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Artificial intelligence in the era of ChatGPT - Opportunities and challenges in mental health care

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Chat Generative Pre-training Transformer (ChatGPT)[1] is a powerful AI-based chatbot system launched on November 30, 2022, by San Francisco-based OpenAI. It gained massive attention and currently has over 100 million users, which makes it the fastest-growing consumer application.[1]

It is a transformer-based neural network system that uses a vast neural network to produce a human-like language through which it communicates. The AI-based programs are programmed with unlimited text data to understand the context and relevancy of human communications.

There is massive competition in this segment as multiple similar, better-advanced apps are on the verge of being launched, like Google Bard,[2] Microsoft Bing AI, Chinese Ernie bot, Korean SearchGPT, Russian YaLM 2.0, Chatsonic, Jasper Chat, Character AI, Perplexity AI, and YouChat.

ChatGPT and other AI platforms hold enormous potential in many fields, including mental health. They carry vast utilization possibilities and are coming in a big way. From chats and games to writing computer programs, music compositions, songs, and teleplays to writing essays, letters, scientific papers, abstracts, and introductions, it will affect one and all in a big way. It is not hard to predict that they will make a massive difference in the mental healthcare delivery system.

There is a huge treatment gap in mental health care in developing, lower, and lower-middle-income countries. According to WHO, there is a 76%–85% treatment gap in developing countries regarding mental disorders. According to National Mental Health Survey, in India, the treatment gap reported for any mental disorder is as high as 83%. A huge deficit of mental health professionals far below the specified norms and an inequitable resource distribution make the gap more prominent.[3] AI and digital interfaces are emerging as viable alternatives for reducing this gap and making psychiatric diagnosis and treatment accessible and affordable.

The ability of ChatGPT and other AI-based chatbots to generate human-quality responses can provide companionship, support, and therapy for people who have problems with accessibility and affordability in terms of time, distance, and finances. The ease, convenience, and simulation of talking to another human being make it a superior app for providing psychotherapies. The ChatGPT and AI-based chatbots are programmed and trained with vast knowledge about psychiatric conditions and respond with empathy. Still, they cannot diagnose specific mental health conditions and provide treatment details reliably and accurately.

Though there is a lot of excitement associated with the use of AI in various psychiatric conditions, there are several areas of concern with its use. To start with, ChatGPT and other AI are trainable and are trained using web-based information and utilize the reinforcement learning technique with human feedback. If not prepared with proper responses and from authentic sites, they can provide wrong information regarding the condition and inappropriate advice, which may be potentially harmful to persons with mental problems.

Confidentiality, privacy, and data safety are significant areas of concern.[4] Any person utilizing an AI-based app for their mental health condition and therapy is bound to share important personal details about themselves and family members, making them potentially vulnerable in situations of breach of confidentially and in scenarios of the data breach.

Other concerns are the lack of proper standardization and monitoring, the universality of applications, misdiagnosis, wrong diagnosis, inappropriate advice, and the inability to handle crises.[4] There are also concerns regarding their safety, efficacy, and tolerability.

These pose significant concerns about the ethical issues related to using ChatGPT and AI-based apps in academics, diagnosis, treatment, and therapy.

There is a definite need to regulate and monitor AI-based apps. American Psychiatric Association (APA) has formulated

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a digital psychiatry task force to evaluate and monitor AI and mental health-related apps for their efficacy, tolerability, safety, and potential to provide mental health care.[5]

APA has come up with an innovative initiative of the App Evaluation Model called App Advisor.[5] APA's App Evaluation Model has been adopted and replicated by several other healthcare organizations, e.g., the Division of Digital Psychiatry and BIDMC at Harvard University App Evaluation, Health Navigator App Evaluator Model and Assessment tools, NYC Department of Health and Mental Hygiene: NYC Well App Advisor, to name a few.[6]

With the vast difference in awareness, education, language, and level of understanding in the Indian population, Indian Psychiatric Society and other stakeholders should start to evaluate and regulate AI-based global and local apps for their safety, efficacy, and tolerability and guide the general public for proper and safe use.

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REVIEW ARTICLE

Epidemic of Depression and Anxiety in child and adolescent population during COVID-19 pandemic: A systematic review and meta analysis of the prevalence of depression and anxiety

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ABSTRACT

COVID-19 has caused mayhem in the life of people. It has disrupted the social fabric of life. The children and adolescent population has been particularly affected by its direct and indirect effects. This systematic review aims to find the prevalence of depression and anxiety in children and adolescent age groups. We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines for finding the prevalence of depression and anxiety. We found the total number of participants to be 71,016. A random effect model was used for conducting meta-analysis. The prevalence of depression was mentioned in 17 studies of 23 and the pooled prevalence was 27% [95% confidence interval: 21%-36%] and heterogeneity (I^2 statistics; P <.00001) was 100%. The prevalence of anxiety was found in 20 studies of 23 and the pooled anxiety prevalence was 25% (95% confidence interval: 16%-41%) and heterogeneity (I^2 statistics; $P < .00001$) was found to be 100%. The summary of the findings has been provided. Due to high heterogeneity, moderator analysis was performed separately for depression and anxiety subgroups. The study design consisted of cross-sectional studies and some studies conducted through online surveys. The age range varied considerably from 1 year to 19 years; 5 studies had participants aged more than 19 years, but the mean age of the total sample was less than 18 years. We conclude that indeed there is a mental health epidemic among the child and adolescent population. We recommend early intervention and tailored made strategies should for management. As the pandemic is enduring, rigorous monitoring should be done. This age group is under extra pressure owing to a large uncertainty about their studies as well their future.

Key words: Child and adolescent age group, COVID-19, depression and anxiety, mental health, pandemic

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INTRODUCTION

In December 2019, the first patient with pneumonia of an unknown cause was reported in China and then it was subsequently linked to a seafood market in Wuhan, China.[1] COVID-19 has spread worldwide and has changed dramatically normal life-disrupting social and economic functioning comparable to the Spanish flu pandemic of 1918.[2] As of now, worldwide 54,301,156 confirmed cases have been reported along with 1,316,994 deaths worldwide. COVID-19 has spread rapidly leading to a high number of fatalities.[3]

As per recent studies, the pediatric age group constitutes 1%-2% of the diagnosed cases with a median age in the range of 3.3–11 years and a male/female ratio to be 1.15–1.55. The incidence of COVID-19 was lower among the children and adolescent age group in comparison with the adult population with death being a rare phenomenon. The possible reason could be a difference in the immune system function of children and adolescents or could be due to differences in the expression/function of the cellular receptor for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)-Angiotensin-converting enzyme 2 (ACE2).[4] In a time of an emergency like a pandemic, the psychological health of children and adolescents is at risk mainly due to their limited coping skills and understanding of the situations. Response of a child or an adolescent to adversity varies and it depends upon multiple factors such as previous exposure to similar kinds of situations, current physical and psychological health, socioeconomic circumstances, and the cultural background of the family. Different studies have elicited that crises have a derogatory impact on the psychological impact on the wellbeing of the child and concomitantly there has been a rise in the incidence of psychiatric disorders worldwide.[5] The influence of COVID-19 in the lives of children has been substantial and it should not be belittled as this pandemic has led to social isolation and restrictions, which are particularly disrupting for children and be both baffling and petrifying. Although apart from anxiety a rise in stress, depressive symptoms, insomnia, denial, anger, and fear has been observed globally.[6] This systematic review and meta-analysis aim to find the pooled prevalence of both depression and anxiety in children and adolescent age groups during the COVID-19 pandemic.

METHOD

This systematic review aims to find out the prevalence of depression and anxiety in the child and adolescent age group during the COVID-19 pandemic. We searched data from PubMed, Google Scholar, Science Direct, Medline, and Cochrane. The search was conducted as per Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[7]

We followed PICOS criteria for our search which stands for Participants (P): Child and adolescent population during this pandemic; Intervention (I): no intervention was done; Comparison (C): no comparison or control group; Outcome (O): prevalence of depression and anxiety in the study population; and Study design (S): published cross-sectional studies. As per Methley *et al.,* PICOS process for systematic review and meta-analysis is beneficial when there are limited resources unlike PICO and SPIDER.[8]

We searched with MESH terms "COVID-19 AND anxiety, DEPRESSION, AND STRESS AND CHILDREN OR ADOLESCENT"; "COVID-19 AND ANXIETY OR STRESS AND CHILDREN AND ADOLESCENT"; COVID-19 AND ANXIETY OR STRESS AND CHILDREN OR ADOLESCENT; COVID-19 AND DEPRESSION OR STRESS AND CHILDREN AND ADOLESCENT; COVID-19 AND DEPRESSION OR ANXIETY AND CHILDREN AND ADOLESCENT; COVID-19 AND PSYCHOLOGICAL EFFECTS AND CHILDREN OR ADOLESCENT; "COVID-19 AND PSYCHOLOGICAL EFFECTS AND CHILDREN AND ADOLESCENT".

Additional filters were also applied for age, and period, we included journal articles and clinical studies involving human subjects, we excluded these categories by applying filters that are review articles, case series, case reports, and case-control studies.

Quality assessment

We adopted Newcastle-Ottawa Quality Assessment Scale for cohort studies to perform a quality assessment of cross-sectional studies for the systematic review. In our version of the scale, we have specifically assigned 1 star for self-reported outcomes because many of the studies used self-reporting questionnaires. The 4 items in the selection criteria had a maximum score of 5 stars; comparability had a maximum of 2 stars with 3 stars for the outcome. Quality assessment was done by one author (S.C.).[9]

Data extraction

The study data were extracted from January 2020 to April 2021. Data extraction was done by 2 authors (G.M. and V.V.) and was put in predefined categories in table format in MS word and excel sheets. Any discrepancy or controversy was sorted out mutually by 3 authors (G.M., V.V., and S.C.). Inclusion and exclusion criteria for vetting search results along with their rationale are given in Box 1. Box 2 shows the sources of literature search and retrieval.

Data analysis

All included studies have been conducted independently. We took mild, moderate, and severe symptoms in the analysis. The data analysis was done in Cochrane's Revman software which is available free for academic purposes. Pooled prevalence along with 95% was calculated using the inverse variance method. This method weighs pooled prevalence estimates by their sample size. The random effect model was

used to find variations across studies. The between-study heterogeneity was assessed through I^2 statistics. A Forest plot was created to reflect pooled prevalences and funnel plots were used for observing publication bias. As the heterogeneity was high in this meta-analysis, therefore, we performed a moderator analysis. Bornstein *et al.* recommended that moderators should be examined when the number of studies is more than 10.[10]

RESULTS

Using the strategy described more than 4,245 citations were sourced. After screening, 4,191 abstracts were excluded and 54 were selected. Of these, 2 full texts were not available and 3 were duplicate records. Further 25 records did not meet the inclusion and exclusion criteria and in 3 studies the prevalence of depression and anxiety were not mentioned. Finally, 22 studies were considered suitable for inclusion in the review [Figure 1, Tables 1 and 2]. The summary of the results along with the statistical techniques used in the various studies has been provided in Tables 1 and 2. We found the total number of participants to be 71,016. Both anxiety and depression were mentioned in 14 studies of a total of 22 studies. The study design consisted of cross-sectional studies and some studies conducted through online surveys. The age range varied considerably from 1 year to 19 years; 5 studies had participants aged more than 19 years but we included them as the mean age of the total sample was less than 18 years.

Box 1: Inclusion and exclusion criteria for vetting of search results along with rationale

Criteria	Criteria	Rationale
Inclusion	1. The study should have been done on the child and adolescent population age group.	A dearth of systematic review in child and adolescent age group.
	2. The study design should be cross-sectional and should include the prevalence of depression and anxiety.	We aimed to find out the increase in the prevalence of depression and anxiety due to COVID-19, and in addition, the results are readily available in cross-sectional studies.
	3. The study should be available in the English language.	To avoid any confusion in the interpretation of the paper and maximum output is available in English.
	4. The study should have a score of 5 or more on the Newcastle Ottawa scale (NOS).	For maintaining the Quality of the included studies.
Exclusion	1. Review article case series, case reports.	Are not suitable for systematic review. Anecdotal evidence.
	2.NOS<5	Quality not suitable
	3.Age of study participants >19 years.	This age range captures the WHO definition of *adolescent* (10-19 years) and also the overlapping definition of a *young person* (15-24 years).
	4. The studies do not mention the prevalence of anxiety and depression.	Not serving the primary purpose.
	5. Studies including subjects with pre-existing psychiatric illness.	Can skew the data.

Box 2: Sources of literature search and retrieval

Peer-reviewed literature sources	Medline
	EMBASE
	PsycInfo
	Web of Science
	CINAHL
Grey literature sources	WHO website
	Centre for disease control website
	UNESCO website
	UNICEF website

Prevalence of depressive symptoms in children and adolescents during COVID-19

The random-effects meta-analysis from 17 studies of a total of 22 studies revealed a prevalence rate of 27% (95% confidence interval [CI]: 21%-36%) [Figure 2a]. The funnel plot was symmetric, indicating a low risk of publication bias, shown in Figure 2b. The between-study heterogeneity statistic was significant (I^2 = 100%; Tau^2 = 0.34; $Chi^2 = 41592.79$, df = 16) ($P < .00001$) [Figure 2a]. Significant moderators were present [Table 3]. The overall effect of the moderators including month, region of publication, and mean age of study participants was insignificant (adjusted R square = 0.602; P =0.089). The geographical region as a moderator was insignificant adjusted R^2 = -0.015 (b [standardized coefficient] = 0.230; P =0.391) (number of studies belonging to South Asia (N) = 14; prevalence of depression = 27% (CI: 19%-38%); Europe (N) = 1, the prevalence of depression = 24% (CI: 23%-25%); Middle East (N) = 1 prevalence of depression = 57% (CI: 55%-59%);

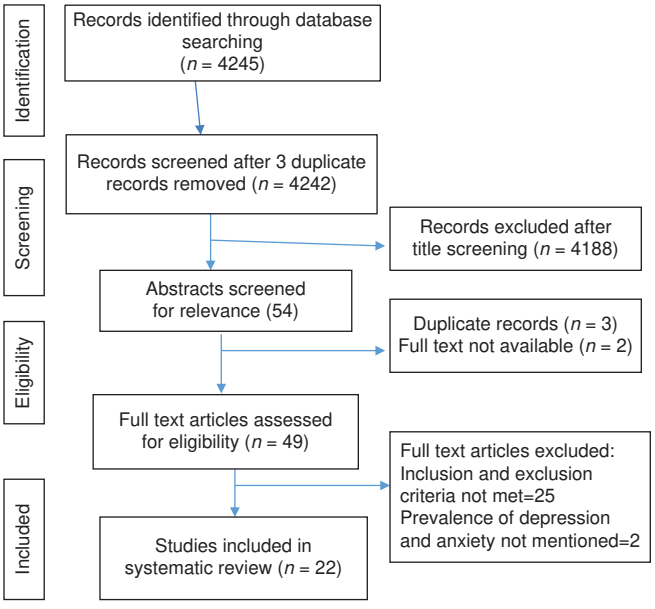

Figure 1: Search process

Table 1: Prevalence of Depression and Anxiety in children and adolescents during COVID-19 pandemic

Author/name of study/year of publication	Study Design (Sample Size, Type of study)	Participant's age range (Mean age)	Scales used for assessment of anxiety & depression	Prevalence of Psychiatric symptoms	NOS Scale
Crescentini C *et al*.[11] Italy 2020	*N*=721 online survey	Age: 6- 18 years	Hospital Anxiety and Depression Scale	Anxiety (90/721) -12.4% Depression (64/721)--8.8%	5
Dong H *et al*.[12] 2020 China	*N*=2050 Cross-sectional	Age 6-18 years	DASS-21	Depression- (*n*=362) -17.66% Anxiety (*n*=298)- 15.54% Stress- (*n*=145) 7.07%	6
Zhou SJ *et al*.[13] 2020 China	*N*=8079 Online survey	12-18 years	PHQ-9 GAD-7	Depression-43.7% Anxiety -37.4% Mixed -31.3%	5
Chen, F *et al*.[14] 2020 China	*N*=1036 Cross-sectional study	6-15 years	DSRS-C SCARED	Depression: 112 (10.81%) Anxiety: 196 (18.92%) Both Anxiety and Depression: 68 (6.56%)	6
Abawi O *et al*.[15] 2020 Netherland	*N*=75 Cross-Sectio-nal study	7.6-15.2 years (mean-10.5)	Peds QL	Anxiety: 24/75 (32%)	5
Duan L *et al*.[16] 2020 China	*N*=3613 Cross-sectional Design	Age: 7-18 Years	SCAS CDI	Depression: 22.28%	6
Smirni P, *et al*.[17] 2020 Italy	*N*=148 Cross-Sectional Design	Age range: 17-19	SAS EAQ	Over 50% had a high SAS score and the index score reached 52.7. SAS mean score: males (43.5 ± 4.6) vs. Female: (39.3 ± 3.7; *P*=0.003) EAQ mean score: M: 57.9±10.4 vs. F: 58.3 ± 8.3; *P*= 0.88).	5
Tang, S *et al*.[18] 2021 China	Cross-sectional online survey *N*=4391	6-17 years	DASS-21	Anxiety 1080 (24.9%) Depression: 857 (19.7%) Stress: 659 (15.2%).	5
Omar Al Omar *et al*.[19] 2020. Oman, Saudi Arabia, Jordan, UAE, & Egypt	*N*=1,057 Online Cross-Sectional	15-25 Years	DASS-21	Depression: 57% Anxiety: 40.5% Stress: 38.1%	6
Yeasmin S *et al*.[20] 2020. Bangladesh	*N*=384 Cross-Sectional study	5-15 Years	RCADS	Subthreshold mental disturbances- 43% (mean Major Depressive Disorder (MDD)-10; 2.8) Mild Depression mean MDD-10; 8.9):30.5% Moderately (mean MDD-10; 15.9):19.3% Severe disturbances (mean MDD-10; 25.2):9.2%	5
Garcia de Avila MA *et al*.[21] 2020. Brazil	*N*-289	6-12 years (Mean- 8.84)	CAQ NRS	Based on CAQ ≥9, anxiety was 19.4% (n=56) Based on NRS >7, anxiety was 21.8%	6
Chen S *et al*.[22] 2020 China	*N*- 7772 Cross-sectional study	Students of grades 7 to 12	PHQ-9 GAD-7	Middle School students Anxiety: 1171/5107 (22.92%) High School student's Anxiety: 920/2665 (34.52%);	6
Fitzpatrick O. *et al*.[23] 2020 USA	Cross-Sectional study *N*=133	Age range=1- 19 years; Mean age =8.21	GAD-7 PHQ-9.	Anxiety/stress (24%) &depression (20%).	5
Kılınçel Ş *et al*.[24] 2020. Turkey	*N*=745 Online cross-sectional	12-18 year (Mean age=16.83)	STAI	Anxiety: (279) 37.4%	5
Pigaiani *et al*.[25] 2020 Italy	*N*=306 Cross-Sectional study	15–21 Years (Mean age=18.1)	3 socio-demographic questions; 30 questions exploring lifestyle behaviors, coping strategies, and subjective wellbeing	Anxiety: 122/306 (39.9%)	5

Contd...

Table 1: Contd...

Author/name of study/year of publication	Study Design (Sample Size, Type of study)	Participant's age range (Mean age)	Scales used for assessment of anxiety & depression	Prevalence of Psychiatric symptoms	NOS Scale
Sama *et al*.[26] 2020. India	N=400 Online survey	Up to 16 years	Questionnaire-based: Details about the children & child's family history based	Irritation: 73.15% Anger: 51.25% Depression: 18.7% Anxiety :17.6%	5
Chen *et al*.[27] 2021 China	Phone-based We Chat Wenjuanxing application N=9554	11-20 years	CES-D GAD-7	Depression - 36.6% Anxiety -19%	6
Liu *et al*.[28] 2020 China	Online Survey N=5175	Mean age-13.37 years	PHQ-9 GAD-7	Depression- 12.33% Anxiety-6.26%	6
Cao *et al*.[29] 2021. China	N=11,681 Cross-sectional	12 to 18 years	PHQ-9 GAD-7	Depression: 35.2% Anxiety : 20.5%	5
Hou *et al*.[30] 2020 China	N=859 Cross-sectional study	Aged 16 years and below	PHQ-9 GAD-7	Anxiety: 85% Depression: 71% Post-traumatic stress disorder: 54%	6
Xie *et al*.[31] 2020 China	N=1784 Cross-sectional online survey.	Children grade 2–6	CDI-S; Screen for Child Anxiety Related Emotional Disorders	Depression: 403 (22.6%) Anxiety: 337 (18.9%)	5
Qi H. *et al*.[32] 2020. China	N=9554 Cross-sectional online survey	11-20 Years	GAD-7	Anxiety: 1814 (19.0%)	6

Depression, Anxiety and Stress Scale - DASS-21; Patient Health Questionnaire - PHQ-9 ; Generalized Anxiety Disorder questionnaire - GAD-7; Depression Self Rating Scale for Children- DSRS-C; Screen for Child Anxiety Related Disorders -SCARED; Pediatric Quality of Life Inventory- Peds QL; Chinese Version of Spence Child Anxiety Scale –SCAS; Child Depression Inventory –CDI; Zung Self-Rating Anxiety Scale –SAS; Emotional Awareness Questionnaire –EAQ; 47-item Revised Child Anxiety and Depression Scale- RCADS; The Children's Anxiety Questionnaire –CAQ; Numerical Rating Scale –NRS; State-Trait Anxiety Inventory-STAI; Center for Epidemiological Studies-Depression Scale- CES-D; Children's Depression Inventory–Short Form -CDI-S

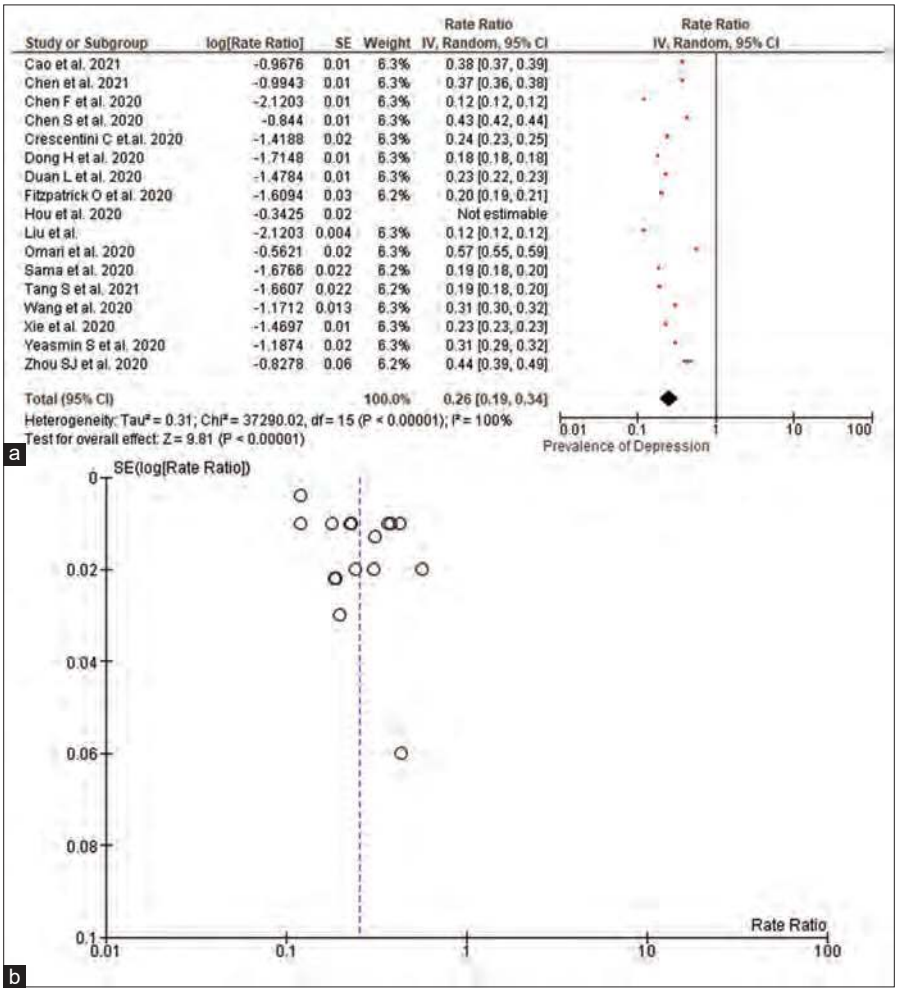

Figure 2: (a) Pooled Prevalence of Depression. (b) Funnel Plot for the pooled prevalence of Depression

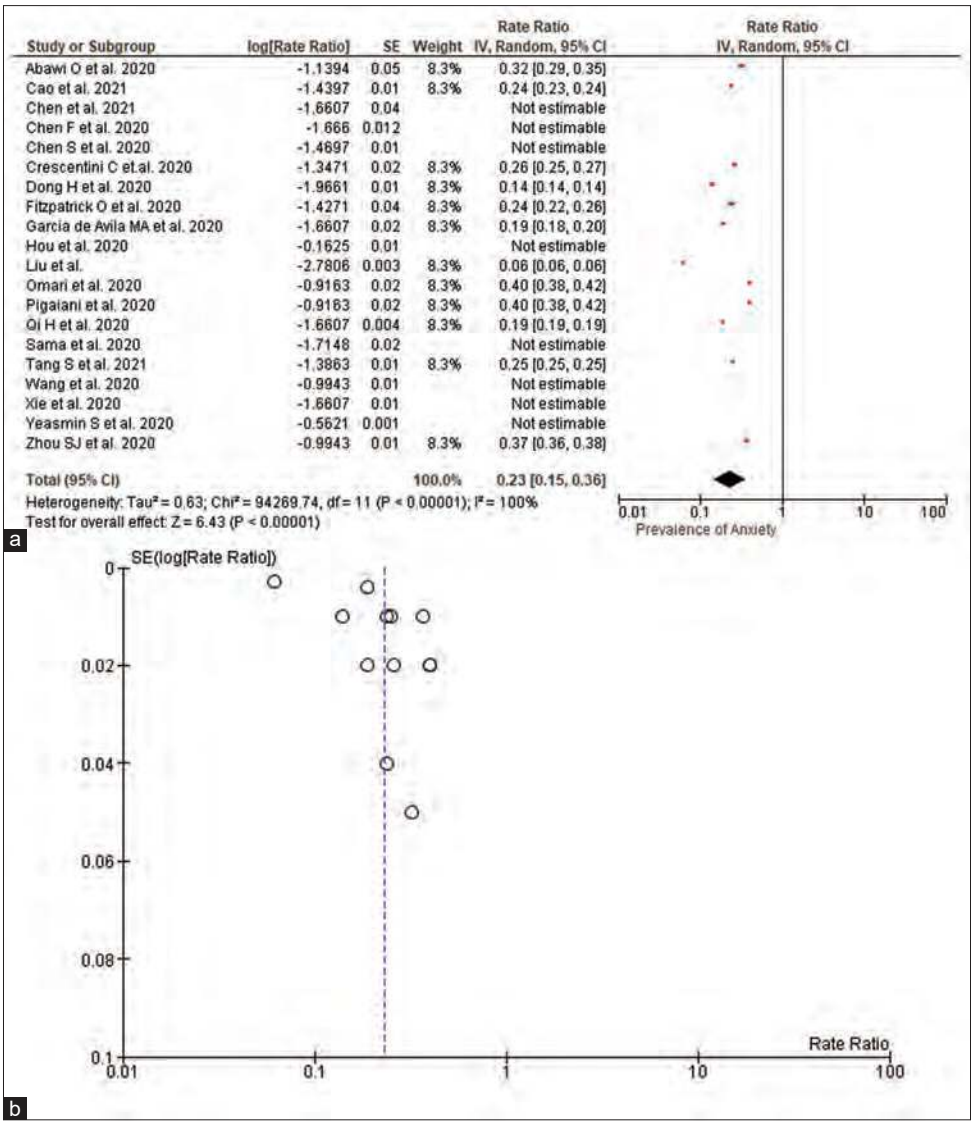

Figure 3: (a) Pooled Prevalence of Anxiety. (b) Funnel Plot for the pooled prevalence of Anxiety

North America (N) = 1 prevalence of depression = 20% (CI: 19%-21%). The effect of the mean age was also explored, only 8 studies mentioned mean age. The age was a significant moderator and as the age increased the prevalence also increased (adjusted R^2 = 0.622 b (standardized coefficients) = 0.822 (*P* value =.012). The month of data collection was also insignificant (adjusted R^2 = -0.06; b [standardized coefficient] = 0.125; *P* =.658).

Prevalence of anxiety symptoms in children and adolescents during COVID-19

The random-effects meta-analysis from 20 studies of a total of 22 studies revealed a prevalence rate of 25% (95% CI: 16%-41%) [Figure 3a]. The funnel plot was symmetric, indicating a low risk of publication bias, shown in Figure 3b. The between-study heterogeneity statistic was significant (I^2 = 100%; Tau^2 = 1.22; Chi^2 = 581499.11, df = 19) (*P* <.00001) [Figure 3a]. Significant moderators were present. The overall effect of all 4 moderators was insignificant. The month of publication was not a significant predictor (Adjusted R^2 = 0.046; standardized coefficient (b) = 0.123; *P* value =0.627). Other moderators like the proportion of the female participants and region of the publication also had no significant effect (adjusted R^2 = 0.066; b = -0.412 [*P* value =0.237] and adjusted R^2 = 0.008; b = 0.219 [*P* value =.367], respectively). The only significant predictor was the mean age of the participants. The pooled anxiety increased with the mean age of the study participants (Adjusted R^2 = 0.598; b = 0.799) (*P* value =.003) [Table 4].

DISCUSSION

The present study provides an estimate of global depression and anxiety among youth during the COVID-19 pandemic. Across 22 studies with a total sample size of 71,016, we found a prevalence of 27% for depression and 25% for anxiety. Compared to prepandemic global estimates,

Table 2: Highlights of the included studies and statistical techniques used in the study

	Study Title/First Author	Highlights about results of various studies	The statistical technique used for analysis
1	Crescentini *et al*.[10] 2020 Italy	Gender, Age, and Psychological factors (fear of the contagion) were associated with internalizing symptoms	Multiple Regression analysis
2	Dong *et al*.[11] 2020 China	Female gender, Depression, and Stress were correlated with Young's Internet Addiction Test	*t*-test, ANOVA test, Pearson's $\chi 2$ test, or Fisher's exact test Linear regression for a total score of DAS-21 and EAQ
3	Zhou *et al*.[12] 2020 China	Female gender and being a high school senior (The higher the grade students had higher their chances of developing depression and anxiety) A negative association between the level of awareness regarding the COVID-19 pandemic and psychological well-being	Multivariate analysis
4	Chen, *et al*.[13] 2020 China	For depression, a significant correlation was noted with gender, age, education of parents, companion on weekdays, and physical exercise. For anxiety: the correlates were gender, physical exercise, and companionship on weekdays. Female gender was associated with both depression and anxiety Higher age children and adolescents were more depressed but no such association was seen for anxiety.	Logistic regression
5	Abawi *et al*.[14] 2020 Netherland	Children (median age: 10.5 years) with obesity had lower Paediatric Quality of Life Inventory (PedsQL) questionnaire Out of the total sample, females were 52% During follow-up visits, participants reported that addressing COVID-19-related concerns alleviated their anxiety levels.	For quantitative analysis of PedsQL scores t-test and Mann-Whitney test were used Qualitative analysis was reported using Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist
6	Duan L *et al*.[15] 2020 China	For anxiety correlates included female gender, residentship of urban regions, and emotion-focused coping style. The correlates for depression: internet or smartphone addiction Protective factors for depression were	Descriptive statistics For differences in the anxiety of respondents t-test and analysis of variance (ANOVA) were applied Multiple linear regression model and bivariate logistic regression analysis were used for the analysis of the level of anxiety and depression and their predictors Pearson correlation for analysis of the association between depression, anxiety, coping styles, and internet addiction
7	Smirni *et al*.[16] 2020 Italy	Zung self anxiety score and Emotional awareness questionnaire were applied The total SAS score was significantly higher for females. No significant association was found between total SAS and EAQ scores.	Descriptive statistics Pearson correlation for analysis of relationship b/w SAS and EAQ.
8	Tang *et al*.[17] 2021 China	Students in senior grades had higher symptomatology Discussion regarding COVID-19 had a negative correlation with psychological symptoms and was positively correlated with life satisfaction.	For analysis of group differences in levels of depression, anxiety, stress, and life satisfaction Chi-square tests, Independent sample *t*-tests, and ANOVA were used Multivariate analyses of variance (MANOVA) were conducted for quarantine-related variables and levels of depression and anxiety
9	Omari Al Omar *et al*.[18] 2020. Oman, Saudi Arabia, Jordan, UAE, & Egypt	The predictors that significantly correlated with stress, anxiety, and depression were female gender, being in contact with a friend and/or a family member with mental illness, being in quarantine for 14 days, and use of the internet	Descriptive statistics Multi-variate analysis for predictors related to COVID-19 and DASS-21
10	Yeasmin *et al*.[19] 2020. Bangladesh	Predictors of depression in children were level of parental education, having a relative affected by COVID-19, and parents going to work during the pandemic.	Descriptive statistics Confirmatory factor analysis for assessment of the component's child mental health
11	Garcia de Avila *et al*.[20] 2020. Brazil	Higher childhood anxiety questionnaire scores (CAQ) were correlated with social distancing without parents; more persons living together in the home, and the education level of guardians.	Logistic Regression
12	Chen S *et al*.[21] China 2020	Anxiety was statistically high in Wuhan as compared to other urban areas, but depressive symptoms showed no such difference The direct positive predictive value for depressive and anxiety symptoms was associated with grade level, gender, infection of a relative, and online study whereas location and sibling status have indirect predictive value.	Chi-square analysis for location and mental health T-test for location and different rearing styles Path analysis for demographic variables such as study grade level, location of living residence, gender, sibling status, pandemic-related information (e.g., relatives who participated in COVID-related work, relatives who were suffering from COVID-19), parental rearing styles, and emotional well-being of adolescents (anxiety and depression)

Contd...

Table 2: Contd...

