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ROLE OF BIOFEEDBACK THERAPY FOR REDUCING AFFECTIVE SYMPTOMS OF SCHIZOPHRENIA: A HOSPITAL-BASED COMPARATIVE STUDY.

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Abstract

Background
Schizophrenia is a debilitating disorder making it a challenge for clinicians to manage its heterogeneous symptom profile. Antipsychotics remain the main modality of its treatment. However, some symptoms persist after an optimal dose of antipsychotics. The affective and cognitive symptoms need a holistic approach for resolution. Biofeedback is a noninvasive procedure showing its effectiveness in various mental illnesses. Integration of biofeedback adjunctive to medications can help in attaining treatment goals in schizophrenia.

Objectives
It is to determine the role of biofeedback as an adjunctive therapy technique to traditional pharmacotherapy in patients with schizophrenia in improving affective symptoms.

Methodology
Sixty patients diagnosed with schizophrenia were selected for the study after fulfilling the inclusion and exclusion criteria. Patients were allotted to either the test group or control group by alternate allocation method. All patients were titrated to an optimal fixed dose of antipsychotic medications during 1st week of allotment to study. Biofeedback therapy was given 3 sessions per week for 3 weeks to patients in the test group. Positive and negative syndrome scale (PANSS) was applied for all patients at baseline. Hamilton Anxiety Rating Scale (HAM-A) and Calgary Depression Scale for Schizophrenia (CDSS) were applied at baseline and after 4 weeks to measure anxiety and depressive symptoms respectively. After 4 weeks the results were compared between both groups using statistical analysis.

Conclusion
The outcome of the study found that biofeedback therapy is effective in reducing anxiety and depressive symptoms in patients receiving biofeedback therapy compared to those who did not receive it.

Recommendation
Further studies in a larger cohort are needed to formulate sound and consistent conclusions.

Keywords: Schizophrenia; Biofeedback; affective symptoms; HAM-A, HAM-D
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Introduction
Schizophrenia is a chronic debilitating illness that has a high impact on global health burden. Although it has a low prevalence it is considered as the twelfth most disabling disorder as per global epidemiology data. The disabled burden is mostly in the middle aged population from 30 years to 40 years of age [1]. The symptom complex of schizophrenia varies across patient profiles and also across the course of illness. Broadly the symptoms are categorized into positive, negative, affective, and cognitive domains. The affective or emotional domains are usually presenting with anxiety, irritability, and sadness [2]. Antipsychotic drugs which block the dopamine D2 receptors are the mainstay of treatment modality in schizophrenia [3]. These drugs drastically improve the psychotic symptoms such as positive symptoms and negative symptoms of schizophrenia. However, the affective and cognitive symptoms cause poor performance in social functioning in these patients. Also, these drugs have their limitations, side effect profiles, and financial burden on patients which create hindrances in treatment [4]. Therefore, the treatment of schizophrenia remains a tactical challenge. A holistic approach by integrating pharmacological and nonpharmacological interventions can satisfy the treatment goal [5].

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Biofeedback is one such non-pharmacological intervention that has clinical application in various mental illnesses [6, 7]. Its effect on reducing stress and anxiety in patients suffering from anxiety disorder is well documented in the literature [8, 9& 10]. Some of the studies used either biofeedback therapy or relaxation therapy in schizophrenia patients showing positive results in reducing anxiety [11, 12& 13]. A recent meta-analysis which includes 21 researches found biofeedback is effective in reducing self-reported depression in patients with major depressive disorder (MDD) [14]. In another systematic review, the effect of biofeedback on several symptom domains of schizophrenia was found to be inconclusive due to inadequate sample size and variability in study methodologies [15]. There is a dearth of literature that focuses on the effect of biofeedback on affective symptoms of schizophrenia. The present study was designed to assess the effect of biofeedback therapy along with deep breathing exercises in reducing the affective symptoms in schizophrenia patients.

Methodology

Study Design

It was a hospital-based longitudinal study.
Criteria: Patients diagnosed with schizophrenia as per the International Classification of Diseases (ICD-10) were selected for the study [16]. All the patients who participated in the study were between 18 years to 50 years of age. Patients with a history of mental retardation, other neurological or psychiatric disorders, stroke, brain injury, substance abuse, or previous exposure to relaxation training were excluded from the study.

