Research Article

Correlation of some demographic parameters with clinical parameters of metabolic syndrome, bipolar affective disorders, and its therapeutics

Dinesh Singh Rathor, Mujahed M, Sudhir Kumar, Rakesh Kumar Jain, Anil Kumar Sisodia

Institute of Mental Health and Hospital, Agra, Uttar Pradesh, India

Correspondence to: Dinesh Singh Rathor, E-mail: drnimhans@gmail.com

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ABSTRACT

Background: Metabolic syndrome (MetS) has been found to be highly prevalent worldwide ranging from 11.2% to 47%. It is suggested that bipolar affective disorder (BPAD) and MetS share common risk factors including the treatment of the latter one, especially second-generation antipsychotics. The study tries to find out a significant correlation among various parameters, if any. **Objectives:** (i) To determine physical parameters such as blood pressure (BP) and waist circumference in drug-naïve and drug-free patients vis-a-vis in control subject across various sociodemographic parameters; (2) to find out the prevalence of MetS in drug-naïve/drug-free patients of bipolar disorder and control subjects and to compare with that of control subjects. **Materials and Methods**: The study was a comparative, cross-sectional, case-control, hospital-based study using purposive sampling method. Patients were taken up for the study from October 2013 to June 2015. The study included cases (79 = drug-naïve 36 + drug-free 43; aged 16-55 years) and control (50). For control, people with General Health Questionnaire 12 score <15 were selected. All patients were diagnosed as BPAD as per the criteria laid by the WHO (ICD-10 DCR), and only those were selected who had never received medications in their lifetime or were drug-free for at least 1 year. API criteria for the diagnosis of MetS for Asian Indians were used. Subjects crossing cutoff values in 3 or more parameters were considered to have MetS. Those crossing cutoff values in 2 or 1 parameter were considered sub-MetS (SMet2 and SMet1, respectively). **Results:** Percentage of married individuals was high in control group. Control group had exclusively Hindu population. Moreover, there were more urban people in control group. Otherwise, there was no significant difference in sociodemographic profiles of bipolar patients and control group. Patients had systolic BP (SBP) 120.27 ± 5.74 and control had 116.32 ± 5.67, both in the normal range, but the difference was significant statistically. Age and gender had a significant positive correlation with waist circumference but not with BP. Marital status had a significant correlation with waist circumference, but age can be considered here as a confounding factor. Age of individual had a positive correlation with waist circumference. Sex of individual in control group had a significant correlation with waist circumference. Education level had a negative correlation with waist circumference. **Conclusion:** Some factors (such as age, education, gender, marital status, and SBP) affect the factors already known to be correlated to MetS. Causal web analysis could give an exact level of their contribution and/or progression of the MetS in the cases of bipolar affective disorder, irrespective of drug status.

KEY WORDS: Clinical Parameters; Metabolic Syndrome; Bipolar Affective Disorders

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INTRODUCTION

Gerald Reavan first described metabolic syndrome (MetS) in 1988, and he named it syndrome X. It is also known as insulin resistance syndrome. MetS is a complex disorder characterized by central obesity, dyslipidemia, abnormal glucose tolerance, and hypertension.[1]

MetS has been found to be highly prevalent worldwide ranging from 11.2% to 47%. It is suggested that bipolar affective disorder (BPAD) and MetS share common risk factors including endocrine disturbances, dysregulation of sympathetic nervous system, and unhealthy behavior such as overeating, physical inactivity, smoking, and use of alcohol.[2,3]

Moreover, psychotropic drugs used for the treatment of BPAD lead to weight gain and metabolic disturbances, including alterations in lipid and glucose metabolism. Studies suggest that impaired glucose tolerance and insulin resistance are more common in patients with BPAD as compared to the general population.[4]

Second-generation antipsychotic drugs (SGA) are commonly used for the treatment of BPAD. A psychiatrist needs to be aware of medication side effects in detail and also of the comorbid condition of the disorder itself. SGA have been increasingly associated with significant metabolic complications including hyperlipidemia[5] insulin resistance or diabetes mellitus and obesity.[6]

To make the matter more complex, there are ethnical and racial differences in parameters of MetS. Very few studies have been conducted in India to find the prevalence of MetS in bipolar disorder.

By doing this study, we could know the prevalence of MetS at baseline in drug-naïve and drug-free BPAD patients and we will be able to decide risk and benefits of SGA in the treatment of bipolar disorder.