	Study Title/First Author	Highlights about results of various studies	The statistical technique used for analysis
13	Fitzpatrick O. *et al*.[22] 2020 USA	The sample consisted of participants with different ethnicity and regions (American Indian=2%; Asian=15%; Black or African-American=7%; multiracial=8%; White=72%; Hispanic or Latino=12%) Care-giver reported symptoms of their children Symptoms were positively correlated with the number of children at home.	Linear regression was used for the analysis of quantitative data and thematic analysis for qualitative data analysis.
14	Kılınçel Ş *et al*.[23] 2020 Turkey	State anxiety was related to former psychiatric referral, Having a COVID positive patient in the family or neighborhood, and The most common means for obtaining COVID-related information.	Descriptive statistics
15	Pigaiani *et al*.[24] Italy 2020	Factors responsible for anxiety and change in subjective well-being were familial issues, female gender, and adaptive coping styles	Descriptive statistics
16	Sama *et al*.[25] 2020. India	Predictors for depression and anxiety were the use of gadgets, sleep, weight gain 76% of the children in the study reported a persistent urge to go out to play and socialize with friends.	Descriptive statistics Pearson correlation for finding an association between predictors and the development of depression and anxiety
17	Chen *et al*.[26] China 2021	Two surveys were done; 1st Feb 2020 and 2nd April 2020 There was a rise in depression and anxiety during the 2nd survey. Feb: depression=36.6% (95% CI: 35.6–37.6%) & anxiety 19% (95% CI: 18.2–19.8%). April: anxiety=57.0% (95% CI: 55.4–58.6%) and Depression=36.7% (95% CI: 35.2–38.2%) Predictors for depression and anxiety were female gender, being a student in senior secondary grade, concern about entering a higher grade in school Protective factors were sleep >/=6 hrs/d and exercise of>=30 min/day	Descriptive statistics Multivariable analysis for findings out predictors for depression and anxiety
18	Liu *et al*.[27] China 2020	Positive predictors for depression and anxiety were suicidal ideation, familial quarrels, problem in learning during online classes, urban residence, and children & adolescents not living with parents had higher chances of developing depression and anxiety after lockdown. Female gender was correlated with anxiety	Descriptive statistics Univariate logistic regression
19	Cao *et al*.[28] China 2021.	Two groups (Single child v/s children with siblings) were compared for depression anxiety Depression: Single child=35.2% Non-Single child=38.8% Anxiety: Single child=20.5% Non-Single child=24.7%	Multivariate analysis of variance (MANOVA) was used for finding differences in resilience, PHQ-9, GAD, and 5 subscales of the Childhood Trauma Questionnaire (CTQ). Binary logistic regression to find a relation between depression and anxiety with only child status
20	Hou *et al*.[29] 2020 China	Female gender and poor academic record were predictors of depression and anxiety	Multivariate analysis
21	Xie *et al*.[30] 2020 China	Low worry about COVID-19 and High optimism about the pandemic predicted a low risk of developing depression.	Generalized linear regression for a continuous variable Logistic regression for a binary variable
22	Qi H. *et al*.[32] 2020. China	Predictors causing anxiety were female gender, sleep<6 hr/day, being a student of senior secondary grade, concern about graduation, more homework in school Negative predictors (protective against anxiety) were exercise between 30 hr/day-60 min/day, and sleep>8 hr/day	Multiple logistic regression

Positive predictors: Increased anxiety and depression. Negative predictors: Decreases anxiety and depression

the prevalence of depression and anxiety has drastically increased.[33-38]

The rise in the prevalence of depression and anxiety is multifactorial. Children and adolescents during quarantine or lockdown are experiencing isolation from their friends, teachers, community activities, and extended family. Duration of the quarantine period, stress, monotonous life, lack of infection, and stigma increases the negative impact on psychological health. They are more likely to have a negative psychological impact than the adult population. In young children, the anxiety was mainly attributable to the fear of getting ill either for themselves or their family members while the older children manifested anxiety by repeatedly inquiring about COVID-19. In another study on school and college-going students, it was found that home

Table 3: Moderator Analysis for Depression

Moderator/ Constant Predictor	No of studies	Pooled Prevalence of Depression	Regression analysis (*P*)
1 Region of the published study	South Asia-14 Middle East-1 North America- 1 Europe- 1	27% (19%-38%) Only single study Only single study Only single study	Adjusted R^2 = -0.015 standardized coefficient beta (b) = 0.23 (*P*=0.391)
2 Age	8	26% (17%-39%)	Adjusted R^2=0.622 standardized coefficient beta (b) = 0.822 (*P*=0.012)
3 Month/ Time of the Publication	16	26% (19%-34%)	Adjusted R^2 = -0.06 standardized coefficient beta (b) = 0.125 (*P*=0.658)
4 Gender (Female)	8		Adjusted R^2=0.274; standardized beta (b) = -0.523 (*P*-.183)

Table 4: Moderator analysis of anxiety

Moderator/ Constant Predictor	No of studies	Pooled Prevalence of Anxiety	Regression analysis (*P*)
1 Region of the published study	South Asia-11 Middle East-1 North America-1 Europe-4	22% (13%-36%) 40% (38%-42%) 24% (22%-26%) 28% (20%-40%)	Adjusted R^2=0.048; b=0.219 (*P*=0.37)
2 Mean age of the participants	11	23% (15%-36%)	Adjusted R^2=0.638; b=0.79 (*P* =0.003)
3 Month/Time of the Publication	18	25% (15%-41%)	Adjusted R^2=0.015; b=0.123 (*P* =0.627)
4 Gender (Female)	10	25% (18%-35%)	Adjusted R^2=0.006; b = -0.412 (*P* value=0.237)

confinement was associated with increased anxiety and stress mainly due to uncertainty regarding their socialization and physical activities with their peers.[39,40]

As per a rapid systematic review by Loades *et al*., children and adolescents are more likely to experience depression and anxiety during isolation and if isolation persists then these symptoms may also advance in severity. Loneliness has been described as a painful emotional experience of a discrepancy between actual and desired social contact and has been linked with increased anxiety in children adolescent age group. About one-third of adolescents reported loneliness due to social isolation and quarantine.[41,42]

The impact of school closure on mental health can not be missed. Schools in India have been closed since March, although the central government has permitted the reopening of schools in mid-October. However, the decision regarding the manner and timing in which schools are to be open has been left to the discretion of the state government. Sudden school closures have led learning to be shifted from the classroom to online platforms. This sudden transition has created a state of confusion among teachers about their roles. In a country like India, there are several roadblocks including internet connectivity, as reported by an NSO survey that about 3/4th of students in India did not have internet access. There are other logistics problems as well like it is very difficult to teach maths online and not all teachers are tech-savvy. The student's focus is also an issue that is being reported by the teachers. A study found that older adolescents and youth are anxious and stressed out regarding the cancellation of their examinations and academic events as it has left them uncertain regarding their future.[43,44]

Children in nuclear families with both parents working especially in the healthcare sector are facing much more difficulties because their children remain unattended at home and this can lead to risky behaviour including substance abuse. Confusion and uncertainty regarding examination dates and the reopening of school can lead to stress and anxiety in students. The resulting interruption increases already existing discrepancies within the education system but also in other aspects of their lives.[45,46]

In a survey by Young Minds in children and adolescents, 58% of participants had a positive effect after meeting their classmates in school, while 30% reported a negative effect and 12% had no effect. Following a routine of going to school gives a structure in life and it had a positive effect on 47% of participants, while 30% reported a negative effect and 19% were neutral about the situation. Similarly, students reported a positive effect after seeing their teachers and doing extracurricular activities. The possible reason could be that students may feel productive after going to school.

Now let us consider the other side of the coin as revealed by this survey; after the opening of schools, some participants reported that travelling to school (36%) and social distancing (51%) measures had a negative effect on them. These students reported that going to school after a long hiatus was an overwhelming experience and their stress and anxiety were mostly related to home assignments given by the school. Also, some students expressed that their school should give less home assignments as they will require some time for adjustment.[47,48]

As shown in Tables 2-4, we found that the female gender and grade level of the study subjects were the two prime risk factors that were consistently reported across all the studies, although female gender was statistically insignificant. Other factors such use of excessive use of the internet, concern about graduation, and concern about COVID-19 infection were also reported. Exercise and adequate sleep were protective against depression and anxiety.

One particular study by Kılınçel *et al*. focussed on "State anxiety" which is defined as a momentary reaction to adverse events with arousal in the sympathetic nervous system, while "trait anxiety" is more of a stable personality trait. It is associated with psychopathology and constant arousal of the sympathetic nervous system. Spielberg's considered both trait and state anxiety as one-dimensional while other authors considered it a multidimensional construct. They found state anxiety was found to increase by 2.41 times in the group that was using mostly television as a source of information about COVID. State anxiety increased by 4.39-fold in subjects having a prior psychiatric referral and by 3.81-fold having a COVID positive patient in the family or surroundings.[24,49]

In one study, it was found that young children between the age of 3 and 6 years are more likely to be anxious than older children between the age of 6 and 18 years. Although in our systematic review, we found age to be directly proportional with psychiatric comorbidity. In young children, the anxiety was mainly attributable to the fear of getting ill either for themselves or their family members, while the older children manifested anxiety by repeatedly inquiring about COVID-19. In another study on school-going and college-going students, it was found that home confinement was associated with increased anxiety and stress mainly due to uncertainty regarding their socialization and physical activities with their peers.[40]

It has been observed that economic recession is associated with a rise in familial conflicts. Similarly, COVID-19 has affected the economy worldwide, many countries have recorded a decline in their GDP suggestive of a shrinking economy. Financial instability can lead to stress and consequent marital conflicts which can further escalate into domestic violence. Most of the parents are now working from home in a confined space and they can easily displace their anger and frustration related to their work onto their family members including children in addition, the possibility of escape from a conflicting situation is also limited in the current situation which further increases their exposure to an abusive family member. Many studies have significantly revealed that an increase in domestic violence is related to a rise in mental health adversity in children and can cause long-term consequences.[50,51]

The sudden arrival of new pathogenic agents has left many people psychologically vulnerable across the globe without a corresponding increase in their coping or resilience.

Various strategies have been advised to cope up by increasing resilience which includes simple tasks like helping other families, giving financial aid to persons in need, and giving encouragement to people who feel down and out. Notably, a minuscule thing like a general message of hope given by healthcare personnel and scientists has been found to be helpful in increasing individual resilience.

Higher social support is associated with less chances of developing psychological distress and it is especially required in the communities in pandemic areas.[52-55]

Limitations

The limitations of this meta-analysis are that most of the included studies were from Asia and particularly China. Also, most of them got published early, when the pandemic had just started. Very few studies were aconducted on psychiatric morbidity in children with special needs since during lockdown these children were unable to access therapies. Most of the studies used online platform to disseminate the self rating forms that were completed by either parents or children themselves. Finally, more longitudinal studies with baseline assessment of depression and anxiety would be appropriate to further instrospect this issue.

CONCLUSIONS

The take away message from this systematic review and meta-analysis is that there is a pandemic of depression and anxiety. There is an urgent need to improve the psychological wellbeing of children and adolescent on an individual level. The intervention should also include individual considerations since our meta-analysis revealed significant heterogeneity in the included studies.

Highlights

1. Pandemic has posed an unrivalled hazard to the mental health of children and adolescents.
2. Relatively high incidence and prevalence of depression and anxiety in the child and adolescent population. The pooled prevalence of depression and anxiety in children and adolescents during COVID-19 has been calculated.
3. Characteristics of the included studies have been summarised in the table.
4. Significant moderators have been explored.

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Conflicts of interest

There are no conflicts of interest.

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ORIGINAL ARTICLE

Exploring the path to pathos "Lived experiences of parents of children with autism spectrum disorder": An interpretative phenomenological analysis

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ABSTRACT

Background: Children with autism spectrum disorder (ASD) require lifetime support by the family, thus posing a great amount of stress among parents. Understanding lived experiences of parents who provide lifelong support will guide in planning effective treatment for children with ASD. In view of this, the study was aimed to depict and understand the lived experiences of parents of children with ASD and making sense of it.
Methods: This interpretative phenomenological analysis research design was carried out on 15 parents of children with ASD coming to the tertiary care referral hospital of eastern zone of India. In-depth interviews were conducted to understand the lived experiences of parents.
Results: The current study identified six themes: major symptom recognition; myths, beliefs, and stigma related to children with ASD; help seeking behavior; coping with challenging experiences; support system; uncertainties, insecurities, and gleam of hope.
Conclusion: Lived experiences were found to be predominantly difficult for most of the parents of children with ASD, and inadequate services pose a major challenge to them**.** The findings highlight the need for involving the parents in the treatment programs as early as possible or extending appropriate support to the family.

Key words: Autism spectrum disorder, in-depth interviews, interpretative phenomenological analysis, lived experience, parents

INTRODUCTION

Autism spectrum disorder (ASD) is a neurodevelopmental illness of children associated with impairment in social and communicative skills with restricted repetitive pattern of activities. An estimated prevalence of ASD is at least 1% in high-income countries,[1] 1.4% in South Asia,[2] and 1 in 500 in India.[3]

"Lived experiences" are the first-hand experiences of the primary caregivers of the cases which influence their perception, knowledge, and response to these experiences. Exploration of these lived experiences helps us to understand how people live through and respond to these experiences.

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The family is the primary caregiver for a child with ASD. A child with ASD requires lifetime support by the family, thus posing a great amount of stress among parents. Parenting a child with ASD is challenging. Studies have shown that parenting a child with ASD is more stressful than parenting a child with a developmental delay and other neurodevelopmental disorders.[4] The severity of symptoms of autism, parents' inability to regulate self and societal stigma, and lack of social support are some of the factors that contribute to the increase in stress among parents.[5-7] Parents face stigma, social isolation, and rejection because of which they become withdrawn.[8] They don't interact much with other family members or friends because of the stigma attached with autism. Also, the care needed by an autistic child leads to significant changes in the lifestyle of parents. They prioritize the needs of their autistic child because of which they engage less in social activities or avoid going to the family functions.[9] Safe *et al*.,[10] 2012 in their study found that the mothers experienced stress and challenges in dealing with the child and accepting the child for who he is. Parents relied more on the extended family for support[11] and religious practices.[12] Parents are also concerned about the future of child in their absence.[13,14]

Caring a child with autism is difficult, and so it is important to study these experiences that the carers have, so as to better understand their stress. Cultural differences exist in how parents understand and accept the problems of the child. In India, children with ASD are diagnosed 6–10 months later in comparison to that in the West.[15] This is because of the cultural beliefs present in the community. Understanding local perspectives helps in strengthening community-based care and improving outcomes.[16] It is also important because it has been seen from studies of different countries that in case of autism, people do turn to alternative forms of treatment for ASD.[9,17,18] There is also a huge treatment gap in terms of very few mental health professionals and specialized centers to provide help to such children.

In India, very few studies have been done to understand the indigenous perspectives. Till date as per review of literature, very few studies on lived experience with qualitative study design have been attempted with specific objectives from India. Most of the other studies from India have tried to assess one aspect like challenges, coping strategies unmet needs of children with ASD,[19] parental belief and care practices for children with ASD,[20] initial symptom recognition.[15] A study by Desai *et al*.,[13] 2012 was on parental experiences in school-going children and adolescents diagnosed with ASD. Another study was a narrative review of historical journey of autism in India.[21] The studies from India have been mostly done on parents from metropolitan cities like Delhi, Chennai, Bangalore, Kolkata (Daley, 2004),[15] or from Goa (Desai *et al.*, 2012, Divan *et al.*, 2012).[13,19] The data have not been taken from rural India which accounts major part of our country. Furthermore, state like Bihar, located in the eastern part of India, which has lowest human development index in terms of healthy life and decent standard of living, it is utmost important to understand the lived experiences of parents of these children. Therefore, the present study aimed to depict and understand the lived experiences of parents of children with ASD and making sense of it.

METHODOLOGY

Participants and setting

It was an interpretative phenomenological analysis (IPA) research design. Sampling done was purposive. Study was conducted between September 2019 and March 2020. Institute ethics committee approval was taken before inclusion of the subjects in the study. The sample for the present study consisted of 28 parents of 15 children in which one mother and one father were interviewed alone, and for other children, both parents were interviewed together. The standards for phenomenological research were taken in consideration for the study.[22,23] Participants who biological parents were having a child already diagnosed with autism spectrum disorder coming to the tertiary care referral hospital in the state of Bihar which is located in the eastern part of India were included. Diagnosis was given by the treating psychiatrist using standard DSM-5 criteria.[24] Hindi, English, Maithili, and Bhojpuri were the most common spoken languages by the parents. No strict inclusion or exclusion criteria were kept, but the children with serious intellectual or physical disability at the time of presentation were excluded. The parents willing to give informed consent were recruited in the study. The patient's socio-demographic details along with clinical variables were recorded with semi-structured pro forma.

Instrument

An in-depth interview guide was based on the previous study by Desai *et al*.,[13] 2012 for the interview. The interview was kept open-ended if some new theme appeared during the interview for more in-depth exploration. The main points which were explored during the interview were: birth and early experiences, when did the parents first notice behavioral differences, help seeking behavior, treatment provided, challenges, and coping strategies used by the parents.

Procedure

All the in-depth interviews were conducted by two researchers in which one acted as a lead interviewer (psychiatrist) and the other as a note taker (clinical psychologist). The interview was video recorded after taking due permission from the parents. Only one mother of a female child refused to give permission for audio or video recording so her interview was handwritten by the interviewer and note taker. Each interview was conducted in the language in which the parents were comfortable. The interviews took around

1–2 hrs in which one or both the parents were interviewed. Data were collected until saturation was achieved.

Data analysis

interpretative phenomenological analysis (IPA) was used to analyze the data. The video-recorded interview was transcribed by the authors after listening again and again. Participants were given a code so as to avoid any bias related to the person giving a particular opinion. The transcription was then translated into English language.

Two researchers independently carried out the first two stages which include transcription and coding. The transcribed data for each interview were read and reread to gain familiarity with the raw data. During this process of familiarization, the emerging codes were highlighted. These emerging codes were compared with each other to identify themes. The categories were written on the left side and common themes that came out were written on the right side. This was done many times so that no theme was left out. It was cross-checked again by the other author. Then, similarities between categories were looked for, and emerging themes were noted (focused coding). Finally, after observing the various themes and refining them, an overall theoretical sense was made (theoretical coding). Memos were written at the end of each interview wherein the researcher summarized the information along with the key insights gained. A coding index was developed to organize the emerging codes into superordinate themes, subordinate themes, and subthemes. The themes were analyzed along with the supporting data (quotes) to fit together in a meaningful way.

The analysis of the data was done by the methods of phenomenological psychology, which were used to elucidate the essential meanings of the parents' lived experiences of their child. The presentation in this report includes both phenomenological findings (i.e., the essential structure and constituent meanings of parents' experiences) and the empirical findings (accounts of related factual trends evident in the data). Analytic rigor was ensured via internal reviews by expert members (consisted of other two independent psychiatrist) of the research team.

RESULTS

Fifteen ASD children participated in the study, and their parents were interviewed. Most of the children were males, aged around the age of 2.8–6.1 years, and the mean age was 4.5 years.

Most of the participants were from urban background, middle socioeconomic status, with well-educated parents. They were mostly Hindu except for one child who belonged to a Muslim family. One of the children had comorbid cerebral palsy (CP) but was a skillfully trained child while seven reported to have comorbid hyperactivity and three had seizure disorder. The socio-demographic and clinical variables are represented in Table 1.

Tables 2 and 3 describe interpretative phenomenological analysis which had superordinate, subordinate, and subthemes. Table 3 also mentions the quotes of the parents.

Table 1: Socio-demographic and clinical characteristics of sample population (*n*=15)

Variables	M (SD)/*n* (%)
Age of child (in years):	
Mean±SD	4.5±1.72
Gender:	
Males	13 (86.67%)
Females	2 (13.33%)
Religion:	
Hindu	14 (93.33%)
Muslim	1 (6.67%)
Age of mother at the time of pregnancy	
Mean±SD	26±3.39
Occupation of mother	
Housewife	8 (53.33%)
Working	7 (46.67%)
Residence:	
Rural	6 (40%)
Urban	9 (60%)
Family type	
Nuclear	7 (46.67%)
Joint	8 (53.33%)
No. Of siblings	
1	6 (40%)
>1	9 (60%)
Birth order	
1st	10 (66.67%)
2nd	3 (20%)
3rd	2 (13.33%)
Prenatal and perinatal events	
Complication during pregnancy	
Decrease iron level (n=1)	Decrease iron level (*n*=1)
Hypothyroidism (n=1)	Hypothyroidism (*n*=1),
Diabetes mellitus (n=1)	Diabetes mellitus (*n*=1)
Jaundice (n=1)	Jaundice (*n*=1)
Duration of pregnancy	preterm (*n*=2)
	Cesarean (*n*=8)
Type of delivery	Breech delivery (*n*=1)
	<2.5 kg/low birth weight (*n*=4)
Weight	Convulsions (*n*=3)
	Phototherapy (*n*=4)
Postnatal complications in child	Kept in incubator (*n*=3)
	Oxygenation (*n*=1)
Precious pregnancy	Intrauterine insemination (*n*=1)
Comorbid diagnosis in children	hyperactivity (*n*=7)
	Seizure (*n*=3)
	CP (*n*=1)
Age at first treatment contact	1-2 (*n*=1)
	2-3 (*n*=5)
	3-4 (*n*=4)
	4-6 (*n*=6)

Table 2: Interpretative phenomenological analysis showing various themes of the lived experiences of the parents (*n*=15)

Superordinate themes	Subordinate themes	Subthemes
Major symptom recognition	Poor social interaction and communication (*n*=15)	
	Repetitive behavior/interest/activities/sensory issues (*n*=13)	
	Speech and language delay (*n*=9)	
	Regression of speech and language (*n*=6)	
	Tantrums (*n*=4)	
	Savant ability	Singing (*n*=2)
Myths, beliefs, and stigma	Family and parental belief regarding speech delay	Child will speak late (*n*=4)
		Grandparents blaming parents for working (*n*=2)
		Nuclear family (*n*=2)
		Child had not lived with other kids (*n*=2)
		Child resemble with shy parent (*n*=2)
		Late talker in family
		Parent (*n*=1)
		Relative (*n*=1)
		Child has no problem (*n*=1)
		Child will get better with medicines (*n*=1)
		Child can hear so will speak (*n*=1)
		Black magic/witchcraft (*n*=1)
	Marginalization/discrimination child	Use of harsh local words (*n*=5)
		Comparison with other kids in family (*n*=3)
		Neglect or rejection from paternal family (*n*=2)
	Affiliate stigma (Impact of autistic kid on parents' lifestyle)	Parents were not able to go or spend time in the neighborhood or social gatherings/relatives, confined at home because of child (*n*=6)
		Loss of job or decreased number of working hour (*n*=3)
		No leisure time (cannot watch movies etc) (*n*=1)
	Negative expressed emotion	Negative comments (*n*=5)
Help seeking behavior	Professionals	Pediatrician (*n*=11)
		Homeopathy doctor (*n*=3)
		Psychiatrist (*n*=2)
		Neurologist (*n*=2)
		ENT (*n*=1)
		Neurosurgeon (*n*=1)
		Ayurvedic doctor (*n*=1)
		Stem cell therapist (*n*=1)
	Reason for visit to other higher mental health centers	Second opinion (*n*=2)
		Peace of mind (*n*=1)
	Alternative way of treatment	Temple/mosque/ojha/pandit/tantrik (*n*=10)
Challenges and coping	Challenges in treatment seeking	Long distance from therapy centre (*n*=7)
		Difficulty in finding services (*n*=7)
		Untrained professional (*n*=3)
		Financial constraint (*n*=2)
		No medicine available (*n*=1)
	Lack of awareness among medical fraternity	Child has no problem, and he will be able to speak after sometime (*n*=4)
		misdiagnosed as ADHD (*n*=4)
		Advised for neuroimaging and DNA test without much exact therapeutic advice (*n*=4)
		Keep the child with other children (*n*=3)
		Provision of alternative medicine (Mentate syrup of Himalaya) (*n*=3)
		Child is very young, talk to him (*n*=1)
	Attitude of professionals working with autism as per parents	Therapists are making money without much professional competence
	Parents' reaction related to diagnosis	Emotional overwhelming/emptiness/nervousness/numbness (*n*=5)
		not able to sleep (*n*=1)
	Negative coping	Felt sad or tensed (*n*=9)
		Felt suffocated (*n*=4)
		Negative thought (*n*=3)
		Protective parenting or not allowing to mingle with other kids (*n*=1)
		Shouting at spouse or other members (*n*=3)
		Beating the child (*n*=2)
		Felt irritated (*n*=2)

Contd...

Table 2: Contd...

Superordinate themes	Subordinate themes	Subthemes
		Felt guilty (*n*=1)
		Self-blame (*n*=1)
		Denial (*n*=1)
	Positive coping	Hopeful (*n*=9)
		Positive parenting (*n*=3)
		Searched the internet/read about it (*n*=3)
		Emotional catharsis (cry)(*n*=2)
		Talk to parents/sibling/colleague (*n*=2)
		Pray (*n*=2)
		Feeling of happiness or cherishing happier moments when milestone in step manner achieved (when the child would start to speak spontaneously, follows instructions, emotionally involve with parents) (*n*=2)
		Teaches child (*n*=1)
		Think about positivity (*n*=1)
Support system	Individuals in the support system (Presence vs absence)	
	Paternal family	present (*n*=12)
		absent (*n*=1)
	Maternal side	present (*n*=12)
		absent (*n*=1)
	Neighbors	present (*n*=1)
		absent (*n*=1)
	office staff	present (*n*=3)
Uncertainties and gleam of hope	Uncertainties (*n*=1)	
	Gleam of hope (*n*=1)	

Superordinate theme 1: Major symptom recognition

The majority of the parents were aware that their children with ASD were different from others; however, later they knew specifically that it was due to ASD. They noticed the presence of speech and communication difficulties, which are the hallmark of ASD, along with the presence of behavioral issues like repetitive behavior and tantrums. Two children also had savant ability of singing.

Superordinate theme 2: Myths, beliefs, and stigma

Stigma as well as myths and beliefs related to children with ASD have to be dealt with by parents on an everyday basis as the critical statements are not just directed toward the child with ASD, but also toward the parents. Many parents reported experiencing social alienation especially due to lack of awareness in society and the tendency to internalize stigma. Four families reported that they had the belief that their child will become normal with time and would start interacting late just like one of the distant relative's child in the family. Two parents reported their family blaming them for working, while the other two tried to normalize by saying that child is shy.

Superordinate theme 3: Help seeking behavior

In the current study, diagnoses were elicited from multiple professionals, including neurologist, psychologists, psychiatrists, and pediatricians. Good number of parents also opted for alternative ways of treatment in the form of going to faith healers, tantriks, ojhas, etc. This indicates a fairly high level of help-seeking behavior from both health professionals and faith healers.

Superordinate theme 4: Challenges and coping

The family members reported challenges at temporal sequence of life situations. Challenges at the level of treatment seeking and dealing with lack of awareness among the medical fraternity despite clear red flag signs of ASD lead to late diagnosis and exhaustion among the parents. Financial constraints were reported by two of the families, while most of them found difficulty in finding services in this region of the country. The untrained professionals in the current scenario were also acknowledged by three of the family members. One of the major challenges is that no medicine is available for ASD per se. This was addressed as a concern by the family members. Most of the parents had negative coping, viz. beating the child, feeling irritated, self-blame, feeling guilt, etc., in our study, while some had positive coping, viz. teaching the child, praying, thinking about positive things, etc.

Superordinate theme 5: Support system

This study spoke about the parents facing inadequate support especially from the paternal side of the family.

Superordinate theme 6: Uncertainties and gleam of hope

One of the parents discussed elaborately about the uncertainties regarding his child future. However, gleam of

Table 3: Excerpts from interviews representing subordinate themes and subthemes

Superordinate theme	Subordinate theme & subthemes	Quote
Major symptom recognition	Poor social interaction and communication	*He would get excited to see other children. He would push them and he would not be able to understand how to react. He wanted to play with other children, but he would not be able to understand how to play with them (9).*
	Repetitive behavior/interest/ activities/sensory issues	*He would keep on going round and round in one room (2). He would barely respond if we would be around (3). He would spin things and would not sit at one place. He would keep on moving his empty hand in a way as if holding something (4). She would always keep toothbrush with her even while sleeping. She Does not chew but swallows' roti, rice (5). He would run away from the whistle of the cooker and avoid rotating fan (6). He would stack toy cars, containers, shoes, cream, shampoo bottles (13).*
	Speech and language delay Regression of speech and language	*He would sometimes speak with joy "papa" when his father would come from outside, but then wouldn't speak further (4). He had become silent after speaking a word or two (like "maa, baba") few months back (6).*
	Savant ability (Singing)	*If once he hears a song, he will be able to remember it later. He would sing songs that we have never heard before (7).*
Myths, beliefs, and stigma	Family and parental belief regarding speech delay Child will speak late Grandparents blaming parents for working Child had not stayed with other kids Child resemblance with shy parent Late talker in the family Child has no problem Child will get better with medicines	*Everyone said in our family that there is a specific time for speech to occur in different child. He will be speaking with time. His father's first cousin also started speaking late. Uncle also had the same problem (1). My father-in-law said that both of us are busy in earning money and are not paying attention on our child (7). Since she has never played with other children, that is why she has not learnt how to play group games (5). As I am a quiet, shy person, that maybe a reason he is not speaking and interacting in front of relatives or guest visiting us (14). My sister said that there is no problem with him. He can speak every word. Gradually with time, he will start speaking spontaneously (2). If we give him some medications, then he will become fine (12).*
	Marginalization/discrimination of child Use of harsh local words Neglect or rejection from paternal family	*He had been called by local harsh words like "pagla hai, albataha, lahera hai" (1). My child had been called upon by derogatory words like "gong (2) loth, vaheer (8) gadha, bewakoof, bolta nahi hai (13)", as if he is mad or moron (15). If he would go and touch someone or some personal belonging of her, she (grandmother) would kick him away like puppy. He would come and tell this to me in gestures and cry (1).*
	Affiliate stigma (Impact of autistic kid on parents' lifestyle) Avoidance of social gatherings and less involvement with office colleagues or relatives Loss of job or decreased number of working hour	*We avoid going to neighbors since he was born. we had a fear that someone will comment about our child (6). I don't not talk about our child with other colleagues because I know that others don't know about autism and make an impression about my child. The sad part is, impression others make will not change even when my child improves with treatment (14). Everything was going well. If this child was healthy then we would have been able to work more, she (mother) had to leave her job (2).*
	Negative expressed emotion	*No one should have child like I have. All the time I feel suffocated because of him (1).*
Help seeking behavior	Alternative way of treatment Temple/Mosque/Ojha/Pandit/Tantrik	*I went to Ajmer shareef, Nizamuddin where I performed holy rituals and prayed for my son (1).* *I went to balajee and prayed for my son. I will go to vaishno devi for pooja when my child will be able to speak (2). We consulted to all from child specialist to ojha to hakeem (8).*
Challenges and coping	Challenges in treatment seeking Difficulty in finding services Untrained professional	*Therapeutic services are very much scarce, confined to urban area only and quality of services offered are not up to mark. Very little dedicated therapy centre, you will find here in our state. Scenario is very much looming here. If your child has autism and you want to get therapy here, then it is very much difficult in our place (7). Our state has a lot of problems in terms of service offered to autistic kids. One Will find many teachers but no one is expert. They are also not concerned with what the child wants, they will teach the activities that they know and not according to the need of the child. Also, very few, only 1-2 specialists who have assistants to perform therapy. These assistants are not qualified much (10).*
	Lack of awareness among medical fraternity Child is very young, talk to him, he will be able to speak, keep the child with other children	*The doctor told us to give him good diet, take care and talk sweetly to him, gradually he will start speaking (1). Keep him close to other children, he will start speaking (3, 13).*

Contd...

Table 3: Contd...

Superordinate theme	Subordinate theme & subthemes	Quote
	Attitude of professionals working with autism as per parents Making money without much professional competence	*Professionals think that there is lot of money in this profession. Some therapist here doing their job with utmost sincerity, but there are some therapists who fool the Guardian (7).*
	Parents' reaction/emotion upon hearing the diagnosis	*Hearing the diagnosis was very much overwhelming for us. My thought process got blocked as if clock had stopped ticking. I was not able to think and process for future action, cursing and blaming to self (3).*
	Negative coping Felt sad or tensed Protective parenting or not allowing child to mingle with other kids Felt guilty Self-blame	*It hurts you when you see the normal kids around are communicating with each other and your child is not been able to play and interact with other kids. If he does not speak, then how will he tell anything, because of this fear he has not been sent anywhere (9). I feel guilty that all of this happened because of my job. I left him for 2 years after which all of this started. If I would have been there for him then things would have been different (3).*
	Positive coping Hopeful Positive parenting Emotional catharsis (tear from eyes) Pray Teaches child Think about positivity	*Of course, I love all my kids but I am more affectionate towards him as he does not speak. If he is in pain, he will only cry. Now I have started to leave things on him sometimes. I give him responsibilities so that he opens up a bit. He would start using his mind and would bring small things from the market. I have not lost hope (1). We worship for him but we know that we have to work harder on this child. We have faith in God. We believe the child will speak (7, 8). We try to calm ourselves, but sometimes automatically we get tears out of our eyes (11).*
Support system	Individuals in the support system (Presence vs absence) Paternal family Maternal side	*She (Grandmother) would care for other children of our family but when it comes to my child, she would start making excuses that she has now become old and she is tired of taking care of children (1). His Baba (Grandfather) had advised us to consult the doctor as our child was not reciprocating his feeling towards him. His baba said that he should be able to understand as per his age certain etiquette, but he is unable to do. So, definitely he should be shown to doctor once (4). My brother told me about a banner mentioning the place to visit if a child has speech difficulty and certain behaviors which are little weird as per the child age. After that we visited that place (6).*
Uncertainties and gleam of hope	Uncertainties Gleam of hope	*We felt really tensed after hearing the diagnosis of our child. We are really concerned about child future. How will everything be in his future? When we look at other children, we sometimes feel bad (9).* *If he will be able to speak spontaneously & involve with others, then we will have happy moment. If he will be able to do this much, we would be satisfied (12).*

*() = Coding of the parents of ASD

hope was also revealed in which family members reported that if their child will be able to speak spontaneously that would be their happiest moment.

DISCUSSION

The purpose of the study was to understand the lived experiences of parents of children with ASD, which helped in understanding the challenges and unmet needs of carers. Present study also provided us a paradigm for feasibility of developing and implementing a parent or family mediated intervention for these children in our state. Previous literature has called for more in-depth, cultural research on parents' subjective processes.[25] Therefore, we have tried to conduct in-depth interviews to better understand the experiences of parents of children with ASD. We decided to conduct our study in the eastern part of India to obtain the local descriptions for understanding the cultural contexts instead of presupposing the experiences from a culturally distant perspective. It was also important for getting insights into Indian parents' perspectives on ASD.

The current study identified six major themes such as "major symptom recognition," "myths, beliefs and stigma," "help seeking behavior," "challenges and coping with challenging experiences," "support system," and "uncertainties and gleam of hope." Some cultural differences from already published studies using the lived experience paradigm have been highlighted across all the major themes.

Cornering the differently abled

Misbelief and stigma was one of the major themes identified in our study. As we have noted the perceived stigma was high as in one of our parents who did not allow for the videography consent of her daughter with ASD. This itself signifies the gravity of the stigma of ASD that too in female children in our culture. Some families reported use of local words by the relatives like "albataha," "gong," "loth," "baheer," and "lahera" along with comparison from other family members as well as inadequate support from paternal family. This was also observed in other studies where the author reported the use of intolerant and derogatory terms such as pagal (mad) or jhalla (idiot) for such children. Also,

a generalized belief in our culture described by healthcare professionals was that "there may be a tendency by our rural mass to accept and tolerate some degree of abnormality as normal." Of course, the current sample of our study was centered not only on parents in the rural areas, but those in the urban and suburban areas as well. Due to the different standards for problematic behavior, even after being from suburban and urban areas, the parents in our study noticed changes in the behavior later. This finding was phenomenologically consistent with the adult distress threshold model described by.[26]

Hustling through the adversities

In the current study as well, diagnoses were elicited from multiple professionals, indicating a fairly high level of help-seeking behavior which is corroborated in a study by Daley *et al.* 2004 where the parents reported seeing an average number of 3.5 doctors before receiving a diagnosis.[21,25-27] The pathway of treatment indicated the financial pressures on families due to the long journey to a diagnosis and the need for expensive and oversubscribed intervention sessions. In addition to previous findings, it was observed in our study that the age of first treatment seeking was two years. This was earlier as compared to the previous Indian studies but still later from Western studies. Also, the parents were well aware of their child's behavior, had good observation, and therefore treatment seeking was better than we had expected. This shows that parents are more cautious about the development of their child and are adopting the principles of westernization. Therefore, earlier the detection, earlier the intervention is possible which can be converted into a full-term treatment plan.

Running through the brick wall

It is imperative to understand the barriers in ASD diagnosis that exist at multiple levels of analysis for the refining of the diagnostic process in order to change the landscape of disability within India particularly in our state which already have poor socio-economic indicators. In this regard, the financial implications for the family of a child with autism are significant. Another challenge reported by parents was availability of minimal therapeutic service for ASD.

Another challenge reported by parents was lack of awareness among the medical fraternity despite clear red flag signs of autism which led to late diagnosis of their child and also some false hopes and killed the time and energy of most of the parents. Similar finding was reported in previous study which revealed that many professionals were not able to diagnose ASD in children.[27]

Plethora of emotions

Many parents did report negative experiences like having to deal with children's behaviors, lack of family recreational time, lack of social life, and ultimately avoidance of embarrassment in social life. Lack of any respite and constant exposure to high levels of stress due to the consistent attention required by the child was particularly reported by the mothers in our study.

Emotional experiences reported were similar to grief reactions. Parents experience feelings of anxiety, helplessness, and remain perturbed as part of their lived experiences. A few parents go through shock and anger as they become aware of the diagnosis of their child. Some parents reported that their own needs take a backseat over the child's needs. The current study also found that the parents will minimize their own emotions, normalize the experiences, and focus on the positive experiences as coping mechanisms. This appears to be somewhat similar to the processes of grief resolution in which the parents move from the perception of specific losses (e.g., routines, socio-emotional needs, and the fear of uncertainty) to accepting the life situation and coping with it. Awareness of the condition and a supportive attitude of the family can help the family overcome stigma and negative emotions. The parents in the current study implicitly described mixed feelings of pride in supporting their child, and some regret over not having an adequate social life.

Pillars of strength

In the absence of appropriate formal support available to them, parents appeared ambivalent of skill fully raising their child with ASD. This study explained the parents facing inadequate support especially from the paternal side of the family. This was corroborated in other studies as well as they revealed that mothers, as the prime caregivers, often sacrificed their professional life to take care of their child's needs, while fathers worked long hours to take over the financial responsibilities of the family.[25]

Silver lining

Also, despite their own uncertainties, insecurities, they do have a gleam of hope. In this context, there is a need to strengthen formal support services in the community and to provide positive behavioral support and specialized services to the parents and children with ASD.

An important limitation of our study is small sample. Our study was not a community-based study as it was done in a government run tertiary care referral hospital. Our study exclusively relied on interviews with parents, whereas systematic direct observations of family life were not conducted. Consequently, the current study could not completely reflect the complex everyday experiences of families. Further research needs to focus on objective methods of analysis with larger samples, including parents from all backgrounds.