Bias

There was a chance that bias would arise when the study first started, but we avoided it by giving all participants the identical information and hiding the group allocation from the nurses who collected the data.
Ethical Consideration: Written informed consent was taken from all participants before enrolling in the study. The study was approved by the Ethics Committee of the Institution.

Data Collection and Analysis

The positive and negative syndrome scale (PANSS) is a widely accepted psychological tool for assessing the severity of illness in schizophrenia [17]. Patients with a PANSS score of < 75th percentile with a total duration of illness of at least one year are considered for the study. All the patients were on a stable dose of oral antipsychotic medications either olanzapine (10mg-20mg) or risperidone (4mg-6mg) during the study period.

Methodology

After considering the inclusion and exclusion criteria the patients were recruited in the study. The patients were assigned to either the test group or control group by alternate allocation method. A socio-demographic datasheet has been filled out for each patient. Hamilton Anxiety Rating Scale (HAM-A) was used to measure the severity of perceived anxiety symptoms [18]. It is a 14-item interviewer-rated scale. Each item in this scale is scored from 0 (absent) to 4 (severe), with a total score of 0-56. Calgary Depression Scale for Schizophrenia (CDSS) was applied to measure the level of depressive symptoms [19]. It is a 9-item interviewer-rated scale. Each item in this scale is scored from 0 (absent) to 3 (severe), with a maximum score of 27. It is a specific and widely used tool that assesses depressive symptoms in schizophrenia and distinguishes those from negative symptoms of the illness. Baseline HAM-A and CDSS were applied to all the study participants. All the patients were psycho-educated regarding the illness in the first week of allotment in two separate sessions each of duration 45 minutes to 60 minutes. During that period the oral antipsychotics optimized to a stable dose of either olanzapine 10mg-20mg/day or risperidone 4 mg -6mg/day. The test group received biofeedback therapy along with oral antipsychotics as mentioned above. The control group received only oral antipsychotics. Anticholinergic medications were prescribed as rescue medications to patients who developed extrapyramidal side effects of antipsychotics. Biofeedback therapy was given 3 sessions in a week on alternate days for 3 weeks to patients in the test group. The effectiveness of biofeedback and relaxation techniques was described and clarified in detail to the patients through each session of biofeedback. Patients were also made aware of the effectiveness of biofeedback training through previous research support in causing relaxation. After 4 weeks of the allotment, the severity of anxiety and depressive symptoms were re assed by using HAM-A and CDSS respectively.

Relaxation and Biofeedback therapy

The biofeedback therapy was carried out in a secluded well-lit and ventilated therapy room with no outside disturbance and external interruption. Each session took approximately 30-40 minutes. In the first session, biofeedback mechanisms and relaxation techniques were introduced to patients. Patients were placed in front of a computer screen on which feedback regarding their physiological state was being shown. For electromyography, electrodes were placed at the frontal part of the head and the occipital area over the scalp. Electrodes were placed at the palmer surface of the index and middle fingers to get a galvanic skin response. The pulse meter was positioned at the index finger of the left hand and the respiratory belt was positioned at the abdomen. Throughout the session, patients were requested to be in a contented position to remain relaxed. Afterward, patients were directed to practice deep breathing exercises as a relaxation technique. Deep breathing involves using the lungs and the abdomen. It was shown to the patients that normally all of us do not use our diaphragms instead perform shallow breathing from the upper chest. As a result, the quantity of oxygen we inhale is limited because of which further stress results in increased shallower breathing. Consequently, feeling of uneasiness and nervousness arises.

Deep breathing boosts the augmented oxygen exchange throughout the chest which brings calmness to the mind and the body.

When the appropriate activity (relaxation technique) increased, the change was notified by a pleasant response (e.g., pleasant tone with changes in graph and images on the screen). In every session, the patients were taught how to follow the steps of the breathing exercises for relaxation. After finishing the practice, we discussed with patients their experience during the practice and re-checked if any modification was needed from the biofeedback indicator. In this therapy, the patients were taught how to apply it in their lives to practice it every day for maximum effect [20].