MATERIALS AND METHODS

The present study aimed at estimating the prevalence of MetS in those patients of BPAD who have never received medications in their lifetime or drug-free for at least 1 year and to compare it with normal healthy control. Following objectives were formulated:

1. To determine physical parameters such as blood pressure (BP) and waist circumference in drug-naïve and drug-free patients vis-a-vis in control subject across various sociodemographic parameters
2. To find out the prevalence of MetS in drug-naïve/drug-free patients of bipolar disorder and control subjects and to compare with that of control subjects.

The study was approved by the hospital Ethics Committee and conducted at the Institute of Mental Health and Hospital, Agra - A tertiary referral center and postgraduate teaching hospital in Uttar Pradesh (India). The study was a comparative, cross-sectional, case-control, hospital-based study, in which subjects were included using the purposive sampling method.

The study included cases (79 = drug-naïve 36 + drug-free 43) and control (50). API criteria for the diagnosis of MetS for Asian Indians were used. Subjects crossing cutoff values in 3 or more parameters were considered to have MetS.[7]

Trying to analyze the risk at different levels, subsyndromal MetS 1 (SMetS1) was used to label those having abnormal levels in any one of the parameters. SMetS2 was used to label those having abnormality in two of the five parameters.

Drug-naïve/drug-free patients were taken up for the study from October 2013 to June 2015. All patients were diagnosed as BPAD as per the criteria laid by the WHO (ICD-10 DCR). Included drug-free patients were aged between 16 and 55 years and gave written and verbal informed consent.

For control, people with General Health Questionnaire 12 score <15 were selected[8]. Patient/people suffering from any other comorbid psychiatric or organic illness or any substance dependence were excluded from the study.

Anthropometric tape with a spring-loaded mechanism was used to measure waist circumference. Sphygmomanometer and stethoscope were used to measure BP with standard procedure. Three BP measurements at 5 min intervals were obtained with the participant, and the mean of these measurements was recorded.

BP was measured when patients were in relaxed, sitting position with back supported, legs uncrossed, and elbow bent over the table and palm facing up, by mercury-based sphygmomanometer having a manually inflatable cuff attached by tubing to the unit that was calibrated in millimeter of mercury.

Waist circumference was measured just above iliac crest, at the end of normal expiration, in the fasting stage with the subject standing, erect, and looking straight forward with feet shoulder width apart and arm crossed over chest in a relaxed manner and observer taking a position to the right side of patients body on one knee, using a nonstretchable flexible tape with spring-loaded mechanism to standardize tape tension during measurement.

Descriptive statistics were used to define the sample characteristics. Independent *t*-test was applied on continuous variables of parameters of MetS to find any significance difference between patient and control groups. Chi-square was used to explore the associations between sample characteristics and different level of MetS.

While applying Chi-square test, either Pearson test or Fisher's exact test was used, depending on number of cells having expected frequencies. ANOVA test was applied for

comparison among 3 groups of drug-naïve patients, drug-free patients, and control subjects. Nonparametric Spearmen correlation test was applied to find any significant correlation between sociodemographic variables and parameters of MetS.

RESULTS

Expectedly, the percentage of married individuals was high in control group. Second, control group had exclusively Hindu population. Moreover, there was a higher proportion of individuals belonging to urban habitat in control group. Otherwise, there was no significant difference in sociodemographic profiles of bipolar patients and control group (Table 1).

As per Table 2, there was no significance difference in the occurrence of MetS and SMetS in patients as compared to control in the study population. Tables 3 and 4 find no significant difference in clinical parameters (waist circumference and BP) of the patient and control groups as per χ^2 test or *P* estimate.

Table 4 describes unpaired *t*-test results. Thus, patients had systolic BP (SBP) 120.27 ± 5.74 and control had 116.32 ± 5.67; both had SBP in normal range, but the difference was significant statistically, clinical significance of which was not known.

Nonparametric Spearmen correlation test was applied to find any significant correlation between sociodemographic variables and parameters of MetS (Table 5). Age and gender had significant positive correlation with waist circumference but not with BP. Marital status had a significant correlation with waist circumference, but age can be considered here as a confounding factor.

Table 1: Sociodemographic profile of sample population of patients of bipolar disorder and control

