## Patient-Reported Outcomes of Symptom Severity and Functional Ability in Major Depressive Disorder: A Cross-Sectional Analytical Study from Western India

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#### ABSTRACT

**Background:** India is home to an estimated 57 million people (18% of the global estimate) affected by depression. Major depressive disorder (MDD) is considered to be a leading cause of disability globally. Everyone experiences depression differently. It is evident that MDD significantly hampers the adaptive functioning of the patients.

**Aim:** We intended to assess the symptom severity and functional ability among individuals with MDD attending outpatient psychiatric units and also to find out the relationship between symptom severity and functional ability.

**Methods:** A total of 142 individuals with MDD were screened, consecutive sampling technique was used to enroll 80 eligible (July 2021 to December 2021) individuals in the study. The data were collected using Hamilton Depression Rating Scale (HAM-D) and Work and Social Adjustment Scale (WSAS). The data were analysed using SPSS version 25 (IBM Corp, Armonk NY).

**Result:** The response rate of the study was 100%. We recorded that 41.3% of participants had mild symptoms and about 36.3% had severe to very-severe symptoms of depression (overall mean &  $SD=16.28\pm5.89$ ). With respect to functional ability, it was recorded that 22.5% of participants experienced significant functional impairment and about 66.3% experienced a moderately-severe disturbance in their functioning (overall mean &  $SD=22.90\pm6.93$ ). There is a positive linear correlation between

symptom severity and functional ability scores (r=0.209). Linear regression showed no predictors significantly predicting the symptom severity and functional ability among participants with MDD.

**Conclusion:** The current study findings are suggestive that the participants with MDD experience depressive symptoms with varied intensity. Since symptom severity is associated with the functioning, resulting in significant impairment in performing daily activities was evident. There is a need for follow-up studies with a more rigorous methodology to have more insight into the trajectory of outcome variables.

Keywords: Major Depressive Disorder,

Symptom Severity, Functional Ability, Crosssectional Analytical Study

#### **INTRODUCTION**

Major depressive disorder (MDD), also known as clinical depression, is a mental disorder characterized by at least two weeks of pervasive low mood, low self-esteem, loss of interest or pleasure in normally enjoyable activities, significant social and functional impairment.<sup>1</sup> An estimated 21.0 million adults in the United States had at least one major depressive episode. This number represented 8.4% of all U.S. adults.<sup>2</sup> The population-based study from India to report on depression shows that the prevalence of depression was 15.1%. India is home to an estimated 57 million people

(18% of the global estimate) affected by depression.<sup>3</sup> The prevalence rate is almost double in women than in men.<sup>4</sup> Depression is a leading cause of disability worldwide and is a major contributor to the overall global burden of disease.<sup>5</sup>

A person with MDD may experiences a depressed mood (feeling sad, irritable, empty) or a loss of pleasure or interest in activities, for most of the day, nearly every day, for at least two weeks. Various other symptoms are also present, which may include poor concentration, feelings of excessive guilt or worthlessness, hopelessness about the future, thoughts about dying or suicide, disrupted sleep, changes in appetite or weight, and feeling especially tired or low in energy.<sup>6</sup>

According to DSM-5, a low-mood and a loss of interest or pleasure in activities (anhedonia)are the two primary depression symptoms. These symptoms, as well as five out of the nine more specific symptoms listed, must frequently occur for more than two weeks (to the extent in which it impairs functioning) for the diagnosis.<sup>7</sup> Clinicians may use validated instruments as screening tools to assist in making the diagnosis of MDD, to quantify symptom severity, and to monitor ongoing symptom severity can range from none/minimal to severe.<sup>8</sup>

Untreated depression has tremendous human costs and financial implications that are a concern for global health. Depressed individuals experience substantial impairments in functioning, quality of life (QOL) and an increased risk for physical and mental disorders (i.e., comorbidity).<sup>9</sup>

A cross sectional study conducted by Tracy Air on symptom severity of depressive symptoms impacts on social cognition performance concluded that further study is needed to determine the relationship between depression episodes and functioning.<sup>10</sup>

Similarly, A recent cross-sectional study conducted to examine the presence of functional disability affected the perceived effectiveness of treatment for people with major depressive episodes (MDE) who received outpatient mental health care. The study population comprised 9992 respondents, representing 9.53 million US adults who had MDE and received outpatient mental health care in the past year. Overall, 58.9% had at least one functional limitation. Concluded that, the presence of functional disability has poorer perceived outcomes of outpatient mental health care for depression.<sup>11</sup>

The above studies and facts show that individuals with MDD experience severe depressive symptoms which affect functional ability. A higher proportion of determining studies suggested the relationship between depression episodes and functioning. Hence, we intended to assess the symptom severity and functional ability among individuals with MDD in Indian context. We also aimed to find out the relationship between symptom severity and functional ability.