Statistical Analysis

After completion of the study, statistical analysis was done by using IBM SPSS software version 20 [21]. The socio-demographic and clinical variables were analyzed by applying an independent t-test for continuous variables and a Chi-square test for categorical variables. Independent t-tests and paired t-tests were used to compare the HAM-A and CDSS scores between the groups and within the groups respectively.

Results

When socio-demographic profiles like age, gender, marital status, and employment status were compared no significant differences were found between the test and control groups. The mean duration of illness in years in the study group (8.80 ± 6.49) and the control group (8.60 ± 6.30) was comparable and no significant difference was found. Also the family history of mental illness in both the groups was comparable. While comparing the severity of illness at baseline, both groups were comparable in the distribution of scores of positive, negative, and general symptoms in PANSS [Table 1].

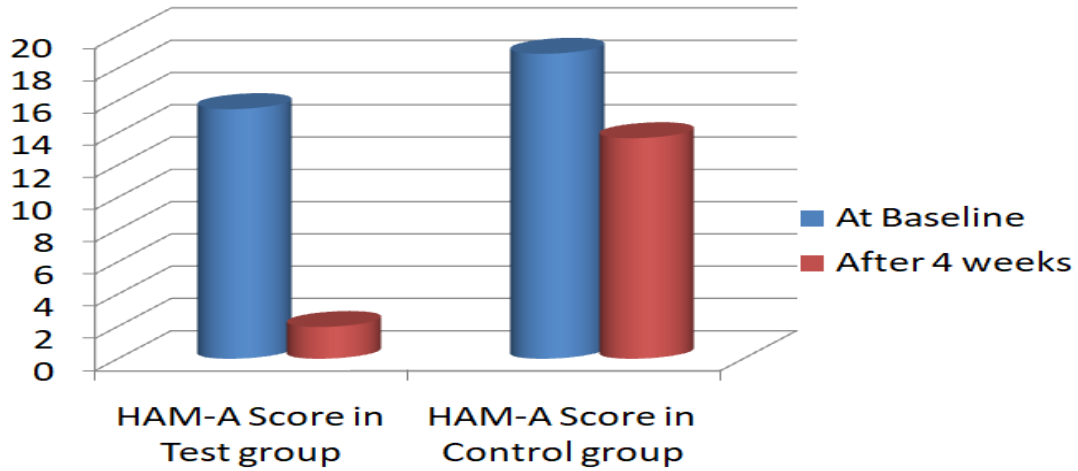
Table 1: Comparison of socio-demographic and clinical variables between two groups

Variables	Category	Test group N=30	Control group N=30	Total N=60	p value*
		Mean ± SD or Numbers (%)	Mean ± SD or Numbers (%)	Mean ± SD or Numbers (%)	
Age of patients (Years)	-	34.50 ± 12.42	34.20 ± 10.95	-	0.277
Duration of Illness (Years)	-	8.80 ± 6.49	8.60 ± 6.30	-	0.889
Positive Scale Score (PANSS)	-	20.77± 2.54	20.93± 1.48	-	0.071
Negative Scale Score (PANSS)	-	21.20±2.66	19.97± 2.43	-	0.833
General Psychopathology Scale Score (PANSS)	-	40.13±2.79	39.43± 2.87	-	0.950
Gender	Female	19(63.33%)	13(43.33%)	32(53.33%)	0.121
	Male	11(36.66%)	17(56.66%)	28(46.66%)	
Occupation	Employed	11(36.66%)	15(50%)	26(43.33%)	0.297
	Unemployed	19(63.33%)	15(50%)	34(56.66%)	
Marital status	Married	17(56.66%)	22(73.33%)	39(65%)	0.179
	Unmarried	13(43.33%)	8(26.66%)	21(35%)	
Family history	Present	11(36.66%)	10(33.33%)	21(35%)	0.787
	Absent	19(63.33%)	20(66.66%)	39(65%)	

*Significance - P value=<0.05

When the severity of anxiety in terms of HAM-A score was compared at baseline between the two groups no significant difference was found. After four weeks when compared between the two groups a statistically significant difference (p= 0.000) was found. In the test group, the score means value with standard deviation (SD) was 1.97 ± 1.90, whereas in the control group, it was 13.67 ± 4.56. In the test and control groups at the baseline, the scores were 15.47 ± 4.49 and 18.90 ± 4.85 respectively [Figure 1].