Variables	Patients (*n*=79) (%)	Control (*n*=50) (%)	χ^2	df	*P*
Age (years)			0.72	1	0.39
<35 years	58 (73)	40 (80)			
>35 years	21 (27)	10 (20)			
Gender			0.00	1	0.98
Male	52 (66)	33 (66)			
Female	27 (34)	17 (34)			
Marital status			9.49	1	0.002**
Unmarried	44 (56)	14 (28)			
Married	35 (44)	36 (72)			
Religion			5.39	1	0.02*
Hindu	71 (90)	50 (100)			
Muslim	8 (10)	0 (0)			
Others	0 (0)	0 (0)			
Education			4.38	3	0.22
Uneducated	7 (9)	8 (16)			
Primary	12 (15)	12 (24)			
Secondary	45 (57)	20 (40)			
Graduate	15 (19)	10 (20)			
Occupation			0.03	1	0.86
Farmer/laborer	20 (25)	12 (24)			
Others	59 (75)	38 (76)			
Socioeconomic status			0.29	1	0.59
LSES	48 (61)	28 (56)			
MSES	31 (39)	22 (44)			
USES	0 (0)	0 (0)			
Habitat			10.99	2	0.004**
Rural	35 (44)	18 (36)			
Sub-Urban	27 (34)	8 (16)			
Urban	17 (22)	24 (48)			

*Significant at *P*≤0.05 **Significant at *P*≤0.01. LSES: Lower socioeconomic status, MSES: Moderate socioeconomic status, USES: Upper socioeconomic status

As per Table 6, the age of individual in control group had a positive correlation with waist circumference. Sex of individual in control group had a significant correlation with waist circumference. Education level had a negative correlation with waist circumference.

DISCUSSION

In this study, 79 patients and 50 controls were taken for study. Of 79 patients, 52 (66%) were male and 27 (34%) were female. The gender imbalance could be attributed to lower help-seeking toward psychiatric care in females of Indian population and was proportional to the outpatient attendance of all patients in our hospital.

Table 2: Different levels of MetS in patients and control groups

MetS categories	Groups		Total	χ^2	df	*P*
	Control (%)	Patients (%)				
Normal	19 (38)	19 (24)	38	4.66	3	0.23
SMetS 1	21 (42)	48 (61)	69			
SMetS 2	9 (18)	10 (13)	19			
MetS	1 (2)	2 (2)	3			
Total	50	79	129			

MetS: Metabolic syndrome, SMetS: Subsyndromal metabolic syndrome

Table 3: Frequencies of individuals across cut-off values of different clinical parameters of MetS

Variable	Patients	Control	χ^2	df	*P*
Waist circumference			0.10	1	0.75
Men<90 cm Women<80 cm	68 (86%)	42 (84%)			
Men≥90 cm Women≥80 cm	11 (14%)	8 (16%)			
BP			0.324	1	0.57
<130/85 mmHg	74 (94%)	48 (96%)			
≥130/85 mmHg	5 (6%)	2 (4%)			

BP: Blood pressure, MetS: Metabolic syndrome

For matching with patients group, out of 50 individuals of control group, 33 (66%) males and 17 (34%) females were included in the study. Of 79 patients, 58 (73%) were <35 years of age and 21 (27%) were >35 years of age. The mean age of patient group was 29.00 ± 7.77 years.

This was due to the inclusion of drug-naïve patients as bipolar disorder has a bimodal peak of onset. The first peak is at late adolescence to early adulthood and second between 40 and 50 years of age. Of 79 patients, 36 were drug-naïve, so 73% patient group was <35 years of age.

Individuals of comparable age were taken in control group. 40 (80%) were <35 years of age, and 10 (20%) were >35 years of age. The mean age of control group was 28.58 ± 8.36 years. There was no significant difference between age group of patients and control.

44 (56%) of patients and 14 (28%) individuals of control group were unmarried. 35 (44%) patients and 36 (72%) individuals of control group were married. There was a significant difference between the marital status of patients and control group.

The majority of patients were unmarried; on the other hand, majority of control group individuals were married, despite matching age groups of both groups. This can be explainable on the basis of socio-occupational disability, stigma related to disorder so that patients were getting difficult to marry suitable match.

71 (90%) patients belonged to Hindu religion, and 8 (10%) patients were Muslim by religion. This was due to population demography and willingness of patients to take part in the study. All the individuals (100%) in control group were Hindu by religion.

There was a significant difference between the religion of patients and control. Major focus of matching in both groups was gender and age group. Hence, unavailability of appropriate gender and age group matching Muslim individual, who was willing to take part in the study as a control, was the reason for this significant difference of religion among patients and control.

