements may also stem from recovery following acute relapses, the substantial reduction in relapse rates emphasizes the tangible benefits of this therapeutic regimen in authentic clinical settings. These findings emphasize the significance of continued research and prospective investigations to corroborate these favorable outcomes and refine treatment protocols tailored to the evolving needs of MS patients.

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Authors’ contribution:
Sana Ghous; data collection, data analysis, manuscript writing, manuscript review
Anjlee Shankar; data collection, data analysis, manuscript writing, manuscript review
Abdul Rahman Soomro; data collection, data analysis, manuscript writing, manuscript review
Abdul Qadir Baloch; concept, data collection, manuscript writing
Asif Ali; concept, data collection, manuscript writing
Alam Ibrahim Siddiqui; concept, manuscript revision

The authors have approved the final version of the article, and agree to be accountable for all aspects of the work.