Figure 1



This implies a significant reduction in anxiety in the test group in comparison to the control group after 4 weeks. Across the period of 4 weeks when both groups were compared to their baseline significant differences (p= 0.000) were found in both groups. This implies the reduction in anxiety scores found in both groups across a period of one month [Table 2]

Table-2: Comparison of HAM-A Score between the groups and within the group at baseline and after 4 weeks

Time/ Group	Group/Time	HAM-A Score (Mean ± SD) (N = 30)	p value*
At Baseline	Test group	15.47 ± 4.49	0.534
	Control group	18.90 ± 4.85	
After 4 weeks	Test group	1.97 ± 1.90	0.000*
	Control group	13.67 ± 4.56	
Test Group	At Baseline	15.47 ± 4.49	0.000*
	After 4 weeks	1.97 ± 1.90	
Control Group	At Baseline	18.90 ± 4.85	0.000*
	After 4 weeks	13.67 ± 4.56	

*Significance - P value=<0.05

For depressive symptoms as measured in CDSS, the score mean value with SD in the test group at baseline was 11.93±2.65, and after the intervention was 4.97±2.72. In the control group at the baseline, the score was 12.67±2.55 and after four weeks the score was 10.20±2.78 [Figure 2].

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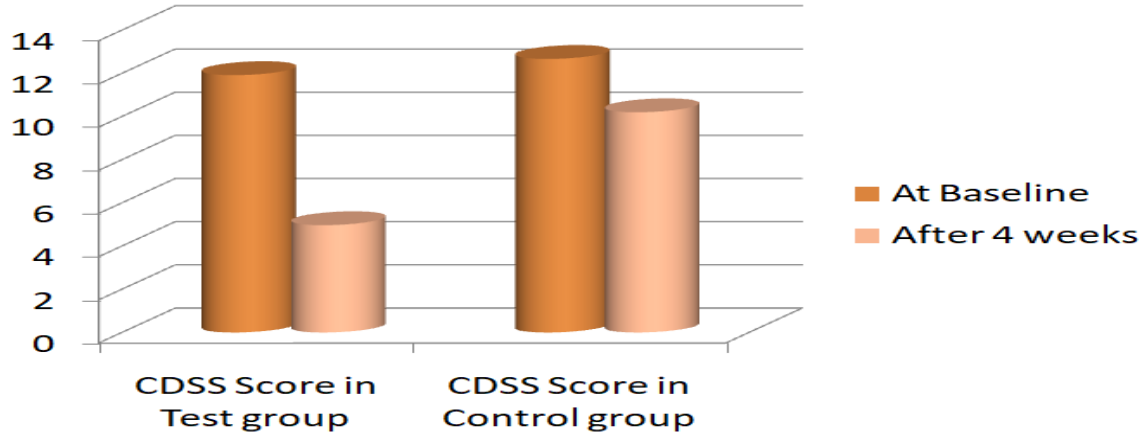
Figure 2



When the baseline scores were compared between two groups no significant difference was found. But when the scores were compared at four weeks a statistically significant difference (p=0.000) was found between the two groups. These scores were reduced significantly more in the test group than in the control group. Across a period of four weeks, in the test group, there was a significant reduction (p=0.000) in CDSS score when compared to baseline. However, this type of improvement was not seen in the control group [Table 3].

Table-3: Comparison of CDSS Score between the groups and within the group at baseline and after 4 weeks

Time / Group	Group/Time	CDSS Score (Mean ± SD) (N = 30)	p value*
At Baseline	Test group	11.93 ± 2.65	0.991
	Control group	12.67 ± 2.55	
After 4 weeks	Test group	4.97 ± 2.72	0.000*
	Control group	10.20 ± 2.78	
Test Group	At Baseline	11.93 ± 2.65	0.000*
	After 4 weeks	4.97 ± 2.72	
Control Group	At Baseline	12.67 ± 2.55	0.904
	After 4 weeks	10.20 ± 2.78	

*Significance - P value=<0.05

Discussion

In the current study, the socio-demographic profile variables were comparable between the two groups. The duration of illness and severity of illness at baseline were comparable between both groups. Patients who successfully attended biofeedback sessions showed a significant improvement in their anxiety symptoms in comparison to those who had not attended. This finding was evident when the HAM-A scores were compared between the groups after four weeks. In one previous study, similar findings were observed by using electroencephalographic (EEG) biofeedback therapy on patients with schizophrenia two sessions per week with a total of six weeks duration [13]. However, in that study patients were taking paroxetine (antidepressant) and benzodiazepine as anxiolytic agents in addition to traditional antipsychotics as pharmacotherapy. In this study, we did not use any additional pharmacotherapy for anxiety symptoms.