Table 4: Descriptive analysis of parameters of metabolic syndrome in patients and control

Variable	Group	*n*	Mean±standard deviation	*t*	df	*P*
Waist circumference	Control	50	79.82±5.11	−0.061	127	0.95
	Patients	79	79.87±4.62			
SBP	Control	50	116.32±5.67	−3.83	127	0.00**
	Patients	79	120.27±5.74			
DBP	Control	50	75.96±5.64	−0.37	127	0.001**
	Patients	79	79.39±5.62			

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, ** $P \leq 0.01$

Table 5: Correlation of sociodemographic variables of patients with parameters of MetS

Variables	Waist circumference cat	BP cat
Age	0.397**	0.266
	0.00	0.018
Gender	0.404**	0.032
	0.00	0.780
Education	−0.196	−0.216
	0.084	0.056
Marriage	0.304**	0.187
	0.007	0.099
Religion	−0.135	−0.087
	0.236	0.444
Socioeconomic status	−0.099	0.102
	0.387	0.369
Habitat	−0.059	0.194
	0.608	0.087
Occupation	0.066	−0.088
	0.563	0.442

BP: Blood pressure, MetS: Metabolic syndrome, **$P \leq 0.01$

Table 6: Correlation of sociodemographic variables of control with parameters of MetS

Variables	Waist circumference cat	BP cat
Age	0.430**	0.330
	0.002	0.019
Gender	0.378**	−0.147
	0.007	0.310
Education	−0.317*	−0.237
	0.025	0.097
Marriage	0.272	0.127
	0.056	0.378
Socioeconomic status	0.277	−0.181
	0.052	0.209
Habitat	0.070	−0.023
	0.628	0.873
Occupation	0.126	−0.124
	0.385	0.390

BP: Blood pressure, MetS: Metabolic syndrome, *$P \leq 0.05$, **$P \leq 0.01$

35 (44%) patients were living in rural area whereas 24 (48%) individuals of the control group were living in urban area. Patients' habitat was in keeping with the population served by our hospital, IMHH. As in control group, working staff of IMHH were also included, resulting in a significant proportion of individuals residing at Agra.

We could grossly conclude that there was no any significant premorbid or morbid hindrance in educational performance or occupation of patients as compared to control and socioeconomic status of patients and controls was comparable.

Geographically close to our venue, a study conducted by Guha et al. at Medical College and Hospital Kolkata on drug-naïve patients of bipolar disorder, also found that there was no significant difference of MetS in drug-naïve patients and control group.[8]

They found that 9% of patients and 8% of control group individuals had MetS. Although finding of our study was in line with findings observed by Guha et al., this finding was in contrast to observations of other workers who have reported a significant increase in the prevalence of MetS in patients of bipolar disorder.

Our study was conducted on drug-naïve and drug-free patients so that confounding effect of psychotropic drugs was eliminated. The mean age of patients in our study was 29 years. Hence, these two factors known to have a positive correlation with MetS may be the reason for the low prevalence of MetS in our study as compared to other studies.[9]

The increased prevalence of MetS and obesity in western studies can be possibly related to dietary habits of these patients who consume more sugar and carbohydrate.[2,10]

48% of patients belonged to lower socioeconomic status, 44% of patients were inhabitant of rural area, and 25% of patients were farmer/labor by occupation. These sociodemographic factors impacting lifestyle of a person can be possible reasons behind our finding of the low prevalence of MetS.

The majority of individuals in both groups had SMetS. This implies that most of the individuals in both groups were at risk of developing MetS. This increased risk of developing MetS should be kept in mind while treating bipolar patients.

Drug-naïve patients had a higher prevalence of MetS1, i.e., 80% as compared to drug-free and control subjects. While drug-free and control subjects had a proportionally higher prevalence of MetS2 as compared to drug-naïve patients. There was no case of MetS in drug-naïve patients.

The prevalence of different levels of MetS in drug-free patients and control subjects was matching as compared to drug-naïve patients. Both drug-free and control subjects had a higher prevalence of SMetS2 and MetS as compared to drug-free patients.

Age could be a confounding factor here. The mean age of drug-naïve patients was 23.00 ± 6.08, which was significantly low on applying ANOVA as compared to mean age of drug-free patients and control subjects. The mean age of drug-free patients was 32.93 ± 7.52, and the mean age of control subjects was 29.00 ± 7.78.

The previous studies have shown that SGAs can cause MetS or increased risk of its isolated parameters such as obesity, insulin resistance, hypertension, and lipid abnormalities.[11]

As the prevalence of different levels of MetS in drug-free and control subjects were relatively matching, we can draw a conclusion that drug-free patients have no increased relative risk of developing MetS due to the use of psychotropic medicines after stoppage of drugs for at least 1 year.

On applying independent *t*-test on measured waist circumference values in both groups, no significant difference was found between both groups. Chi-square test was applied on categories of waist circumference below and above cutoff values of both groups.

Findings of our study were matching with the study of Guha et al.[12] conducted on drug-naïve patients at Kolkata, while findings were in contrast with most Western studies.

This difference can be explainable on the basis of ethnic differences, lifestyle of those societies, and continued treatment with psychotropic drugs of patients participated in studies. Different ethnic population has different waist circumference, to be considered as risk factor for cardiovascular diseases.