In conclusion, the lived experiences of parents seemed to be variable. While the lived experiences are predominantly difficult for many parents, some of them also report

transformational experience coinciding with greater understanding of ASD. However, these findings are generalized to parents from middle socio-economic status, who usually have access to mental health resources. More research would be required to understand the experiences of families of children with autism and those from different strata of our society.

Ultimately, the exploration of the journey and experiences of the parents of children with ASD may aid in the early recognition and may serve as a key to future opportunities and solutions to the pathos of both the parents of and the child living with ASD.

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Conflicts of interest
There are no conflicts of interest.

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ORIGINAL ARTICLE

High craving is associated with fewer abstinent days and lesser time to relapse during treatment in severe alcohol use disorder

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ABSTRACT

Background: Craving, an integral aspect of addictive processes, underlies heavy alcohol consumption and alcohol use disorder (AUD). Western studies point out that craving is associated with relapse risks in AUD treatment. The feasibility of assessing and following up with craving dynamicity is not studied in the Indian context.
Aim: We aimed to capture craving and explore its association with relapse in an outpatient facility.
Methods: Among 264 treatment-seeking male participants (mean [SD] age = 36 [6.7] years) with severe AUD, craving was assessed according to the Penn Alcohol Craving Scale (PACS) at treatment initiation and two follow-up visits (median follow-up: 1, 2 weeks). Days to drink and percentage of days abstinent were acquired during the follow-ups (maximum follow-up days = 355). Those lost to follow-up were censored and considered as having relapsed.
Results: High craving was associated with fewer days to drink when considered as a sole predictor ($P = 0.030$). With covariates including medication at treatment initiation, high craving was marginally associated with fewer days to drink ($P = 0.057$). Baseline craving was negatively associated with proximal percentage of days abstinent ($P = 0.015$) and cravings at follow-ups negatively correlated with cross-sectional abstinent days (FU1: $P = 0.009$, FU2: $P = 0.019$). Craving reduced significantly over time ($P < 0.001$), irrespective of the drinking status in follow-ups.
Conclusion: Relapse is a real challenge in AUD. The utility of craving assessment in identifying relapse risk in an outpatient facility helps in identifying an at-risk population for future relapse. Thus better-targeted approaches in treating AUD can be developed.

Key words: Alcohol use disorder, craving, days to drink, Penn Alcohol Craving Scale, relapse

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INTRODUCTION

Relapse in alcohol use disorder (AUD) is a significant deterrent on one's road to recovery. Relapse substantially

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diminishes the impact of management strategies, especially in the treatment-seeking population. Understanding and addressing relapse predictors is of paramount importance in addressing this risk. In addition to the compelling evidence of the association of craving with relapse to drinking,[1–4] craving reduction can explain the treatment effects in AUD.[5] Moreover, assessment of craving offers a potential opportunity to intervene through anti-craving medications and counseling for craving management.

A recent review on relapse in AUD highlighted craving and other factors like the severity of dependence, comorbidities of psychiatric and other substance use disorders, and negative emotions as potential associations with alcohol relapse.[6] Interestingly, all the studies assessing craving in this review are from Western populations. We wondered whether craving assessment in the Indian population is feasible and has predictive utility in drinking outcomes. Even among treatment-seekers, alarmingly high relapse rates form a solid rationale for assessing craving as a potential factor for relapse prevention.[7–9]

In the Indian context, studies ranging in sample sizes (23–112) assessed the Penn Alcohol Craving Scale to capture craving.[10–12] Although all of these studies aimed to identify relapse, none followed up with the subjects for a longer time to assess its dynamic nature: whether craving changed over time and, most importantly, whether craving predicted relapse in subsequent visits. There are varying views among clinical practitioners treating alcohol use disorder regarding the clinical usefulness of craving assessments. This is because of mixed evidence on whether or not a strong association exists between craving and alcohol use.[6] The initial hesitation to discuss craving among patients seeking care for alcohol use disorder in our setting adds further complexity to this dimension. There is no clarity on whether craving in the severe AUD population can be an objective treatment outcome. While consumption measures are considered outcome measures in all the treatment facilities, we see a lacuna in using craving assessments in this context. Also, in order to have a more comprehensive understanding of craving, a recent review suggested assessing temporal fluctuations, in addition to frequency and intensity.[6]

To explore the feasibility of craving assessments before treatment initiation and subsequent follow-ups, we conducted a study among participants with severe AUD-seeking treatment at a tertiary treatment facility. Here, we show that high craving is associated with fewer abstinent days and lesser time to relapse during AUD treatment; most importantly, craving responds to treatment. Our findings demonstrate the utility of craving assessment in identifying relapse risk in an outpatient facility in the treatment-seeking AUD population. This will point us to identify an at-risk population for future relapse in AUD, and make better-targeted treatment approaches possible.

MATERIAL AND METHODS

Participants characteristics and craving data

This study was conducted at the outpatient de-addiction facility of a tertiary care center. This study was part of a PhD thesis on exploring epigenetic correlates of chronic alcohol consumption and relapse. Thus, the participants were restricted to males to avoid sex-dependent effects on the epigenome.

Consecutive participants seeking treatment for AUD at the outpatient department were invited to participate in the study. The institutional ethics committee approved the study, and written informed consent was obtained from all participants willing to participate. Any comorbid substance use other than nicotine was excluded.

Diagnosis of alcohol use disorder was based on the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) criteria for AUD.[13] All subjects had severe AUD as per the DSM-5 and endorsed craving criterion. Two medical professionals, including a psychiatrist, assessed all the participants. At this first contact, demographic details and alcohol consumption–related measures were acquired. The latter included a quantity-frequency assessment using the National Institute on Alcohol Abuse and Alcoholism - Quantity Frequency (NIAAA-QF) questionnaire,[14] dependence severity using the Severity of Alcohol Dependence Questionnaire (SADQ),[15] age at first alcohol use, and age of dependence. We calculated last month's alcohol consumption to obtain a single measure of recent alcohol consumption. We achieved this from the typical drink/day and the number of drink days in a week (drinks/day $\times$ drink days in a week $\times$ 10) collected from the NIAAA-QF questionnaire. We calculated the dependence duration by subtracting the age of dependence from the age at the time of presentation. Pack-years (pack used per day $\times$ years of smoking) were collected for smoking history.

Penn Alcohol Craving Scale (PACS)

Craving was assessed according to the PACS.[16] PACS has five items that capture the intensity of craving for alcohol from the frequency of thoughts on drinking, strength of craving, length of time spent in craving, difficulty in resisting alcohol when available, and subjective overall craving intensity in the past week. All of our participants spoke Tamil or Kannada language. A translated version of the questionnaire was used to capture craving. The same investigator administered craving assessments for all the participants.

Treatment

The participants were treated as usual during the study period. Treatment included a detoxification regimen (with benzodiazepines) or anti-craving medications (baclofen, naltrexone, acamprosate) as appropriate. The participants all sought treatment in the outpatient clinic and were given a date for a follow-up visit.

Follow-up details

During follow-up visits, treatment outcome was assessed by the participants' abstinence/relapse/lapse status. We defined abstinence as complete alcohol-free days during the follow-up period. If the participant had relapsed or lapsed to alcohol, alcohol consumption in the interim period was recorded by timeline followback (TLFB) method.[17] From this, we calculated the percentage of abstinent days by dividing abstinent days by follow-up days (i.e., abstinent days/follow-up days × 100). The participants were reassessed for PACS craving and prescribed anti-craving as appropriate.

Missing data

Only participants for whom baseline total PACS scores were available were included in the final sample ($N = 264$). Those lost to follow-up in any subsequent visits were censored at the last visit. Those who remained abstinent through the study duration were also censored as the outcome (drinking) did not occur.[18] Only in an event of relapse, the time to relapse is noted as the time to drink.

The schema of the study is provided in Figure 1.

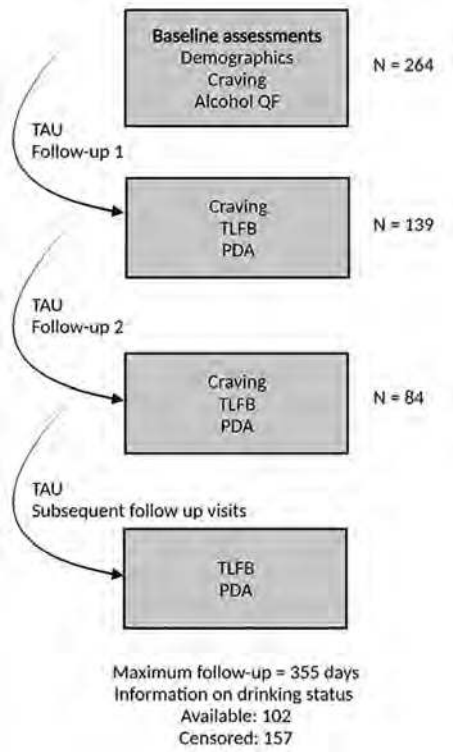

Figure 1: Schema of the study. *Note.* This flowchart illustrates the study flow with the collected relevant data. A total of 264 participants were assessed at baseline; after the maximum follow-up of 355 days, information on drinking status was available for 102 subjects, and 157 subjects were censored. TAU = Treatment-as-usual corresponds to detoxification and anti-craving medications; QF = Quantity-Frequency; TLFB = Timeline follow back; PDA = Percentage of days abstinent

Statistical analysis

Correlations among demographics and alcohol-related measures, craving at initial presentation, and follow-up measures were assessed using Spearman or Pearson correlation, as appropriate. Strength of correlations were based on the guidelines provided by Cohen *et al*.[19]

We ran a Cox regression survival analysis with time to drink as the dependent variable to examine whether baseline craving predicted time to drink. We dichotomized craving as high and low based on the recent study identifying ≥15 total PACS scores as an indicator of clinically significant alcohol craving (PACS total score ≥15 was considered to have high craving).[18] Days elapsed from an outpatient visit to the day of resumption of drinking were used as an indicator for days to drink. We hypothesized that high-craving scorers would have fewer days to drink. To control for other confounders that could potentially affect the time to drink, we performed a multivariate Cox regression analysis with age at presentation, current alcohol consumption over the past month, treatment provided, and dependence severity from the SADQ. We dichotomized all the continuous variables based on median splits and treated them as binary variables (median age = 36 years, median SADQ = 27.5, median past month alcohol consumption = 336 grams, median pack-years = 20).

We assessed the reduction in craving scores captured over time to understand whether craving responded to treatment. For this, PACS scores at initial presentation and follow-up visits (1 and 2) were analyzed using repeated measures ANOVA. We also conducted a two-way repeated measures ANOVA for abstainers or those who had relapsed as available from the follow-up treatment outcome. For this, we held craving scores as a dependent variable and time and abstinence status (abstinent/relapsed) as independent variables. No appreciable difference in repeated craving measures was observed when abstainers and those who relapsed at each follow-up were considered.

All analyses were conducted in RStudio.[19] In all the statistical tests, a P value ≤ 0.05 was considered significant.

RESULTS

With a larger aim to assess craving construct in outpatient facilities amongst the treatment-seeking population in severe AUD, we recruited 264 participants with a mean age of 36 years at initial presentation. By assessing the craving at initial presentation and subsequent follow-ups, we aimed to explore the predictive utility of the craving construct in predicting the percentage of days abstinent and the time to relapse.

Demographic data

All the participants reported some craving at initial presentation (range of total PACS scores in our data at initial presentation was 6–28). Detailed baseline information of

the participants is available in Table 1. All the participants endorsed the craving criterion in the DSM-5 for AUD diagnosis, and all belonged to the severe AUD spectrum of the DSM-5. The majority belonged to the Hindu religion (98%), were married (68%), and had been dependent on alcohol for an average duration of nine years. The vast majority (95%) consumed alcohol more than half a week, with a typical 134 g per drinking day. Around 68% had a comorbid nicotine use disorder with average pack-years of 100. There were no significant associations between craving at initial presentation and alcohol-related measures, as summarized in Table 2.

Table 1: Baseline subject characteristics

Characteristic	*n*=264*
Age	36 (7)
Religion	
Hindu	258 (98%)
Others	6 (2.3%)
Marital Status	
Married	179 (68%)
Single/Separated	85 (32%)
Dependence Duration (in years)	9.1 (6.4)
Drink days/week	
1-3 days	12 (4.5%)
4-7 days	252 (95%)
Typical drinks/drink day (alcohol units)	13.4 (7.1)
Maximum drinks last month (alcohol units)	21 (10)
Dependence severity (SADQ)	27 (7)
Family History of AUD	
Present	169 (93%)
Absent	12 (6.6%)
Missing data	83
Nicotine Use Disorder (NUD)	
NUD absent	80 (32%)
NUD present	168 (68%)
Pack-years	100 (170)
Missing data	10

*Mean (SD); *n* (%). *Note.* This table demonstrates the demographics and baseline alcohol-related measures of all participants assessed at baseline. Missing data is marked as appropriate. Percentage calculations pertain only to available data. SADQ=Severity of Alcohol Dependence Questionnaire; NUD=Nicotine use disorder. Pack-years were calculated by the number of packs smoked per day×number of years of smoking

Craving measures and follow-up information

After assessing 264 participants at initial presentation, the first follow-up data were available for about half of the baseline participants ($N = 139$) with a median follow-up of seven days (IQR: 7, 14). About 22% maintained complete abstinence until the first follow-up. The median craving scores at this first follow-up visit were 10 (IQR: 8, 13). The median PDA at follow-up 1 (FU1) was 71% (60%, 92.5%).

On the second follow-up, information was available for 84 participants. At the end of 14 median days of follow-up from the day of initial presentation, about 18% remained abstinent, and the median craving recorded was 3 (0, 5). About 36% ($N = 30$) reported no craving, as recorded by 0 in total PACS scores. The median PDA at follow-up 2 (FU2) was 67% (50%, 73%).

We had information for two subsequent follow-ups with abstinence and relapse status; however, no craving scores were available for these visits. Information about follow-up visits is available in Table 3.

Censoring and days to drink

The data were censored at the previous visit if any participant was lost to follow-ups and if the event of drinking did not occur, that is, those who remained abstinent. On the whole, the range of follow-up was 0–355 days with mean days to drink being 11.34 days.

High craving is associated with a shorter time to resume drinking in AUD

We performed a Cox regression survival analysis to explore the influence of craving on time to drink [Figure 2]. We found that when considered alone, high craving (PACS total scores ≥ 15) at the time of treatment-seeking significantly increased the risk for fewer days to drink (HR = 1.62, 95% CI = 1.05 to 2.05, $P = 0.030$) during treatment. The median days to drink were approximately 10 days less with high

Table 2: Means, standard deviations, and correlations with confidence intervals for Baseline craving and alcohol-related measures

Variable	M	SD	1	2	3	4	5	6
1. Baseline craving	16.38	3.94						
2. Age	36.17	6.75	.02 [-.11, .14]					
3. Dependence severity	26.73	7.28	-.09 [-.21, .03]	.02 [-.10, .14]				
4. Dependence duration	9.06	6.39	-.04 [-.16, .08]	.61** [.53, .68]	.04 [-.08, .16]			
5. Age of dependence	27.11	5.82	.06 [-.06, .18]	.49** [.39, .58]	-.02 [-.14, .10]	-.39** [-.49, -.28]		
6. Age at first alcohol drink	21.05	5.40	.12 [-.00, .24]	.33** [.22, .44]	.05 [-.07, .18]	-.24** [-.35, -.12]	.65** [.57, .71]	
7. Alcohol consumption last month (grams)	359.85	204.48	.03 [-.09, .15]	.04 [-.08, .16]	-.06 [-.18, .06]	.06 [-.06, .18]	-.02 [-.14, .10]	-.01 [-.14, .11]

Note: M and SD are used to represent mean and standard deviation, respectively. Values in square brackets indicate the 95% confidence interval for each correlation. The confidence interval is a plausible range of population correlations that could have caused the sample correlation (Cumming, 2014). *Indicates $P<.05$. **Indicates $P<.01$

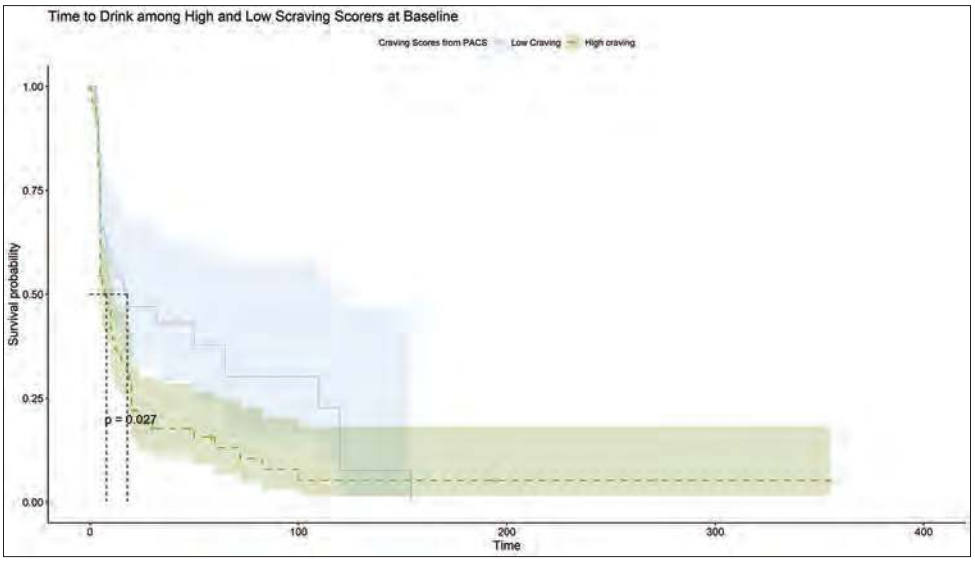

Figure 2: Survival curves on predicting days to drink with levels of craving as the sole predictor. *Note.* This figure depicts the survival curves from the model with only craving (high craving: ≥15 in total PACS scores and low craving: <15 in total PACS scores). X-axis represents time in days, and Y-axis represents the survival probability or proportion of people abstinent. The blue and green lines are survival curves representing low and high craving groups, respectively. The shaded portion around the survival curves represent 95% confidence intervals. A vertical drop in the line represents the event (relapse). Vertical tick marks on the survival curves indicate censoring. The median days to drink are depicted in dashed black lines (high-craving group: 8 days, low-craving group: 18 days). PACS = Penn Alcohol Craving Scale

Table 3: Craving and follow-up information of the study participants

Characteristic	Median (IQR)	*n*
Baseline		
Craving at baseline	16 (14, 19)	264
Follow-up 1		
Follow-up days	7 (7, 14)	139
Percentage of days abstinent (PDA - in %)	71.43 (60.0, 92.5)	
Craving at FU1	10 (8, 13)	
Follow-up 2		
Follow-up days	14 (9, 30)	84
Percentage of days abstinent (PDA - in %)	66.7 (50.0, 73.2)	
Craving at FU2	3 (0, 5)	
Follow-up 3		
Follow-up days	30 (14, 49)	54
Percentage of days abstinent (PDA - in %)	66.7 (50.0, 72.6)	
Follow-up 4		
Follow-up days	107 (58, 140)	35
Follow-up 5		
Follow-up days	131 (86.25, 186.5)	19

This table summarizes the follow-up information. Craving scores were assessed at baseline, and follow-up visits 1 and 2. PDA=Percentage of days abstinent, calculated by the number of abstinent days between previous and current visits/follow-up days expressed in percentages; FU=Follow-up; IQR=Inter-quartile range

craving at initial presentation (8 days) than those with lower craving at initial presentation (18 days).

High craving is marginally associated with a shorter time to drink in AUD when controlling for covariates

To investigate the effects of other potential confounders for time to resumption to drinking while on treatment for AUD, we performed a multivariate Cox regression analysis for craving at treatment initiation on relapse event, with age, current alcohol consumption, medication at initial presentation, and dependence severity as covariates [Figure 3]. We observed that the main effect of craving in the final model was marginally significant (HR = 1.54, 95% CI = 0.99 to 2.41, $P = 0.057$). Among the covariates, we observed that those treated with drugs other than benzodiazepines (anti-craving drugs) reported a reduced risk of relapse (HR = 0.54, 95% CI = 0.33 to 0.86, $P = 0.01$). All other covariates were non-significant.

Associations among craving and outcome measures

To explore how craving and abstinence during follow-up are associated, we prepared a correlation matrix to depict the inter-correlations among craving scores (at initial presentation and follow-ups) and the percentage of abstinent days during follow-ups [Table 4]. We observed that craving at initial presentation was negatively correlated with immediate follow-up (follow-up 1) abstinent days ($r = -0.22$, CI: −0.38, −0.04). There were small cross-sectional correlations between craving and abstinent days only for the follow-up visits; that is, craving at follow-up 1 significantly negatively correlated with abstinent days at follow-up 1 ($r = -0.23$, CI: −0.39, −0.06); similarly for follow-up 2, significantly negatively correlated with craving scores at follow-up 2 (r = −0.28, CI: −0.49, −0.05). This suggests that craving at initial presentation is only associated with the proximal abstinent days, whereas craving is associated with the cross-sectional abstinent status during follow-up.

Table 4: Means, standard deviations, and correlations with confidence intervals for craving measures and follow-up percentage of days abstinent

Variable	*M*	*SD*	1	2	3	4	5
1. Baseline Craving	16.38	3.94					
2. Craving FU1	10.29	3.75	0.09 [−0.08, 0.25]				
3. Craving FU2	2.94	2.95	0.12 [−0.09, 0.33]	−0.05 [−0.26, 0.17]			
4. PDA FU1	73.06	22.13	−0.22* [−0.38, −0.04]	−0.23** [−0.39, −0.06]	−0.09 [−0.31, 0.14]		
5. PDA FU2	62.25	20.23	−0.05 [−0.28, 0.19]	−0.09 [−0.31, 0.15]	−0.28* [−0.49, −0.05]	0.02 [−0.23, 0.26]	
6. PDA FU3	60.35	20.75	0.22 [−0.11, 0.51]	−0.01 [−0.33, 0.31]	0.13 [−0.21, 0.44]	0.20 [−0.15, 0.50]	0.00 [−0.34, 0.34]

M and *SD* are used to represent mean and standard deviation, respectively. Values in square brackets indicate the 95% confidence interval for each correlation. The confidence interval is a plausible range of population correlations that could have caused the sample correlation (Cumming, 2014). *Indicates *P*<0.05. **Indicates *P*<0.01. FU1/FU2=Follow-up visits 1 and 2, PDA=Percentage of days abstinent

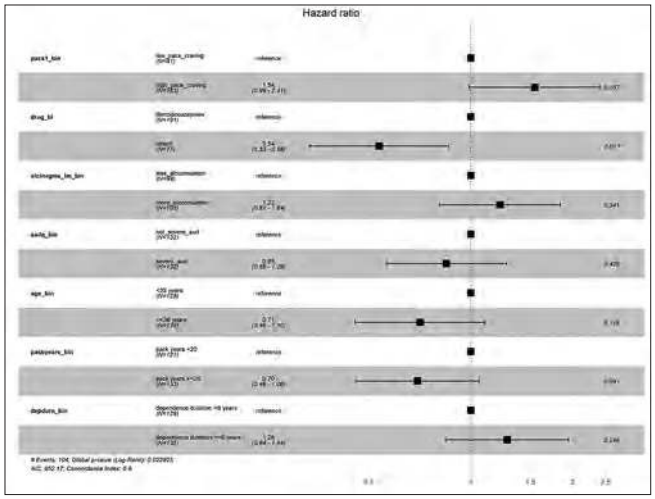

Figure 3: Cox proportional hazards for days to drink. *Note.* The results of the Cox proportional hazards regression analyses relapse are depicted in this figure. After adjusting for treatment at baseline, alcohol consumption in the past month, dependence severity (SADQ), age at presentation, pack-years, and dependence duration, high craving was marginally associated with relapse to drinking (HR = 1.54, 95% CI [0.99, 2.41]). All continuous variables (craving and all covariates) are split at the median to create binary variables and one of them is held as reference. Treatment at baseline with drugs other than benzodiazepines (baclofen or other anti-craving drugs), showed lesser risk to relapse. Other covariates did not show any significant effects. Pacs1_bin = Craving total scores from PACS; drug_bl = Baseline medication, categorized as Benzodiazepines vs others; alcinvgms_lm_bin = Alcohol consumption in the past month (median 336 grams); sadq_bin = SADQ Severity of Alcohol Dependence Questionnaire (median 27.5 corresponding to moderate dependence), age_bin = Age at presentation (median 36 years), packyears_bin = packyears (median 20 years), depdurn_bin = Dependence duration (median 8 years)

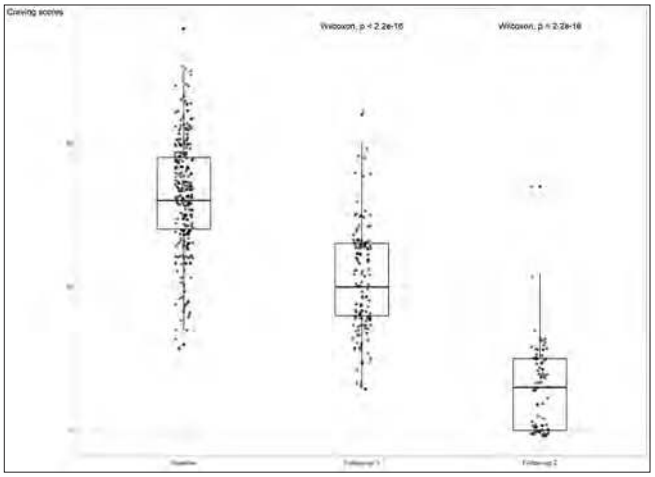

Figure 4: Craving reduces with time. *Note.* Total craving scores from baseline, and follow-up visits (1 and 2). This figure illustrates that craving reduces with initiation of treatment at baseline. Boxes span the interquartile range, with ends representing the upper and lower quartiles. Horizontal line inside the box depicts median value. Repeated measures testing revealed that craving reduced significantly from baseline to follow-up and from baseline to follow-up 2. The significance representations are from pairwise comparisons. Individual data points are depicted in grey-black and outliers are included in the analyses. All participants were consuming alcohol at baseline and were under treatment at follow-ups 1 and 2. Median follow-up days for follow-up visits 1 and 2 are one and two weeks, respectively

Craving comes down with treatment initiation

Finally, we ran a repeated measures ANOVA to understand whether craving responded to treatment. We observed that craving was statistically significantly different at three time points: initial presentation and follow-up 1 and 2 ($F(2, 166) = 347.81$, $P < 0.0001$, generalized eta squared = 0.72). *Post hoc* analyses with a Bonferroni adjustment revealed that all the pairwise differences were statistically significant ($P < 0.05$) [Figure 4]. No appreciable difference in repeated craving measures was observed when relapsers and abstainers at each follow-up were analyzed separately; $P < 0.001$ for both abstainers and relapsers.

We did not find any significant differences when exploring the reduction in craving scores over time for abstainers and those who had relapsed at FU1 and FU2. This suggests that, once treatment is initiated, craving decreases with time irrespective of drinking.

DISCUSSION

Craving, one of the criteria for diagnosing alcohol use disorder, is associated with relapse, as evident in the

Western population. However, its utility in severe AUD in the Indian context is yet to be disentangled. We examined whether craving assessments were feasible and useful in a treatment-seeking population while being treated at an outpatient facility in a tertiary care hospital. We found that during treatment for severe AUD, high craving at treatment initiation was associated with fewer abstinence days, and high-craving scorers relapsed sooner than those who had less craving. Most importantly, craving responded to treatment during follow-ups. No longitudinal assessments on craving have been attempted so far in the Indian population for its utility in predicting relapse in treatment-seekers. In this scenario, we place our findings as a validation of longitudinal craving assessments in the Indian population and its predictive utility for proximal relapse risk in severe AUD.

Our findings are consistent with McHugh *et al*.[2] and Stohs *et al*.[4] who reported that craving predicts relapse in subsequent follow-ups. In line with this, our study strengthens the current claim that high craving is associated with relapse in AUD and is highly relevant in treatment settings for AUD. In addition to this, our results also suggest that those who have high cravings can relapse quickly. A quicker relapse can bring down the patients' confidence over AUD treatment and can be viewed as a failure of efforts to stay abstinent. This can be a critical factor in potentially affecting their return to treatment. With immense efforts to retain patients in AUD treatment, assessing craving at treatment initiation can help clinicians identify an at-risk group for early resumption of drinking. If identified to have a high craving at treatment initiation, this group at risk of relapse can benefit from being given a shorter time for follow-up than traditional weekly turn-ups. Checking their relapse status over the phone during the interim period until the next visit is also a viable option. Strengthening the craving reduction by aiding them with psychological interventions might be immensely beneficial.

Our results suggest that craving was negatively associated with abstinent days only proximally, specifically in the week after treatment began. We did not find evidence for associations of craving at initial presentation and abstinent days in subsequent follow-ups. This is in contrast to a study on treatment-seekers in the Indian population.[12] Although said study concluded that craving was associated with relapse after a month, it was limited by sample size and that no anti-craving medication or other treatment had been provided. On the other hand, our study included anti-craving medications for all who completed successful detoxification. The lack of association between craving at initial presentation and abstinent status in subsequent follow-ups could be because of the treatment initiation. This assumption is strengthened by our finding on reduction of craving in subsequent follow-ups and that high craving was no longer predictive of time to relapse when covariates, including medication, are added to the model. We observed that using medications other than benzodiazepines was an indicator of reduced relapse risk. This could be interpreted as a prescription of anti-craving at initial presentation instead of benzodiazepines, which only indicates a better status regarding withdrawal severity at presentation. Thus, an association with reduced relapse risk in anti-craving treatment compared with benzodiazepines is explainable.

We did not find craving to be associated with drinking or dependence-related measures at initial presentation. As Flannery *et al*.[16] suggested, this indicates a good discriminant validity of the PACS. However, we also observed that craving became more correlated with cross-sectional abstinent days during treatment. This result suggests that the more the number of days a subject remained abstinent, the lesser the craving they reported during follow-up visits. This finding can be leveraged to engage treatment-seekers who feel craving is an overpowering criterion for their continuation of drinking. They can be explained about the possibilities of craving lowering with medication and by encouraging to maintain more abstinent days.

Limitations and strengths

Our study has a few limitations. This study was restricted only to male subjects. The skewed high prevalence of AUD among males and the study being part of the epigenome study restricted only to males limited us in exploring the gender differences in craving and its dynamicity. It was particularly challenging to overcome the initial hesitancy of the participants to discuss craving. However, the authors note that developing a good rapport with the treatment-seeking subjects is a helpful way to elicit craving, particularly in an outpatient setting. Authors underscore that participants are responsive to discussing craving once rapport is established and show greater engagement. A test-retest was not possible as the inherent nature of the study to assess craving in the outpatient setting. Future studies should capture craving construct in in-patient settings to confirm our findings.

Despite these limitations, our results build on the existing evidence of craving and its association with alcohol relapse. We provide new insight into the relationship between craving and time to resume alcohol among treatment-seekers aiming for abstinence. These results should be taken into account when considering outpatient care. While previous research on craving in the Indian context has focused on relapse, we provide evidence from repeated measures assessment of craving construct by capturing its dynamicity and responsiveness to treatment.

In summary, we conclude that craving assessment is highly feasible and valuable in an outpatient facility among the Indian population seeking treatment for AUD. The potential of the craving construct in identifying the immediate risk of relapse is further strengthened in this study. Also, the

usefulness of anti-craving medications in mitigating craving and, thus, its associated risk of relapse will be helpful for clinicians treating those with AUD.

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Conflicts of interest

There are no conflicts of interest.

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ORIGINAL ARTICLE

The emotional facial recognition performance of Chinese patients with schizophrenia: An event-related potentials study

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ABSTRACT

Background: Patients with schizophrenia have deficits in identifying and recognizing emotional facial expressions.
Aim: This study aimed to explore the event-related potential (ERP) responses of patients with schizophrenia (SZ) and healthy controls (HC) using the Chinese Facial Affective Picture System (CFAPS).
Methods: This study included 30 SZs and 31 HCs. We asked them to complete the task based on the oddball paradigm, in which three emotional faces (happy, fearful, and neutral) were used as target stimuli. Additionally, the amplitude and latency of the N170 component and the P300 component were recorded synchronously.
Results: Compared with HCs, SZs had significantly smaller amplitudes of N170 and P300 to all facial expressions. The pairwise comparison revealed that fearful faces could trigger a significantly larger P300 amplitude in HCs than neutral faces, while the such a difference was not found in SZs.
Conclusion: These findings indicated that SZs had a noticeable deficiency in the structural coding of face recognition and available attentional resources.

Key words: Chinese faces, emotional faces, event-related potential, schizophrenia

INTRODUCTION

Schizophrenia is a chronic mental disease, accompanied by several symptoms, such as hallucination, delusion, behavioral disturbance, abulia, affective flattening, social withdrawal, etc.[1] These symptoms are associated with poor social cognition, causing the confused perception of social cues in patients with schizophrenia (SZs).[2] As an indispensable component of social cognition, the recognition of emotional facial expressions has become an independent determinant of patients' social functions.[3]

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Several types of researches, including meta-analyses, revealed that SZs have deficits in identifying and recognizing emotional facial expressions.[4,5] However, whether such deficits still exist in specific emotional faces remains controversial. A scholar demonstrated that SZs have impairments in all emotional faces, especially in fearful, disgustful, and neutral faces, as well as error patterns of misunderstanding neutral faces as negative cues.[6] Moreover, another article has revealed that SZs had more difficulties recognizing happy faces than fearful ones.[7] Furthermore, a functional magnetic resonance imaging (fMRI) study has proposed that SZs had significantly weaker amygdala activation in processing fearful faces than healthy controls (HCs).[8] Meanwhile, another fMRI study has

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suggested that amygdala activation of SZs to fearful facial expression was relatively more minor when compared to neutral facial expression.[9]

Researchers have applied event-related potentials (ERPs) to investigate the impairments of emotional face perception in SZs. The N170 component, a negative component whose peak appears at about 150～180 ms, is regarded as the reflection of early visual processing of human faces. Numerous studies have found lower negative N170 amplitudes in SZs compared with HCs during the assessment of emotional faces.[10-13] However, a non-significant reduction in N170 amplitude has been repeatedly reported previously.[14-16]

The P300 component, whose peak appears at about 300 ms after the stimulus onset, is an index of attentional resources.[17] Previous findings of the P300 in facial recognition experiments revealed the reduced amplitudes in SZs compared with that in HCs.[5] The results are mixed regarding specific emotional faces, such as fear, neural, happiness, etc., A recent study has revealed that fearful and happy faces triggered smaller P3a amplitude in SZs than HCs.[18] Others reported that negative faces could trigger a greater P300 amplitude in HCs, whereas a smaller P300 amplitude was observed in SZs compared with positive faces.[19,20]

Moreover, some researchers found an attenuated P3 amplitude in patients with impulsive aggression or violent criminal convictions during oddball tasks.[21,22] It was found that violence could be an independent risk factor for impaired cognitive-executive functioning. Meanwhile, others indicated particular patterns of P300 amplitude to negative stimuli in aggressive groups. They reported that non-violent participants showed an enhanced P300 amplitude to negative stimuli, such as social and physical threat words, by comparison with neutral stimuli, while the such difference was not found in violent participants.[23,24] However, few studies have concentrated on the ERP response to emotional faces in violent schizophrenic patients. Frommann *et al*.[25] demonstrated that schizophrenic patients with a history of violence had larger N250 amplitudes to emotional faces than schizophrenic patients without any history of violence. It was suggested that larger N250 amplitudes could be due to the higher arousal of violent patients to emotional faces.

Two main objectives were assessed in the present study. Firstly, it was attempted to replicate previous studies with the Chinese Facial Affective Picture System (CFAPS) to compare ERP responses of SZs and HCs, including the N170 and P300 components, among three facial expressions (happy, fearful, and neutral). Another objective was to indicate whether the ERP responses of patients with schizophrenia could be correlated with their level of violence.

METHODS

Participants

A total of 30 patients who were diagnosed with schizophrenia, according to the 5th edition of The Diagnostic and Statistical Manual of Mental Disorders (DSM-V), were enrolled as participants. The inclusion criteria were as follows: (i) participants aged 20-50 years old; (ii) participants who were right-handed; (iii) participants who had a normal or corrected-to-normal vision; (iv) participants who had no history of epilepsy, or serious brain trauma, severe encephalitis, brain tumor, or organic brain diseases; (v) participants who had no history of alcohol consumption or drug abuse in the past 5 years; (vi) participants who were not treated with electroconvulsive treatment during the past 3 years; (vii) participants who were in stable status for at least 3 months to avoid significant alterations in symptoms or medication. All participants voluntarily participated in the experiment, and they were recruited from the Psychiatric Outpatient Department and In-patient Department of Fuzhou Neuro-Psychiatric Hospital (Fuzhou, China).