Also in that study, the duration of illness was taken as six months in comparison to one year as in this study. Another previous research using Progressive Muscle Relaxation (PMR) training in comparison to resting relaxation found improvement in state anxiety in schizophrenia patients [11, 12]. In this study, we used deep breathing exercises as relaxation training for patients who were receiving biofeedback therapy which is more advantageous than either biofeedback therapy or relaxation training alone. We found a significant reduction in anxiety in both groups over 4 weeks when compared to their baseline [Table 2]. This contradicted the effectiveness of biofeedback therapy. This finding can be explained by considering the delayed effect of 2nd generation antipsychotics that our patients were using during the study period [22]. Also, risperidone and olanzapine are known to improve anxiety symptoms in anxiety disorders [23]. So in this study pharmacotherapy might act as a confounding factor.

In this study although the severity of depressive symptoms at baseline was comparable, after 4 weeks the test group showed more reduction in score than the control group. This difference was significant statistically (p=0.000). Over 4 weeks both the groups showed improvement in depressive symptoms. However, the difference was significant (p=0.000) only in those who had received biofeedback therapy. Some previous studies examine the effect of biofeedback on negative symptoms and depressive symptoms in schizophrenia. The results are inconclusive. Also in those studies, depressive symptoms are measured by using the PANSS scale which could not differentiate depressive from negative symptoms of schizophrenia [15]. In this study, we used a specifically designed tool CDSS which specifically measures the depressive symptoms of schizophrenia. However, the confounding effect of risperidone and olanzapine used by our patients during the study period cannot be undermined. The effectiveness of these medications in the management of depression and negative symptoms of schizophrenia is evidenced in the literature [24, 25].

It is postulated that the body and mind are interconnected. We can alter our physical activity to alter our mental state. Based on this principle we can use biofeedback effectively to reduce stress and anxiety [26]. Using a PET scan it is seen that the activity of the left anterior cingulate, globus pallidus, and cerebellar vermis activity increases by biofeedback in healthy volunteers. This finding further supports the mind-body dualism concept [27]. Deep breathing, which is also known as diaphragmatic breathing, is known to stimulate the vagus nerve which in turn activates the parasympathetic activity inducing relaxation [28]. Considering this evidence and findings from this study it can be hypothesized that biofeedback along with deep breathing can alter the physiological process of the body. This altered physiological process can change the mental state of schizophrenia patients to relieve their anxiety and depressive symptoms.

Conclusion

Schizophrenia remains a disorder with a presentation of heterogeneous symptom complex. Although antipsychotics are the mainstay of treatment for schizophrenia, to optimize the treatment goal a holistic approach is needed. Non-pharmacological and noninvasive procedures like biofeedback can be considered complementary to pharmacotherapy in illness management. Biofeedback seems to alter the physiological process in schizophrenia patients towards better healing. It can reduce the affective symptoms like anxiety and depressive symptoms in schizophrenia. However, more number of randomized trials with longer duration of studies are required to generalize these findings.

Limitations and Recommendation

The present study was not randomized properly. It has a small sample size and a short period (4 weeks) of study duration. Concurrent pharmacological treatment might act as a confounding factors. The number of biofeedback sessions is also less. Further studies in a larger cohort are needed to formulate sound and consistent conclusions. More number of multicentre randomized studies taking a larger sample size and longer follow-ups are required to generalize the findings.

List of Abbreviations

PANSS- Positive and negative syndrome scale
HAM-A- Hamilton Anxiety
CDSS- Calgary Depression Scale for Schizophrenia
MDD- major depressive disorder
ICD- International Classification of Diseases
IBM- International Business Machines
SPSS- Statistical Package for Social Sciences
SD- standard deviation
EEG- electroencephalographic
PMR- Progressive Muscle Relaxation
PET- positron emission tomography

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Conflicts of interest

No conflict of interest declared.

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