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TO STUDY THE EFFECTIVENESS OF COGNITIVE BEHAVIORAL THERAPY (CBT) ON INSOMNIA IN PATIENTS OF SYSTEMIC LUPUS ERYTHEMATOSUS AT IGMC, SHIMLA

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Abstract: Introduction: Systemic lupus erythematosus (SLE) is an autoimmune disease, often with multisystemic involvement. Symptoms may manifest over a wide spectrum, with varying clinical presentations from mild mucocutaneous manifestations to multiorgan and severe central nervous system involvement. Of the various systems which can be affected by SLE, one of the more common yet relatively unexplored system is the central nervous system. NPSLE is one of the most complex and challenging manifestations of SLE, which involves the central nervous system (CNS), peripheral nervous system (PNS) and autonomous nervous system (ANS). The most common symptoms of NPSLE include mild cognitive dysfunction, mood disorders, anxiety, headaches, and psychosis. Aim: To study the effectiveness of Cognitive Behavioral Therapy (CBT) on neuropsychiatric manifestations in patients of SLE. Results: Sleep quality and insomnia as assessed by Insomnia Severity Index (ISI) scores was 10.30 ± 4.0 in the treatment arm at the post intervention as compared to 14.80 ± 2.80 in the standard arm at the post intervention ($p<0.001$). Patients reported improvement in insomnia after treatment with CBT as compared to controls as per ISI scale (from 13.8 ± 3.02 to 10.3 ± 4). Conclusion: CBT improves quality of sleep and insomnia as represented by ISI scores. Thus, CBT or CBT-based interventions can be used with the pharmacological treatment of the SLE patients.

Index Terms **- CBT, Insomnia, NPSLE, ISI**

I. INTRODUCTION

Systemic lupus erythematosus (SLE) is an autoimmune disease with a relapsing-remitting course.[1,2] NPSLE is one of the most complex and challenging manifestations of SLE, which involves the central nervous system (CNS), peripheral nervous system (PNS) and autonomous nervous system (ANS). The pathogenesis of Neuropsychiatric manifestations of SLE (NPSLE) is multifactorial. Two major pathways proposed for explaining the pathogenesis in NPSLE are an ischaemic pathway involving large and small blood vessels and second mechanism is an autoimmune-mediated neuroinflammatory pathway with complement activation which is associated with most diffuse neuropsychiatric manifestations such as psychosis, mood disorders,

cognitive dysfunction and acute confusional states.[3-7] The utilization of CBT for managing and ameliorating psychiatric manifestations of NPSLE has been explored recently. Randomised controlled trials (RCTs) have found that CBT is associated with a significant reduction in the level of depression, anxiety and daily stress and a significant improvement in Quality of Life (QoL) and somatic symptoms throughout the entire follow-up period.[8,9] Management protocols usually centre around long-term patient survival, maintaining an acceptable quality-of-life, and preventing relapses as much as possible.[2] The present study was done to assess the effectiveness of CBT on quality of sleep and insomnia in patients of SLE.

II. RESEARCH METHODOLOGY

It was a single-blinded randomized clinical trial study conducted at Indira Gandhi Medical College and Hospital, Shimla. Patients of SLE, fulfilling 2019 EULAR/ACR (European League Against Rheumatism/ American College of Rheumatology) classification criterion for SLE and clinically stable for last 3 months attending Rheumatology Department from November 2020 to December 2021 were recruited into the study. A total of 40 patients were included after applying inclusion and exclusion criteria and they were divided into 2 groups (Control and CBT), each group containing 20 patients.

Inclusion criteria: Patients with age more than 18 years and up to 60 years and who give their consent to participate in the study.

Exclusion criteria: Subjects with acute confusional state, severe cognitive impairment, alcohol use disorder and other substance use disorders, chronic liver disease, chronic kidney disease, chronic viral infections like Hepatitis B, Hepatitis C, pregnancy, cerebrovascular accidents, coronary artery disease, malignancies and other intracranial disorders, persons who are unable to read and write in Hindi or English and suffering from severe psychiatric disorder.

III. RESULTS AND DISCUSSION

Results:

A total of 40 patients who fulfilled inclusion criteria were recruited in the study after obtaining the informed consent. They were divided into Control and CBT group, each group containing 20 patients. The median ISI value in 40 patients was 14.00 (11.00, 16.00). There was no statistically significant difference between the median values of ISI total score in CBT group at 14.00 (11.75, 16.00) and that of control group at 14.00 (10.75, 16.00) (p=0.7) at baseline. After intervention with CBT, the median ISI value in 40 patients was 13.0 (10.0, 16.0). There was statistically significant difference between the median values of ISI total score in CBT group at 10.5 (6.8, 14.00) and that of control group at 15.5 (12.0, 17.0) (p<0.001).

