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(REVIEW ARTICLE)

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Pharmacotherapy of systemic lupus erythematosus: A comparison of lupus disease activity with rituximab and sifalimumab

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Abstract

Systemic Lupus Erythematosus is a disease that affects millions worldwide. Research indicates that people suffering from lupus respond well to monoclonal antibody treatment aimed at characteristic immune cell markers. By targeting immune cell markers, the immune system is subsequently suppressed in a way such that lupus disease activity is decreased. Monoclonal antibody treatments targeted towards a variety of immune cell markers have historically been shown to result in decreases in lupus disease activity. Many studies have assessed lupus disease activity with monoclonal antibody treatments, but few have compared different treatments.

A systematic review of a study that assessed the lupus disease activity for those taking rituximab was then compared to the findings of another study which assessed the lupus disease activity with those taking sifalimumab.

The patients treated with sifalimumab had significantly decreased lupus disease activity when compared with other matched controls. Those who were treated with rituximab had significantly decreased lupus disease activity when compared with other matched controls. However, those who were treated with rituximab had a greater reduction of lupus disease activity as compared to control groups than did those who were treated with sifalimumab.

Monoclonal antibody treatments for systemic lupus erythematosus are widespread. It is critical that these treatments are compared in order to find those with the greatest efficacy. For this review, rituximab seemed to have a greater reduction of disease activity than did sifalimumab. Further studies with greater sample sizes assessing multiple other side effects of monoclonal antibody immunosuppression are needed.

Keywords: Systemic Lupus Erythematosus; Rituximab; Sifalimumab; Autoimmune Disease; Monoclonal Antibody Therapy; Immune Hypersensitivity

1. Introduction

There is sufficient information to suggest that persons suffering from systemic lupus erythematosus (SLE) respond well to monoclonal antibody therapy (1). The two prominent monoclonal antibody treatments for the treatment of SLE are the anti-CD20 agents such as rituximab and the anti-interferon-α agents such as sifalimumab (1,2).

Anti-CD20 agents such as rituximab are directed against the antigen expressed on the surface of immature and mature B cells, thus preventing their hyperactivity which is traditionally thought to be implicated in the pathogenesis of SLE (1). Anti-interferon-α agents such as sifalimumab are directed towards interferon-α, which has been shown to be also implicated in the pathogenesis of SLE, with prior studies finding substantially upregulated levels in biopsies of patients with SLE compared to controls (2).

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It is well known that both of these monoclonal antibody therapies have significant effects in reducing Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI 2K), but little has been done to compare their efficacies (1,2). This is especially important to know such that a physician can prescribe the best pharmacological intervention to treat a patient with SLE

2. Methods

2.1. For the study conducted using rituximab (1)

SLE patients with lupus nephritis attended the rheumatologic department of Omdurman Military Hospital and received rituximab. A total of 40 patients were treated with 500 mg once/week for 1 month. Hematological parameters and inflammatory markers were compared at admission and after 6 months. Assessment of the outcomes was measured through the SLEDAI score.

2.2. For the study conducted using sifalimumab (2)

431 patients with SLE were randomized and received monthly intravenous sifalimumab (200 mg, 600 mg or 1200 mg) or placebo. The primary efficacy endpoint was the percentage of patients achieving an SLE responder index response at week 52.

3. Results

3.1. For the study conducted using rituximab (1)

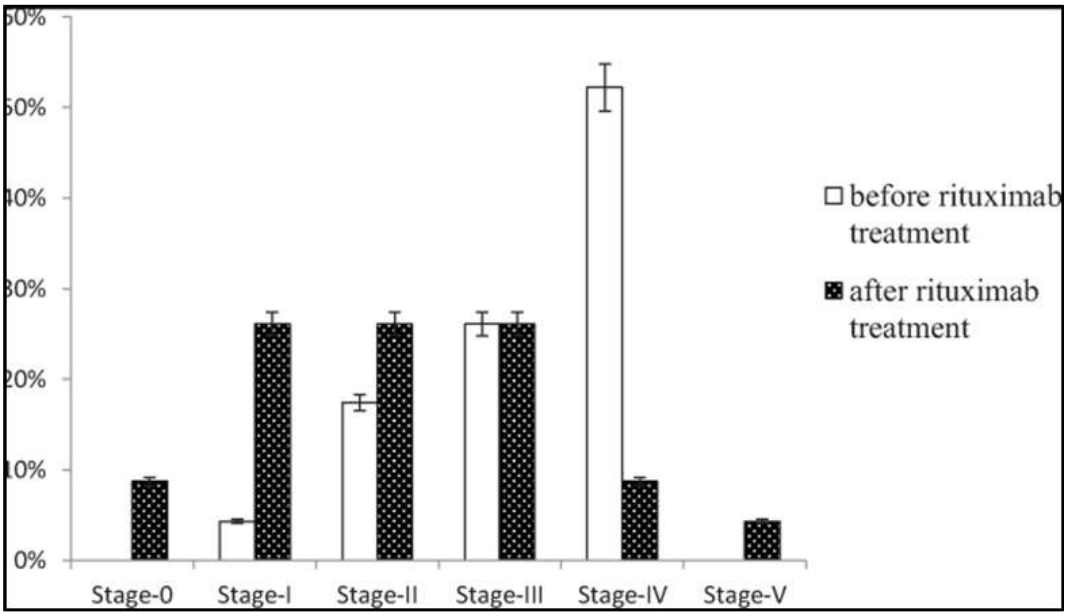

Figure 1 SLEDAI 2K Scores Before and After Rituximab

The above (**Figure 1)** shows the scores of SLE Disease Activity Index 2000 (SLEDAI 2K) before and after Rituximab treatment (N=40).