We also included 31 HCs who were matched for age, handedness, and eyesight to SZs. They were all from the surrounding community and recruited through newspaper advertisements, leaflets, the Internet, etc. They were also evaluated to ensure the absence of (i) a history or family history of psychiatric illness; (ii) a history of epilepsy, serious brain trauma, severe encephalitis, brain tumor, and other organic brain diseases; (iii) a history of alcohol consumption or drug abuse in the past 5 years; (iv) history of receiving antiepileptic or psychoactive drugs that could affect the electrical activity of the brain.

Patients' risk of violence was determined by the Modified Overt Aggression Scale (MOAS). This assessment was measured based on four models, verbal aggression, aggression against objects, aggression against self, and aggression against others.[26] Well-trained psychiatrists performed all the assessments.

Experimental stimuli

The emotional faces were derived from the CFAPS, compiled by the National Key Laboratory of Cognitive Neuroscience and Learning, Beijing Normal University.[27] Previous studies[28,29] showed that the recognition performance of non-native faces was markedly worse than that of native faces. Hence, the Chinese emotional faces might improve participants' performance and arouse more significant electro-encephalic responses. It contained 7 standard emotional faces: anger, disgust, fear, sadness, surprise, neutral, and joy, of which three emotional faces (happy, fearful, and neutral) were herein selected as experimental stimuli. Examples of the experimental stimuli are shown in Figure 1a.

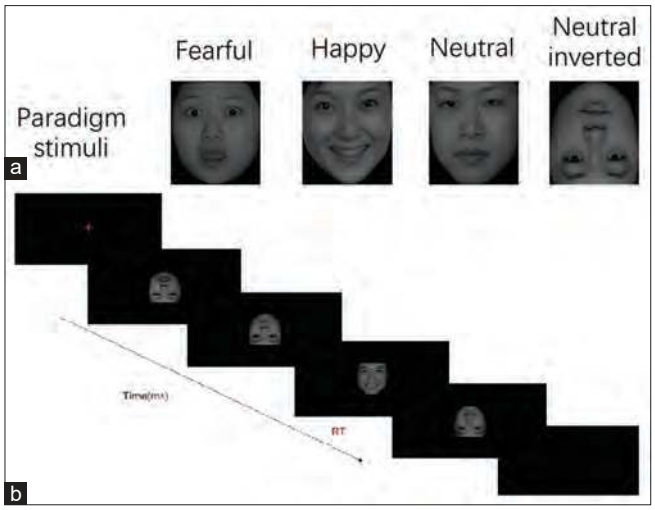

Figure 1: Examples of the experimental stimuli (a) and the sequences of events within a single-task trial (b)

Because of cultural and ethnic differences, humans prefer facial information about their races. Thus, the present study utilized affective pictures of Chines faces as emotion-elicitation material to avoid the race effect. A total of 36 emotional pictures (male (18) vs. female (18)) were selected from the CFAPS for each facial expression (happy, fearful, and neutral). There was no significant difference in the potency of the three emotional pictures (mean: neutral = 5.67, happy = 5.77, fearful = 5.66; F (2.106) = 0.657, $P = 0.521$). This research also concluded 50 neutral inverted facial images as responded stimuli. Moreover, the background, contrast, and brightness of all facial images were consistent, and the images were resized to 640 × 480 pixels by the Picture Manager software.

Experimental stimuli were displayed on a 17-inch flat color display, with a resolution of 1024 x 768, and the screen background was set to black (RGB = 0,0,0). The experimental program was written by the E-Prime 1.0 software.

Task procedure

The experiment was conducted in a special laboratory under the conditions of proper temperature, sound insulation, and closure. Participants were 100 cm seated in front of a computer screen to complete a designed task. The task was designed based on the classical oddball paradigm and contained three rounds, and each round included 252 trials. We randomly presented one of the three upright facial expressions (happy, fearful, and neutral) as target stimuli (10% probability) and inverted neutral faces as standard stimuli (90% probability) in each round. A single-task trial was processed in the following sequence [Figure 1b]: Step 1. A cross was presented for 1,000 ms on the center of the screen; Step 2. One of the above-mentioned faces appeared in the central area for 1,000 ms, followed by a black screen for 800-1500 ms (in order to relieve visual fatigue). Then, Step 2 was repeated, and participants were asked to press the space bar when they observed the emotional faces. At the end of each round, participants were arranged to close their eyes and rest for 20 min.

Electroencephalogram (EEG) recording and analysis

The recording of the brain electrical activity included the left mastoid as a reference electrode, while the average values of the left and right mastoids were used as references during offline analysis. The electrode cap was covered with a 64-channel amplifier, which was placed by the 10-20 System (Compumedics Neuroscan Inc., Charlotte, NC, USA). The electrodes that recorded the horizontal electrooculogram were placed at the outer canthi of both eyes. The electrodes placed above and below the left eye were utilized to record the vertical electrooculogram. All electrode locations were maintained below 5 kΩ. A 0.01–100 Hz band-pass filter was applied to amplify the EEG and electrooculogram, and the sampling frequency was set to 1000 Hz/channel. Data processing was performed by the CURRY 8 software (Compumedics Neuroscan Inc.) and re-referenced to the averaged values of the mastoids. A regression method was used to erase the ocular artifacts from data through the CURRY 8 software, and the data were digitally filtered with a band-pass filter of 0.1 Hz (12 dB/octave) -30.0 Hz (24 dB/octave). The segments for each trial were extended from 200 ms before the stimulus onset to 1000 ms thereafter. Then, the baseline correction was processed by deducting the average activity of the baseline period of each channel from all trials. The trials with extensive artifacts whose EEG voltages exceeded the limits of ± 80 μV were automatically rejected from the analysis. The electrodes selected, consistently with previous literature, the N170 peaks were measured at P7 and P8 electrode positions,[30-32] while the P300 peaks were measured at Cz and Pz electrode positions.[5,14,33]

The statistical analysis was carried out using SPSS 23.0 software (IBM, Armonk, NY, USA). Data were presented as mean ± standard deviation (SD). Repeated measures analysis of variance (ANOVA) was utilized to compare differences in facial emotion recognition between-within of repeated measures of two groups of 2 (group) × 3 (emotional faces), followed by the pairwise comparison. $P < 0.05$ was considered statistically significant. Pearson's correlation analysis was used to assess the correlation of patients' MOAS scores with their N170 and P300 amplitudes in response to emotional faces, respectively.

RESULTS

General data

Overall, a total of 64 participants completed the experiment. However, due to the excessive artifacts and wider margin of disturbances, the data of 2 patients and 1 HC were excluded. Last, the data of 30 SZs (male (16) vs. female (14)) and 31 HCs (male (16) vs. female (15)) were analyzed. SZs and HCs have

no difference in age, years of education, reaction time, or accuracy. The accuracy of nearly 100% indicates that all the subjects have completed the experimental task seriously. Table 1 concludes the characteristics of the two groups.

N170 component

The ANOVA between-within of repeated measures of two groups of 2 (group) × 3 (emotional faces) exhibited a significant main effect of group ($F[1,59] = 225.13$, $P < 0.001$) with patients (M = -3.03 μV, SD ± 0.094), eliciting smaller N170 amplitudes compared with control group (M = -5.01 μV, SD ± 0.092). There was no significant main effect of facial expression ($F[2,58] = 1.457$, $P = 0.237$) or interaction between the group and facial expression ($F[2,58] = 1.809$, $P = 0.168$). The pairwise comparison showed that the N170 amplitudes were significantly smaller among all three facial expressions [happy ($P < 0.001$), fearful ($P < 0.001$), and neutral ($P < 0.001$)] in SZs. All the pairwise comparisons were corrected by Bonferroni correction. No significant difference was found in the N170 latency between the two groups ($F[1,59] = 0.011$, $P = 0.916$). The mean N170 amplitudes and latency of faces in both groups are illustrated in Table 2.

P300 component

The ANOVA between-within of repeated measures of two groups of 2 (group) × 3 (emotional faces) also revealed a significant main effect of group ($F[1,59] = 57.286$, $P < 0.001$), in which the P300 amplitudes of SZs (M = 2.911 μV, SD ± 0.065) were smaller than those of HCs (M = 3.603 μV, SD ± 0.064). The significant main effect was also found in stimulus type ($F[2,58] = 10.731$, $P < 0.001$), in which the fearful faces triggered more positive P300 amplitudes compared with neutral faces ($P = 0.002$) and happy faces ($P < 0.001$). There was no significant interaction between the group and facial expression ($F[2,58] = 2.732$, $P = 0.074$). The pairwise comparison showed that the P300 amplitudes were smaller among all three facial expressions (happy, fearful, and neutral) in SZs than HCs [happy ($P < 0.001$), fearful ($P < 0.001$), and neutral ($P < 0.001$)]. Moreover, a significantly larger P300 amplitude was validated in the fearful faces compared with that in neutral faces ($P = 0.002$) and happy faces ($P < 0.001$) in HCs, while the such difference was not found in SZs. All the pairwise comparisons were corrected by Bonferroni correction. No significant difference was detected in the P300 latency between the two groups ($F[1,59] = 0.069$, $P = 0.794$). The mean P300 amplitudes and latency of faces in both groups are illustrated in Table 2.

Table 1: Sample description (mean±SD)

	SZs (n=30)	HCs (n=31)	t	P
Age (years)	32.53±9.70	31.23±8.93	0.548	0.586
Education (years)	10.93±3.4	11.23±4.4	-0.290	0.773
Reaction time (ms)	653.55±78.95	614.98±72.49	1.986	0.052
Accuracy (%)	96.16±1.79	96.67±1.93	-1.061	0.293
Duration of illness (years)	7.17±4.6			
Modified overt aggression scale	17.4±3.6			

Correlation analysis

Correlations were calculated between patients' MOAS scores with their N170 and P300 amplitudes, respectively. It was revealed that the MOAS scores of patients were significantly correlated with their P300 amplitudes ($r = –0.059$, $P = 0.001$) [Figure 2]. However, there was no significant correlation between MOAS scores and N170 amplitudes ($P = 0.189$).

DISCUSSION

One primary objective of the present experiment was to indicate whether facial emotional recognition significantly decreased in SZs compared with HCs. To accomplish this objective, we compared the two groups ERP responses elicited by the three upright facial expressions (happy, fearful, and neutral).

The present research revealed that all three facial expressions (happy, fearful, and neutral) showed lower negative N170 amplitudes in SZs than that in HCs. This finding is consistent with that of several previously reported studies, in which SZs showed N170 deficits in the recognition of facial expressions.[10-13] The N170 component, which appeared in the early stage of facial coding, could be affected by several factors, such as facial expressions, faces of different races, face orientation (upright or inverted), etc.[34] The results of the present study suggested that SZs had important deficiencies in the structured coding of face recognition. However, one research found no significant difference in the N170 amplitude between SZs and HCs.[35] The authors believed that their ERP program was more accessible than the oddball program, indicating that patients' facial coding function could afford some easy tasks. Therefore, the next study will concentrate on indicating how

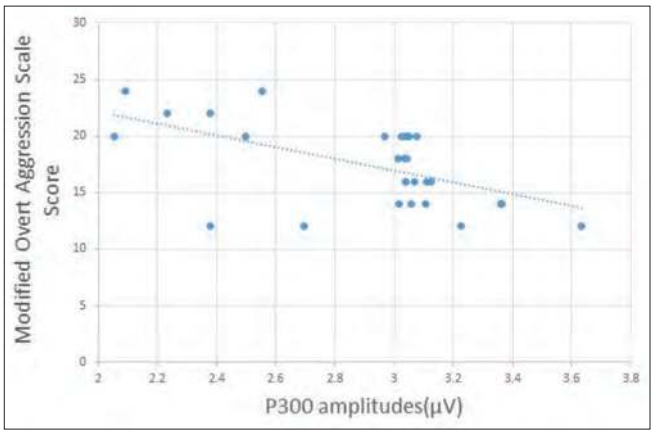

Figure 2: Correlations between MOAS scores and P300 amplitudes of SZs

Table 2: Comparison of the schizophrenia and healthy control for N170, P300 amplitude and latency for three emotional faces

	SZs (*n*=30)	HCs (*n*=31)	*F*	*P*
N170 amplitude (μV)				
Neutral	-3.018±0.112	-4.892±0.110	142.538	<0.001
Happiness	-2.956±0.114	-5.093±0.112	179.576	<0.001
Fear	-3.124±0.111	-5.039±0.109	152.598	<0.001
F	1.392	1.787		
P	0.257	0.177		
Overall Test				
Group (*F, P*)	225.130, <0.001			
Face (*F, P*)	1.457, 0.237			
Interaction (*F, P*)	1.809, 0.168			
P300 amplitude (μV)				
Neutral	2.887±0.070	3.540±0.069a	43.772	<0.001
Happiness	2.838±0.077	3.378±0.076	25.185	<0.001
Fear	3.008±0.099	3.891±0.098[a,b]	40.306	<0.001
F	1.300	12.345		
P	0.280	<0.001		
Overall Test				
Group (*F, P*)	57.286, <0.001			
Face (*F, P*)	10.731, <0.001			
Interaction (*F, P*)	2.732, 0.074			
N170 latency (ms)		P300 latency (ms)		
Overall Test		Overall Test		
Group (*F, P*)	0.011,0.916	Group (*F, P*)	0.069, 0.794	
Face (*F, P*)	1.771,0.179	Face (*F, P*)	0.828, 0.440	
Interaction (*F, P*)	2.320,0.107	Interaction (*F, P*)	0.155, 0.857	

Data are presented as mean±SD. [a]Means *P*<0.05 when compared to happy faces. [b]Means *P*<0.001 when compared to neutral faces. All the pairwise comparisons were corrected by Bonferroni correction

patients perform and whether the N170 amplitudes can be improved in easy face recognition tasks.

As previously described, the P300 component could reflect the allocation of attentional resources.[36] In the present study, the mean P300 amplitudes significantly decreased among all three facial expressions (happy, fearful, and neutral) in SZs, and this finding is consistent with that of previous research,[5,18,37] indicating that SZs may have a deficit in attentional resources. Moreover, compared with neutral or positive stimuli (neutral or happy faces), negative stimuli could trigger larger P300 amplitudes in HCs, while there was no significant difference among stimulus types in SZs. This result is highly consistent with An *et al*.,[19] in which negative stimuli aroused a greater P300 amplitude HCs, while there was a smaller P300 amplitude in SZs compared with positive stimuli. A recent fMRI study also reported a similar result, demonstrating that HCs had a significantly different activation of the left amygdala in sad compared with neutral stimuli, while SZs did not have such differences.[38] As mentioned above, SZs had deficits in recognizing facial expressions,[4,5] thus, one explanation for our result could be attributed to different types of facial expressions.

Besides, a previous study reported a similar result related to the P300 amplitude of different subtypes of schizophrenia,[39] in which negative stimuli triggered a larger amplitude compared with positive stimuli in paranoid schizophrenics, whereas the data of non-paranoid schizophrenics were matched with An *et al*.[19] Ueno *et al*.[39] demonstrated that these diverse patterns of P300 amplitude in different subtypes of schizophrenia were due to distinct emotional arousal levels caused by emotional faces. Therefore, we assume that patients in our study also had particular emotional arousal levels when assessing facial expressions. Moreover, the allocation of attentional resources varied based on the arousal levels of different emotional facial expressions.[36] Thus, the results indicated that patients had different distribution patterns of attentional resources on facial expressions, causing the misunderstanding of social cues and unacceptable behaviors in public.

Furthermore, the results of the present study exhibited that patients' amplitudes of P300 peaks were significantly negatively correlated with MOAS scores, indicating that patients with more violent behavior had lower positive P300 amplitudes in the face recognition task. This finding is similar to a result that was previously reported,[21,22] in which patients with impulsive aggression or violent criminal convictions had decreased P300 amplitudes compared with non-violent controls during the oddball tasks. As mentioned earlier, the P300 component could reflect the allocation of attentional resources.[36] Therefore, we suggest that aggressive patients with schizophrenia may have poor ability of attentional resources during facial recognition tasks. Furthermore, preceding research demonstrated that larger N250 amplitudes were found in schizophrenic patients with a history of violence than in schizophrenic patients without

a history of violence during the emotion recognition task. They argued that patients' higher arousal activated by emotional faces might cause larger N250 amplitudes.[25] Thus, whether the decreased P300 amplitudes in patients with schizophrenia were influenced by their higher arousal in the emotional facial recognition task should be further assessed.

One limitation of our study is that the SZs groups received antipsychotic medication. The dose of antipsychotic medication differed based on their weight, age, the severity of symptoms, etc. A meta-analysis in China indicated a significant but small improvement of P300 amplitude in SZs who received antipsychotic medication compared to those without medication.[40] Another meta-analysis found no significant difference in P300 amplitude between SZs who were under medication and not.[41] Since our study showed that the P300 amplitudes of SZs were smaller than those of HCs, the effect of medication might not account for the difference in P300 amplitude.

CONCLUSIONS

In summary, our findings replicated previous studies. Firstly, the lower negative N170 amplitudes and the lower positive P300 amplitudes were found in emotional facial expressions of SZs, indicating that patients could have a deficit in the structural coding of face recognition and available attentional resources. Secondly, the negative stimuli (fearful faces) could trigger a larger P300 amplitude in SZs, which could be related to different facial expressions or different distribution patterns of attentional resources. Moreover, patients with more violent behaviors had lower positive P300 amplitudes in the face recognition task, which suggested that aggressive SZs, may have poor ability of attentional resources during facial recognition tasks.

Ethics approval

This work has been carried out in accordance with the Declaration of Helsinki (2000) of the World Medical Association. This study was approved by the Ethics Committee of Fujian Medical University Affiliated Fuzhou Neuropsychiatric Hospital. (201802).

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Conflicts of interest

There are no conflicts of interest.

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ORIGINAL ARTICLE

Psychometric properties of Psychosocial Inventory for Caregivers (PIC) scale

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ABSTRACT

Background: There are various psychosocial challenges associated with caregiving in persons with mental illness. So, the present study attempts to develop a 62 itemed Psychosocial Inventory for Caregivers (PIC) scale in order to assess the different psychosocial problems in caregivers of persons with mental illness.
Aim and Objective: The study aims to develop and test the PIC scale in a population with the objective to assess its reliability and validity.
Methodology: The present study used a cross-sectional descriptive research design. Caregivers of persons with mental illness were the samples for the present study. Convenient sampling was used to collect 340 samples, based on the item-to-response ratio of 1:4. The study was conducted in the in-patient/out-patient department of LGBRIMH, Tezpur, Assam. Permission to conduct the study was taken from Institutes Ethics Committee (IEC). Proper written consent was taken from the participants after explaining to them the study.
Result: Confirmatory factor analysis (CFA) was performed in SPSS version 25.0. The internal consistency of the PIC scale was found to be 0.88. The convergent validity of the PIC scale was acceptable because the average variance extracted (AVE) was above 0.50. The square root of the average variance explained was greater than the inter-factor correlation of the PIC scale, hence, discriminant validity was established.
Conclusion: With the development of a PIC scale, a comprehensive assessment can be done to know the various factors and consequences related to caregivers of a person with mental illness.

Key words: Caregivers, mental illness, psychosocial, scale construction

INTRODUCTION

According to the National Mental Health Survey Report[1] mental illnesses are health conditions involving changes in emotion, thinking, or behavior (or a combination of these). Mental illnesses are associated with psychological distress and deterioration in activities of daily living. The lifetime prevalence of mental disorders was found to be 13.7%. The prevalence rate of schizophrenia and other psychosis, mood disorders, the neurotic and stress-related disorders was found to be 0.64%, 5.6%, and 6.93% respectively. With the data on the prevalence of mental disorders in India, it is quite clear that mental disorder in an alarming situation and immediate care is necessary.

Measuring the psychosocial problems in caregivers of persons with mental illness

There is ample literature stating that caring for an individual with mental illness is burdensome and stressful to many

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family members and contributes to psychiatric morbidity. challenges related to caregiving of persons with mental illness can be physical, psychological, and social, as issues related to caring burden, family functioning, and caregiver resilience.

i. **Physical Health:** Research studies on the physical health of caregivers of persons with mental illness have shown that around three-fifths of caregivers have poor health status (including heart attack/heart disease, cancer, diabetes, and arthritis) and functional disability when compared to non-caregivers. Moreover, these studies also stated that caregivers suffer from increased rates of physical ailments (including acid reflux, headaches, and pain/aching), an increased tendency to develop serious illnesses, and high levels of obesity and bodily pain.[2,3]
ii. **Psychological Distress:** Long-term caregiving may lead to emotional and behavioral problems in caregivers, social isolation, financial crunch, poor quality of life, poor and physical and mental health.[4] Thus, the psychological impact of caregiving on family members is yet another area that alters the quality of caregiving. Literature shows that "psychological distress" is associated with different combinations of symptoms ranging from depression and general anxiety symptoms to personality traits, functional disabilities, and behavioral problems. Research has shown psychological distress such as anxiety, depression, and insomnia among caregivers of psychiatric out-patients is twice as high as in the general population.[5,6]
iii. **Social Problem:** Saleh *et al*.[7] showed that 15% of caregivers of persons with mental illness have been experiencing stigma, social isolation, and poor support. Research finding reveals that social support is important for the well-being of the family affected by mental illness families and collaborative plans should include strategies to assist family members and consumers in dealing with stigma and poor social support.[8]
iv. **Careburden:** Caring for a person with mental illness is an upsetting stressor in any family, regardless of its strengths and resources and coping present in the family member with severe mental illness. The presence of a person with mental illness impacts family members in several ways, disrupts the family dynamics, and deterioration of occupational and social functioning, collectively enhancing the burden of care.[9,10]
v. **Family Functioning:** Theories related to family functioning indicate that if a family is having a long stay person with mental illness, in the family, the overall family dynamics (family boundaries, power structure, problem-solving and decision-making, communication, role functioning, cohesion, and behavior control) of the family is disrupted leading to family conflicts and poor prognosis of the disorder.[11,12]
vi. **Caregiver Resilience:** If family caregivers are resilient they can cope well with family issues.[13] Resilience theory focuses on the strengths possessed by individuals or families that enable them to overcome adversity.[14,15]
vii. **Expressed Emotions:** EE can be recognized as a severe psychosocial stressor and elevates the recurrence of the illness. EE comprises criticism, hostility, and emotional over-involvement (EOI). Critical comments are basically abusive words by caregivers when the patient is unable to perform the given activities accordingly. Hostility in another hand can be rated as a consequence of unmanageable anger and irritation followed by critical comments and leads to rejection of the patient. Hostility refers to emotional and physical violence towards the patient. EOI refers to over-emotionality and overprotective behavior toward the patient.[16]

Need for the study

Although numerous studies have been conducted on family caregivers of mentally ill patients in India, a comprehensive scientific study on the development of a tool for caregivers has not been conducted to determine their problems, factors, and challenges. There are established tools to assess psychosocial problems (depression, anxiety stress, care burden, expressed emotions, family functioning, etc) in caregivers of persons with mental illness. But no specific tool is there to see the overall psychosocial issues among caregivers. Therefore, in this study, a tool has been developed (Psychosocial Inventory for Caregivers - PIC) to measure the psychosocial issues in caregivers of persons with mental illness in the Indian context. In India, to date, there are very less tools that can comprehensively assess the psychosocial issues related to caregiving. So, the development Psychosocial Inventory for Caregivers (PIC) can help mental health professionals to measure issues related to caregiving and can encompass different domains of caregiving issues/problems on one scale.

AIM AND OBJECTIVE OF THE STUDY

Aim:

To develop and test the Psychosocial Inventory for Caregivers (PIC) of Persons with Mental Illness.

Objectives:

1. To develop a psychosocial inventory for caregivers of persons with mental illness and to assess its applicability and suitability in caregivers of persons with mental illness.
2. To assess the reliability (internal consistency) and validity of the developed tool.

Operational definitions

A person with Mental Illness: The person diagnosed with mental illness based on (ICD-10) criteria[17] by a psychiatrist in the in-patient/out-patient department of LGB Regional Institute of Mental Health, Tezpur.

Caregiver of Person with Mental Illness: Adult caregivers staying at hospital premises with the patient and fulfilling >3 criteria to be a caregiver proposed by Pollak and Perlick[18] which include [(spouse, parent or spouse equivalent, b) most frequent contact with the patient, c) supports patient financially, d) most frequent collateral participant in patient's treatment, e) is the person contacted in case of an emergency)].

Methodology

The present study used a cross-sectional descriptive research design. Data was collected by using a self-reported questionnaire and conducting personal interviews (PI) with caregivers of persons with mental illness. Permission for translating the scale into the native language was taken from all the concerned authors. WHO guidelines were used for translation purposes. Back Translation, Forward Translation, and Expert Validation was done with the help of experts. The person with mental illness who were taking treatment regularly from the in-patient/out-patient department of LGB Regional Institute of Mental Health of Tezpur, Assam, and their respective caregivers formed the universe of the study. Caregivers of persons with mental illness were the samples for the present study. Convenient sampling was used to select 340 samples from the population. According to Hinkin *et al*.[19] the 'item to response ratio' must be ranged from 1:4 to 1:10. Here, in the present study, the researcher selected an item to response ratio of 1:4, which meant that the total number of samples should be more than 4 times the total items of the new scale. Therefore, the final sample size was kept as (total number of items in the new scale = 84 *4) which equaled 336 samples. Hence 340 samples were selected.

Description of the tools used in the study

1. **Socio-demographic and clinical data sheet:** Socio-demographic and clinical sheet was self-prepared by the researcher to assess the age, religion, community, education, occupation, domicile, marital status, family type, and family income of both patients and caregivers. A clinical data sheet was developed to assess the onset of illness, history of illness, total duration of illness, number of admission, and diagnosis of the patient with mental illness. The socio-demographical and clinical data sheet was validated by 03 subject matter experts from the field of psychiatric social work.
2. **Patient Health Questionnaire (PHQ)[20]:** The Patient Health Questionnaire of 9 items was developed for assessing depressive severity. It followed a Likert scoring and responses are recorded as 0, 1, 2, or 3 for "not at all," "several days," "more than half the days," and "nearly every day," respectively. The total score of the scale is obtained by summing up all the responses, giving a range of total scores between 0 – 27. The cut-off points of 5, 10, 15, and 20 represented mild, moderate, moderately severe, and severe levels of the problem. Internal reliability for the PHQ-9 is reported as "excellent" with an Cronbach's α of 0.89 and 0.86, whereas, test-retest reliability is excellent with a kappa of 0.84.
3. **Depression, Anxiety, and Stress Scale (DASS)[21]:** The Depression, Anxiety, and Stress Scale - 21 Items (DASS-21) is designed to measure the emotional states of depression, anxiety, and stress. Cronbach Alpha of DASS 21 in was found to be falling in the range of 0.74 to 0.84. It is a Likert scale: 0 means did not apply to me, 1 = Applied to me to some degree, 2 = Applied to me to a considerable degree, and 3 = Applied to me very much. DASS-21 needs to be multiplied by 2 to calculate the final score. Scoring cut off of normal, mild, moderate, severe, and extremely severe are-
   Depression (0-4, 5-6, 7-10, 11-13,14+), Anxiety (0-3, 4-5, 6-7, 8-9, 10+), Stress (0-7,8-9,10-12,13-16,17+)
4. **Multi-dimensional Scale for Perceived Social Support (MSPSS)[22]:** It was 12 item, 7-point Likert scale designed to measure perceptions of support from 3 sources: Family, Friends, and a Significant other. It was validated to be used in both clinical and non-clinical settings. In studies, it was found that reliability was in the range of 0.54 to 0.73. MSPSS had a Cronbach's alpha of 0.92. The scale followed a Likert scoring (1 = very strongly disagreed, 2 = strongly disagreed, 3 = mildly disagreed, 4 = neutral, 5 = mildly agreed, 6 = strongly agreed, 7 = very strongly agreed). The total score was obtained by summing up all the 12 items, then dividing by 12. The sub-domain items and their cut off are as follows-
   Sub domains are significant other (1,2,5&10), friends (6,7,9 &12), family (3,4,8 &11) and cut offs are low support (1 to 2.9), moderate support (3 to 5) and high support (5.1 to 7)
5. **Zarit Burden Interview (ZBI)[23]:** It was a 22-item interview schedule that does a comprehensive assessment of both the objective and the subjective burden of the individual. The Cronbach's alpha value for the ZBI items was 0.93. It comprised a Likert style format, 0: Never, 1: Rarely, 2: Sometimes, 3: Quite Frequently, 4: Nearly Always. The total score could be calculated by summing up all the items (ranges 0-88) and the cut off is as follows-
   Cut offs are Little/no burden (0-21), mild to moderate burden (21-40), moderate to severe (41-60), severe burden (61-88)
6. **General Functioning Family Assessment Device (GF-FAD)[24]:** General functioning was a subscale of the McMaster Family Assessment Device that had been designed to measure family functioning. It assessed the seven domains in a family, like problem-solving, communication, roles, affective responsiveness, affective involvement, behavioral control, and general functioning. It had different versions (60 items, 12 items, and 3 items), the present study used the 12-item version of the scale. Cronbach's alpha ranged from 0.79 to 0.81, indicating good internal consistency of the instrument. The scale followed a Likert-type scoring pattern from 1

to 4. 1 = strongly agree, 2 = agree, 3 = disagree and 4 = strongly disagree. The higher the score, the more problematic the family member perceives the family's overall functioning.

7. **Connor-Davidson Resilience Scale (CD-RISC)**[25]: This was a self-reported questionnaire developed to screen people for high, intermediate, or low resilience and is appropriate for use in a clinical setting. It has 2 items, 10 items, and 25 items versions. The present study used 25 items scale because of its rich psychometric properties. Cronbach alpha of the scale ranges from 0.30 to 0.89. The 25-item scale is evaluated in a 5-point Likert scoring ranging from 0 to 4, where, not true at all (0), rarely true (1), sometimes true (2), often true (3), and true nearly all of the time (4). The ranges are between 0 to 100. Higher scoring indicated, higher resilience and vice versa.
8. **Family Questionnaire (FQ)**[26]: It was a brief self-report questionnaire developed to measure the EE (expressed emotion) in the form of emotional over-involvement and critical comment,/hostility) of caregivers of persons with a major mental health disorder. Cronbach alpha ranging from. 80 and. 69. The scoring pattern of the scale was dichotomized into high or low EOI and/or CC/hostility based on cut-off scores - Total score was obtained by summing up all the items.
   Cut offs are emotional over-involvement (high=27, low=23); Critical comment/hostility (High=27, low=23)

Statistical analysis

In the present study quantitative analysis of the data was done by using IBM- Statistical Package for the Social Sciences (SPSS) version 25.0 for Windows was used.

Ethical clearance

Ethical clearance to conduct the study was given by the Institute Ethics Committee (IEC), of LGB Regional Institute of Mental Health, Tezpur. The participants were oriented about the nature of the study. They were explained that participation is entirely voluntary. After explaining the rationale of the study, proper written informed consent was get signed by them.

RESULTS

The mean age of the patient was M = 32.3 and the standard deviation was SD = 11.6. The majority of the caregivers were male (72.6%), Hindu (75.9%), from the general category (37.1%), hailing from a semi-urban background (66.5%), mostly married (60.9%), educated up to high school (34.4), unemployed (49.4%), with the nuclear family type (61.8%) and having upper-lower socioeconomic status (59.7%). The mean ages of the caregivers were M = 37.5 and the standard deviation was SD = 11.8. Most of the caregivers were educated up to graduation (29.1%), working in the private sector (31.5%), related as a brother (35.0%) to the patient, and around (9.1%) left their job because of their patient's illness.

In the clinical profile, the majority of patients were having the onset of illness as insidious (76.5%), with a history of mental illness in the family (48.5%), diagnosed with Schizophrenia (65.9%), with the primary caregiver (97.9%). The mean total duration of the illness (in days) of the patient was found to be (M = 494.9; SD = 636.1) and the mean total duration of the caregiving (in days) of the caregivers was found to be (M = 494.9; SD = 636.0).

The magnitude of the problems in caregivers of persons with mental illness (n = 340) with Pre-existing established tools

As cited in Table 1 physical health problems were found to be in (38.2%) of the caregivers, severe depression in (0.6%) of the caregivers, severe anxiety issues in (26.2%) of the caregivers, and mild stress in (11.8%) of caregivers. Social support from significant others was found to be poor in (45.3%) of the caregivers, social support from friends was found to be poor in (45.3%) of the caregivers, and social support from family was found to be poor in (46.2%) of the caregivers. The level of care burden was severe in (9.4%) of the caregiver, problem-related with family functioning was present in (73.8%) of the caregivers, emotional over-involvement was high in (85.0%) of the caregivers, and critical comment/hostility was high in (55.3%) of the caregivers.

As cited in Table 1 the findings of the Physical Health Subscale of the PIC scale showed that the majority of caregivers having moderate physical health problems (36.2%), and (10.9%) were having severe physical health problems. In the Psychological Distress Subscale of the PIC Scale, majority of respondents were having a moderate level of psychological distress (42.1%) and to severe level of psychological distress was present (17.1%) of respondents. In the Social Support Subscale of the PIC Scale moderate level of problems in social support was present at (49.7%), followed by a severe level of social support problems at (20.6%). In the Family Functioning Subscale of the PIC Scale, a moderate level of problem related to family functioning was present in (41.5%) of respondents, whereas, a severe level of problem-related to family functioning was present in (19.1%) of the respondents. In the resilience subscale of the PIC Scale, moderate problem related to resilience was present in 38.8% of the respondent and severe problem related to resilience was present in 14.1% of the respondent. In the Care Burden Subscale of the PIC Scale moderate level of care, the burden was present in (50.9%) of the caregivers followed by a severe level of care burden (36.2%). In the Critical Domain Subscale of the PIC Scale, severe level of critical comment was present in 34.4% of the caregivers, a severe level of over-involvement in 34.4% of the caregivers, and a severe level of hostility in 19.1% of the caregivers.

Table 1: Magnitude of the problems in caregivers of persons with mental illness (*n*=340) with PIC Scale

Variable		Frequency	Percentage (%)
PIC (Physical Health Subscale)			
Minimal/No Problem		77	22.6
Mild		103	30.3
Moderate		123	36.2
Severe		37	10.9
PIC (Psychological Distress Subscale)			
Minimal/No Problem		46	13.5
Mild		93	27.4
Moderate		143	42.1
Severe		58	17.1
PIC (Social Support Subscale)			
Mild Problem		97	28.5
Mod. Problem		169	49.7
Sev. Problem		70	20.6
No Problem		04	1.2
PIC (Family Functioning Subscale)			
Mild Problem		130	38.2
Mod. Problem		141	41.5
Sev. Problem		65	19.1
No Problem		04	1.2
PIC (Resilience Subscale)			
Mild		148	43.5
Mod.		132	38.8
Severe.		48	14.1
No Problem		12	3.50
PIC (Care Burden Subscale)			
Minimal/No Problem		10	2.90
Mild		34	10.0
Moderate		173	50.9
Severe		123	36.2
PIC (Expressed Emotion- Critical Comment)			
Minimal/No Problem		97	30.6
Mild		88	25.9
Moderate		41	9.1
Severe		114	34.4
PIC (Expressed Emotion- Emotional Over-involvement)			
Minimal/No Problem		104	40.9
Mild		88	25.9
Moderate		31	9.10
Severe		117	34.4
PIC (Expressed Emotion- Hostility)			
Minimal/No Problem		195	57.4
Mild		53	15.6
Moderate		27	7.9
Severe		65	19.1
Resilience	Minimum	Maximum	Mean & SD
	9.0	76.0	Mean=39.3; SD=14.2

Note: PIC=Psychosocial Inventory for Caregivers of Persons with Mental illness

Table 2: Internal Consistency (Cronbach Alpha), mean and standard deviation of the final 62 item scale (Psychosocial Inventory for Caregivers)

Scale	Total Number of Items	Internal Consistency (Cronbach Alpha)	Mean	Standard Deviation
Psychosocial Inventory for Caregivers (PIC)	62	0.88	141.85	16.31

Table 3: Inter consistency (Cronbach alpha) of all the 10 factors of the scale (Psychosocial Inventory for Caregivers)

Factors	No. of items	Mean	Standard Deviation	Cronbach alpha
Physical Health Subscale	10	24.10	5.29	0.88
Psychological Health Subscale	08	20.37	4.53	0.88
Social Support				
Family Support	04	8.39	2.03	0.68
Community Support	03	6.45	1.64	0.67
Family Functioning Subscale	05	10.56	2.45	0.76
Resilience Subscale	07	14.69	12.75	0.83
Care Burden Subscale	05	12.40	6.40	0.75
Expressed Emotion Subscale				
Critical Comment	06	14.33	3.23	0.81
Emotional Over-involvement	07	16.19	19.29	0.89
Hostility	07	14.34	4.86	0.92

Note: M=Mean; SD=Standard Deviation, α=Cronbach's Alpha

As cited in Table 2 the internal consistency (Cronbach's Alpha) of the PIC scale was found to be 0.88. Mean (141.85) and Standard Deviation (16.31).