Specifically, we have formulated three primary objectives: (1) to assess the symptom severity and functional ability among individuals with MDD, (2) to find out the correlation between symptom severity and functional ability among individuals with MDD, and (3) to find out the predictors of the outcome variables. Further, we hypothesized there will be a statistically significant correlation between symptom severity and functional ability among individuals with MDD.

## MATERIALS AND METHODS

## Study design

A quantitative approach with a cross-sectional analytical design was used.

## Setting

This study was conducted at an outpatient psychiatry unit of a tertiary care institution in Rajasthan. This institute of national importance (INI) is one of the apex institutions established in 2013 by the Ministry of Health & Family Welfare, Government of India. It is a 960 bedded tertiary health care INI. It has a separate 40 bedded in-patient psychiatry unit. Mental

health services comprise in-patient and outpatient consultations with approximately 20000-22000 old and new consultations per annum of which 400-500 required admission. Treatment modalities consist of Psychopharmacological, physical, psychosocial, and AYUSH therapies. The average in-patient treatment usually spans a period of two to three weeks.

## Participants

The accessible population was individuals with major depressive disorders (MDD) registered and consulting at the outpatient psychiatric units of AIIMS Jodhpur. Inclusion criteria were: (1) registered patients and consulting at the out-patient psychiatric units of AIIMS Jodhpur, (2) individuals with MDD diagnosed by the treating psychiatrist based on the ICD criteria, (3) aged between 18 years to 65 years, (4) comprehend Hindi or English language. On the other hand, exclusion criteria were: (1) Individuals with MDD who have co-morbid medical disorders (Ex: HIV/AIDS. Neurological Cancer. conditions, Renal failure, etc.,).

## Sample and Sampling technique

The study was conducted from mid July 2021 to December 2021. All individuals with MDD who met the inclusion criteria were invited to participate in the study. A total of 142 individuals were screened, 43 were excluded for having co-morbid medical conditions, eight were not willing remaining and the 11 were not comprehending either Hindi or English language. Finally, the remaining 80 individuals with MDD were recruited (in the specified duration) by employing the consecutive sampling technique.

## Measures

Socio-demographic data and clinical characteristics of participants were collected through self-report forms developed by the investigator. Standard measures were used to assess outcome variables.

- 1. Socio-demographic data comprised of age in years, gender, type of religion, completed education in years, occupational status, family monthly income, current marital status, type of family, and area of residence.
- 2. Clinical characteristics contained age at onset of illness, duration of present illness, history of relapse, duration of treatment with psychotropic medication, family history of psychiatric illness, and history of substance use.
- 3. Symptom severity of the MDD was assessed with Hamilton Depression Rating Scale (HAM-D). HAM-D is a health professional-rated 21-item depression scale designed to rate the severity of depression in patients, which takes approximately 20-25 minutes to complete. Calculate the patient's score based on the first 17 responses, despite the test having 21 different sections. The HAM-D demonstrates high internal consistency, with alpha coefficients of .84. Notably, Indian studies utilized this scale to assess symptom severity among persons with depression (Raj et al.,  $2021)^{12}$ .
- 4. Functional ability was assessed using the Work and Social Adjustment Scale (WSAS) developed by Mundt et al.  $(2002)^{13}$ . It is a five-item standard scale that assesses functional impairment which included items on the ability to work, home management, social leisure activities, private leisure activities, and close relationships of the patients with mental illness. Each question is rated on a 9-point scale and responses are summed to derive a total score. The highest score is 40. The severity of impairment ranges on the WSAS are as follows: Score 0-10= Mild functional impairment, 11-20= Significant functional Impairment, and  $\geq 20=$ functional Moderately severe Impairment. WSAS possesses highly acceptable internal consistency (0.94) adequate reliability and test-retest (0.73).Particularly, Indian studies

utilized this scale to assess functional ability among persons with SMI (Sreevani et al., 2013)<sup>14</sup>.

#### **Statistical analysis**

The data were analyzed using Statistical Package for Social Sciences (SPSS) version 25 (IBM Corp, Armonk NY). Descriptive statistics such as frequency, percentage, mean and standard deviation were computed to summarize the sociodemographic and clinical characteristics. Inferential statistics such as Karl Pearson correlation and linear regression were used to find out correlation and predictors of outcome variables respectively. For all the computations, the p-level was set as <0.05.

