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

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Abstract: Introduction: Systemic lupus erythematosus (SLE) is a disease which is autoimmune in nature, often with multisystemic 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 which involves the central nervous system (CNS), peripheral nervous system (PNS) and autonomous nervous system (ANS) is one of the most complex and challenging manifestations of SLE. NPSLE can be mild or severe, focal or diffuse, acute or chronic, with a negative impact on the patient's quality of life. 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: Anxiety as assessed by Generalized Anxiety Disorder-7 tool was 6.90 ± 2.27 in the treatment arm at the post intervention as compared to 9.50 ± 2.26 in the standard arm at the post intervention (p = 0.002). Patients receiving CBT showed improvement in GAD-7 scores as compared to control group (from 9.90 ± 3.4 to 6.90 ± 2.27). Conclusion: CBT improves anxiety symptoms as represented by GAD-7 scores. Thus, CBT or CBT-based interventions can be used with the pharmacological treatment of the SLE patients.

Index Terms **- CBT, Anxiety, NPSLE, GAD-7**

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 anxiety 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 GAD-7 value in 40 patients was 10.0 (8.0, 12.2). There was no statistically significant difference between the median values of GAD-7 total score in CBT group at 9.5 (7.8, 13.2) and that of control group at 11.0 (9.0, 12.0) (p=0.4) at baseline. After intervention with CBT, the median GAD-7 value in 40 patients was 8.00 (6.75, 10.00). There was statistically significant difference between the median values of GAD-7 total score in CBT group at 7.00 (5.00, 8.25) and that of control group at 9.00 (8.00, 11.25) (p=0.002).

Table 1: GAD scoring at baseline

Characteristic	N = 40[1]
GAD-7-Q1-Baseline	
0	12.00 (30.00%)
1	9.00 (22.50%)
2	10.00 (25.00%)
3	9.00 (22.50%)
GAD-7-Q2-Baseline	
0	8.00 (20.00%)
1	9.00 (22.50%)
2	8.00 (20.00%)
3	15.00 (37.50%)
GAD-7-Q3-Baseline	
0	13.00 (32.50%)
1	11.00 (27.50%)
2	7.00 (17.50%)
3	9.00 (22.50%)
GAD-7-Q4-Baseline	
0	9.00 (22.50%)
1	8.00 (20.00%)
2	12.00 (30.00%)
3	11.00 (27.50%)
GAD-7-Q5-Baseline	
0	10.00 (25.00%)
1	11.00 (27.50%)
2	11.00 (27.50%)
3	8.00 (20.00%)
GAD-7-Q6-Baseline	
0	10.00 (25.00%)
1	13.00 (32.50%)
2	10.00 (25.00%)
3	7.00 (17.50%)
GAD-7-Q7-Baseline	
0	9.00 (22.50%)
1	11.00 (27.50%)
2	10.00 (25.00%)

3	10.00 (25.00%)
GAD-Total-Baseline	
Median, (IQR))	10.0, (8.0, 12.2))
Range	3.0, 16.0
Mean (SD)	10.4 (3.1)
[1]n (%)	

Table 2: GAD scoring at baseline in groups

Characteristic	CBT, N = 20[1]	CONTROL, N = 20[1]	p-value[2]
GAD-7-Q1-Baseline			0.2
0	9.00 (45.00%)	3.00 (15.00%)	
1	3.00 (15.00%)	6.00 (30.00%)	
2	5.00 (25.00%)	5.00 (25.00%)	
3	3.00 (15.00%)	6.00 (30.00%)	
GAD-7-Q2-Baseline			0.6
0	5.00 (25.00%)	3.00 (15.00%)	
1	6.00 (30.00%)	3.00 (15.00%)	
2	3.00 (15.00%)	5.00 (25.00%)	
3	6.00 (30.00%)	9.00 (45.00%)	
GAD-7-Q3-Baseline			0.7
0	7.00 (35.00%)	6.00 (30.00%)	
1	6.00 (30.00%)	5.00 (25.00%)	
2	2.00 (10.00%)	5.00 (25.00%)	
3	5.00 (25.00%)	4.00 (20.00%)	
GAD-7-Q4-Baseline			>0.9
0	4.00 (20.00%)	5.00 (25.00%)	
1	4.00 (20.00%)	4.00 (20.00%)	
2	6.00 (30.00%)	6.00 (30.00%)	
3	6.00 (30.00%)	5.00 (25.00%)	
GAD-7-Q5-Baseline			0.9
0	5.00 (25.00%)	5.00 (25.00%)	
1	6.00 (30.00%)	5.00 (25.00%)	
2	6.00 (30.00%)	5.00 (25.00%)	
3	3.00 (15.00%)	5.00 (25.00%)	
GAD-7-Q6-Baseline			0.7
0	6.00 (30.00%)	4.00 (20.00%)	
1	7.00 (35.00%)	6.00 (30.00%)	
2	5.00 (25.00%)	5.00 (25.00%)	
3	2.00 (10.00%)	5.00 (25.00%)	
GAD-7-Q7-Baseline			0.2
0	3.00 (15.00%)	6.00 (30.00%)	
1	4.00 (20.00%)	7.00 (35.00%)	
2	5.00 (25.00%)	5.00 (25.00%)	