This Table 3 showed the internal consistency, mean and standard deviation of each factor or domain[Physical Health Subscale (M = 24.1, SD = 5.29, α = 0.88); Psychological Distress Subscale (M = 20.3, SD = 4.53, α = 0.88); Social Support Subscale {Family Support (M = 8.39, 2.03, α = 0.68), Community Support (M = 6.45, SD = 1.64, α = 0.67)}; Family Functioning Subscale (M = 10.5, SD = 2.45, α = 0.76); Resilience Subscale (M = 14.6, SD = 12.7, α = 0.83); Care Burden Subscale (M = 12.4, SD = 6.40, α = 0.75); EE = Expressed Emotion Subscale {Critical Comment (M = 14.3, SD = 3.23, α = 0.81), Emotional Over involvement (M = 16.1, SD = 19.2, α =0.89), Hostility (M = 14.3, SD = 4.86, α = 0.92)}], along with a total number of item in each of the domain.

This Table 4 showed the reliability of the PIC, the study used Cronbach Alpha and CR, and the value was above 0.70. The convergent validity of PIC was acceptable because the average variance extracted (AVE) was above 0.5.

In this Table 5, the bold numbers are the square root of AV (average variance). The bold numbers listed diagonally are the root of the variance shared between the constructs and their measures. The off-diagonal elements are the correlation among the construct. In this table square root of the average variance explained was greater than the inter-factor correlation for the PIC scale Hence, discriminant validity was established for the scale (Psychosocial Inventory for Caregivers).

DISCUSSION

Socio-demographic and clinical findings

The majority of the caregivers were male (72.6%), Hindu (75.9%), from the general category (37.1%), hailing from a

Table 4: Composite Reliability and convergent validity [{Loading, Cronbach Alpha, Composite reliability (CR), Average Variance Extracted (AVE)}] of Psychosocial Inventory for caregivers (PIC) Scale

Factors	Items	Loading	Cronbach Alpha	Composite Reliability (CR)	Average Variance Extracted (AVE)
Physical	1	0.54	0.88	0.98	0.43
	2	0.45			
	3	0.43			
	4	0.55			
	5	0.52			
	6	0.51			
	7	0.75			
	8	0.81			
	9	0.90			
	10	0.86			
Psychological	11	0.45	0.88	0.97	0.44
	12	0.51			
	13	0.48			
	14	0.64			
	15	0.49			
	16	0.78			
	17	0.91			
	18	0.86			
Social (Family)	19	0.80	0.68	0.91	0.43
	20	0.77			
	21	0.59			
	22	0.40			
Social (Community)	23	0.74	0.67	0.92	0.56
	24	0.60			
	25	0.89			
Family Functioning	26	0.50	0.76	0.96	0.52
	27	0.62			
	28	0.81			
	29	0.84			
	30	0.79			
Resilience	31	0.62	0.83	0.98	0.50
	32	0.45			
	33	0.49			
	34	0.73			
	35	0.86			
	36	0.84			
	37	0.86			
Care Burden	38	0.49	0.75	0.96	0.48
	39	0.47			
	40	0.71			
	41	0.87			
	42	0.85			
Expressed Emotion (CC)	43	0.56	0.81	0.95	0.34
	44	0.48			
	45	0.57			
	46	0.58			
	47	0.67			
	48	0.63			
Expressed Emotion (EOI)	49	0.71	0.89	0.98	0.46
	50	0.67			
	51	0.72			
	52	0.67			
	53	0.67			
	54	0.68			
	55	0.68			
Expressed Emotion (H)	56	0.68	0.92	0.98	0.61
	57	0.63			
	58	0.87			
	59	0.74			
	60	0.87			
	61	0.87			
	62	0.81			

Note: CC=Critical Comment; EOI=Emotional Over-involvement; H=Hostility

semi-urban background (66.5%), mostly married (60.9%), educated up to high (34.4), unemployed (49.4%), with the nuclear family type (61.8%) and having upper-lower socioeconomic status (59.7%). The mean ages of the caregivers were M = 37.5 and the standard deviation was SD = 11.8. Most of the caregivers were educated up to graduation (29.1%), worked in the private sector (31.5%), related as a brother (35.0%) to the patient, and around (9.1%) left their job because of their patient's illness. The above-mentioned findings were in line with other Indian studies conducted in the past on persons with different mental illness and their caregivers.[5,6,27] In the clinical findings, the majority of patients were having the onset of illness as insidious (76.5%), with a history of mental illness in the family (48.5%), diagnosed with Schizophrenia (65.9%), with a primary caregiver (97.9%). The mean total duration of the illness (in days) of the patient was found to be (M = 494.9; SD = 636.1) and the mean total duration of the caregiving (in days) of the caregivers was found to be (M = 494.9; SD = 636.0). A similar kind of clinical profile was found in other Indian studies and the findings were in line with the present study.[8,9,10,28]

The magnitude of problems in caregivers of persons with mental illness

The findings of the Physical Health Questionnaire (PHQ) showed that the majority of caregivers were having physical health problems (38.2%), whereas, the findings of the Physical Health Subscale of the PIC scale showed that the majority of caregivers were having moderate physical health problems (36.2%), and (10.9%) were having severe physical health problems. Studies conducted in past on the physical health status of caregivers also came up with similar findings. The study conducted by Ancoli-Israel & Cooke[29] on insomnia and its effect on functioning in elderly caregivers' populations showed that 45% – 62% of older adults have sleep-disordered breathing, and around 45% have periodic limb movements of sleep compared to less than 10% in young adults. The study conducted by Newman *et al*.[30] showed that hypertension and cardiovascular disease were also considered to be major physical symptoms in caregivers. In a study by Tong *et al*.[31] the prevalence of back pain in caregivers of persons with mental illness was found to be 43.5%. Another study by Gupta *et al*.[32] showed a high prevalence rate of headache (48.0%) and hurt burnt (31.7%)

Table 5: Discriminant Validity of the Psychosocial Inventory for caregivers (PIC) Scale

Factors	AVE	CR	Cronbach Alpha	Phy	Psy	SS		FF	R	CB	EE		
						(Fam)	(Comm)				(CC)	(EOI)	(H)
Phy	0.43	0.98	0.88	0.66									
Psy	0.44	0.97	0.88	0.51	0.66								
SS (Family)	0.43	0.91	0.68	-0.24	-0.20	0.66							
SS (Community)	0.56	0.92	0.67	-0.28	0.28	-0.24	0.75						
Family Functioning	0.52	0.96	0.76	0.19	-0.21	-0.43	-0.35	0.72					
Resilience	0.50	0.98	0.83	-0.32	0.21	-0.14	-0.34	-0.12	0.70				
Care Burden	0.48	0.96	0.75	-0.15	-0.14	0.26	-0.17	0.38	-0.03	0.69			
Expressed Emotion (CC)	0.34	0.95	0.81	0.39	0.36	-0.27	3.6	-0.31	0.36	-0.14	0.58		
EOI	0.46	0.98	0.89	-0.15	-0.40	-0.03	-0.17	0.06	-0.15	0.08	-0.19	0.68	
Hostility	0.61	0.98	0.92	0.02	0.13	-0.18	0.29	-0.11	0.12	-0.11	0.11	0.01	0.78

Note: AVE=Average Variance Extraction; CR=Composite Reliability; Phy=Physical Health Subscale; Psy-Psychological Distress Subscale; SS=Social Support Subscale; Fam=Family Support; Comm=Community Support; FF=Family Functioning; R=Resilience Subscale; CB=Care Burden Subscale; EE=Expressed Emotion Subscale; CC=Critical Comment; EOI=Emotional Over involvement; H=Hostility

in caregivers of persons with mental illness.

In the present study, Depression Anxiety & Stress Scale showed a moderate level of depression in (37.4%) of respondents and a severe level of depression in (0.6%) of the respondent. The level of anxiety was at a moderate level in (35.4%) of respondents, severe in (26.2%) of the respondents, and extremely severe in (3.8%) of the respondents. The level of stress was at a mild level in (11.8%) of the respondent. In the Psychological Distress Subscale of the PIC Scale, majority of respondents were having a moderate level of psychological distress (42.1%) and to severe level of psychological distress was present (17.1%) of respondents. The study conducted by Vijayalakshmi[33] on depression in caregivers of persons with mental illness showed a prevalence of 42.5%. Another study by Stanley, Bhuvaneswari & Bhakyalakshmi[34] showed depression (12%), anxiety, and stress (24% each) in caregivers of persons with mental illness. A study by McGilloway[35] showed a high level of psychological distress (31.2%) in caregivers of persons with mental illness.

The Multidimensional Scale for Perceived Social Support showed social support from significant others was found to be poor in caregivers (45.3%), and support from friends and family was also found to be poor (43.5%) and (46.2%) respectively. In the Social Support Subscale of the PIC Scale moderate level of problems in social support was present in (49.7%), followed by a severe level of social support problems in (20.6%). The study conducted by Dam *et al*.[36] showed that poor social support was an important predictor of stress. Another study by Cohen & Wills[37] showed that poor quality of social support can be detrimental and lead to adverse physical and mental health outcomes. Chien *et al*.[38] highlighted that poor social support leads to poor functioning and poor prognosis.

The General Functioning Scale of Family Assessment Device highlighted the problem related to family functioning in the majority of the respondents (73.8%). In the Family Functioning Subscale of the PIC Scale, a moderate level of problems related to family functioning was present in (41.5%) of respondents, whereas, a severe level of problems related to family functioning was present in (19.1%) of the respondents. A similar finding was reported in the study where it was highlighted that caregivers with higher levels of care burden have poor general functioning.[39] Another study by Sun *et al*.[40] showed that poor family functioning and care burden were predictors of depression. Poor levels of family functioning, and poor levels of cognitive function due to long hours of caregiving were related to higher care burden.[41]

Connor-Davidson Resilience Scale showed poor resilience in the majority of respondents (Mean = 39.3; Standard Deviation = 14.2). In the resilience subscale of the PIC Scale, moderate problem related to resilience was present in 38.8% of the respondent and severe problem related to resilience was present in 14.1% of the respondent. Studies conducted by Joling *et al*.[42] showed poor resilience and highlighted that having a negative outlook, perceived loss of social relationships, and feeling isolated are the main cause of poor resilience in caregivers. A study conducted by Bekhet & Avery[43] highlighted poor resilience is common in caregivers of persons with mental illness because of stressful and difficult circumstances, demand, frustration, lack of social support, draining/exhaustion, and negative feelings (sadness, anger).

In Zarit Burden Interview Scale care burden was found to be at a moderate to severe level (53.8%) in caregivers. In the Care Burden Subscale of the PIC Scale moderate level of care, the burden was present in (50.9%) of the caregivers followed by a severe level of care burden (36.2%). A study conducted by Hajebi, Naserbakht & Minoletti[44] showed a moderate to severe level of care burden in the majority (73.0%) of caregivers of persons with Schizophrenia. The study explained that severe care burden in primary caregivers is because by relapses in the patient, poor prognosis, high level of expressed emotion in the family, and lesser awareness of

the illness. Further, they explained that stressors for patients act as a burden for the primary caregiver, which was in line with the findings of the present study. Moreover, the study by Kuchhal *et al*.[45] showed a severe level of care burden in 42.3% of their caregivers and put socio-demographic variables like (low education, unemployment, and low income) as a reason for care burden in the caregivers of persons with mental illness. All these points supported the findings of the present study.

The Family Questionnaire highlighted the high level of emotional over-involvement in 85.0% of the caregivers and critical comment was high in 55.3% of the caregivers. In the Critical Domain Subscale of the PIC Scale, severe level of critical comment was present in 34.4% of the caregivers, a severe level of over-involvement in 34.4% of the caregivers, and a severe level of hostility in 19.1% of the caregivers. In a study by Wang *et al*.[46] the critical comment was found to be at 21.7% and emotional over-involvement was 43.4%, which was supporting the findings of the present study.

Internal Consistency (Cronbach Alpha), mean and standard deviation of the final 62-item scale (Psychosocial Inventory for Caregivers)

The internal consistency (Cronbach's Alpha) of the PIC scale was found to be 0.88. Internal consistency of the pre-existing established tools was also found to be in line with the properties of the PIC scale. The internal consistency (Cronbach's Alpha) of the Physical Health Questionnaire scale was found to be 0.86.[20] Cronbach Alpha of Depression Anxiety Stress Scale (DASS 21) in different studies was found to be falling in the range of 0.78 to 0.89 and 0.86 to 0.94.[47,48] Cronbach Alpha of the Multi-dimensional Scale for Perceived Social Support (MSPSS) was found to be in the range of 0.54 to 0.73,[49] 0.86 to 0.90.[46] Cronbach Alpha of Zarit Burden Interview (ZBI) was estimated as 0.93.[23] Cronbach's alpha of the General Functioning scale of the Family Assessment Device ranges from 0.79 to 0.81, indicating good internal consistency of the instrument.[50,51] Cronbach Alpha of Connor Davidson Resilience Scale was found to be in the range of 0.30 to 0.89.[52,53] Cronbach alpha of the Family Questionnaire to evaluate expressed emotions ranges from 0.69 and 0.80.[26]

Reliability, Convergent, and discriminant validity of the PIC Scale

A study on the psychometric properties of the tool has shown that if the value of CR is more than 0.70, the reliability of the construct is acceptable.[54] The convergent validity of PIC was acceptable because the average variance extracted (AVE) was above 0.5. According to Pervan *et al*.[55] for the establishment of convergent validity the expected average variance (AV) should be greater than 0.5, also Fornell and Larcker[56] have suggested that if the average variance (AV) falls below the cutoff of 0.5 but CR falls above 0.6, therefore the convergent validity of a specific construct stands adequate. Hence, in the case of PIC, both reliability and convergent validity were established. According to Gu *et al*.[57] for the discriminant validity establishment, the diagonal element should be larger than the off-diagonal elements. In the case of the PIC scale, the square root of the average variance was greater than the inter-factor correlation for the PIC scale Hence, discriminant validity was established for the PIC scale.

CONCLUSION

In recent years, there has been a growing concern about the consequences experienced by patients' caregivers. Various tools have been developed separately to measure the various consequences related to caregiving. With the development of a new scale, a comprehensive assessment can be done to know the various factors and consequences related to caring for a person with mental illness with a single tool. This extension of this understanding of the caregiver experience can help practitioners/professionals improve interventions and improve caregiver well-being. This tool will make it possible to evaluate caregivers who face difficulties and might need additional support.

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Conflicts of interest

There are no conflicts of interest.

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Appendix - I

The Final Tool
PSYCHOSOCIAL INVENTORY FOR CAREGIVERS (PIC)
Please circle the appropriate box based on your caregiving experience
1=strongly disagree; 2=disagree; 3=agree; 4=strongly agree

Domains	Item No.	Items	Responses			
Physical Health Subscale	1	Do you feel exhausted most of the time?	1	2	3	4
	2	Do you feel you have disturbed sleep?	1	2	3	4
	3	Do you feel pain in your body, all the time?	1	2	3	4
	4	Do you feel your appetite has decreased significantly?	1	2	3	4
	5	Do you often experience dry mouth?	1	2	3	4
	6	Do you often experience body ache?	1	2	3	4
	7	Do you often experience nausea, vomiting?	1	2	3	4
	8	Do you often experience abdominal pain and cramps?	1	2	3	4
	9	Do you often sweat a lot?	1	2	3	4
	10	Do you often experience a headache?	1	2	3	4
Psychological Distress Subscale	11	Do you feel you are often preoccupied with negative thoughts?	1	2	3	4
	12	Do you often feel stressed out all the time?	1	2	3	4
	13	Do you feel you are unable to concentrate on your household activities/work?	1	2	3	4
	14	Do you often end up in anger outburst?	1	2	3	4
	15	Do you often feel irritable?	1	2	3	4
	16	Do you feel nervous most of the time?	1	2	3	4
	17	Do you feel, you no longer enjoy your life?	1	2	3	4
	18	Do you feel you are often preoccupied with negative	1	2	3	4
Social Support Subscale (Family Support)	19	Do you feel you have people around you who care about you? *	1	2	3	4
	20	Do you get financial help in the process of care giving for your relative? *	1	2	3	4
	21	Do you feel your family contributes significantly to a crisis? *	1	2	3	4
	22	Do you feel due to the extensive support of your friends and family, care giving has become an easy task? *	1	2	3	4
Social Support Subscale (Community Support)	23	Do you feel you have friends who understand you? *	1	2	3	4
	24	Do you feel there is a lack of resources available regarding mental health services in your locality?	1	2	3	4
	25	Do you have enough community support? *	1	2	3	4
Family Functioning Subscale	26	Does your family respect emotions of every member? *	1	2	3	4
	27	Does your family have any definite norms? *	1	2	3	4
	28	Do you feel there is no free flow of information in the family? *	1	2	3	4
	29	Does your family able to come together, whenever there is a crisis in the family? *	1	2	3	4
	30	Do you feel comfortable in sharing your problems within the family? *	1	2	3	4
Resilience Subscale	31	Does your family accept suggestions from friends and neighbours? *	1	2	3	4
	32	Does your family accept new ideas? *	1	2	3	4
	33	Does your family discuss family issues often? *	1	2	3	4
	34	Does your family indulge in making plans? *	1	2	3	4
	35	Do you think your family instead of thinking of the outcome, focus on hard work? *	1	2	3	4
	36	Does your family always count on strengths instead of weaknesses? *	1	2	3	4
	37	Does your family treat your relative as an important part of the family? *	1	2	3	4
Care Burden Subscale	38	Do you feel that you are unable to give time to other relations?	1	2	3	4
	39	Do you feel there is no one to share the care burden?	1	2	3	4
	40	Do you feel that you should pause the care giving role?	1	2	3	4
	41	Do you feel resentful because you have cut down on your own expenses due to care giving costs?	1	2	3	4
	42	Do you feel that care giving is a financial burden for you?	1	2	3	4
Expressed Emotion Subscale (CC)	43	Do you often criticize your relative for small things?	1	2	3	4
	44	Do you feel that your relative is a source of problem for you?	1	2	3	4
	45	Do you feel that the behaviour of your relative irritates you?	1	2	3	4
	46	Do you often appreciate your relative? *	1	2	3	4
	47	Do you feel that living with your relative is a harder task?	1	2	3	4
	48	Do you often comment on your relative behavior?	1	2	3	4
Expressed Emotion Subscale (EOI)	49	Do you feel your relative can't take any decision in your absence?	1	2	3	4
	50	Do you feel your relative is still like a small child who has no understanding?	1	2	3	4
	51	Do you blame yourself for everything?	1	2	3	4
	52	Do you feel your relative always needs extra care?	1	2	3	4
	53	Do you often show pity towards your relative?	1	2	3	4
	54	Do you spend lots of money on providing care to your relative?	1	2	3	4
	55	Do you often neglect your self-care and personal needs?	1	2	3	4

Contd...

Appendix - I: Contd...

The Final Tool
PSYCHOSOCIAL INVENTORY FOR CAREGIVERS (PIC)
Please circle the appropriate box based on your caregiving experience
1=strongly disagree; 2=disagree; 3=agree; 4=strongly agree

Domains	Item No.	Items	Responses			
Expressed Emotion	56	Do you easily get angry with your relative?	1	2	3	4
Subscale (H)	57	Do you ever verbally abuse your relative?	1	2	3	4
	58	Do you ever physically abuse your relative?	1	2	3	4
	59	Do you ever mock/make fun of your relative condition?	1	2	3	4
	60	Do you feel ashamed of your relative's presence?	1	2	3	4
	61	Do you ever stop communicating with your relative?	1	2	3	4
	62	Do you ever have an urge of screaming/yelling at your relative?	1	2	3	4

ORIGINAL ARTICLE

Subjective cognitive deficits and its correlates among patients with bipolar disorder: Findings from the bipolar disorder course and outcome study from India (BiD-CoIN study)

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ABSTRACT

Aim: This study aimed to evaluate the prevalence of subjective cognitive complaints and their association with clinical variables, insight, and disability.

Methodology: Seven hundred and seventy-three subjects with bipolar disorder (BD), recruited across 14 centers, currently in the euthymic phase were cross-sectionally evaluated on Cognitive Complaints in Bipolar Disorder Rating Assessment (COBRA).

Results: The mean total COBRA score was 9.79 (SD: 6.99), and 322 (41.7%) of the participants were found to have subjective cognitive complaints when the cut-off of >10 was used. Compared to those without cognitive complaints, those with cognitive complaints more often had depression as the first episode in their lifetime, had a higher prevalence of alcohol dependence, a higher number of depressive episodes (first five years of illness, lifetime, and per year of illness), a higher number of manic episodes in the first five years of illness, more often had depressive or indeterminate predominant polarity, lower prevalence of at least one-lifetime episode with psychotic symptoms, higher severity of residual symptoms, spent more time in the episodes in the lifetime, had poorer insight and higher disability.

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Conclusion: The present study suggests subjective complaints complaints are associated with more severe illness, higher levels of residual symptoms, poor insight, and higher disability.

Key words: Bipolar disorder, cognitive complaints, disability, insight

INTRODUCTION

Bipolar disorder (BD) is a chronic disorder, which is characterized by recurrent episodes of mania/hypomania and depression, with intervening periods of clinical remission.[1] Traditionally, it was believed that cognitive impairment in subjects with BD is short-lasting and is seen during affective episodes.[2] However, this understanding has changed over the last 2–3 decades, and it is now well-known that cognitive impairments are seen in patients with BD, even during the euthymic phase.[2] Available data also suggests that cognitive impairments in patients with BD are associated with poor functioning,[3-9] impaired quality of life,[10] and poorer psychosocial adjustment.[11-13]

Various domains of neurocognition, which have been reported to be affected in subjects with BD include attention/processing speed, verbal fluency, working memory, verbal learning/memory, and executive functions, including cognitive flexibility and inhibitory control.[14,15] A meta-analysis of studies on cognitive function assessed by objective measures in BD found the following domains to be affected during the euthymic phase: verbal learning (0.81) and long-delay verbal free recall (0.78), followed by delayed non-verbal recall (0.80), semantics (0.75), verbal fluency, verbal interference (0.75) and set-switching tasks (0.73), immediate non-verbal memory (0.73), sustained visual vigilance (0.69) and speeded visual scanning (0.65), psychomotor speed (0.66), working memory (0.65), executive functions concerning problem-solving tasks (0.54), visuospatial function (0.55), and phonemic (0.51) fluency. During the acute bipolar depressive episode, the domains affected are verbal memory (1.20), phonemic fluency (0.93), attention (0.80), and executive function in speeded set-shifting (0.64). In the manic/mixed states, impairment is noted in verbal learning (1.43) and delayed free verbal recall (1.05), attention (0.79–0.90), general executive function (0.72) and speeded set-shifting (0.64), semantic fluency (0.59), and letter fluency (0.51).[16]

Several clinical variables are associated with objective cognitive impairment in patients with BD. A recent meta-analysis reported that the most critical clinical variables that influence cognitive impairment in patients with BD include the subtype of BD (i.e., type-I or type-II) and the presence or absence of psychotic symptoms in the episodes. This meta-analysis showed that compared to BD-II, those with BD-I have a higher level of global cognitive impairment and higher impairment in specific domains such as verbal memory, processing speed, executive function speed, and executive function accuracy.[6] Similarly, the presence of psychotic symptoms in BD is associated with higher cognitive impairment in verbal memory, processing speed, speed of executive functioning, accuracy of executive functioning, working memory, and social cognition.[6]

Objective neurocognitive impairment in subjects with BD is associated with insight,[17,18] number of manic episodes, number of hospitalizations, and duration of illness.[11,14,19] Variables that have shown an inconsistent association with neurocognitive impairments in patients with BD include age, age of onset, gender,[20] substance use,[20,21] and medications.[20]

However, a majority of studies evaluating cognitive impairment in patients with BD are based on neurocognitive batteries, which are time-consuming and are not used routinely in clinical practice. Keeping this in mind, in recent years, some of the authors have designed user-friendly instruments that are time economical and measure subjective cognitive complaints. Further, there is a lack of consensus with regard to subjective and objective cognitive impairment in patients with BD. One of the studies, which evaluated both subjective and objective cognitive performance of 70 patients with BD, reported that although there is a significant correlation between the subjective and objective performance on global measures, but not at the individual cognitive domain level. This study also showed that subjective cognitive impairment was associated with self-rated psychosocial difficulties, and both these variables were predicted by depressive symptoms.[22] Another study, which included only 15 patients with BD reported a lack of correlation between subjectively reported and objectively measured cognitive impairment in patients with BD.[23] Other studies which have evaluated subjective cognitive dysfunction in patients with BD conclude that subjective cognitive dysfunction is predicted by the severity of depression, anxiety, and manic symptoms, rather than diagnosis, age, gender, and alcohol abuse. A study that assessed subjective complaints and objective impairment among[24] patients with BD, in different phases of the illness, suggested that there was a significant correlation between subjective and objective cognitive performance among the patients in the euthymic phase, but the same was not seen among patients in acute episodes and subjective complaints were associated with depressive symptoms.[25]

However, most of the studies, which have evaluated subjective neurocognitive functions in BD, have small sample sizes. They have included a heterogeneous sample (i.e., including euthymic subjects and those currently in an episode) and have not assessed the association of subjective cognitive complaints with psychosocial outcomes. This study aimed to evaluate the prevalence of subjective cognitive complaints in subjects with BD. Additionally, the study aimed to assess the association of subjective cognitive complaints with the course of illness, residual symptoms and other clinical variables, insight, and disability.

METHODOLOGY

This cross-sectional study was conducted across 14 teaching institutes in India. The study received ethical clearance from all the participating sites' local institutional ethics committees, and all the participants provided written informed consent before enrollment. This study focused on understanding the course and outcome of BD in the form of the number of episodes, residual symptoms, disability, insight, and subjective cognitive dysfunction.[26-28] In this paper, we focus on cognitive dysfunction and its association with other variables.

All the participants fulfilled the diagnosis of BD as per the Diagnostic and Statistical Manual for Mental disorders, Fourth edition[29] (DSM-IV), and confirmed by using the Mini-International Neuropsychiatric Interview (MINI-PLUS).[30] For inclusion into the study, the participants were required to be in the age ≥ of 18 years, have an illness of at least ten years, and currently in clinical remission. Clinical remission was defined by using Hamilton Depression Rating Scale (HDRS)[31] and the Young Mania Rating Scale (YMRS),[32] with patients having a score of ≤7 on both scales. Patients were also required to be able to read Hindi/English. Those with organic brain syndrome, intellectual disability, organic BD, and medically too sick to participate were excluded.

The course of the BD was evaluated by using the National Institute of Mental Health - Retrospective Life Charts - Clinician and Self-rated versions (NIMH: LCM - P and S/R).[33] Cognitive functions were evaluated by using the Cognitive Complaints in Bipolar Disorder Rating Assessment (COBRA),[34] and insight was evaluated by using the insight scale for affective disorders (ISAD).[35] Both these scales were translated into Hindi using World Health Organization methodology, recommended for translation and back-translation. Disability was evaluated by using the Indian Disability Evaluation Assessment Scale (IDEAS).[36]

ISAD: This clinician-administered scale, based on the Scale for Unawareness among Mental Disorders (SUMD), was developed to assess insight in patients with mood disorders. It consists of 17 items, rated on a 6-point scale, varying from 0 (cannot be evaluated or item not relevant) to 5 (no awareness). The scale has been found to have adequate face and content validity of its items.[35]

COBRA: The Bipolar Disorder Program was developed by the COBRA at the Hospital Clinic of Barcelona to detect the main daily cognitive complaints experienced by bipolar patients. It is a 16-item self-report instrument for subjective assessment of cognitive dysfunctions in BD patients, including executive function, processing speed, working memory, verbal learning and memory, attention/concentration, and mental tracking. The scores partially correlate with the objective assessment of memory and executive functions.[34] A higher total score suggests a higher level of subjective complaints. A score of >10 is considered to be an indicator of the presence of cognitive impairment. It has high convergent validity and high internal consistency.

IDEAS: The IDEAS evaluates disability in four domains, namely, self-care, interpersonal activities, communication and understanding, and work. Each item is scored on a 5-point scale with a range of 0–4, i.e., from no (0) to profound disability (4). In addition, the duration of illness is also given weightage while calculating the disability score. The total disability score is obtained by summing up the ratings on the four domains. The global disability score is calculated by adding the "total disability score" and duration of illness score. A global disability score of more than 7 signifies a disability of >40%.

Statistical Package for Social Sciences, the fourteenth version (SPSS-14) (SPSS for Windows, Version 14.0. Chicago, SPSS Inc.) was used to analyze the data. The mean and standard deviation were computed for the continuous variables. Categorical variables were analyzed as frequency and percentages. Comparisons were made by using the t-test, Chi-square test, and Fischer's exact test. Correlations were assessed using Pearson correlation coefficient and Spearman rank correlation as per the requirement. Regression analysis was carried out to evaluate the predictors of subjective cognitive complaints.

RESULTS

The study sample comprised of 773 subjects, with a maximum of 107 (13.8%) patients from one of the centers in Mumbai, followed by 92 (11.9%) patients from Chandigarh center (PGIMER, Chandigarh), 63 (8.2%) patients from Bardwan center, 58 (7.5%) patients each from a center in Kalyani and another in Kolkata, 52 (6.7%) patients from Manipal center, 51 (6.6%) patients from Puducherry, 50 (6.5%) patients each from Mullana, second centers in Mumbai and New Delhi, 49 (6.3%) patients from Jodhpur center, 47 (6.1%) from Silchar center, 25 (3.2%) patients from Ahmedabad, and 21 (2.7%) patients from Murshidabad center.

The mean total COBRA score was 9.79 (SD: 6.99), with a range of 0–40. When the cut-off of >10 was used, 322 (41.7%) of the participants were found to have subjective cognitive impairment.

Comparison of socio-demographic and clinical profile of those with and without subjective cognitive complaints

The mean age of the participants was 45.66 (SD: 10.5) years and the mean duration of education in years was 10.3 (SD: 4.45) years. The majority of the participants were male (63.6%), currently married (82.7%), on paid employment (65.7%), from nuclear families (57.6%), rural locality (53%), and Hindu by religion (73.2%). The mean income of the patients was rupees 24,463 (SD: 21,665), with a range of 1,000 to 1,00,000 and a median of 18,000. When those with cognitive complaints were compared to those without cognitive complaints, those with cognitive complaints were more often married, from non-nuclear families, and Hindu by religion [Table 1].

In terms of clinical profile, compared to those without cognitive complaints, those with cognitive complaints more often had depression as the first episode in the lifetime, had higher prevalence of alcohol dependence, higher number of depressive episodes in the lifetime, higher number of depressive episodes per year of illness, higher number of manic and also depressive episodes in the first 5 years of disease, more often had depressive or indeterminate predominant polarity, lower prevalence of at least 1 lifetime episode with psychotic symptoms, higher severity of residual depressive and manic symptoms, more often had depression as the most recent episode, spent more time in the episodes in the lifetime, spent more time in the manic episodes in the lifetime, had overall higher severity of the lifetime depressive episodes, higher proportion of them consulted a faith healer in the lifetime, were less often hospitalized for BD, and less often had history of being treated with electroconvulsive therapy (ECT) [Table 2].

In terms of insight and disability, compared to those without cognitive complaints, those with cognitive complaints had poorer insight and a higher level of disability in all the domains of IDEAS, and a higher proportion of them had benchmark disability [Table 2].

In terms of treatment received at the time of assessment, compared to those without cognitive complaints, those with cognitive complaints, were less often not on any medications, were more often on a combination of mood stabilizers, antidepressants, and antipsychotic medications (with or without benzodiazepines), less often were receiving only mood stabilizers, were more often on antidepressants, less often on lithium and more often on valproate, and were more often getting a benzodiazepine [Table 3].

Regression analysis

We used regression analysis to assess the predictors of subjective cognitive complaints. In the regression analysis, the total COBRA score was used as the dependent variable and other variables which differed significantly between the two groups were used as independent variables. In the enter method, only 12.1% of the variance of the subjective cognitive complaints was explained by affective morbidity index, duration of current remission, the total number of manic episodes in first 5 years of illness, the severity of depressive episodes, HDRS total score, YMRS total score, number of depressive episodes per year, total time spent in the episodes in a lifetime (in months), ISAD total score, depressive affective morbidity index, manic affective morbidity index, self-care, communication and understanding, duration of manic/hypomanic episodes in months, interpersonal relationship domain of IDEAS, and the total number of depressive episodes.

In the stepwise method, the maximum variance was explained by IDEAS interpersonal relationship domain (7.4%), followed by the affective morbidity index (1.4%), HDRS total score (1%), and severity of depressive episodes (0.5%).

Additionally, we also carried out the binary logistic regression analysis to assess the factors associated with the presence of subjective cognitive impairment. The odds of having subjective cognitive complaints were higher for those who were married, from extended/joint families, having depressive-manic-interepisodic course, having alcohol dependence in the lifetime, no lifetime psychotic episodes, intermediate predominant polarity, and having benchmark disability [Table 4].

DISCUSSION

In the present study, when the cut-off of >10 was used, 41.7% of the participants were found to have subjective cognitive impairment with a mean COBRA score of 9.79 (SD: 6.99). Previous studies which have used COBRA in patients of BD suggest the mean scores to a range of 8.32 (SD: 6.6)[37] to 17.01 (7.69),[38] and the findings of the present study are within this reported range. Although many studies have used COBRA to assess subjective cognitive complaints in patients with BD, there is a relative dearth of data concerning the proportion of patients with BD having subjective cognitive complaints. A study from China, by using the Chinese version of COBRA, suggested that 72.14% of patients with BD have a subjective cognitive impairment, with the highest prevalence among those with bipolar depression (97.62%), followed by a 78.0% among the patients who were currently euthymic and 43.75% in patients who were presently hypomanic/manic.[25] The reason for the lower prevalence of cognitive complaints in our euthymic BD patients is not apparent. Still, factors such as the different versions of the instrument, education, and age may confound the findings. Nevertheless, the presence of cognitive complaints in two-fifths of the sample in euthymia underscores the need

Table 1: Comparison of demographic variables of patients with and without cognitive complaints

	Whole Sample *n*=773	Cognitive complaints present *n*=322 Mean (SD)/ Frequency (%)	Cognitive complaints absent *n*=451 Mean (SD)/ Frequency (%)	Chi-square test/*t*-test (*P*)	Correlation coefficient
Age (in years) - Mean and SD [range]	45.66 (10.50) [18-75]	45.75 (10.97) [22-70]	45.59 (10.16) [18-75]	-0.201 (0.841)	*r*=0.015 (0.201)
Gender *n* (%)					
Male	492 (63.6)	211 (65.5)	281 (62.3)	0.843 (0.359)	*r*=0.85 (0.396)
Female	281 (36.4)	111 (34.5)	170 (37.7)		
Marital status *n* (%)					
Currently single	134 (17.3)	44 (13.7)	90 (19.9)	5.189 (0.023)*	*r*=-1.757 (0.079)
Currently married	639 (82.7)	278 (86.3)	361 (80.0)		
Years of education - Mean and SD [range]	10.30 (4.45) [0-21]	10.48 (4.29) [0-20]	10.18 (4.56) [0-21]	-0.921 (0.357)	0.041 (0.259)
Occupation					
Unemployed and housewives	265 (34.3)	111 (34.5)	154 (34.1)	0.009 (0.925)	*r*=1.510 (0.131)
Employed and earning	508 (65.7)	211 (65.6)	297 (65.9)		
Patient's income in rupees - Mean and SD [range]	24463 (21665) [1000-100,000] Median 18000	23434.78 (20248) [1000-100000]	25247.23 (22613.13) [1000-100000]	*U*=69938 (0.38)	-0.027 (0.453)
Family type *n* (%)					
Nuclear	445 (57.6)	167 (51.9)	278 (61.7)	7.352 (0.007)**	*r*=-2.816 0.005)**
Non-nuclear	328 (42.4)	155 (48.1)	173 (38.4)		
Residence *n* (%)					
Rural	410 (53.0)	138 (42.9)	225 (49.9)	3.730 (0.053)	*r*=-1.945 (0.052)
Urban	363 (47.0)	184 (57.1)	226 (50.1)		
Religion *n* (%)					
Hindu	566 (73.2)	244 (75.8)	322 (71.4)	8.632 (0.05)	
Muslim	150 (19.4)	53 (16.5)	97 (21.5)		
Sikh	36 (4.7)	18 (5.6)	18 (3.9)		
Christian	19 (2.5)	5 (1.6)	14 (3.1)		
Others	02 (0.3)	2 (0.6)	0		
Religion *n* (%)					
Hindu	566 (73.2)	244	322	1.83 (0.17)	*r*=0.071 (0.94)
Non-Hindu	207 (26.8)	78	129		

to regularly assess cognitive complaints among patients with BD. Also, cognitive remediation strategies should be readily available for these patients to reduce cognitive impairment in the functioning of patients with BD.