#### **Ethical Consideration**

An ethical clearance certificate was obtained from the Institutional Ethical Committee (IEC), (No. IEC/2021/2381, dated:20/01/2021). Participants were informed of the study objectives, duration, and all other necessary information before signing a consent form to participate in this study. Confidentiality was upheld throughout the study.

#### **RESULTS**

#### Socio-demographic and clinical characteristics of the participants with MDD

All eligible participants completed the responses within the stipulated time. Data was collected by the investigator on a one-to-one basis; therefore, the response rate was 100 %.

Table 1 depicts the socio-demographic details of the participants. The mean age of participants was  $33.40\pm13.67$ , the majority of them were male (67.5%), and belongs to the Hindu religion (77.5%). About 37.5% were graduates and most of them (65%) were unemployed. Nearly one-third have an income of more than 35000 per month. Half (52.5%) of participants were unmarried and were living in a nuclear family. The majority (67.5%) were residing in an urban area. The mean distance from the home to the hospital was  $8.55\pm4.39$  kilometers. The details of clinical characteristics were portrayed in table 2.

Variat	Mean $\pm$ SD / f (%)	
Age		33.40±13.67
Gender	Male	54 (67.5%)
	Female	26 (32.5%)
Religion	Hindu	62 (77.5%)
	Muslim	18 (22.5%)
Educational Qualification	Secondary	28 (35.0%)
	Higher Secondary	22 (27.5%)
	Graduation & above	30 (37.5%)
Occupation	Unemployed	52 (65%)
	Employed	28 (35%)
Income	≤5000	06 (7.5%)
	5001 - 15000	16 (20%)
	15001 - 25000	20 (25%)
	25001 - 35000	10 (12.5%)
	≥35001	28 (35%)
Marital Status	Unmarried	42 (52.5%)
	Married	38 (47.5%)
Family type	Nuclear	42 (52.5%)
	Joint	38 (47.5%)
Residence	Urban	54 (67.5%)
	Rural	26 (32.5%)
Home to Hospital Distance	8.55±4.39	

Table 1: Sociodemographic characteristics (frequency & percentage/ mean & standard deviation) of the participants (N=80)

SD-Standard Deviation; f-frequency; %-percentage

Variable	Mean $\pm$ SD /f (%)		
Age of onset	27.80±12.11		
Duration of Present illness (months)	9.98±10.98		
No. relapse	2.58±0.74		
No. hospitalization	2.05±0.59		
Duration of Treatment with Psychotre	40.15±27.68		
No. medication per day	3.25±1.40		
Medication frequency per day	2.15±0.53		
Side effects Yes		30 (37.5%)	
	No	50 (62.5%)	
Family history	Yes	36 (45%)	
	44 (55%)		
Substance Abuse	Yes	32 (40%)	
	No	48 (60%)	

Table 2: Clinical Characteristics (frequency & percentage/ mean & standard deviation) of the Participants (N=80)

SD-Standard Deviation; f-frequency; %-percentage

## Symptom severity and functional ability among participants with MDD

It was observed that 41.3% of participants had mild symptoms and about 36.3% had severe to very-severe symptoms of depression. The mean score of symptom severity is 16.28±5.89.

With respect to functional ability, it was recorded that 22.5% of participants

experienced significant functional impairment and about 66.3% experienced a moderately-severe disturbance in their functioning. The mean functional ability score was  $22.90\pm6.93$ .

Figure 1 and Table 3 depict the details of symptom severity and functional ability of participants respectively.

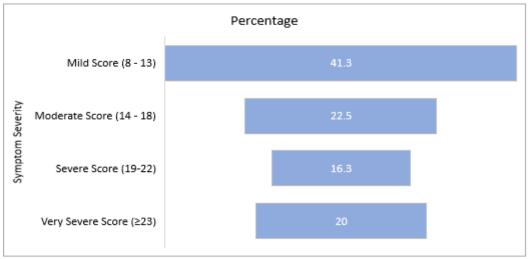


Figure 1: Percentage Distribution of Participants on Levels of Symptom Severity

Levels of Functional Ability	Score	Frequency	Percentage (%)
Mild functional impairment	0 - 10	9	11.3
Significant Functional Impairment	11-20	18	22.5
Moderately Severe Functional Impairment	≥21	53	66.3