Table 1: ISI at baseline

Characteristic	N=40
ISI-Total-Baseline	
Median, (IQR))	14.00, (11.00, 16.00))
Range	7.00, 20.00
Mean (SD)	13.65 (3.15)
[1]n (%)	

Table 2: ISI at baseline in groups

Characteristic	CBT, N = 20[1]	CONTROL, N = 20[1]	p-value[2]
ISI-Total-Baseline			0.7
Median, (IQR))	14.00, (11.75, 16.00))	14.00, (10.75, 16.00))	
Range	7.00, 19.00	8.00, 20.00	
Mean (SD)	13.80 (3.02)	13.50 (3.35)	
[1]n (%)			
[2]Fisher's exact test; Wilcoxon rank sum test			

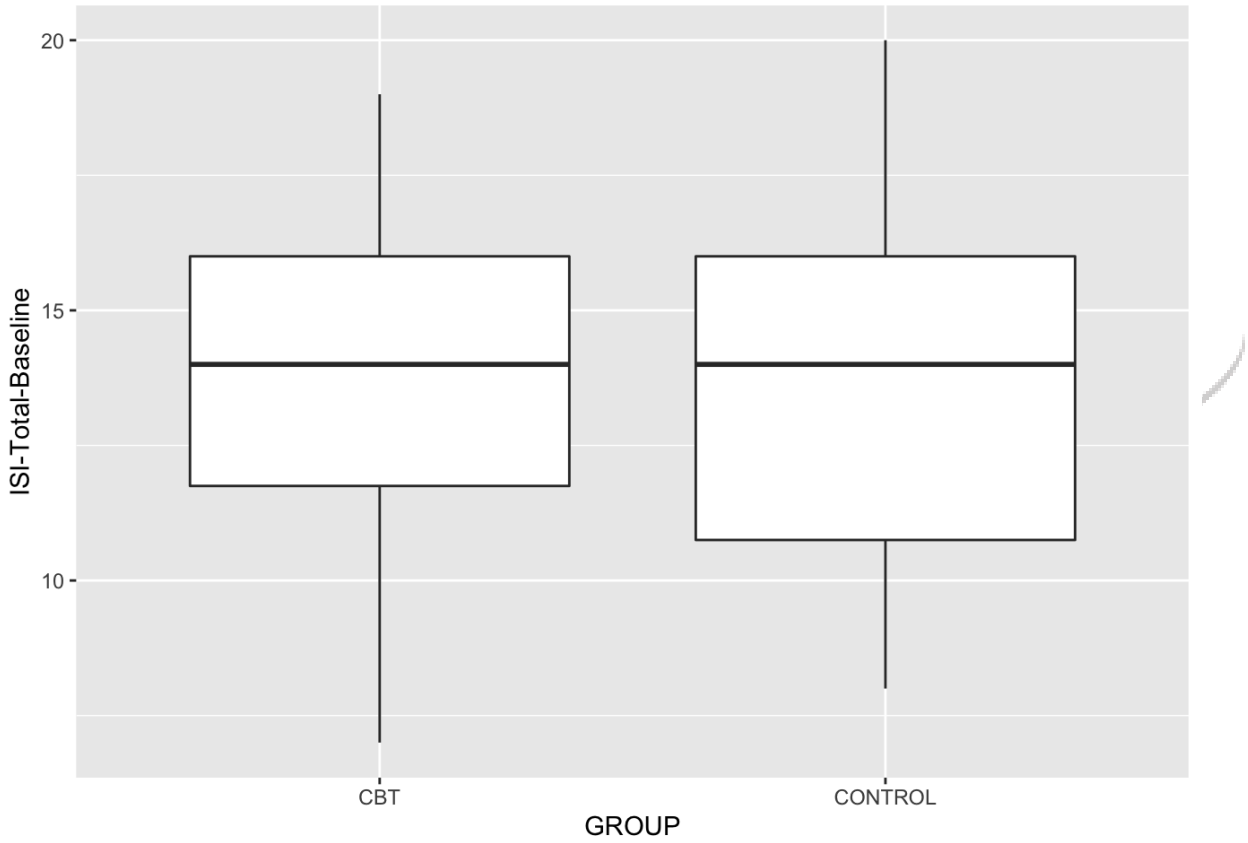

Figure 1: The median ISI value in 40 patients was 14.00 (11.00, 16.00). There was no statistically significant difference between the median values of ISI total score in CBT group at 14.00 (11.75, 16.00) and that of control group at 14.00 (10.75, 16.00) (p=0.7).