In our study, age did not have an association with the presence or absence of cognitive complaints or the severity of cognitive dysfunction. There is a lack of consensus on this association, with some of the studies suggesting that younger people have a lower level of cognitive complaints. In contrast, others suggest that older people have higher cognitive complaints.[39] However, many studies refute this association.[40] A meta-analysis concluded that age does not influence cognitive impairments.[4,20] In the present study, age of onset also did not emerge as a factor that was associated with subjective cognitive complaints. Some of the studies suggest that early age of onset, especially onset during the pediatric age group, is associated with higher cognitive impairment.[41] Accordingly, this lack of association in the present study could be attributed to very few patients with childhood-onset BD.

We found that those with cognitive complaints have more severe illness and a higher level of residual symptoms. The higher severity of illness as indicated by the higher number of depressive episodes in the lifetime and per year of illness, the higher number of manic and also depressive episodes in the first five years of illness, spent more time in the episodes in the lifetime, spent more time in the manic episodes in the lifetime, and had overall higher severity of the lifetime depressive episodes. It has been suggested that neurocognitive impairments in patients with BD may be due to neurodevelopmental and neurodegenerative processes.[42] Accordingly, it can be said that the association of neurocognitive complaints with higher severity of illness over the years may be due to neurodegenerative processes, arising due to the toxic effect of higher number and more severe episodes in the lifetime, consistent with neuro-progression in the long-term course of BD, at least in a proportion of patients.[20]

Findings of the present study of the association of cognitive complaints with alcohol dependence are supported by previous studies, which also suggest higher severity of cognitive impairment among those with comorbid substance use.[20,21] Accordingly, it can be said that it is essential to address substance use in patients with BD, to minimize its impact on neurocognitive functioning. Clinicians should psychoeducate the patients about the association of substance use with cognitive complaints and aim for complete abstinence to minimize the negative impact on cognitive functioning.

Table 2: Clinical profile of the participants with and without cognitive complaints

Clinical Variables	Whole Sample Mean (S.D) [Range]/*n* (%) *n*=773	Cognitive complaints present *n*=322 Mean (SD)/ Frequency (%)	Cognitive complaints absent *n*=451 Mean (SD)/ Frequency (%)	Chi-square test/*t*-test (*P*)	Correlation coefficient
Age of onset (years)	26.30 (8.54)	26.24 (7.936)	26.33 (8.967)	0.148 (0.88)	*r*=0.058 (0.107)
Duration of illness (months)	232.05 (94.55)	232.87 (97.70)	231.47 (92.34)	-0.202 (0.84)	*r*=-0.035 (0.325)
Diagnosis *n* (%)					
BD type I	714 (92.37)	299 (92.9)	415 (92.0)	0.188 (0.665)	*r*=0.052 (0.652)
BD type II	59 (7.63)	23 (7.1)	36 (7.9)		
Nature of first episode *n* (%)					
Manic/Hypomanic	449 (58.1)	164 (50.9)	285 (63.2)	11.601 (0.001**)	*r*=-1.539 (0.124)
Depressive	324 (41.9)	158 (49.0)	166 (36.8)		
Duration of current remission (months)	32.84 (50.04) Median 12.0	28.94 (45.774)	35.63 (52.752)	1.837 (0.067)	*r*=-0.151 (<0.001***)
Substance use disorder:					
Alcohol dependence	80 (10.3)	44 (13.7)	36 (7.9)	19.03 (0.001**)	*r*=-1.245 (0.214)
Cannabis dependence	13 (1.7)	5 (1.6)	8 (1.8)	6.90 (0.128)	*r*=-0.108 (0.914)
Tobacco dependence	136 (17.6)	48 (14.9)	78 (17.3)	1.313 (0.85)	*r*=-0.186 (0.853)
Opioid dependence	9 (1.2)	4 (1.2)	5 (1.1)	1.035 (0.795)	*r*=0.536 (0.592)
Patients with substance use disorder	177 (22.5)	80 (24.8)	97 (21.5)	1.185 (0.276)	*r*=-0.329 (0.742)
Life history of BPAD					
Mean number of depressive episodes in the lifetime	3.36 (5.51) Median=2.0	3.93 (6.216)	2.95 (4.911)	-2.460 (0.014)*	*ρ*=0.135 (0.000***)
Mean number of manic episodes in the lifetime	3.68 (4.75) Median=2.0	3.57 (4.628)	3.76 (4.851)	0.560 (0.576)	*ρ*=-0.011 (0.758)
Mean number of hypomanic episodes in the lifetime	0.81 (2.97) Median=0	0.92 (3.149)	0.73 (2.839)	-0.879 (0.380)	*ρ*=-0.047 (0.196)
Mean number of mixed episodes in the lifetime	0.22 (1.52) Median=0	0.29 (2.282)	0.18 (0.525)	-1.001 (0.317)	*ρ*=-0.041 (0.260)
Mean number of total episodes in the lifetime	8.58 (10.60) Median=6.0	9.15 (11.637)	8.17 (9.797)	-1.266 (0.206)	*ρ*=0.059 (0.101)
Mean number of manic episodes per year of illness	0.21 (0.3) Median=0.1385	0.2135 (0.362)	0.2067 (0.239)	-0.310 (0.756)	*ρ*=0.011 (0.766)
Mean number of depressive episodes per year of illness	0.19 (0.39) Median=0.1143	0.2369 (0.491)	0.1659 (0.285)	-2.530 (0.012*)	*ρ*=0.151 (0.000***)
Mean number of hypomanic episodes per year of illness	0.048 (0.198) Median=0.00	0.0588 (0.239)	0.0402 (0.161)	-1.288 (0.198)	*ρ*=-0.044 (0.225)
Mean number of mixed episodes per year of illness	0.0115 (0.051) Median=0	0.0135 (0.070)	0.0101 (0.031)	-0.894 (0.372)	*ρ*=-0.042 (0.244)
Mean number of total episodes per year of illness	0.49 (0.74) [0.4-14]	0.548 (0.946)	0.459 (0.566)	-1.47 (0.140)	*ρ*=0.087 (0.015*)
Mean number of depressive episodes in the first 5 years	0.99 (1.86) Median=1	1.17 (1.83)	1.17 (1.53)	0.029 (0.97)	*ρ*=0.129 (<0.001***)
Mean number of manic episodes in the first 5 years	1.17 (1.66) Median=1	1.17 (2.37)	0.87 (1.37)	-2.21 (0.027*)	*ρ*=0.011 (0.754)
Mean number of hypomanic episodes in the first 5 years	0.128 (0.602) Median=0	0.136 (0.744)	0.122 (0.476)	-0.334 (0.738)	*ρ*=-0.015 (0.682)
Mean number of mixed episodes in the first 5 years	0.041 (0.229) Median=0	0.037 (0.233)	0.044 (0.226)	0.422 (0.673)	*ρ*=-0.037 (0.30)
Mean number of total episodes in the first 5 years	2.39 (3.35) Median=2	2.51 (4.44)	2.31 (2.28)	-0.824 (0.410)	*ρ*=0.033 (0.357)
Mean number of manic episodes per year of illness in the first 5 years	0.235 (0.333) Median=0.2	0.234 (0.366)	0.235 (0.307)	0.029 (0.977)	*ρ*=0.011 (0.75)
Mean number of depressive episodes per year of illness in the first 5 years	0.198 (0.372) Median=0.2	0.233 (0.475)	0.173 (0.275)	-2.21 (0.027*)	*ρ*=0.129 (<0.001***)
Mean number of hypomanic episodes per year of illness in the first 5 years	0.025 (0.120) Median=0	0.027 (0.148)	0.024 (0.095)	-0.334 (0.738)	*ρ*=-0.015 (0.682)
Mean number of mixed episodes per year of illness in the first 5 years	0.008 (0.045) Median=0	0.007 (0.046)	0.008 (0.045)	0.422 (0.673)	*ρ*=-0.037 (0.303)
Mean number of total episodes per year of illness in the first 5 years	0.478 (0.671) 0.4 [0-14]	0.502 (0.889)	0.462 (0.457)	-0.824 (0.410)	*ρ*=0.033 (0.357)

Contd...

Table 2: Contd...

Clinical Variables	Whole Sample Mean (S.D) [Range]/*n* (%) *n*=773	Cognitive complaints present *n*=322 Mean (SD)/ Frequency (%)	Cognitive complaints absent *n*=451 Mean (SD)/ Frequency (%)	Chi-square test/*t*-test (*P*)	Correlation coefficient
Predominant polarity (Harvard Definition-with mixed)					
Depressive	226 (29.2)	109 (33.9)	116 (25.7)	7.99 (0.018*)	*r*=-0.003 (0.950)
Mania/hypomania/mixed	457 (59.1)	171 (53.1)	286 (63.4)		
Indeterminate	90 (11.6)	41 (12.4)	49 (10.9)		
Predominant polarity (Harvard Definition-without mixed)					
Depressive	244 (31.6)	112 (34.8)	132 (29.3)	9.370 (0.009**)	*r*=-0.003 (0.944)
Mania/Hypomania	434 (56.1)	161 (50.0)	273 (60.5)		
Indeterminate	95 (12.3)	49 (15.2)	46 (10.2)		
Predominant polarity- (Barcelona Definition)					*r*=-0.011 (0.813)
Depressive	159 (20.6)	75 (23.3)	84 (18.6)	10.82 (0.004**)	
Mania/Hypomania	354 (45.8)	125 (38.8)	229 (50.8)		
Not determined	260 (33.6)	122 (37.9)	138 (30.6)		
Recurrent mania ≥3 episodes of mania without depression	115 (14.9)	41 (12.7)	74 (16.4)	2.004 (0.157)	*r*=-0.018
Recurrent mania ≥ Two episodes of mania without depression	76 (9.8)	26 (8.1)	50 (11.1)	1.922 (0.166)	*r*=-0.018 (0.705)
Affective morbidity Index					
Manic	27.11 (68.46)	31.75 (86.87)	23.79 (51.30)	-0.68 (0.492)	*ρ*=0.037 (0.301)
Depressive	17.59 (26.47)	21.70 (31.22)	14.65 (22.05)	-3.81 (<0.001***)	*ρ*=0.138 (<0.001***)
At least one lifetime episode with psychotic symptoms	326 (42.2)	111 (34.5)	215 (47.7)	13.42 (<0.001***)	*ρ*=-0.141 (0.003**)
Mean HDRS score	3.10 (3.25) Median=3	3.78 (3.96)	2.62 (2.54)	-4.944 (<0.001***)	*ρ*=0.215 (<0.001***)
Mean YMRS score	2.30 (4.3) Median=2	2.85 (4.79)	1.91 (3.88)	-3.018 (0.003**)	*ρ*=0.180 (<0.001***)
Polarity of most recent episode					
Depression	323 (41.8)	159 (49.3)	164 (36.4)	13.083 (<0.001***)	-0.158 (<0.001***)
Mania/Hypomania/Mixed	450 (58.2)	163 (50.6)	287 (63.6)		
Time spent in episodes (months)	27.24 (30.13) Median=18	31.37 (32.91)	24.29 (27.64)	-3.238 (0.001**)	*ρ*=0.155 (<0.001***)
Time spent in depression (months)	2.43 (1.13) Median=3	2.52 (1.11)	2.36 (1.15)	-1.839 (0.066)	*ρ*=0.070 (0.051)
Time spent in mania/hypomania/ mixed (months)	3.29 (3.67) Median=2	3.71 (4.72)	2.98 (2.63)	-2.742 (0.006**)	*ρ*=0.078 (0.030*)
Lifetime suicidal attempts	242 (31.3)	100 (31.1)	142 (31.5)	0.016 (0.899)	*r*=0.002 (0.953)
Average severity of manic or hypomanic episodes	2.19 (0.40) Median=2	2.19 (0.412)	2.19 (0.406)	0.310 (0.757)	*r*=-0.002 (0.953)
Average severity of depressive episodes (%)	1.87 (0.80) Median=2	1.96 (0.790)	1.80 (0.803)	-2.865 (0.004**)	*r*=0.513 (0.000***)
Lifetime history of breakthrough episodes	282 (36.4)	123 (38.2)	159 (35.3)	0.563 (0.453)	*r*=0.078 (0.029*)
Lifetime history of Faith-healing treatment *n* (%)	671 (86.7)	293 (90.9)	378 (83.8)	8.912 (0.003**)	*r*=0.019 (0.000***)
Lifetime history of Mood stabilizer prophylaxis *n* (%)	770 (99.5)	320 (99.4)	450 (99.8)	2.87 (0.23)	*r*=0.038 (0.295)
Lifetime history of Discontinuing prophylaxis on their own *n* (%)	712 (92.0)	304 (94.4)	408 (90.5)	3.362 (0.067)	*r*=0.074 (0.040*)
Number of patients with a history of relapse due to poor medication adherence *n* (%)	505 (65.2)	208 (64.6)	297 (65.9)	0.089 (0.766)	*r*=-0.037 (0.300)
Any history of hospitalization *n* (%)	402 (51.9)	138 (42.9)	264 (58.5)	19.24 (<0.001***)	*r*=-0.177 (0.000***)
Any history of electroconvulsive therapy *n* (%)	183 (23.6)	60 (18.6)	123 (27.3)	7.760 (0.005**)	*r*=-0.106 (0.003**)
Obesity# *n* (%)	457 (59.0)	204	253	4.34 (0.037*)	*r*=0.055 (0.13)
RCAD	45 (5.8)	19 (5.9)	26 (5.8)	0.006 (0.937)	*r*=0.027 (0.451)
SAD	73 ()	35 (10.9)	38 (8.4)	1.312 (0.252)	*r*=0.036 (0.312)
ISAD total score - Mean and SD [range]	34.23 (33.69) Median=21	27.65 (21.73)	20.06 (19.90)	-4.99 (<0.001***)	*r*=0.243 (<0.001***)

Contd...

Table 2: Contd...

Clinical Variables	Whole Sample Mean (S.D) [Range]/*n* (%) *n*=773	Cognitive complaints present *n*=322 Mean (SD)/ Frequency (%)	Cognitive complaints absent *n*=451 Mean (SD)/ Frequency (%)	Chi-square test/*t*-test (*P*)	Correlation coefficient
IDEAS Domain scores					
Self-care	0.25 (0.53) [0-3] Median=0	0.35 (0.621)	0.17 (0.445)	-4.840 (<0.001***)	*r*=0.168 (<0.001***)
Interpersonal relations	0.42 (0.65) [0-3] Median=0	0.63 (0.783)	0.27 (0.489)	-7.873 (<0.001***)	*r*=0.177 (<0.001***)
Communication and understanding	0.34 (0.62) [0-3] Median=0	0.48 (0.698)	0.24 (0.541)	-5.544 (<0.001***)	*r*=0.146 (<0.001***)
Work	0.64 (0.88) [0-4] Median=0	0.85 (1.005)	0.49 (0.749)	-5.839 (<0.001***)	*r*=0.170 (<0.001***)
Total IDEAS score	1.64 (2.22) [0-12] Median=1	2.32 (2.62)	1.16 (1.74)	-7.399 (<0.001***)	*r*=0.289 (<0.001***)
IDEAS Global score	5.64 (2.22) [4-16]	6.31 (2.61)	5.16 (1.74)	-7.34 (<0.001***)	*r*=0.289 (<0.001***)
IDEAS benchmark Disability					
Upto 7 (no benchmark disability)	631 (81.6)	230 (71.4)	401 (88.9)	38.30 (<0.001***)	
>7 (benchmark disability)	142 (18.4)	92 (28.6)	50 (11.1)		

*P<0.05; **P<0.01; ***P<0.001. r=Pearson Correlation coefficient, ρ - Spearman rho Rank Correlation, RCAD: Rapid Cycling Affective Disorder, SAD: Seasonal Affective Disorder

Available studies suggest that compared to those without psychotic symptoms during the episodes, the presence of psychotic symptoms in patients with BD is associated with higher cognitive impairment in the domains of verbal memory, processing speed, speed of executive functioning, the accuracy of executive functioning, working memory, and social cognition.[6] However, in the present study, those with cognitive complaints had a lower prevalence of at least one-lifetime episode with psychotic symptoms. The lack of association in the present study could be attributed to the fact that we assessed psychotic symptoms only as present or absent in the lifetime and did not evaluate the total number of psychotic episodes. Consistent with our findings, few studies suggest a lack of association of cognitive impairment with psychotic symptoms in patients with BD.[6] Furthermore, compared to BD-II patients, those with BD-I have a higher level of global cognitive impairment, specifically in verbal memory, processing speed, executive function speed, and executive function accuracy.[43] However, we did not find any such association with subtypes of BD. It is important to note that some of the previous studies which have reported this association have relied on objective assessment instruments to assess cognitive impairment, which has been shown to have only a modest correlation with subjective cognitive complaints.[22]

Further, in contrast to expected, in the present study, those with cognitive complaints less often had a history of being treated with ECT.[44] This could be attributed to the relatively higher use of ECT in patients with BD in the Indian context, and better control of symptoms with ECT, which counteract the residual symptoms of BD.

We found a lower proportion of those with cognitive complaints had prior treatment with ECT, contrary to the studies that report cognitive impairments in those receiving ECT.[44,45] Relatively higher use of ECT in patients with BD in the Indian context may lead to better control of symptoms, which counteract the residual symptoms of BD.

In terms of other treatment variables compared to those without cognitive complaints, those with cognitive complaints were less often not on any medications, were more often on a combination of mood stabilizers, antidepressants, and antipsychotic medications (with or without benzodiazepines), less often were receiving only mood stabilizers, were more often on antidepressants, less often on lithium and more often on valproate, and were more often getting a benzodiazepine. Existing literature suggests that both ongoing medications and long-term use of medications in patients with BD influence the level of cognitive complaints.[20] The associations found in the present study can be understood as a reflection of a higher number of medications having an adverse impact on cognitive functions. Another possible explanation could be that the use of a higher number of medications among those with cognitive complaints was indicative of more severe illness and hence, required a higher number of medications. However, the effect of drugs on cognitive complaints is far from clear, and there is a need to evaluate their impact during long-term use.

In the present study, neurocognitive complaints were associated with a higher level of residual psychopathology, poorer insight, and a higher level of disability in all the domains. These associations are supported by the existing literature.[17,18,46,47] The implications of these findings include adequate symptom control and proper psychoeducation of patients to improve their insight into the illness is of paramount importance for the management of BD. Some of the studies which have evaluated the association of insight and neurocognitive impairment suggest that neurocognitive

Table 3: Comparison of the treatment profile of those with and without cognitive complaints and association of cognitive complaints

Clinical Variables	Whole Sample Mean (S.D)/*n* (%) *n*=773	Cognitive complaints present *n*=322 Mean (SD)/ Frequency (%)	Cognitive complaints absent *n*=451 Mean (SD)/ Frequency (%)	Chi-square test/*t*-test (*P*)
None	23 (3.0)	6 (1.9)	17 (3.8)	34.73 (<0.001***)
MS + AP	200 (38.3)	77 (23.9)	123 (27.3)	1.106 (0.293)
MS + AD	29 (13.2)	12 (3.7)	17 (3.8)	0.001 (0.975)
MS + AD + AP	51 (20.4)	37 (11.5)	14 (3.1)	21.44 (<0.001***)
MS only	119 (21.7)	31 (9.6)	88 (19.5)	14.09 (<0.001***)
AP only	9 (1.7)	1 (0.3)	8 (1.8)	0.126
AP + AD	4 (1.0)	1 (0.3)	3 (0.7)	FE=0.645
MS + AP + BZD	100 (12.9)	42 (13.0)	58 (12.9)	0.006 (0.94)
MS + AD + BZD	73 (9.4)	30 (9.3)	43 (9.5)	0.010 (0.919)
MS + AD + AP + BZD	108 (13.9)	59 (18.3)	49 (10.9)	8.69 (0.003**)
MS + BZD	49 (6.3)	23 (7.1)	26 (5.8)	0.601 (0.438)
AP + BZD	4 (0.5)	2 (0.6)	2 (0.4)	FE=1
AP + AD + BZD	4 (0.5)	1 (0.3)	3 (0.7)	FE=0.645
Antipsychotics				
None	290 (37.5)	102 (31.7)	188 (41.7)	8.027 (0.005**)
Olanzapine	245 (31.7)	111 (34.5)	134 (29.7)	1.966 (0.161)
Risperidone	74 (9.6)	41 (12.7)	33 (7.3)	6.366 (0.012*)
Quetiapine	86 (11.1)	39 (12.1)	47 (10.4)	0.543 (0.461)
Aripiprazole	26 (2.4)	12 (3.7)	14 (3.1)	0.224 (0.636)
Lurasidone	13 (1.7)	3 (0.9)	10 (2.2)	1.878 (0.171)
Haloperidol	22 (2.8)	8 (2.6)	14 (3.1)	0.261 (0.609)
Chlorpromazine	17 (2.2)	6 (1.9)	11 (2.4)	0.289 (0.591)
Antidepressants				
None	507 (65.6)	199 (61.8)	339 (75.2)	15.86 (<0.001***)
Escitalopram	38 (4.9)	25 (7.8)	13 (2.9)	9.577 (0.002**)
Sertraline	175 (22.6)	88 (27.3)	87 (19.3)	6.932 (0.008**)
Fluoxetine	31 (4.0)	17 (5.3)	14 (3.1)	2.309 (0.129)
Paroxetine	3 (0.4)	1 (0.3)	2 (0.4)	FE=1
Venlafaxine	9 (1.2)	3 (0.9)	6 (1.3)	0.260 (0.866)
Bupropion	10 (1.3)	6 (1.9)	4 (0.9)	1.403 (0.389)
Mood stabilizers				
None	44 (5.7)	9 (2.8)	35 (7.8)	6.335 (0.012*)
Lithium	301 (38.9)	115 (35.7)	186 (41.2)	4.050 (0.044*)
Valproate	342 (44.2)	156 (48.4)	186 (41.2)	3.954 (0.047*)
Carbamazepine	16 (2.1)	5 (1.6)	11 (2.4)	0.728 (0.394)
Lithium + Valproate	57 (7.4)	25 (7.8)	32 (7.1)	0.123 (0.726)
Lamotrigine	13 (1.7)	6 (1.9)	7 (1.6)	0.110 (0.740)
Benzodiazepines'				
None	434	166 (51.6)	268 (59.4)	4.727 (0.030*)
Clonazepam	112 (14.5)	56 (17.4)	56 (12.4)	3.752 (0.053)
Diazepam	39 (5.0)	20 (6.2)	19 (4.2)	1.566 (0.211)
Lorazepam	44 (5.7)	13 (4.0)	31 (6.9)	2.815 (0.093)
Chlordiazepoxide	139 (18.0)	64 (19.9)	75 (15.6)	1.342 (0.247)
Etizolam	4 (0.5)	3 (0.9)	2 (0.4)	FE=0.654
Daily dosage of lithium - Mean and SD [range]	799.58 (211.42) [300-1350] Median 900	777.78 (226.69)	813.79 (200.13)	1.582 (0.115)
Daily dose of valproate - Mean and SD [range]	932.71 (349.84) [200-2000] Median 1000	930.66 (353.45)	934.40 (347.61)	0.106 (0.915)

MS: Mood Stabilizer; AP: Antipsychotics; AD: Antidepressant

impairment leads to poor insight in patients with BD.[48] The association of higher neurocognitive complaints with a higher level of disability suggests that neurocognitive complaints are an important marker of BD, which influences the psychosocial outcomes of BD. Hence, all efforts must be made to minimize the neurocognitive complaints in patients with BD to improve psychosocial outcomes.

However, in the regression analysis, only 12.1% of the variance of the subjective cognitive impairment was explained by all the variables studied. Among the various variables, the maximum variance was explained by IDEAS interpersonal relationship domain (7.4%), followed by the affective morbidity index (1.4%), HDRS total score (1%), and severity of depressive episodes (0.5%). However, it is important to

Table 4: Binary logistic regression depicting the variables having significant association

Variables	B	S.E.	Wald	df	Sig.	Exp (B)	95% C.I. for EXP (B)	
							Lower	Upper
Marital Status								
Single	Ref							
Married	0.454	0.201	5.135	1	0.023	1.575	1.063	2.333
Family Type								
Nuclear	Ref							
Extended/Joint	0.400	0.148	7.325	1	0.007	1.491	1.117	1.992
Polarity of first lifetime episode								
MDI	Ref							
DMI	0.503	0.148	11.532	1	0.001	1.654	1.237	2.212
Alcohol Dependence								
Absent								
Present	0.601	0.238	6.399	1	0.011	1.825	1.145	2.907
Harvard Predominant Polarity								
Depressive	Ref							
Mania	-0.116	0.250	0.215	1	0.643	0.890	0.545	1.454
Intermediate	-0.446	0.165	7.347	1	0.007	0.640	0.464	0.884
At least one psychotic episode								
Absent	Ref							
Present	-0.549	0.150	13.321	1	<.001	0.577	0.430	0.776
Polarity of most recent episode								
Depression	Ref							
Mania	-0.606	0.162	13.975	1	<.001	0.545	0.397	0.750
Hypomania	-0.450	0.245	3.376	1	0.066	0.638	0.395	1.030
Mixed	-0.203	0.327	0.385	1	0.535	0.817	0.430	1.549
Any history of hospitalization in lifetime								
Absent	Ref							
Present	-0.654	0.148	19.592	1	<.001	0.520	0.389	0.694
Any history of ECT in the past								
Absent	Ref							
Present	-0.493	0.178	7.682	1	0.006	0.611	0.431	0.866
Benchmark Disability Present								
Absent	Ref							
Present	1.166	0.194	36.030	1	<.001	3.208	2.192	4.694

note that the association of subjective cognitive compliants and interpersonal relationship domain of disability may be more of an impact of cognitive impairment rather than a cause of the same. In the binary logistic regression analysis, the odds of having subjective cognitive complaints were higher for those who were married, from extended/joint families, having depressive-manic-interepisodic course, having alcohol dependence in the lifetime, no lifetime psychotic episodes, intermediate predominant polarity, and having benchmark disability. These findings suggest clinical variables, i.e., the variables describing the life course of BD influence the subjective cognitive complaints than other variables.

The limitations include a lack of objective measures for the assessment of cognitive functions. Although we evaluated the relationship of subjective cognitive complaints with current prescriptions, this study was not designed to assess the impact of long-term treatment on cognitive functions. The assessment of cognitive complaints was cross-sectional. Hence, the present study's findings do not provide any information about the longitudinal course of cognitive complaints in patients with BD.

To conclude, the present study suggests that about two-fifths of patients with BD have subjective cognitive complaints. Cognitive complaints are associated with more severe illness, higher levels of residual symptoms, use of a higher number of medications, poor insight, and higher disability. Accordingly, any rehabilitation effort for patients with BD should focus on cognitive remediation, which should start as early as possible during the longitudinal course of illness. Further, efforts must be made to minimize residual psychopathology, which is also considered to have a negative impact on cognitive functioning.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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ORIGINAL ARTICLE

Prevalence and correlates of personality disorders in males with alcohol dependence syndrome undergoing inpatient treatment in a tertiary care hospital in South India

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ABSTRACT

Background: Globally, about half the patients with alcohol dependence syndrome have a comorbid personality disorder (PD). Indian studies that have explored this are sparse.
Objectives: The present study was conducted to estimate the prevalence of personality disorders in individuals with alcohol dependence syndrome undergoing inpatient treatment and to determine the sociodemographic and clinical correlates of PDs in these patients.
Methods: This cross-sectional observational study was conducted among the inpatients of the psychiatry department in a tertiary care teaching hospital. Adult male patients with DSM-IV TR diagnosis of alcohol dependence were evaluated for the presence of PDs using Structured Clinical Interview for DSM IV Axis II Personality disorders**.** The severity of alcohol dependence was assessed using the Severity of Alcohol Dependence Questionnaire.
Results: One hundred male inpatients with alcohol dependence syndrome were recruited. Of them, 48 (48%) participants had at least one PD with a 95% confidence interval of 0.38-0.58. Antisocial and avoidant PDs were found in 26 (26%) and 13 (13%) patients, respectively. The mean age at first drink was lower in participants with PD when compared to those without any PD (18.13 ± 4.46 vs. 20.79 ± 4.61 years, respectively). Also, the amount of alcohol consumption per day was significantly higher in those with PD when compared to those without any PD (15.9 ± 6.81 vs. 13.17 ± 4.34 units per day).
Conclusion: About half of males with alcohol dependence syndrome undergoing inpatient treatment had at least one PD. Antisocial and avoidant PDs were the most common PDs in this population. Individuals with comorbid PD had a lower age at first drink and higher daily alcohol consumption.

Key words: Alcohol abuse, alcohol dependence syndrome, alcoholism, personality disorder

INTRODUCTION

There is substantial comorbidity between alcohol use disorders and personality disorders (PDs). National Epidemiologic Survey on Alcohol and Related Conditions, a

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large nationwide study in the United States, reported that more than one-fourth of patients with alcohol use disorder had at least one PD.[1] A more recent review reported that more than half the patients with certain PDs (antisocial PD and borderline PD) have alcohol use disorder.[2] Similarly, about half the patients with alcohol use disorder have comorbid PDs.[3] Patients with alcohol use disorder and comorbid PD are difficult to retain in treatment and they tend to drink more frequently.[3] The heterogeneity in the prevalence of personality disorders in alcohol use disorder populations is attributed to problems in the tools used for diagnosis.[3]

A few Indian studies have studied the comorbidity between PD and alcohol use disorder. A hospital-based Indian study found that the prevalence of PDs in alcohol dependence patients was about 30% using International Personality Disorder Examination.[4] Another Indian study that used Millon Clinical Multiaxial Inventory-III found that depressive, narcissistic, and paranoid PDs were prominent in the alcohol dependence group.[5] Determination of the prevalence of PDs in alcohol-dependent individuals using a clinician-administered semi-structured diagnostic interview will be a valuable addition to the literature from India. In the above context, the present study was conducted to estimate the prevalence of personality disorders in individuals with alcohol dependence syndrome undergoing inpatient treatment and to determine the sociodemographic and clinical correlates of personality disorders in these patients.

METHODS

The participants for this cross-sectional observational study were drawn from the in-patient ward of the department of psychiatry in a tertiary care–teaching hospital in South India using a consecutive sampling technique. In our setting, patients with alcohol dependence syndrome who present to the outpatient or emergency services with alcohol dependence syndrome are offered admission along with one caregiver. The patients undergo thorough medical and psychiatric evaluation. Benzodiazepines and multivitamin supplementation are initiated. Once the withdrawal symptoms subside, the patients are started on individual psychotherapy addressing the alcohol dependence syndrome and its consequences. Occupational therapy and other psychosocial interventions are initiated as per the need of the patient.

The study was approved by Institute Ethics Committee Reference number RC/18/86. Male patients in the age group of 18-60 years admitted to the psychiatry ward with a Diagnostic and statistical manual of mental disorders fourth edition, Text Revision (DSM-IV TR) diagnosis of alcohol dependence syndrome were eligible to participate in the study. Critically ill patients and patients with psychotic syndrome or hearing impairment were excluded. Eligible participants who provided a written informed consent underwent further assessments.

The assessments were conducted after the resolution of alcohol withdrawal symptoms (based on a consistent score of less than 8 on Clinical Institute Withdrawal Assessment–Alcohol revised scale). The sociodemographic (age, marital status, education, occupation, and socio-economic status) and clinical details (including details of alcohol use–age at first drink, duration of alcohol consumption, duration of alcohol dependence, amount of alcohol consumed per day) were collected using a semistructured proforma. The presence of Axis I psychiatric disorders was evaluated based on a clinical interview with the patient and the informant. The severity of alcohol dependence was assessed using Severity of Alcohol Dependence Questionnaire.[6] The presence of personality disorders was assessed using Structured Clinical Interview for DSM IV Axis II Personality disorders (SCID II).[7] The information obtained from the patient was corroborated by the informants and ward observations. The data collection was done from November 2018 to July 2020.

Tools used

The 20-item Severity of Alcohol Dependence Questionnaire is a reliable and valid instrument to measure the severity of alcohol dependence in various clinical settings.[6] This self-report tool takes about five minutes to complete. Each item is scored on a 4-point scale with a score of 0 to 3. The total score can range from 0 to 60. A score of less than 16, 16-30, and more than 30 indicates mild, moderate, and severe alcohol dependence, respectively.

SCID-II[7] is a semistructured instrument to diagnose personality disorders based on DSM IV criteria. It is a clinician-rated instrument and the trained interviewer clarifies and confirms the presence of acknowledged symptoms by asking for examples. This gives a reliable and valid assessment of the presence of various PDs based on DSM IV criteria. In addition to covering the 10 standard DSM-IV Axis II PDs, SCID II assesses for the presence of depressive PD and passive-aggressive PD.

Assuming the prevalence of PDs in individuals with alcohol-dependence syndrome to be 40% based on previous reports and an acceptable deviation of 10%, a sample of 96 participants would be required to estimate a similar prevalence at a confidence level of 95%. The statistical analysis was carried out using Statistical Package for Social Sciences software version 20 (IBM Corp., Armonk, NY, USA). Sociodemographic and clinical variables were summarized using frequency and percentage for categorical variables and mean and standard deviation for continuous variables. Chi-squared test/Fisher's exact test was used to evaluate the association between various sociodemographic parameters and the presence of personality disorders. Student *t*-test was

used to determine whether alcohol-related clinical variables differed between the two groups namely participants with and without PDs. A two-tailed *P* value <.05 was considered to be statistically significant.

RESULTS

One hundred male patients with alcohol dependence syndrome were recruited for the study. The mean age of the participants was 41.16 ± 8.91 years. Most participants were married and belonged to Hindu religion. Unskilled, semiskilled, and skilled workers together constituted about half of the participants [Table 1]. Half of the participants had moderate alcohol dependence and more than one-fourth had severe alcohol dependence. The mean duration of alcohol dependence was 9.62 ± 6.3 years [Table 2]. A past history of withdrawal seizures was reported by 43 (43%) patients, while 29 (29%) patients had a past history of delirium tremens.

In our study, 48 (48%) participants had at least one PD. Antisocial and avoidant PDs were the most common PDs in the study population [Table 3]. Chi-squared test/ Fisher's exact test was used to evaluate the association between the sociodemographic parameters (religion, marital status, education, occupation, and socioeconomic status) and presence of any PD. No association was noted between any of the above parameters and the presence of PD in the study population. Similarly, there was no association between comorbid smoking, oral tobacco use, cannabis use, and the presence of PDs. Alcohol dependent individuals with comorbid PD were noted to have lower age at first drink and higher daily alcohol consumption compared to those without comorbid personality disorder. Other alcohol-related variables like duration of alcohol consumption, duration of alcohol dependence, and severity of alcohol dependence were not different between these two groups [Table 4].