3	8.00 (40.00%)	2.00 (10.00%)	
GAD-Total-Baseline			0.4
Median, (IQR))	9.5, (7.8, 13.2))	11.0, (9.0, 12.0))	
Range	3.0, 15.0	5.0, 16.0	
Mean (SD)	9.9 (3.4)	10.8 (2.7)	
[1]n (%)			
[2]Fisher's exact test; Wilcoxon rank sum test			

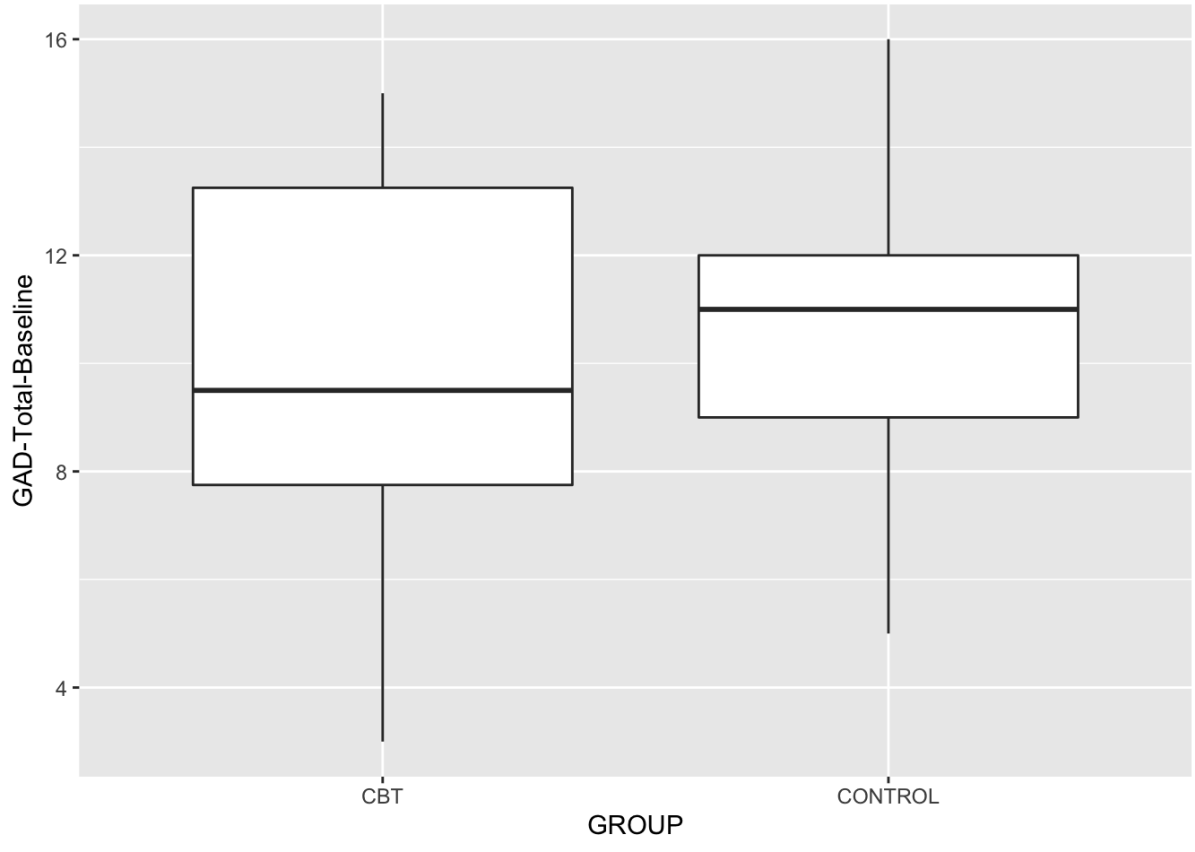

Figure 1: The median GAD-7 value in 40 patients was 10.0 (8.0, 12.2). There was no statistically significant difference between the median values of GAD-7 total score in CBT group at 9.5 (7.8, 13.2) and that of control group at 11.0 (9.0, 12.0) (p=0.4).