Table 3: Post intervention ISI

Characteristic	N = 40[1]
ISI-Total-post intervention	
Median, (IQR))	13.0, (10.0, 16.0))
Range	5.0, 19.0
Mean (SD)	12.6 (4.1)
[1]n (%)	

Table 4: Post intervention ISI in groups

Characteristic	CBT, N = 20[1]	CONTROL, N = 20[1]	p-value[2]
ISI-Total-post intervention			<0.001
Median, (IQR))	10.5, (6.8, 14.0))	15.5, (12.0, 17.0))	
Range	5.0, 16.0	10.0, 19.0	
Mean (SD)	10.3 (4.0)	14.8 (2.8)	
[1]n (%)			
[2]Fisher's exact test; Wilcoxon rank sum test			

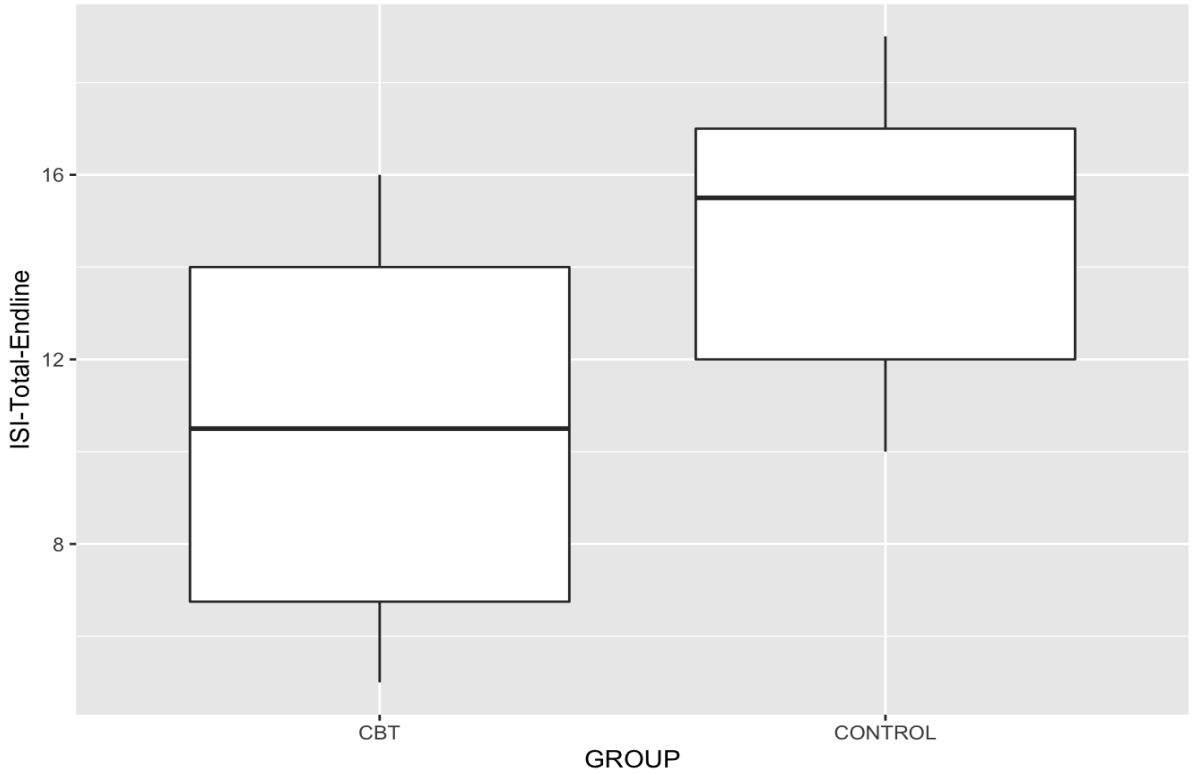

Figure 2: The median ISI value in 40 patients was 13.0 (10.0, 16.0). There was statistically significant difference between the median values of ISI total score in CBT group at 10.5 (6.8, 14.00) and that of control group at 15.5 (12.0, 17.0) (p<0.001).

Discussion:

The present study was a single-blinded randomized clinical study conducted in the Department of Psychiatry at Indira Gandhi Medical College and Hospital, Shimla. Effect of CBT on sleep quality and insomnia in patients of SLE was assessed. Pre- and post-intervention assessment of ISI scores was conducted on both the groups and compared to understand the improvement of insomnia due to CBT intervention in SLE patients.

Insomnia is highly prevalent in patients of SLE. In the index study, we found that although there was no significant difference in ISI scores between the intervention and control group at the baseline, post intervention the intervention group had a significantly better sleep quality as compared to the control group, as reflected by lower ISI score in the intervention group (10.30 ± 4.00 in the intervention group; 14.80 ± 2.82 in the control group, $p<0.001$). The mean differences between the groups in ISI score showed significant improvement from baseline ($p=0.008$). Our findings are similar to those seen by Pouyanfard et al that there is a significant increase in the sleep quality in patients of multiple sclerosis when they are treated with Mindfulness based Cognitive Therapy (MBCT) as compared to those who are not.[10]

CBT has shown to improve mental health of patients. ISI scores showed significant improvement in insomnia and quality of sleep with CBT. Thus, it can be said that CBT or CBT-based interventions can be used with the pharmacological treatment of the SLE patients.

IV. ACKNOWLEDGEMENT

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