The mean SLE Activity Index 2000 (SLEDAI 2K) was significantly decreased after 6 months of rituximab use (34.5±13.7 vs 12.3±16.1; P. value = 0.000) with mean difference = −22.2 (Figure 1).

3.2. For the study conducted using sifalimumab (2)

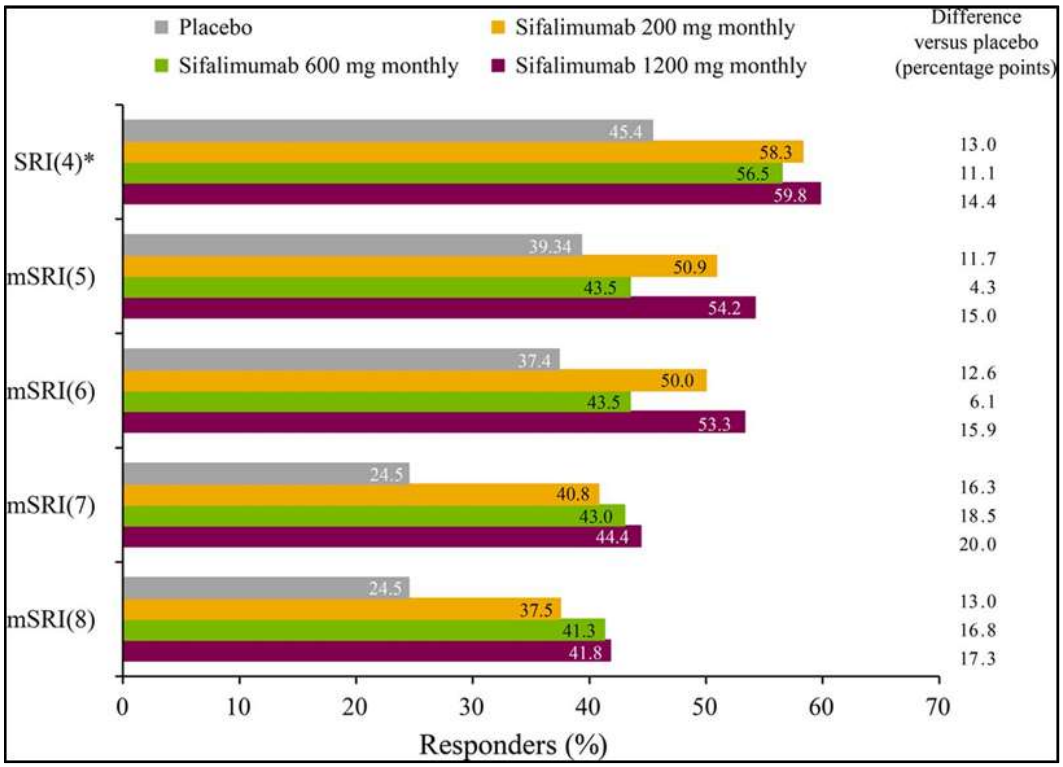

Figure 2 Modified Systemic Lupus Erythematosus Indices per Treatment

The above (**Figure 2**) shows those patients achieving an mSRI response with 5-, 6-, 7-, or 8-point decreases in SLEDAI-2K scores

At week 52, the Cochran–Armitage trend test of all treatment groups showed that the number of patients achieving the primary endpoint was greater for sifalimumab versus placebo (p=0.053). Pairwise comparisons demonstrated that this effect was consistent for each sifalimumab dosage (200 mg monthly: 58.3%, p=0.057; 600 mg monthly: 56.5%, p=0.094; 1200 mg monthly: 59.8%, p=0.031) compared with placebo (45.4%) with improvements reaching a peak at week 24, after which there was a plateau in the effect.

4. Conclusion

Our analysis suggests that while both sifalimumab and rituximab are effective in reducing lupus disease activity, rituximab seemed to decrease lupus disease activity 7% more. This also suggests that B-cell hyperactivity may be more strongly implicated in the pathogenesis of SLE as compared to rising levels of interferon-α. The analyses are limited in the sense that they both couldn't accurately control for the dosage of monoclonal antibody treatment, the severity of the SLE, and possible comorbidities. Additionally, the length of the research study could not be controlled. There is also the likelihood that there is another immune marker that may be even more implicated in the pathogenesis of SLE than B-cells or interferon-α. Also, further studies must be conducted with larger sample sizes controlling for age and other demographic factors. While rituximab shows promising results, there is plenty more investigation that must be conducted to find the most effective monoclonal antibody treatment for SLE.

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