Hence, the International Diabetes Federation has given different cutoff values of waist circumference for different ethnic population.[13] Relatively young age and drug-naïve, drug-free status of patients in our study can be the reason for the low occurrence of increased waist circumference in our study.

On comparing BP of patients and control, there was significantly high values of SBP (P = 0.00 on *t*-test), and diastolic BP (DBP) (P = 0.001 on *t*-test) in patients as compared to control, though both groups have mean SBP and DBP below cutoff values. The mean SBP/DBP values of patients were 120.27/79.39.

5 (6%) patients had BP above cutoff values. 2 (4%) control individuals had BP above cutoff values. On applying Chi-square test, no significant difference was found between categories of individuals of patients and control below and above cutoff values.

Although attempts have been made to study the sociodemographic factors of MetS in bipolar disorder in previous studies, none of the sociodemographic variable has emerged as a consistent predictor of MetS.

In our patient sample, we found no significant difference in the prevalence of MetS in age groups above and below 35 years of age. Some studies have shown that patients of bipolar disorder with MetS were older than those without MetS.[14-18]

However, some studies have found no significant difference in age of patients with MetS.[19] On correlation analysis, age had a significant correlation with waist circumference.

Control group individuals had significant MetS difference across age groups. Individuals >35 years of age had more prevalence of SMetS2 and MetS. On correlation analysis, a significant correlation was found between age and waist circumference same as in patient group.

This signifies that in general population, MetS was associated with increasing age, but patients have MetS irrespective of their age. Hence, bipolar disorder can be in itself considered as risk factor for patients as compared to the general population.

Age was also found to have a significant correlation with waist circumference in both patients and control group. Hence, our finding was similar to some other studies that patients have no significant difference across age groups with MetS.[19] However, age has a significant correlation with waist circumference (a component of MetS) in both patient and control groups.

From the current study, gender appears to be affecting MetS in both patient and control groups. Females had a higher prevalence of MetS and subsyndrome as compared to males in both patient and control groups.

On correlation analysis, gender was found to have a significant correlation with waist circumference and high-density lipoprotein (HDL) level. More females were found to be above cutoff values of waist circumference, and HDL, defined for female gender as compared to males.

Mattoo and Singh found a trend of female preponderance for the prevalence of MetS across different diagnoses among psychiatric inpatients.[20] The issue of gender differences in the prevalence of MetS has been unresolved so far.

Education level was significantly different in patients with different levels of MetS. Uneducated patients were skewed on both sides of MetS spectrum, 58% were normal and 29% had MetS. While the major bulk of patients with education up to a secondary or graduate level had SMetS1.

Such skewness of data among uneducated individuals themselves indicates that it may be an incidental finding. No previous studies have reported a significant difference in MetS across different education levels. No other sociodemographic variables were found to be significantly affecting different levels of MetS in patients and control group.

Marriage was found to be significantly correlated with waist circumference in patients. However, age can be a confounding factor here, and as age was significantly correlated with waist circumference in patients in this study, we cannot draw a decisive conclusion from the correlation of marriage with waist circumference in patients in our study.

Religion, socioeconomic status, and habitat were not having any significant correlation with different parameters of MetS in patients. In our study, we did not find any significance difference in different level of MetS in patients and control group.

However, in contrast, many studies have pointed increased prevalence of MetS in patients.[10,21-23] These studies were conducted on patients taking psychotropic medications. Antipsychotic drugs were known to have significant effects on weight, lipoproteins, and overall on the prevalence of MetS.

These factors should be kept in mind while treating patients as we did not find any significant difference in different level of MetS in drug-naïve and drug-free patients. Hence, from our study, we can draw a conclusion that bipolar disorder itself is not a risk factor for developing MetS.

CONCLUSION

Percentage of married individuals was high in control group. Control group had exclusively Hindu population. Moreover, there were more urban people in control group. Otherwise, there was no significant difference in sociodemographic profiles of bipolar patients and control group. Patients had SBP 120.27 ± 5.74 and control had 116.32 ± 5.67, both in the normal range, but the difference was significant statistically. Age and gender had a significant positive correlation with waist circumference but not with BP. Marital status had a significant correlation with waist circumference, but age can be considered here as a confounding factor. Age of individual had a positive correlation with waist circumference. Sex of individual in control group had a significant correlation with waist circumference. Education level had a negative correlation with waist circumference. In short, some factors (such as age, education, gender, marital status) affect the factors (such as waist circumference and SBP) already known to be correlated to MetS. Causal web analysis could give an exact level of their contribution and/or progression of the MetS in the cases of bipolar affective disorder, irrespective of drug status.

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