Table 3: Post intervention GAD

Characteristic	N = 40[1]
GAD-7-Q1	
0	13.00 (32.50%)
1	15.00 (37.50%)
2	9.00 (22.50%)
3	3.00 (7.50%)
GAD-7-Q2	
0	11.00 (27.50%)
1	15.00 (37.50%)
2	8.00 (20.00%)
3	6.00 (15.00%)
GAD-7-Q3	
0	10.00 (25.00%)
1	13.00 (32.50%)
2	13.00 (32.50%)
3	4.00 (10.00%)
GAD-7-Q4	
0	18.00 (45.00%)
1	6.00 (15.00%)
2	13.00 (32.50%)
3	3.00 (7.50%)
GAD-7-Q5	
0	11.00 (27.50%)
1	12.00 (30.00%)
2	14.00 (35.00%)
3	3.00 (7.50%)
GAD-7-Q6	
0	14.00 (35.00%)
1	10.00 (25.00%)
2	13.00 (32.50%)
3	3.00 (7.50%)
GAD-7-Q7	
0	7.00 (17.50%)
1	19.00 (47.50%)
2	10.00 (25.00%)

3	4.00 (10.00%)
GAD-Total-post intervention	
Median, (IQR))	8.00, (6.75, 10.00))
Range	4.00, 13.00
Mean (SD)	8.20 (2.59)
[1]n (%)	

Table 4: Post intervention GAD in groups

Characteristic	CBT, N = 20[1]	CONTROL, N = 20[1]	p-value[2]
GAD-7-Q1			0.038
0	4.00 (20.00%)	9.00 (45.00%)	
1	9.00 (45.00%)	6.00 (30.00%)	
2	7.00 (35.00%)	2.00 (10.00%)	
3	0.00 (0.00%)	3.00 (15.00%)	
GAD-7-Q2			0.024
0	7.00 (35.00%)	4.00 (20.00%)	
1	10.00 (50.00%)	5.00 (25.00%)	
2	3.00 (15.00%)	5.00 (25.00%)	
3	0.00 (0.00%)	6.00 (30.00%)	
GAD-7-Q3			0.2
0	5.00 (25.00%)	5.00 (25.00%)	
1	7.00 (35.00%)	6.00 (30.00%)	
2	8.00 (40.00%)	5.00 (25.00%)	
3	0.00 (0.00%)	4.00 (20.00%)	
GAD-7-Q4			0.13
0	12.00 (60.00%)	6.00 (30.00%)	
1	3.00 (15.00%)	3.00 (15.00%)	
2	5.00 (25.00%)	8.00 (40.00%)	
3	0.00 (0.00%)	3.00 (15.00%)	
GAD-7-Q5			0.2
0	6.00 (30.00%)	5.00 (25.00%)	
1	8.00 (40.00%)	4.00 (20.00%)	
2	6.00 (30.00%)	8.00 (40.00%)	
3	0.00 (0.00%)	3.00 (15.00%)	
GAD-7-Q6			0.4
0	7.00 (35.00%)	7.00 (35.00%)	
1	6.00 (30.00%)	4.00 (20.00%)	
2	7.00 (35.00%)	6.00 (30.00%)	
3	0.00 (0.00%)	3.00 (15.00%)	
GAD-7-Q7			0.13
0	4.00 (20.00%)	3.00 (15.00%)	
1	9.00 (45.00%)	10.00 (50.00%)	

2	7.00 (35.00%)	3.00 (15.00%)	
3	0.00 (0.00%)	4.00 (20.00%)	
GAD-Total-post intervention			0.002
Median, (IQR))	7.00, (5.00, 8.25))	9.00, (8.00, 11.25))	
Range	4.00, 12.00	6.00, 13.00	
Mean (SD)	6.90 (2.27)	9.50 (2.26)	
[1]n (%)			
[2]Fisher's exact test; Wilcoxon rank sum test			