DISCUSSION

About half of the treatment-seeking male patients with alcohol dependence syndrome had at least one PD in the present study. Antisocial and avoidant PDs were the most commonly diagnosed PDs in this population. Paranoid, borderline, and obsessive-compulsive PDs were also present in about one-tenth of the individuals in the present study. The reported prevalence of PDs in alcohol use disorders varies considerably in previous studies.[2] Our findings are broadly similar to previous studies conducted in Canada and Germany.[8,9] Using SCID-II, Zikos *et al*.[8] found that 59% of alcohol use disorder patients had at least one PD and cluster B PDs were the most common subtype. Similarly, Preuss *et al*.[9] reported a 60% PD prevalence in alcohol-dependent inpatients. They found obsessive-compulsive and borderline PDs to be most

Table 1: Sociodemographic details of the participants

Variable	*n* (%)
Marital status	
Unmarried	11 (11%)
Married	86 (86%)
Separated/divorced/widowed	3 (3%)
Religion	
Hindu	88 (88%)
Christian	10 (10%)
Muslim	2 (2%)
Educational status	
Illiterate	6 (6%)
Primary school certificate/Middle school certificate	60 (60%)
High school certificate/Intermediate/Post high school	20 (20%)
Graduate/postgraduate	14 (14%)
Occupation	
Unemployed	9 (9%)
Unskilled worker	27 (27%)
Semi-skilled worker/Skilled worker	34 (34%)
Clerical/shopkeeper/farmer	24 (24%)
Semi-professional/Professional	6 (6%)
Socio-economic status	
Lower	41 (41%)
Lower-middle	14 (14%)
Middle	37 (37%)
Upper-middle	7 (7%)
Upper	1 (1%)

Table 2: Alcohol-related variables in the study participants

Alcohol-related variable	Mean (SD)
Age at first drink (in years)	19.51 (4.71)
Duration of alcohol consumption (in years)	21.72 (7.94)
Duration of alcohol dependence (in years)	9.62 (6.38)
Alcohol consumption per day (in units)	14.48 (5.79)
Severity of Alcohol Dependence Questionnaire (SADQ) score	24.56 (9.24)
Severity of alcohol dependence based on SADQ	N (%)
Mild alcohol dependence	22 (22%)
Moderate alcohol dependence	50 (50%)
Severe alcohol dependence	28 (28%)

Table 3: Prevalence of personality disorders in treatment-seeking alcohol-dependent individuals

Variable	*n* (%)	Confidence interval
Any personality disorder	48 (48%)	95% CI (0.38-0.58)
One personality disorder	29 (29%)	95% CI (0.20-0.38)
Two personality disorders	12 (12%)	95% CI (0.06-0.18)
Three personality disorders	7 (7%)	95% CI (0.02-0.12)
Type of personality disorder		
Antisocial personality disorder	26 (26%)	95% CI (0.17-0.35)
Avoidant personality disorder	13 (13%)	95% CI (0.06-0.20)
Paranoid personality disorder	9 (9%)	95% CI (0.03-0.15)
Borderline personality disorder	8 (8%)	95% CI (0.03-0.13)
Obsessive-compulsive personality disorder	8 (8%)	95% CI (0.03-0.13)
Narcissistic personality disorder	7 (7%)	95% CI (0.02-0.12)
Dependent personality disorder	2 (2%)	95% CI (0-0.04)
Depressive personality disorder	2 (2%)	95% CI (0-0.04)
Passive-aggressive personality disorder	1 (1%)	95% CI (0-0.03)

Table 4: Comparison of alcohol-related variables in alcohol-dependent individuals with and without any personality disorder

Alcohol-related variable	With at least one personality disorder Mean (SD)	Without personality disorder Mean (SD)	*t*	*P*
Age at first drink (in years)	18.13 (4.46)	20.79 (4.61)	2.931	0.004
Duration of alcohol consumption (in years)	21.13 (8.28)	22.27 (7.64)	0.719	0.474
Duration of alcohol dependence (in years)	9.48 (6.1)	9.75 (6.68)	0.211	0.833
Amount of alcohol consumption per day (in units per day)	15.9 (6.81)	13.17 (4.34)	-2.404	0.018
SADQ* score	25.31 (10.3)	23.87 (8.19)	-0.781	0.437

*Severity of Alcohol Dependence Questionnaire, $P<0.05$ considered significant.

common in their study population. An earlier multicentric study from the United States also reported a 58% prevalence of PDs in participants with alcohol dependence syndrome with antisocial, borderline, and paranoid PDs being the most commonly identified disorders.[10] A multicentric study from the United Kingdom reported a PD prevalence of 53% in alcohol service sample.[11] A Spanish study[12] also reported a similar PD prevalence of 44.3% in treatment-seeking alcohol-dependent subjects. Obsessive-compulsive PD was the most commonly diagnosed personality disorder in this study.

The prevalence of PD found in our study is clearly higher than an earlier Indian study[4] which reported a 30% prevalence in a hospital-based population of alcohol dependence subjects using the International Personality Disorder Examination. This study also found obsessive-compulsive and antisocial PDs to be the most prevalent PDs in this population. Antisocial PD was found in 21% of alcohol-dependent subjects in another Indian study[13] that used the Present Status Examination as the study tool. The variations in the prevalence rates of PDs in the present study and previous studies may be partially attributed to the differences in the prevalence rates in the general population in the different catchment areas. Alternatively, the nature of study tools (structured vs. semi-structured; self-report vs. clinician administered), the timing of assessment during the course of alcohol withdrawal, the degree of substance use comorbidity, and the sample size could influence the prevalence reported.

Several hypotheses have been put forward to explain the greater prevalence of PDs in alcohol use disorders. Among them, the four models that have been supported by empirical literature are predisposition/vulnerability, complication/scar model, exacerbation, and spectrum models.[14,15]

Age at first drink and average alcohol consumption per day were associated with the presence of PD in the present study. Surprisingly, the severity of alcohol dependence was not associated with the presence of PD. Preuss *et al*.[9] found that different PDs were associated with age at first drink and severity of alcoholism in their study population. An earlier study linked the presence of antisocial PD and borderline PD to more severe alcoholism.[10] Zikos *et al*.[8] reported that Cluster B PD group achieved alcohol milestones at a younger age and they had more severe psychosocial problems. Several sociodemographic and clinical factors were found not to be associated with prevalence of PDs in the present study. Our study was probably underpowered to detect these associations as we calculated the sample size based on our primary objective. The analysis regarding associated factors should be considered exploratory in nature.

Despite the high prevalence of PDs in individuals with alcohol dependence syndrome, it is not a usual practice to systematically evaluate treatment seekers for the presence of PDs. Several reports have highlighted the role of PDs in the treatment outcome of alcohol-dependent patients.[2,3,16] One recent meta-analysis[17] did not find any difference in treatment outcomes of alcohol-dependent patients with and without PDs. However, the authors have reported the quality of evidence of all the included studies to be low or very low.

The use of SCID-II which is a reliable and valid instrument to assess PDs is a major strength of the present study. SCID-II being a semistructured interview administered by a trained clinician is superior to fully structured instruments used in several previous studies.

The findings of the present study have to be interpreted with the following limitations in mind. The study was done on male patients with alcohol dependence syndrome in an inpatient setting. Outpatients and nontreatment seekers were not included and hence the findings cannot be generalized to all patients with alcohol dependence syndrome. Inclusion of only treatment-seeking individuals might have overestimated the prevalence of PDs (Berkson's bias).

CONCLUSION

About half of male patients with alcohol dependence syndrome undergoing inpatient treatment had at least one PD. Antisocial and avoidant PDs were the most common PDs in this population. Individuals with comorbid PD had a lower age at first drink and higher daily alcohol consumption.

In future, studies conducted on a representative sample from the community, outpatients, and inpatients are

required to estimate the prevalence of PDs in patients with alcohol dependence syndrome in various settings. The role of PD on the pattern and clinical correlates of relapse and its implication in treatment outcomes merit further study. Considering the high prevalence of PDs noted in patients with alcohol dependence, evaluation of the same using validated tools can be incorporated as part of standard care of management of these patients.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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ORIGINAL ARTICLE

Resilience and its relationship with disability in persons with bipolar disorder and schizophrenia: A comparative study

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ABSTRACT

Background: Resilience is the capacity to bounce back from adversity. Severe mental illnesses are associated with poor and heterogeneous functional outcomes. Symptom remission is inadequate to achieve patient-oriented outcome, and positive psychopathology constructs like resilience have emerged as possible mediators. An exploration of resilience and its association with functional outcomes can drive therapeutic endeavors.
Aim: To assess and compare the influence of resilience on disability among patients diagnosed and treated for bipolar disorder and schizophrenia in a tertiary care facility.
Methods: Study design – Hospital-based, cross-sectional, comparative design; study population – patients of bipolar disorder and schizophrenia with 2–5 years illness and Clinical Global Impression – Severity (CGI-S) <4; sampling procedure – consecutive sampling; sample size – 30 patients each; scales used – Connor–Davidson Resilience Scale (CD-RISC), Indian Disability Evaluation and Assessment Scale (IDEAS), and CGI-S; patients were evaluated with IDEAS, and 15 persons with and without a significant disability were recruited in each group of schizophrenia and bipolar disorder.
Results: The mean CD-RISC 25 score for persons with schizophrenia was 73.60 ± 13.87, whereas that for persons with bipolar disorder was 78.10 ± 15.26. For schizophrenia, only CDRISC-25 scores are statistically significant ($t = -2.582$, $P = 0.018$) for predicting IDEAS global disability. For bipolar disorder, CDRISC-25 scores ($t = -2.977$, $P = 0.008$) and CGI-severity scores ($t = 3.135$, $P = 0.005$) are statistically significant for predicting IDEAS global disability.
Conclusion: When disability is factored in, resilience is comparable in persons with schizophrenia and bipolar disorder. Resilience independently predicts disability in both groups. However, the type of disorder does not significantly affect the relationship between resilience and disability. Irrespective of diagnosis, higher resilience is associated with lower disability.

Key words: Bipolar disorder, disability, resilience, schizophrenia

INTRODUCTION

The construct of resilience has been popular as well as mental health parlance for many years now, but over the last few decades, its understanding has evolved significantly,

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primarily driven by research in ecology, psychology, and medical sciences. The initial transition of resilience from an ecological and sociological concept occurred via the developmental psychopathology lens, whereby it was conceptualized as a protective factor against inevitable environmental transgressions. But modern-day resilience research has revealed that it is a multidimensional concept involving multiple homeostatic systems. One of the most accepted definitions currently for resilience conceptualizes it as "the capacity of a dynamic system to withstand or recover from significant challenges that threaten its stability, viability, or development".[1] The contemporary definition takes a much more atheoretical yet dynamic approach, as resilience can be seen to operate at many levels according to this definition. The various systems employed to understand human behavior, including genetic, epigenetic, neurochemical, psychological, psychosocial, or cultural – and the eclectic combination of them – can all be explored for the framework of resilience.

With this new framework of understanding, a fresh look is warranted to understand how resilience affects severe mental illnesses (SMIs). SMIs like schizophrenia and bipolar disorder have a prevalence of 1.9% and tend to affect all domains of life and necessitate long-term care services. The National Mental Health Survey of India 2015–16 found that three out of four persons with a severe mental disorder experienced significant disability in work, social, and family life.[2] It is, hence, pertinent to examine various factors that contribute to this disability. Resilience is emerging as one such important factor.[3]

Any major mental disorder like schizophrenia or bipolar disorder is a state of immense flux for the system, and the body's natural equilibrium is disrupted. This homeostasis requires active moderation and the systems employed to maintain allostasis – contribute to resilience. The allostasis manifests in the form of adaptive psychophysiological events that can be understood through the psychosocial paradigms as well. Mihali propounded a resilience theory based on this framework whereby "the effects of resilience, which is conferred by environmental, genetic, and social factors, can preclude, reverse, or slow the progression of schizophrenia".[4] At least a couple of major longitudinal naturalistic studies have suggested the presence of protective factors that contribute to better outcome and sustaining recovery in persons with schizophrenia.[5,6] Among more familiar factors like premorbid personality and attitudinal systems, greater resilience too predicted the severity of symptoms and has been considered as an intervening variable between psychopathology and global functioning.[5]

In bipolar disorder too, resilience has been found to have a strong relationship with relapse rates and residual symptoms.[7-9] Hofer found that once resilience was factored in, remitted patients of bipolar disorder and healthy control had a comparable quality of life.[10] Initial assumptions that resilience might affect functioning indirectly via its effect on neurocognition, self-esteem, or insight have not been translated in the form of evidence. There is a distinct lacuna of knowledge on how resilience is related to functioning, especially disability. While a few studies have explored the same in remitted patients,[10,11] Hofer suggested that including persons with acute illness has significant merits.[10]

While a multitude of treatment outcomes have been examined to understand illnesses, most of them focus on hospital populations, attempting to examine clinical characteristics. While dissecting the different components of mental illnesses is important, the "natural history" of disease remains incomplete without understanding its impact on social adjustment and behavior. Disability assessment aims to quantify the extent to which the manifestations of a certain disorder represent maladaptive responses to particular aspects of the social environment (WHO, 1988). Clinical remission is not the therapeutic end-point, but a means to achieve reintegration of the afflicted into the society. The objective evaluation of disability serves utmost importance for interactions at various levels including treatment, recovery-oriented strategies, assessing the effectiveness of measures, broader socio-political policies, and welfare activities. Disability is not just an eligibility criterion for financial remuneration but a credible clinical variable. Psychiatric disabilities are further unique as, unlike other chronic medical illnesses, the manifestations are different and the translation from clinical to social is less discreet, rather complementary to each other.[12]

Bipolar disorder and schizophrenia are among the most disabling disorders worldwide. While advancements in pharmacotherapeutic and psychosocial interventions are being increasingly diversified and the illnesses being explored across all levels of understanding, including genetic, epigenetic, connectomics, psychological, and social – the framework is still essentially a "deficit model" of psychopathology. Recent research has provided valuable insights into what determines the heterogeneous outcomes associated with these disorders, and positive psychopathology constructs like resilience, coping, and internalized stigma are being seen as possible answers.[11,13] While some major studies have shown that resilience can influence the recurrence of episodes, functioning, and cognitive impairments, they also point out significant cross-cultural differences.[14] There is an urgent need to evaluate resilience in Indian patients to increase this momentum. A focus on resilience in such patients represents an important shift in our understanding of these illnesses and is expected to translate into practical therapeutic endeavors. One interesting avenue for future research would involve an examination of resilience-enhancing interventions customized for patients with bipolar disorder

or schizophrenia to limit disability and enhance the quality of life.

The current study aims to assess and compare the influence of resilience and internalized stigma on treatment effectiveness (as reflected in disability scores) among patients diagnosed and treated for bipolar disorder and schizophrenia in a tertiary care facility.

METHODS

The study was conducted at a teaching psychiatric hospital and a tertiary care psychiatric facility in the Northeastern part of India. The study population was persons with schizophrenia or bipolar disorder attending OPD or IPD services of the hospital and fulfilling inclusion criteria. The study had a cross-sectional, comparative design with consecutive sampling procedures and was carried over a period of 6 months. Ethics approval was obtained from the Institutional Ethics Committee, LGBRIMH Tezpur on 24/12/2020.

2.1 Sample size estimation – Previous studies in the study population have shown mean CDRISC scores in patients with schizophrenia and bipolar disorder to be significantly different, and using the previously recorded effect size and sample standard deviation,[15] sample size was calculated as per *t*-statistic formula [a = 0.05, b = 0.1, q1 = q0 = 0.5, E = 13, S = 17; www.sample-size.net/sample-size-means]. The calculated sample sizes were 38 for each group, but in view of feasibility and previous studies,[16] the sample size of 30 patients, each with schizophrenia and bipolar disorder, was studied.

2.2 Inclusion and exclusion criteria – The inclusion criteria were: a) patients diagnosed with bipolar affective disorder (F31) or schizophrenia (F20) as per ICD 10 (DCR), b) duration of illness at least 2 years and at most 5 years, c) Clinical Global Impression – Severity (CGI-S) score 4 (moderately ill) or less, d) patients aged between 18 and 45 years, and e) patients who gave written informed consent. The exclusion criteria were: a) patients with mood or psychotic disorder secondary to other medical condition, schizoaffective disorder, personality disorders, intellectual disability, b) patients who were receiving electroconvulsive therapy, c) patients with co-morbid debilitating medical illness, and d) patients who were unable to read or write Assamese/English.

2.3 Tools used – a) *Connor–Davidson Resilience Scale (CD-RISC)* – 25 item self-rated instrument that has been validated in clinical populations and Assamese translation validated in the region.[17] Has been used in patients with CGI-S <4[8]; b) *Indian Disability Evaluation and Assessment Scale (IDEAS)* – validated for use by mental health professionals in the region. Global disability score >7 is considered a significant disability; c) *CGI-S scale* – clinician rated with robust efficacy.

2.4 Procedure – Patients from OPD or IPD of the psychiatric hospital were recruited based on the inclusion and exclusion criteria. The treating team comprising of a senior psychiatrist and a resident psychiatrist made clinical diagnoses and referred patients to the investigators who assessed disability in the patients and, based on IDEAS global disability score of more or less than 7, allotted participants in either group – with or without significant disability. Fifteen participants were recruited in each such group, and hence 30 for each disorder group. The CGI-S and CD-RISC scales were eventually used to assess symptom severity and resilience, respectively.

2.5 Statistical analysis - Statistical analysis on the data was done as per plan using the IBM-SPSS v25.0 software. For statistical significance, the *P* value is considered to be <0.05. Data was checked for normality using the Shapiro–Wilk test. For discreet variables, Chi-square test was used, and for the continuous variables, the independent sample *t*-test was used. For testing the hypothesis, linear regression analysis was used.

RESULTS

Majority of patients in both schizophrenia and bipolar disorder groups were males (66.7% of those with schizophrenia and 63.3% of those with bipolar disorder). Persons with schizophrenia and bipolar disorder both most commonly practiced the Hindu religion (43.3% of those with schizophrenia and 36.7% of those with bipolar disorder). Education level was most commonly secondary in both the groups (40% in the schizophrenia group and 36.7% in the bipolar disorder group). Persons with schizophrenia were most commonly from the lower socioeconomic status (50%), while those with bipolar disorder were most commonly from upper lower strata (40%). A majority of persons with schizophrenia had rural domicile (83.3%), similar to those with bipolar disorder (60%). Family type was joint for a majority of those with schizophrenia (60%), while nuclear and joint family were equally represented in those with bipolar disorder (46.7% each). There was a significant difference between the two groups only for domicile status, where persons with bipolar disorder were significantly more from urban domicile. The mean age of participants with schizophrenia was 30.57 ± 9.34 years, and the mean age of those with bipolar disorder was 31.10 ± 10.77 years. Persons with schizophrenia had on average 5.13 ± 1.92 members in their family, whereas those with bipolar disorder had 4.77 ± 2.01 family members [Table 1].

The mean symptom severity, as assessed by the CGI-S scale, was 2.30 ± 0.95 for persons with schizophrenia and 2.17 ± 1.12 for persons with bipolar disorder. The mean

IDEAS global Disability score for persons with schizophrenia was 7.83 ± 3.34, whereas that for persons with bipolar disorder was 6.30 ± 2.89. There was no statistically significant difference between the groups with respect to any of the clinical variables. The mean CD-RISC 25 score for persons with schizophrenia was 73.60 ± 13.87, whereas that for persons with bipolar disorder was 78.10 ± 15.26. There was no statistically significant difference between the CD-RISC scores of the two populations [Table 1].

Within each disease group, a comparison between those with and without significant disability (IDEAS Global disability score >7) revealed statistically significant differences in both symptom severity and CD-RISC 25 total scores [Table 2].

A Linear regression analysis model is examined with IDEAS Global Disability score as the dependent variable and gender, age, family type, number of family members, domicile, religion, education, socioeconomic status (SES), severity (CGI-S), and resilience (CDRISC-25 score) as predictor variables for each disease group. In the Schizophrenia group, the *R*-Squared value for the goodness of fit of the model is 0.674. The ANOVA statistic for ascertaining the probability of predictor variables predicting the outcome more than the residual variables is statistically significant ($F = 3.932$, $P = 0.005$). Among the individual predictor variables, only CDRISC-25 scores are statistically significant ($t = -2.582$, $P = 0.018$) for predicting the dependent variable (IDEAS global disability score). The variance inflation factor (VIF) for assessing multicollinearity is below 10 for all variables,

Table 1: Comparison of sociodemographic profile of the two groups of disorders (schizophrenia and bipolar disorder) [Discreet variables – Chi-square test; Continuous variables – Independent sample *t*-test]

Variables	Sub-classification	Groups [*n* (%)]		χ^2/t	*P*
		Schizophrenia (*n*=30)	Bipolar (*n*=30)		
Gender	Male	20 (66.7%)	19 (63.3%)	1.193	0.551
	Female	10 (33.3%)	11 (36.7%)		
Religion	Hindu	13 (43.3%)	18 (60%)	4.606	0.203
	Muslim	11 (36.7%)	11 (36.7%)		
	Christian	2 (6.7%)	0 (0%)		
	Others	4 (13.3%)	1 (3.3%)		
Education	Primary	10 (33.3%)	6 (20%)	2.310	0.511
	Secondary	12 (40%)	11 (36.7%)		
	Matriculation	6 (20%)	9 (30%)		
	Graduate	2 (6.7%)	4 (13.3%)		
Socioeconomic status	Lower middle	5 (16.7%)	8 (26.7%)	1.874	0.392
	Upper lower	10 (33.3%)	12 (40%)		
	Lower	15 (50%)	10 (33.3%)		
Domicile	Rural	25 (83.3%)	18 (60%)	4.022	0.045*
	Urban	5 (16.7%)	12 (40%)		
Family type	Nuclear	11 (36.7%)	14 (46.7%)	1.193	0.551
	Joint	18 (60%)	14 (46.7%)		
	Extended	1 (3.3%)	2 (6.7%)		
Age (years)		30.57 ± 9.34	31.10 ± 10.77	-0.205	0.838
Number of family members		5.13 ± 1.92	4.77 ± 2.01	0.721	0.474
CGI-S score		2.30 ± 0.95	2.17 ± 1.12	0.498	0.621
IDEAS global disability score		7.83 ± 3.34	6.30 ± 2.89	1.897	0.063
CD-RISC 25 score		73.60 ± 13.87	78.10 ± 15.26	-1.195	0.237

*$P<0.05$

Table 2: Comparison of clinical variables between persons with and without significant disability, in both schizophrenia and bipolar disorder groups

Disease groups	Clinical variable	Disability group	*n*	Mean	SD	*t* score	*P*
Schizophrenia	CGI (Severity)	Significant disability	15	2.87	0.74	4.023	0.000**
		No significant disability	15	1.73	0.80		
	IDEAS Global Disability Score	Significant disability	15	10.60	2.26	8.292	0.000**
		No significant disability	15	5.06	1.26		
	CDRISC-25 Total score	Significant disability	15	65.73	13.37	−3.736	0.001**
		No significant disability	15	81.47	9.35		
Bipolar disorder	CGI (Severity)	Significant disability	15	2.60	1.18	2.273	0.031*
		No significant disability	15	1.73	0.88		
	IDEAS Global Disability Score	Significant disability	15	8.67	1.00	7.951	0.000**
		No significant disability	15	3.93	2.08		
	CDRISC-25 Total score	Significant disability	15	70.47	13.10	-3.126	0.004**
		No significant disability	15	85.73	13.64		

indicating that the variables are not producing said effect due to intercorrelation [Table 3].

Similarly, when analyzed for the bipolar disorder group, the *R*-squared value of the model is 0.657. The ANOVA statistic for ascertaining the probability of predictor variables predicting the outcome more than the residual variables is statistically significant ($F = 3.637$, $P = 0.008$). Among the individual predictor variables, CDRISC-25 scores ($t = -2.977, P = 0.008$) and CGI-Severity scores ($t = 3.135, P = 0.005$) are statistically significant for predicting the dependent variable (IDEAS global disability score). Among these two significant predictors, CGI-S has a regression coefficient of 0.554 (positive correlation) and CDRISC-25 has a regression coefficient of − 0.471 (negative correlation). VIF is below 10 for all variables [Table 4].

CDRISC-25 as an input variable predicts the outcome variable (IDEAS global disability score) in a statistically significant manner ($t = -3.706, P < 0.001$). The regression coefficients of the CD-RISC score over the disability score are different for schizophrenia ($\beta = -0.531$) and bipolar disorder ($\beta = -0.471$) groups [Tables 3 and 4]. The interaction effect of the condition variable and input variable is not statistically significant ($t = 1.793$, $P = 0.078$), which indicates that disease groups do not significantly affect the relationship between CDRISC-25 scores and IDEAS global disability scores [Table 5].

DISCUSSION

The present study is the first study in India to compare the effects of resilience on disability across diagnosis to the best of our knowledge. Previously resilience has been linked to residual functioning in both schizophrenia and bipolar disorder,[14-16] but the current study used a novel methodology to see the association between resilience and disability. By using a consecutive type of sampling to recruit the equal number of persons with and without significant disabilities, selection bias was reduced which has often been reported in studies assessing functional outcomes at tertiary care centers.

Our study also included persons with schizophrenia and bipolar disorder across stages of illness. A number of

Table 3: Relationship between disability and sociodemographic and clinical variables in schizophrenia group [*n*=30; Linear regression analysis]

Model summary ANOVA statistics	*R*-square=0.674 *F*-value=3.932			Durbin–Watson statistic=1.796 *P*=0.005*			
Model	Unstandardized coefficients		Standardized coefficients	*t*	Sig.	Collinearity statistics	
	B	Std. error	Beta			Tolerance	VIF
(Constant)	19.716	10.641		1.853	0.080		
Gender	−0.116	1.108	−0.015	−0.104	0.918	0.781	1.280
Age	−0.004	0.059	−0.011	−0.072	0.944	0.736	1.360
Family type	0.840	1.767	0.128	0.476	0.640	0.236	4.234
Family members	−0.250	0.394	−0.134	−0.636	0.532	0.384	2.607
Domicile	0.603	1.697	0.064	0.355	0.726	0.532	1.878
Religion	−0.064	0.714	−0.018	−0.089	0.930	0.408	2.450
Education	−0.559	0.832	−0.142	−0.672	0.510	0.385	2.599
Socioeconomic status	−0.975	1.132	−0.206	−0.861	0.400	0.299	3.344
CGI-S	1.292	0.646	0.343	2.002	0.060	0.583	1.715
CDRISC-25 score	−0.137	0.053	−0.531	−2.582	0.018*	0.406	2.465

a. Dependent variable: IDEAS Global disability score

Table 4: Relationship between disability and sociodemographic and clinical variables in bipolar disorder group [*n*=30; Linear regression analysis]

Model summary ANOVA statistics	*R*-square=0.657 *F*=3.637			Durbin–Watson statistic=1.120 *P*=0.008*			
Model	Unstandardized Coefficients		Standardized Coefficients	*t*	Sig.	Collinearity Statistics	
	B	Std. error	Beta			Tolerance	VIF
(Constant)	12.416	5.946		2.088	0.050		
Gender	−1.892	1.125	−0.335	−1.682	0.109	0.456	2.192
Age	0.020	0.061	0.076	0.323	0.750	0.323	3.095
Family type	−0.934	1.164	−0.209	−0.802	0.433	0.265	3.772
Family members	0.462	0.356	0.335	1.300	0.209	0.271	3.688
Domicile	0.357	1.561	0.064	0.229	0.822	0.229	4.361
Religion	−0.726	0.784	−0.178	−0.926	0.366	0.486	2.056
Education	−0.568	0.596	−0.197	−0.953	0.353	0.420	2.379
Socioeconomic status	0.162	0.851	0.046	0.190	0.851	0.311	3.215
CGI-S	1.375	0.439	0.554	3.135	0.005*	0.578	1.730
CDRISC-25 score	−0.086	0.029	−0.471	−2.977	0.008*	0.722	1.386

a. Dependent variable: IDEAS Global disability score

Table 5: Comparison between the two groups (schizophrenia and bipolar disorder) of the effect of resilience (CDRISC-25) on disability (IDEAS global disability score)

Model	Unstandardized coefficients		Standardized coefficients	*t*	Sig.
	B	Std. error	Beta		
1					
(Constant)	28.049	5.381		5.213	0.000
CDRISC-25	−0.264	0.071	−1.183	−3.706	0.000
Disease group	−6.760	3.368	−1.045	−2.007	0.050
Interaction effect (Resilience*Disease group)	0.078	0.044	1.150	1.793	0.078

studies have been done on recovered or remitted patients, but the authors have consistently reported the need for assessing patients with acute illness.[14,15] We found that the use of the CGI-severity scale is a feasible way to recruit participants. Any apprehension regarding the influence of psychopathology on resilience was dealt with by employing appropriate statistical analysis that independently assesses the association between symptom severity and resilience. Also, the use of CD-RISC 25 is appropriate as it assesses personal as well as social factors of resilience. The role of social support and social cognition in sustaining recovery has been well established,[18] and to examine resilience as a possible mediator of this role, it is important to use instruments that assess these factors as well. It has also been found previously that duration of illness is a significant factor associated with disability for both schizophrenia and bipolar disorder.[19,20] In view of this, we only included patients with 2–5 years illness.

The present study found the majority of participants in both groups to be male, Hindu, educated up to secondary, belonging to lower SES and living in a joint family setup. These findings follow a similar trend with other such hospital-based studies on the same population.[21] There was a significant difference between the two groups only in domicile setup, where a greater number of persons with bipolar disorder belonged to urban areas compared to schizophrenia. Our study recruited mildly symptomatic to asymptomatic population and owing to the commonly encountered course of schizophrenia where remission is more commonly seen with medications as compared to the episodic course of bipolar disorder, whereby symptom reduction and relapse-free duration is more common. This can lead to an overrepresentation of those with better access to follow-ups among the bipolar disorder group.

We found that when disability was factored in methodologically, there was no significant difference in resilience levels between persons with schizophrenia and bipolar disorder. Previous studies have reported significantly low resilience levels in people with schizophrenia compared to bipolar disorder,[15] but the important role of disability is reflected in our study.

Linear regression analysis reveals that disability as an outcome depends significantly on sociodemographic variables and individual variables. It is important to note that variables like gender, socioeconomic status, education are broad sociological factors, but there was no significant overlap in how they influence disability, which indicates that each of these factors independently influences the outcome. Resilience has been dismissed as a similar broad psychosocial factor by some early commentators,[22] but our results indicate that it independently and significantly predicts disability in both schizophrenia and bipolar disorder. Additionally, in persons with bipolar disorder, symptom severity significantly predicted disability. This has been reported previously[23] and is expected as asymptomatic stages often show complete functional recovery.

Finally, it is evident that resilience significantly predicts disability in both groups, but on determining the effect of the disorder group on this influence, it is seen that there is no significant impact of the type of disorder on how resilience affects disability. This means that independent of the disorder, resilience predicts disability. Mizuno and his group had described similar findings where the quality of life was associated with resilience and resilience was not significantly different between the two disorders.[14] Our study provides support to the school of thought that resilience influences functional outcomes irrespective of diagnosis.

The current study suffers from some important limitations. The cross-sectional design prevents interpretation of causality, and the small hospital-based sample size limits generalizability. A more comprehensive assessment of symptom severity would have led to a better estimation of the relationship between the psychopathology domain and its effect on resilience. The study also fails to assess its objective in the illiterate subset of patients who are most vulnerable to poor functional outcomes and possibly form a majority of the clinical population, especially for schizophrenia.[24] The study also does not look for the differences in the type of resilience as individual and social factors may be different in the two different disorders.

There is a need to devise future studies addressing these lacunae to enrich our understanding of how resilience mediates and interacts with other clinical and sociodemographic factors and its association with patient-centric outcomes like disability.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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BRIEF COMMUNICATION

Association of antenatal anxiety with adverse pregnancy outcomes: A prospective hospital-based study

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ABSTRACT

Background: Anxiety is common in pregnant women. Many studies have shown association of antenatal anxiety with adverse pregnancy outcomes, though the results are conflicting. Further, there are very limited studies on the subject reported from India, due to which, the data is limited. Hence this study was undertaken.

Materials and Methods: Two hundred randomly selected consenting registered pregnant women reporting for antenatal follow up during third trimester of pregnancy were included in the study. Hindi version of Perinatal Anxiety Screening scale (PASS) was used to assess anxiety. Edinburgh Postnatal Depression rating Scale (EPDS) was used to assess comorbid depression. These women were followed up in the post-natal period to assess pregnancy outcomes. Chi-square test, Analysis of Variance (ANOVA) and correlation coefficients were calculated.

Results: Analysis was done for 195 subjects. Most women (48.7%) were between 26 and 30 yrs of age. Primigravidas comprised 11.3 % of total study sample. Mean anxiety score was 23.6 (range 5-80). Adverse pregnancy outcomes were noted in 99 women; however anxiety scores in this group were not different from the group without adverse outcomes. No significant group differences were found with respect to PASS or EPDS scores. None of the women were found to have a syndromal anxiety disorder.

Conclusions: Antenatal anxiety was not found to be associated with adverse pregnancy outcomes. This finding is contrary to the results obtained in earlier studies. More enquiry is needed into this area to replicate the results with clarity in larger samples, in Indian context.

Key words: Adverse pregnancy outcomes, antenatal anxiety, anxiety disorders, birth complications, low birth weight, maternal health, perinatal health

INTRODUCTION

Anxiety in the perinatal period has been found to be associated with adverse pregnancy outcomes such as low birth weight, preterm birth, and obstetric complications.[1–11]

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However such associations have been controversial and often contradictory, affected by factors such as research methodology, tools used, and cultural background of subjects. Research on the subject in India has been sparse and needs deliberation.[12]

Numerous evidences have indicated that birth outcomes may be affected by various factors. Women undergo physical, physiological, social, and emotional changes during pregnancy.[13] Prenatal anxiety has been recognized as a potential etiology leading to preterm birth (PTB) and low birth weight (LBW).[13–15] Additionally, prenatal anxiety, which has been found to be the highest in the third trimester, has been linked to somatic complaints and gestational, obstetric, and neonatal complications.[16] However, findings on this topic have shown a relatively incongruent picture during the last few decades. Some studies reported that maternal anxiety during pregnancy was significantly associated with adverse birth outcomes such as PTB and LBW.[5,8,14,16] On the contrary, others suggested that there is no such association.[17–19] These conflicting results may be related to differences in demography and study designs. Given the inconsistent results in previous studies, this study was planned in the Indian context to examine this relationship. Anxiety symptoms and disorders are common in the perinatal period.[15] If a positive association is found, it may help clinicians determine whether pregnant women should be regularly screened for anxiety.

MATERIALS AND METHODS

This hospital-based prospective study was conducted in the obstetrics and gynecology (OBG) department of a tertiary care hospital in collaboration with the Department of Psychiatry over a period of one year, starting from October 2017. Only those women who were in their third trimester of pregnancy, not on psychotropic medication, and with no known mental illness were considered for the study. Pregnant women presenting to the OBG department were randomly selected and screened for eligibility to be part of the study. They were recruited for the study if they consented and fulfilled the criteria. Once recruited, their general health was assessed as per the study's parameters, and they were administered validated Hindi versions of the Perinatal Anxiety Screening Scale (PASS) and the Edinburgh Postnatal Depression Scale (EPDS) by interns trained to administer the questionnaires. The PASS is an instrument for the assessment of anxiety symptoms during pregnancy and possesses good psychometric properties.[20] It is recommended for research and clinical use. Since comorbid depression may affect neonatal pregnancy outcomes, the same was assessed using EPDS.[21] Demographic data was collected using a semi-structured questionnaire. According to past studies on the subject, and considering 95% confidence level and relative precision (ε) of 20%, the sample size required for the study was calculated to be 130, and 195 subjects were included in the study. These women were then followed up in their postnatal period and were assessed for general health and adverse pregnancy outcomes (Apgar score, delayed cry, birth asphyxia, post-partum hemorrhage, birth weight, gestational age at birth, instrumentation or other adverse events during delivery, cesarian section, intrauterine death, and neonatal death).

Data was collected in Excel sheets and analyzed using the Statistical Package for the Social Sciences version 21 (IBM). Apart from the Chi-squared test for the difference between groups, correlation coefficients were calculated to ascertain the relationship between variables. Ethical clearance from the institutional ethics committee was obtained before the start of the study. All enrolled women were offered treatment in case they were found to have high anxiety levels.

RESULTS

A total of 195 pregnant women were recruited and all completed the study. Demographic parameters are summarized in Table 1. Forty-nine percent of the women ($n = 95$) were in the age group 26–30 years. Eleven percent were primigravida while 49% were second para. All recruited women were educated till at least high school and 48% were graduates. Ten percent of the women reported bad obstetric history, and 30% reported suffering from some medical illness. Adverse pregnancy outcomes, as defined in the study, was reported in 50.8% ($n = 99$) of patients [Table 2]. Nineteen women (9.74%) had a high PASS score (between 42 and 93), out of which only 8 had adverse pregnancy outcomes and 11 did not, and there was no association between adverse pregnancy outcomes and PASS scores (Pearson's $\chi^2 = 3.457$, $P = 0.178$) [Table 3]. Even when the modes of delivery and

Table 1: Demographic characteristics of women participating in the study

Parameters	Frequency	Percentage
Age Distribution		
≤25 years	64	32.8
26-30 years	95	48.7
31-35 years	30	15.4
>35 years	6	3.1
Education		
High School	36	18.5
10 + 2	21	10.8
Graduate	93	47.7
Postgraduate	45	23.1
Bad Obstetric History		
Yes	20	10.4
No	172	89.6
Total	192	100
Medical Illnesses		
None	133	68.2
Hypothyroidism	40	20.5
Gestational diabetes mellitus (GDM)	10	5.1
Primary infertility	4	2.1
Others	8	4.1
Total	195	100

low birth weight were considered separately, no association was found. Furthermore, 44 women (22.6%) had an EPDS score of more than 10, but again there was no association of high EPDS score and adverse pregnancy outcomes [Table 4]. There was no correlation between the EPDS and PASS scores [Table 5]. Those women with high PASS or EPDS scores were offered treatment options. None of them consented for pharmacotherapy, but some were administered supportive psychotherapy when they opted for it. Clinical evaluation did not reveal any syndromal psychopathology in any of the women with high PASS or EPDS score.