## Correlation between symptom severity and functional ability scores

Tal	ble	4:	Correla	tion	between	Symptom	ı	Severity	and
Functional Ability of Participants with MDD									
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Variable	Mean ± SD	Pearson (r)	P (2-tailed)				
Symptom severity	$16.28 \pm 5.89$	0.209	0.062				
Functional ability	22.90±6.93						
p<0.05							

Table 4 reflects the correlation between symptom severity and functional ability scores. There is a positive linear correlation between symptom severity and functional ability scores (r=0.209) which is indicative that as symptom severity increases there is an increase of disturbance in functioning. However, this correlation is non-significant

(p=0.062). The scatter plot graphically represents the (Figure 2) correlation

between symptom severity and functional ability scores.

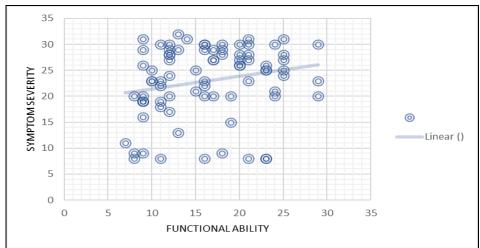


Figure 2: Scatter Plot Diagram Showing the Correlation between Symptom Severity and Functional Ability of Participants with MDD

# Predictors of symptom severity and functional ability

The results of linear regression showed no predictors significantly predicting the symptom severity and functional ability among participants with MDD.

## **DISCUSSION**

Depression continues to be a tenacious disease that has a significant negative impact on both individuals and society, despite significant progress in measuring, predicting, and improving outcomes. Various studies concluded early recognition and early adequate treatment at illness onset are preferable to watch-and-wait strategies. The present cross-sectional study aimed to assess the symptom severity and functional among patients with ability major depressive disorder.

The findings of the study reflect the mild to moderate level of depressive symptoms among participants with MDD. The results are consistent with the finding of a study conducted by Birgit et al., which reported that 67% of patients had mild to moderate depressive symptoms during baseline assessment.<sup>15</sup> Similarly, a correlation study conducted by Gao et al., to find out the correlation between depression symptom severity and quality of life reported majority of the patients (72.1%) had mild to moderate depressive symptoms.<sup>16</sup>

Dysfunction across domains of cognition in depression can contribute to wider functional impairments in daily life.<sup>17</sup> In fact, depression is ranked as the leading cause of disability worldwide and is also a major contributor to the global burden of disease.<sup>18</sup> Functional disability in daily activities is one of the most important consequences of depression, yet it is also one of the least well understood.

It is strikingly evident from the result that majority of the participants with MDD experienced a moderate-severe disturbance in their functioning. In line with this finding, a study conducted by Eiko and Randolph on the impact of individual depressive symptoms on impairment of psychosocial functioning reported that more than half (68.1%) of depressive patients had severe functional impairment.<sup>19</sup>

Symptom severity and impairment in functioning are correlated to each other. The results of the current study are indicative that a decrease in the severity of the symptoms tends to the improvement of functioning among participants with MDD. Similarly, a comparative cross-sectional study reported greater functional impairment was associated with higher depressive symptoms (RR = 1.04; 95% CI

1.02, 1.05) and lower social support (RR = 0.96; 95% CI 0.95, 0.98). Diagnosed cases were found to have higher functional impairment compared to community controls (RR = 1.91; 95% CI 1.74, 2.09).<sup>20</sup> The current study findings are suggestive that the participants with MDD experience depressive symptoms with varied intensity. Since symptom severity is associated with the functioning, resulting in significant impairment in performing daily activities was evident.

### **LIMITATIONS**

The results have to be interpreted in light of their limitations. First, the results may not be generalized at a large scale as the study was conducted in a single institution. Second, the findings should however be viewed with caution as it was conducted on a small sample. Third, to have greater insight into the trajectory of outcome variables, it would have longitudinal study design. Therefore, future research replication of the findings using a more robust methodology enhance to the generalizability of the study results is indispensable.

### CONCLUSION

with Patients MDD experience a combination of depressive symptoms with a varying intensity which negatively affects functioning. The study has generated baseline data from the Indian context with respect to the symptom severity and functional ability among participants with MDD. The findings showed that participants with MDD had mild to moderate levels of depressive symptoms and moderately severe impairment in functioning. There is a need for follow-up studies with a more rigorous methodology to have more insight into the trajectory of outcome variables.

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**Ethical Approval:** Approved from the Institutional Ethical Committee (IEC), All India Institute of Medical Sciences, Jodhpur, Rajasthan.

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