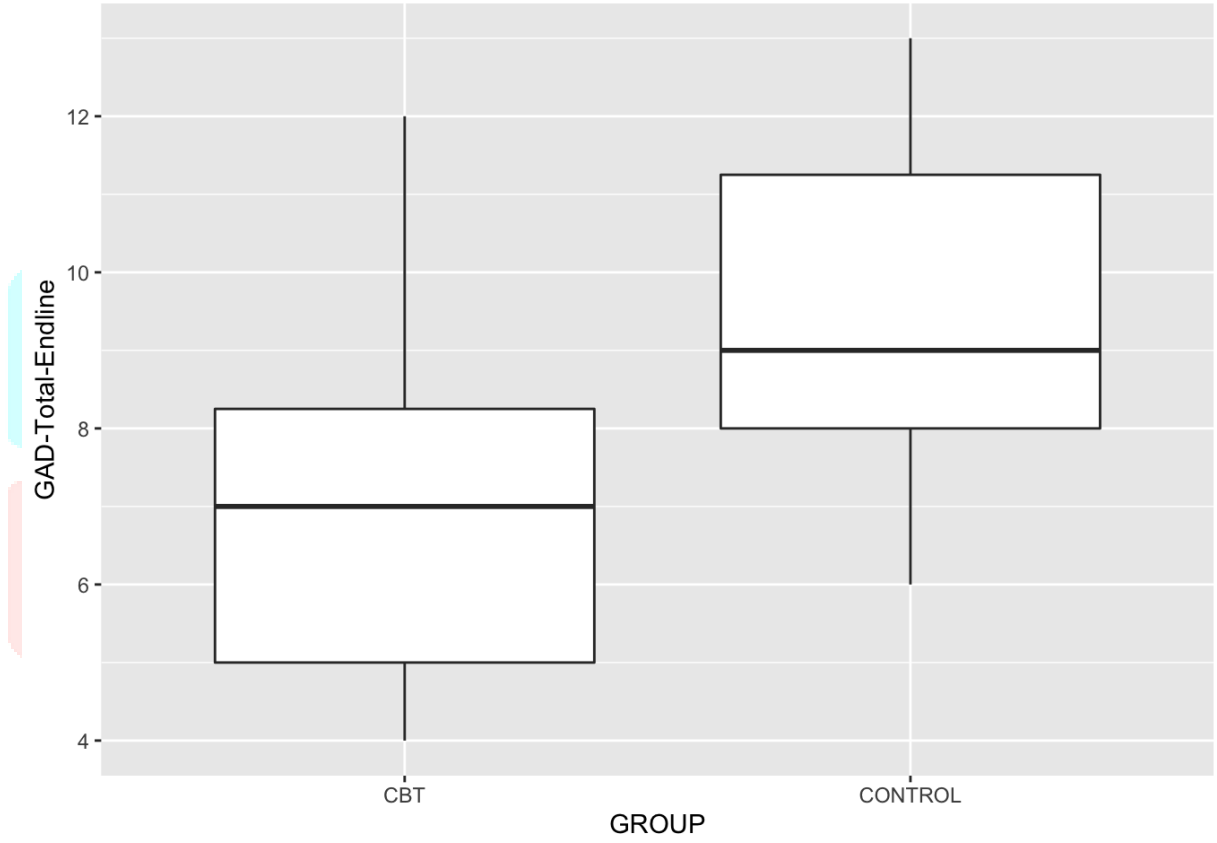

Figure 2: The median GAD-7 value in 40 patients was 8.00 (6.75, 10.00). There was statistically significant difference between the median values of GAD-7 total score in CBT group at 7.00 (5.00, 8.25) and that of control group at 9.00 (8.00, 11.25) (p=0.002).

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 anxiety in patients of SLE was assessed. Pre- and post-intervention assessment of GAD-7 scores was conducted on both the groups and compared to understand the improvement of anxiety due to CBT intervention in SLE patients.

Anxiety has been known to be higher in patients with SLE. In the index study, anxiety as assessed by GAD-7 scores in SLE patients of the intervention group was seen to decrease when comparing baseline to the endline. Anxiety score as measured by the GAD-7

tool was found to be 9.9 ± 3.4 at the baseline, while it was found to be 6.90 ± 2.27 at the endline in the intervention group. We also found that, although anxiety in control group also decreased from baseline to endline, the decrease was not as much as that of the treatment group. The difference between the anxiety scores at the endline between the two groups was also found to be statistically significant (p = *0.002*). Similar results were reported by Kim HA et al (2019) in 18 Korean patients who completed the mindfulness-based cognitive therapy of six sessions.[10] Another study, an RCT published by Solati et al in 2017 found a significant reduction of anxiety in patients of SLE who received mindfulness-based cognitive therapy (MBCT) as compared to the control group.[9]

CBT has shown to improve patients' mental health. GAD-7 scores showed significant improvement in anxiety symptoms 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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