DISCUSSION

In our study, we found no association between perinatal anxiety and adverse pregnancy outcomes. Our findings are contrary to most reported data worldwide. A recent meta-analysis by Ding *et al*.[3] reported that increased pregnancy-related anxiety was associated with low birth weight and preterm births.[3] However most of the studies included in this meta-analysis were from the West and none from India. Moreover, most of the studies used the State-Trait Anxiety Inventory (STAI) for the measurement of anxiety in these women, which is not a specific instrument for measuring perinatal anxiety. Hence the results are likely to be different.[14]

Another similar study from Goa (India) reported a positive correlation between antenatal psychopathology and low birth weight. It used the General Health Questionnaire to assess psychopathology, and the paper came out of a secondary analysis of the data.[12]

A recent meta-analysis similarly claimed a robust association between maternal antenatal anxiety and adverse pregnancy outcomes.[4] Again, this meta-analysis did not include any study from Southeast Asia and most of the instruments used for assessment of anxiety were general anxiety questionnaires.

The strength of the current study was its use of a measure of anxiety screening that covered a wide range of problems associated with pregnancy and assessed anxiety symptoms more accurately.

Absence of clinically significant anxiety could be due to a variety of reasons. Socioeconomic and domestic factors play a role in causation of anxiety. All the women included in the study belonged to families with stable source of income and adequate family support. This is because the hospital where the study was carried out caters to personnel from a particular industrial group who have access to quality health care. Additionally, most of the women were educated (at least till high school), had support at home, and were living with either their mothers or mothers-in-law for care during pregnancy, as is the culturally prevalent norm in Indian families. Robust support system, lack of risk factors, and psychosocial support could be a reason for reduced anxiety levels.

Absence of the association between perinatal anxiety and adverse pregnancy outcomes could be simply because anxiety does not affect pregnancy. Associations discerned in the past have been controversial and based on statistics. A conclusive evidence of the cause of adverse pregnancy outcomes due to anxiety has not yet been proven and the subject still needs to be studied.

Another reason for the lack of correlation could be stigma of mental illnesses. Although all attempts were made to make a rapport with and explain the research to the patients,

Table 2: Various adverse pregnancy outcomes and their distribution

Parameters	Frequency	Percentage
Modes of Delivery		
LSCS	28	14.4
Instrumental	4	2.1
Emergency cesarean section	39	20
Post-partum hemorrhage	5	2.6
Delayed cry	5	2.6
Asphyxia	13	6.7
Other complications	26	13.6
Adverse pregnancy outcomes	99	50.8

Table 3: Perinatal Anxiety Screening Scale (PASS) score differences between various pregnancy outcomes

	PASS Score			Total	Pearson's χ^2	*P*
	'0-20	'21-41	'42-93			
Adverse Pregnancy Outcomes						
Yes	42	49	8	99	3.457	0.178
No	50	35	11	96		
Modes of Delivery						
Vaginal	62	49	13	124	7.34	0.291
LSCS*	11	12	5	28		
Instrumental	1	3	0	4		
Emergency cesarian	18	20	1	39		
Birth Weight (kg)						
≤2.5	12	11	2	25	0.099	0.952
>2.5	80	73	17	170		

*LSCS=Lower segment caesarean section (elective)

Table 4: Edinburgh Perinatal Depression Scale (EPDS) scores across categories of pregnancy outcomes

	EPDS Score		Total	Pearson's χ^2	*P*
	≤10	>10			
Adverse Pregnancy Outcomes					
Yes	79	18	97	2.231	0.135
No	68	26	94		
Mode of Delivery					
Vaginal	91	31	122	2.571	0.463
LSCS	24	3	27		
Instrumental	3	1	4		
Emergency cesarian	29	9	38		
Birth Weight (kg)					
≤2.5	22	2	24	3.347	0.067
>2.5	125	42	167		
Total	147	44	191		

LSCS: Lower segment caesarian section

Table 5: Correlation between Perinatal Anxiety Screening Scale (PASS) and Edinburgh Perinatal Depression Scale (EPDS) scores

	PASS Score	EPDS Score
PASS Score		
Pearson correlation	1	0.436**
Sig. (2-tailed)		0
n	195	191
EPDS score		
Pearson correlation	0.436**	1
Sig. (2-tailed)	0	
n	191	191

**Correlation is significant at the 0.01 level (2-tailed)

social stigma may have prevented them from disclosing their symptoms. Lack of psychological awareness of the recruited women could be another cause of underreporting of symptoms.

An interesting observation in the study was the presence of higher anxiety scores in women who had no adverse pregnancy outcomes, though the result was not statistically significant. It is possible that anxious women resorted to help-seeking and better care, resulting in better pregnancy outcomes. More research is needed to examine this relationship. High EPDS scores, which indicate depression in the subjects, were found in 22.6% of women, but there was no association of the same with either PASS scores or with adverse pregnancy outcomes. However, it may be noted that clinical evaluation did not reveal syndromal psychopathology in these women, which could be the reason why no association was found.

Strengths of the study were a prospective design, and use of specific scales for measurement of anxiety and depression. A major drawback of the study is that it cannot be generalized, since the clientele consisted of members of a particular socio-occupational group having access to quality health care and better socioeconomic status than most Indians. Another possible drawback is selection bias. Since the study was voluntary, those women suffering from higher levels of anxiety may have refused to participate in the study.

Nevertheless, some lessons can be drawn from the study. Despite the study not being generalizable, it can be observed that pregnancy outcomes can be better with adequate support and medical care. Similarly, anxiety and depression can be minimized in pregnant women for better pregnancy outcomes. The current study is one of its kind in India, reporting preliminary data on the subject. Further studies are required to replicate the results in order to the lay the foundation for better mental health care for women in the antenatal period.

Ethical considerations

No intervention was planned in the study and the participating women were offered treatment as usual. Institutional ethics committee clearance was obtained and confidentiality of data was maintained. Written and informed consent was obtained from participants.

CONCLUSION

No significant association was observed between antenatal anxiety and adverse pregnancy outcomes in the current study. Though results are not generalizable to the population, the study provides a foundation for similar studies to assess the relationship between anxiety and adverse pregnancy outcomes in Indian women, which can help in providing better antenatal care.

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Conflicts of interest

There are no conflicts of interest.

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BRIEF COMMUNICATION

Violence against psychiatric trainees from Asian countries: A pilot online survey

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ABSTRACT

Background: Violence against psychiatry trainees is an important issue to the medical profession. However, this matter has been under researched, especially in Asian countries.
Aim: We aimed to explore the rates and factors associated with violence against psychiatric trainees in Asian countries.
Methods: An online, 15 item cross sectional pilot survey was designed and disseminated among psychiatric trainees in Asia through the World Network of Psychiatric Trainees, national and local networks of trainees, and social media. The questionnaire sought to enquire about the experience of physical, verbal, and sexual assaults and its impact. Data were analyzed using Statistical Package for the Social Sciences (SPSS) V20.0.
Results: A total of 467 responses were obtained from psychiatric trainees in 16 countries in Asia. More than two thirds of participants ($n = 325$, 69.59%) reported a history of assault. Psychiatry inpatient units were the most common setting ($n = 239$, 73.54%). A relatively lower proportion of participants from the East Asian countries reported an assault, compared to other countries ($\chi^2 = 13.41$, $P = 0.001$). Sexual assault was more common among women compared to men ($\chi^2 = 0.94$, $P = 0.002$).
Conclusion: Violence against psychiatric trainees seems common across Asian countries. Our findings call for further systematic investigation of the phenomenon and suggest the need to develop programs to protect psychiatric trainees against the threat of violence and its subsequent psychological complications.

Key words: Assault, psychiatry, trainee, violence

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INTRODUCTION

Workplace violence (WPV) is defined as any incident in which a person is abused, threatened, or assaulted in circumstances related to their work, including verbal abuse and threats as well as physical or sexual assaults.[1] WPV has been reported to be common in hospital settings.[2]

A review of WPV in health-care settings over the last two decades demonstrated that most studies on this topic have focused on the occurrence rate, risk assessment, and management, while fewer studies have focused on assessing the psychological consequences of WPV.[1] WPV may result in a lack of job satisfaction, issues with recruitment and retention, and lowered health-related quality of life. In particular, trainee doctors in psychiatry feel less safe at work, probably because of less experience, high clinical exposure, out-of-hours service, and difficulties in accessing colleagues to carry out joint assessments.[3]

Most of the studies on health-care WPV are from North America and Western Europe. Of the studies carried out in Asia, most are from East Asian countries, and the focus has been on the WPV experienced by nurses.[4] So far, such studies focusing on mental health professionals from Asia have not been carried out.

The objectives of this study were (a) to explore the extent of violence against psychiatric trainees in Asian countries; (b) to identify the common settings in which this violence occurs, its physical and psychological impact, and trainee-reported individual and institutional management of violent episodes; and (c) to explore the potential differences in violence experienced related to victim's characteristics such as gender, psychiatry specialty, and training experience.

MATERIALS AND METHODS

Study design: The study was a part of a larger international online survey entitled "Violence Against Psychiatric Trainees (VAPT) study." The VAPT survey was a cross-national survey designed by trainees of the European Federation of Psychiatric Trainees (EFPT) Research Working Group and distributed across all continents.[5]

Study instrument: The survey was conducted using a bespoke tool for the purpose of this project [Appendix 1]. The tool consisted of 15 close-ended multiple-choice questions. The questions sought to gather demographic, training-related, and assault-related variables. Based on previous studies, assaults were subclassified into three types: physical, sexual, and verbal (definitions provided in the appendix). The survey tool was not pretested and validated. However, the usability and functionality of the tool were tested before the actual data collection started. In addition to English, this survey was disseminated in Chinese (after a translation–back translation process) to improve acceptability in mainland China.

Study procedure: Those physicians who were currently in psychiatry training in countries of the United Nations region of Asia were included in the study after an electronic consent was obtained from them. The study followed a convenience snow-ball sampling method. The survey followed an open survey approach. No personal information of the participants was collected or stored. SurveyMonkey platform was used for data collection purposes, except in mainland China, where manual collection through email was used. As per the local needs, we adjusted the data collection method. The survey was disseminated among psychiatric trainees in Asian countries through various online communication channels, including email, Facebook, Twitter, and other messaging apps, harnessing the reach of the World Network of Psychiatric Trainees. Participation in the study was voluntary, and no incentive was provided. The 15 questionnaire items were not randomized and were presented in the same screen. However, to reduce the number/complexity of the questions, adaptive questioning of items and a skip pattern was used. Completeness check was performed before submission. However, respondents were not allowed to review and change their answers. The survey platform would prevent users from re-entering the form using the same navigator and user. Data were collected over 2 years, between June 2018 and August 2020. The results are being reported in accordance with the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) of the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) network.[6]

Data analysis: Data were analyzed using Statistical Package for the Social Sciences (SPSS) V20.0. Descriptive analysis was performed using mean, standard deviation, frequency, percentage, median, and interquartile range (IQR), as appropriate. Group comparisons were performed using the Chi-square test, Fisher's exact test, independent sample *t*-test, or Mann–Whitney U (MWU) test, as appropriate. A P value of <0.05 was considered significant.

Ethical aspects: The study was reviewed and approved by the Research Ethics Committee of the University of Navarra (Pamplona, Spain; ID 2019.083). Participants' identities were maintained confidential, and no personal identifying details were collected. No one except the investigators had access to the data. The study protocol is registered at the Open Science Framework (osf.io/6z4qy).

RESULTS

Sample characteristics

A total of 467 responses were obtained from psychiatric trainees in 16 countries in Asia (data on view, participation, or completion rates are not available). Around 59.32% of total responses were received from India, Bangladesh, and

the People's Republic of China [Table 1]. The participants' characteristics are summarized in Table 1.

Characteristics of WPV

Characteristics of WPV are summarized in Table 1. A total of 325 (69.59%) participants reported a history of assault. Psychiatry inpatient wards/units were the most common setting where assaults took place (n = 239, 73.54%).

The majority of participants did not report the assault to any authority (n = 182, 56.00%), while 53 (16.31%) participants reported the assault, and measures were taken. Feelings of anxiety, rage, and sadness were the most commonly reported consequences of the assault (n = 165, 50.77%). Only a minority of participants reported that training was being provided in their respective hospitals to prevent and manage episodes of aggression, or that there was an established protocol for aggression prevention and management in their hospitals [Table 1].

Variables associated with WPV

Participants with a history of an assault (n = 325, 69.59%) were compared with participants with no history of assault (n = 142, 30.41%) [Table 2]. Those with a history of assault were more advanced in their psychiatry training (MWU = 18140, $P < 0.001$). However, a relatively lower proportion of study participants from the East Asian countries reported an assault (χ^2 = 13.41, P = 0.001) compared to participants from other countries.

Gender differences in assault characteristics

The number of assaults was similar across men (46.77%) and women (53.23) participants (χ^2 = 4.83, P = 0.09). Sexual assault history was more commonly reported by the women participants (χ^2 = 0.94, P = 0.002). Significantly more women participants reported anxiety, rage, and sadness after an assault (χ^2 = 9.93, P = 0.002).

DISCUSSION

This is the first multinational study exploring the phenomenon of violence against psychiatric trainees in Asia. This study was carried out concomitantly in Europe (and globally) by the same research group.[5] Despite its pilot nature, our results showing that around 70% of psychiatric trainees experienced violent assault, while 62% reported recent violence in the past 12 months warrant both further study and immediate action. As expected, verbal WPV was the most common form experienced, similar to previous studies from Western Europe and North America.[5,7,8] It is also in line with a recent meta-analysis which reported a 64.9% 12-month prevalence of WPV among (all) health-care workers in Asian countries.[9]

Almost 48% of the trainees reported a physical assault. This is again in line with previous studies reporting that 25%–56% of trainees experience physical WPV.[10] The rates were similar across genders, similar to what is reported in the existing literature. However, sexual assault was more commonly reported by female trainees, consistent with a previous study.[7] Psychiatric inpatient units and emergency units were the most common settings where the assault occurred. This is again in concurrence with previous studies,[5] and the evidence is similar for WPV experienced by other clinical professionals.[4,8]

Only one in five trainees reported an established protocol being in place in their respective hospitals for reporting violence. Only around 17% of trainees reported the assault to the authorities. Previous studies have also highlighted the lack of existence/awareness of training and reporting protocols for WPV. This is compounded by the popular misconception that WPV is a "normal" experience in mental health service provision.[11] Similarly, lack of training for staff and aggression management plans at their institutions or being unaware of their existence was cited as a common theme among mental health trainees in Europe.[5]

Of interest is the high proportion of psychiatric trainees experiencing WPV in South/South-East Asia. Differences in psychiatric training pathways, service models in mental health, and cultural differences might explain this significant variation.[12] However, it is possible that the heterogeneity in recruitment and the sampling framework might be the contributing factors.

This study has some inherent limitations in methodology and scope. Our non-probabilistic sampling design based on an online survey may have contributed to selection bias and, therefore, lack of representativeness. The lack of cross-national databases and publicly available figures of psychiatric trainees' workforce in Asia precluded random sampling. The survey tool, which was used in European countries, was not prevalidated in Asia. Also, the distribution of responses across countries in Asia was heterogeneous and lacked statistical power for comparisons. The cross-sectional design is vulnerable to recall bias, and hence, we cannot infer causal associations. We did not explore the characteristics of perpetrators or the variable intensity of abuse episodes. The questionnaire was designed and disseminated only in English and Chinese, which might have limited participation. Within Asia, there are significant regional and national differences in psychiatric training, which have not been considered while interpreting our data. Data about the view rate, completion rate, and participation rates are not available. Notwithstanding these limitations, we were able to obtain one of the largest and widest samples of psychiatric trainees in Asia. Our findings are consistent with previously referenced studies.[13,14] The low proportion of trainees reporting abuse and the lack of protocols around institutional training for staff are possible areas for improvement.

Table 1: Total responses obtained, sociodemographic variables, and characteristics of violence against participants

Variable	*n* (%)/mean (SD)
Response rate per country (*n*=467)	
India	125 (26.77)
Bangladesh	87 (18.63)
People's Republic of China	65 (13.92)
Thailand	34 (7.28)
Nepal	30 (6.42)
Myanmar	25 (5.35)
Indonesia	21 (4.50)
Japan	19 (4.07)
Pakistan	15 (3.21)
Sri Lanka	14 (2.99)
Malaysia	13 (2.79)
Hong Kong Special Administrative Region of the People's Republic of China	7 (1.49)
Philippines	4 (0.86)
Republic of China	4 (0.86)
Singapore	3 (0.64)
Vietnam	1 (0.22)
Socio-demographic variables (*n*=467)	
Age (in years)	30.15 (4.22)
Gender	
Male	221 (47.32)
Female	246 (52.68)
Training completed	
0-25%	164 (35.12)
26%-50%	99 (21.20)
51%-75%	81 (17.34)
76%-100%	123 (26.34)
Specialty	
General psychiatry	377 (80.73)
Child and adolescent psychiatry	77 (16.49)
Other specialties (such as addiction, neuropsychiatry, and consultation-liaison psychiatry)	13 (02.78)
Characteristics of violence against participants (*n*=467)	
History of assault (ever)	
Yes	325 (69.59)
No	142 (30.41)
Number of assaults (among those with a history of assault ever)[a]	
Once	83 (25.54)
2-5	185 (56.92)
>5	57 (17.54)
Last assault[a]	
Within last year	202 (62.15)
More than 1 year before	123 (37.85)
Type of assault reported[a,b]	
Verbal	269 (82.77)
Sexual	27 (8.31)
Physical	154 (47.38)
Clinical settings where such assault happened[a,b]	
Emergency department	122 (37.53)
Psychiatry inpatient unit/ward	239 (73.54)
Outpatient unit	117 (36.00)
Community setting	8 (2.46)
Other places	4 (1.23)
Have you reported any of this/these assault(s) to any authority?[a]	
No, it would be unnecessary (not severe/significant enough)	182 (56.00)
No, it would be useless ("I don't believe that would change anything")	53 (16.31)
Yes, and measures were taken	53 (16.31)
Yes, but measures were not taken	41 (12.62)
Did you call the police or another security officer/guard to help or report the assaults in these cases?[a]	
Yes	113 (34.76)
No	212 (65.24)

Contd...

Table 1: Contd...

Variable	*n* (%)/mean (SD)
What kind of impact has these assaults have on you?[a,b]	
Minor physical injuries	45 (13.85)
Major physical injuries (requiring any medical assistance)	1 (0.31)
Feelings of anxiety and/or rage and/or fear	165 (50.77)
Feelings of sadness and/or guilt and/or other depressive symptoms	48 (14.77)
Feelings of lack of support from your institution	51 (15.69)
Serious ideas about leaving your work in mental health	62 (19.07)
Serious ideas about leaving your work in medicine	15 (4.62)
Other psychological distress	7 (2.15)
No impact	88 (27.08)
Is there any training for the staff in your hospital to prevent and manage the aggressions from patients?	
No	242 (51.83)
Yes	173 (37.04)
I don't know	52 (11.13)
Is there any established plan in your hospital to be followed in case of suffering aggressions from patients?	
Not at all.	106 (22.70)
Some actions are usually taken, such as debriefing and defusing, but there is not an established protocol	207 (44.33)
There is an established protocol to be followed	83 (17.77)
I don't know	70 (14.99)
Other	1 (0.21)

[a]*n*=325. [b]More than one response tolerated

Table 2: Comparison of participants with and without history of assault (*n*=467)

Variable	Participants with history of assault (*n*=325) Mean (SD)/*n* (%)/ median (IQR)	Participants with no history of assault (*n*=142) Mean (SD)/*n* (%)/ median (IQR)	*t* (df)/ Chi-square (df)/ MWU; *P*
Age[a]	30.52 (3.92)	29.32 (4.74)	2.85 (464); 0.005**
Psychiatry training completed[b]			
Up to 25%	96 (29.54)	68 (47.89)	16.36 (3); 0.001**
26%-50%	71 (21.85)	28 (19.72)	
51%-75%	60 (18.46)	21 (14.79)	
76%-100%	98 (30.15)	25 (17.60)	
Psychiatry training completed[c]	50.00 (81.50-20.00)	31.00 (68.00-05.00)	18140; <0.001***
Gender[b]			
Male	152 (46.77)	69 (48.59)	0.13 (1); 0.71
Female	173 (53.23)	73 (51.41)	
Specialty[b]			
General psychiatry	263 (80.92)	114 (80.28)	0.49 (2); 0.78
Child and adolescent psychiatry	52 (16.00)	25 (17.61)	
Other specialties	10 (03.08)	3 (02.11)	
Training for aggression prevention and management in the hospital[b]			
Yes	126 (38.77)	47 (33.09)	1.36 (1); 0.24
No/I don't know	199 (61.23)	95 (66.91)	
Established protocol in case of violence present[b]			
Yes	52 (16.00)	31 (21.83)	2.30 (2); 0.31
Some actions are usually taken, but there is not an established protocol	147 (45.23)	60 (42.25)	
No/don't know/other	126 (38.77)	51 (35.92)	
Asian region[b]			
South Asia	195 (60.00)	76 (53.52)	13.41 (2) *n*; 0.001**
South-East Asia	78 (24.00)	23 (16.20)	
East Asia	52 (16.00)	43 (30.28)	

df=degree of freedom, IQR=interquartile range, MWU=Mann-Whitney U, SD=standard deviation. South Asia: Bangladesh, India, Nepal, Pakistan, Sri Lanka; South-East Asia: Indonesia, Malaysia, Myanmar, Philippines, Singapore, Vietnam, Thailand; East Asia: The Hong Kong Special Administrative Region of the People's Republic of China, Japan, The People's Republic of China, The Republic of China. [a]*t*-Test. [b]Chi-square test. [c]MW *U*-test

Future research should obtain accurate prevalence figures with probabilistic samples and validated instruments.[15] The consequences of violence among victims, specific individual differences in the impact of violence, and risk/protective factors should be longitudinally studied. To address the systemic factors perpetuating violence against trainees, national psychiatric associations and the Asian Federation of Psychiatric Associations (AFPA) can take the lead in formulating policies and mandating action at hospitals employing psychiatric trainees, particularly around

reporting and training related to handling workplace-based violence. This includes a need for mandatory processes and protocols in place as relevant to VAPT. An open and dynamic process of reporting and acting on concerns will significantly mitigate the risk of violence against psychiatric trainees.

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Conflicts of interest

There are no conflicts of interest.

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APPENDIX 1

1. What is your country?
2. What is your age?
3. What is your gender?
   a. Male
   b. Female
   c. Non-binary
4. Which is your psychiatry specialty of training?
   a. General (adult) psychiatry
   b. Child and adolescent psychiatry
   c. Other official psychiatric specialties (please specify)
5. Which percentage of training have you already completed (i.e., completed years/total years of training; visual scale 0–100%)?
6. Have you ever been (physically, sexually, or verbally) assaulted (see definitions of assaults in the online survey header) by any patient while working as a psychiatric trainee in a mental health setting?
   a. No (skip to question 14)
   b. Yes (please continue with the next question)
7. How many times have you been assaulted in any of these ways?
   a. Once
   b. 2–5 times
   c. More than 5 times
8. When did the last(s) assault(s) take place?
   a. During the last year
   b. More than a year ago
9. Which type(s) of assault(s) (see definitions) have you suffered? (check what applies)
   a. Verbal
   b. Sexual
   c. Physical
10. In which clinical setting have you suffered this/these assault(s)?
    a. Emergency department
    b. Inpatient ward
    c. Outpatient unit (clinic, hospital department, or other units)
    d. Community settings (patient's home or other settings)
    e. Other (please specify)
11. Have you reported any of this/these assault(s) to any authority?
    a. No, it would be unnecessary (not severe/significant enough)
    b. No, it would be useless ("I don't believe that would change anything")
    c. Yes, and measures were taken
    d. Yes, but measures were not taken
12. Did you call the police or another security officer/guard in these cases to help or report the assaults?
    a. Yes
    b. No
13. What kind of impact has these assaults have on you? (check all that apply)
    a. Minor physical injuries
    b. Major physical injuries (requiring any medical assistance)
    c. Feelings of anxiety and/or rage and/or fear
    d. Feelings of sadness and/or guilt and/or other depressive symptoms
    e. Feelings of lack of support from your institution
    f. Serious ideas about leaving your work in mental health
    g. Serious ideas about leaving your work in medicine
    h. Other psychological distress (please specify)
    i. No impact

14. Is there any training for the staff in your hospital to prevent and manage the aggressions from patients?
    a. No
    b. Yes
    c. I don't know

15. Is there any established plan in your hospital to be followed in case of suffering aggressions from patients?
    a. Not at all
    b. Some actions are usually taken, such as debriefing and defusing, but there is not an established protocol
    c. There is an established protocol to be followed
    d. I don't know
    e. Other (please specify)

The IToP-STEPS: A unique scholarship program to upskill teachers of psychiatry

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THE NEED FOR IToP STEPS

Psychiatry teachers in India play an important role in national mental health services; however, there has been the least emphasis on this aspect.[1] More than 90,000 doctors who graduate every year along with more than 1000 psychiatrists specializing annually are trained by psychiatry teachers across India to provide mental health services.[2] In a country that has a large gap in the treatment of mental health disorders, that affects one in seven as per the Global Burden Study carried out by the World Health Organization (WHO), Indian Council of Medical Research (ICMR), and other organizations, the services of psychiatry teachers are crucial.[3] More so in a country where emphasis on undergraduate psychiatry is inadequate despite the implementation of Competency-based Medical Education (CBME). The involvement of psychiatry teachers and enrichment of teaching skills has been highlighted in recent years with a series of symposiums and workshops carried out since the year 2013 at the Annual National Conference of Indian Psychiatric Society (ANCIPS).[4,5] In the year 2016, a forum for Indian Teachers of Psychiatry (IToP) was inaugurated to enhance the exchange of resources and experiences based on the felt need of psychiatry teachers.[6] The emphasis and continued focus on psychiatry teachers in India for enhancing the quality of neuropsychiatry training won the year 2018 International Neuropsychiatric Association (INA) T N Srinivasan Award. The cash prize from the award was contributed to Minds United for Health Sciences & Humanity Trust, which initiated an annual award for psychiatry teachers for best practices in psychiatry education in association with the Indian Teachers of Psychiatry (IToP) forum.[7] With such incentives for psychiatry teachers to provide the best in the training of medical undergraduates and psychiatry postgraduates, there was the need for a focused faculty development program that is tailored to psychiatry teachers in India, which gave rise to an exclusive scholarship for psychiatry teachers IToP-STEPS (Scholarship for Teachers toward Enrichment of Psychiatry Teaching Skills). The program is an initiative of public charitable trust at Mysore, Minds United for Health Sciences & Humanity Trust, funded by Infosys Foundation in association with the IToP forum. This program was launched across the nation on World Mental Health Day, October 10, 2020, as an online 20-session program. The annual scholarships are open to all faculties across India. Equal representation from government and private institutions is ensured in scholarships provided. The successful psychiatry teachers are rewarded each with INR 10000/- at the end of the program. The peer faculties are also provided with an honorarium of INR 10000/-. The COVID-19 pandemic shifted focus toward online teaching and learning, and the IToP-STEPS online program was rightly planned to ensure undisturbed completion.

Psychiatry teachers' training has not been emphasized in most parts of the world, and to our knowledge, this is the first of its kind across the globe. The success of the program over a period needs to be evaluated, but the completion of the first batch and relevance of the program are documented by the recipients of IToP-STEPS 2020-21.[8] Such kind of structured programs for psychiatry teachers can be utilized as models for many countries where due emphasis on psychiatry education or psychiatry training is not provided, thereby enhancing the quality of mental health services. Online learning which clearly emerged as a major mode of alternative learning during the COVID-19 pandemic has provided an opportunity to make such training programs available to enthusiastic teachers from far and wide geographical locations. Also, without the need for physical infrastructure, online training thus adds to the cost-effectiveness of the program. Additionally, the online mode approach is a new norm in education, and teachers who receive training in such programs have the opportunity to learn online teaching skills. Customized offline and online

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modes of training psychiatry teachers can be planned as per the requirements of the region and guidelines associated with COVID-19 pandemic.

Adopting the program curriculum for IToP-STEPS

With an objective to develop a focused faculty development program that is tailored to psychiatry teachers in India, the unique scholarship thus initiated had to include the basic medical education principles in its curriculum with customization to the subject of psychiatry. The faculty development program for medical college teachers under the aegis of erstwhile MCI (Medical Council of India) began only in 1997, which was a three-day workshop on various aspects of teaching-learning named Basic Medical Education Technology (BMET). This was revised later on with the addition of a module on attitude ethics and communication. The rolling out of CBME in 2019 for undergraduates kicked off curriculum implementation support programs as well for teachers in medical colleges. Apart from these background issues, the peer faculty team of the IToP-STEPS program also had insights from a survey among teachers of psychiatry to improve the quality of undergraduate training while discussing and deliberating on the development of the curriculum. The team finalized the outline of 20 sessions as presented below. Out of these, 16 sessions had standard topics and the last 4 sessions were kept aside for customization as per the dynamic needs of the scholarship recipients. Everyone opined that the program needs to start with an overview of psychiatry education in India and the evolving role of psychiatry teachers. The principles of adult learning, domains of learning namely cognitive, psychomotor and affective domains, the concept of specific learning objectives (SLOs), and teaching-learning methods were included in initial sessions. Since the curriculum document released for implementation of CBME had only competencies mentioned in it, these initial sessions were designed to help the participants to align the goals, competencies, and derived SLOs to teaching-learning methods and subsequently to assessment methods. On a broader note, topics such as reflections and feedback were included as they are vital in the teaching-learning process. Set induction methods, strategies to make lectures interactive, and various small-group teaching methods were also included. Given the current context, sessions on online teaching-learning methods were felt necessary. There was a consensus to include an orientation session on educational research, a session each on concepts like problem-based learning, self-directed learning (SDL), and suggestions for working with students beyond academics. A session on bedside clinics became a part of the program to discuss improvisations both for UG and PG students. Finally, the sessions on the fundamentals of assessments were made part of the curriculum as mentioned in Table 1. A provision was made to revise the curriculum based on inputs from psychiatry teachers and recipients of IToP STEPS award annually so as to make it truly a collaborative and upgraded effort.

Table 1: IToP-STEPS curriculum

Topic	Allotted time (in hours)
Overview of psychiatry education in India	1
Principles of adult learning	1
Effective reflection and feedback	1
How to start any teaching-learning session	1
Specific learning objectives	1
Large group and small group teaching	2
Bedside teaching	1
Online teaching-learning	2
Introduction to educational research	1
Working with students beyond academics	1
Problem-based learning	1
Self-directed learning	1
Assessment	2
Customized teaching-learning*	4

*Candidates were free to choose their areas for customized teaching-learning based on felt needs, and it would be matched to a facilitator

The IToP-STEPS process and methodology

Candidates for the IToP-STEPS scholarship award were selected through a two-step process. In the first stage, a call for applications from interested teachers of psychiatry was circulated through the mailing group of the Indian Psychiatric Society and relevant WhatsApp/social media groups to improve the reach and visibility of the proposed scholarship. Interested candidates had to submit an application form, duly filled-in, along with a motivation letter and a short sample teaching video. These were scrutinized and graded independently by a six-member panel predominantly comprising faculty in the field of psychiatry with domain expertise in medical education; one faculty was from outside psychiatry and had vast experience in medical education.

Next, all the candidates who applied for the scholarship were interviewed sequentially. This was done in multiple sittings, based on the mutual convenience of the participant and members of the expert panel, through adequate prior intimation using online videoconferencing platforms. All members of the panel interviewed every candidate. Following the interview, each expert assigned a combined grade for every applicant, taking into account factors such as their clarity of vision, their interest in medical education, and their potential to influence others. Academic merit or their scholarly profile was not the main criterion; rather, their commitment to medical education and potential impact in terms of dissemination of skills gained through the scholarship was given weightage. Following this process, the experts discussed their individual grades and arrived at a consensus on the candidates to be offered the scholarship. Adequate gender and public versus private sector diversity were also targeted.

The scholarship program was based on the principles of peer-to-peer learning and peer-assisted learning.[9] The curriculum focused on topics relevant to both the content and the process of medical teaching; a complete list of topics

and time allotted is given in Table 1. Assignments related to every session were uploaded on Google Classroom by the respective session facilitators; these were completed and graded before the sessions themselves so that related questions could be discussed during the sessions. Efforts were made to have two student observers for every session: one undergraduate and one postgraduate resident, who were encouraged to give their feedback about the content and delivery of the sessions.

The teaching-learning methodology adopted during the course consisted of interactive lectures and case-based learning to promote critical analysis and learning.[10,11] For instance, participants were given potential scenarios of class strength and the topic to be covered. They were asked to choose the T-L method and discuss the pros and cons. Both synchronous and asynchronous T-L methods were used in a complementary fashion; as an example, the small group discussions between participants on assignments posted in Google Classroom fostered peer-to-peer learning and the broadening of insights. Many sessions used video-based discussions to enhance the take-home message; for instance, in large group teaching, a video of a badly conducted lecture triggered a discussion on how to deal with latecomers and the preparation of a lesson plan prior to the lecture. Participant reflection was encouraged throughout; they could reflect on their T-L experiences and discuss ways to augment them. Self-directed learning was another aspect that was given due emphasis.[12] In sessions such as educational research, the participants were asked to prepare and present a one-page concept proposal of their choice related to research in medical education.

The intended goals were to upskill the young psychiatry teacher to effectively perform as a teacher, researcher, and lifelong learner by honing skills of critical analysis, reflection, and creativity.

Intended outcomes and assessment of IToP-STEPS

Assessment needs to be effective and has to be aligned with the objectives and the teaching-learning strategies. The purpose of this course was to provide knowledge and direction in newer ways of teaching, especially in the context of psychiatry, the newly mandated CBME, and to empower the participants with skills in teaching, assessing, and basics of educational research. The course aimed to motivate future learning, including knowledge, skills, and professionalism. The program targeted assessment for and as learning.[13]

The program included microteaching frequently as a means of learning.[14] This is one of the training techniques that provides a teaching environment, offers an opportunity to enhance skills, and also gains a richer understanding of the process of teaching. It combines the principles of situated learning and reflective practices. The learning was facilitated with peer and teacher feedback. Feedback was the core of the assessment process and was on content, process, skills, and demonstrated values. This was provided in written and oral form. Many sessions had students (undergraduate and postgraduate) also giving feedback. This nearly 360-degree feedback went a long way in helping the participants in improving both knowledge and skills.

Assignments were corrected with feedback offered within a short time. The students were asked to hand in reflections that received feedback and were powerful tools for change.[15] Finally, the importance of entrusting the participants to be a facilitator was a mark of their proficiency in acquiring skills.

Program evaluation of IToP STEPS

As any structured program would always need an evaluation, so does the IToPS-STEPS scholarship program. At the end of one year of teaching-learning activities, an attempt was made by the facilitators to evaluate the program. Such an evaluation is needed to determine whether the program was heading in the right direction for which it was intended and designed. When medical educational programs, like the IToPS-STEPS, are considered, it should be understood that it was fundamentally designed to bring about a "change." The participants in this program, like scholars, facilitators, and internal and external stakeholders, were also interested in change. To determine whether such a desired *"change"* was happening or has happened or not, this program needs to be *"evaluated."*

As an effective program evaluation should focus on the change that is expected to happen, the nature of the change, and whether the change is deemed successful or not, was explored herewith. The Kirkpatrick's approach is one of the most popular evaluation models and has enjoyed widespread popularity among educators. Its major contributions to educational evaluation are the clarity of its focus on program outcomes and its clear description of outcomes beyond simple learner satisfaction. Accordingly, the program gathered data to assess four *hierarchical levels* of program outcomes:

1. *Reaction;* Learner satisfaction or reaction to the program: Assessed by 360-degree feedback and reflections.
2. *Learning:* Measures of learning attributed to the program like knowledge gained, skills improved, attitudes changed: Ensured by assessments of the activities and reflections.
3. *Impact:* Changes in learners' behavior in the context for which they are being trained: Assessed by feedback and reflections.
4. *Outcome:* The entire program's final results in its larger context: Explored by the learners' perceptions expressed during the concluding sessions at the end of one year.

With a fairly conducted above steps of evaluation, the IToPS-STEPS program was found to be proceeding in

the right direction, and the scholars and the facilitators have expressed that they have undergone a change in teaching-learning methodologies. It is further intended to bring wider dimensions to the present curriculum to suit the ever-growing demand for psychiatry teaching skills for medical educators in psychiatry.

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Unmasking of schizophrenia following COVID vaccination

INTRODUCTION

Vaccination has emerged as an essential preventive strategy against the COVID-19 vaccine. A recent review of the literature reported the presence of 11 reports presenting 14 cases of psychiatric manifestations after the COVID-19 vaccinations, with psychosis (n = 5) being the most common manifestation, followed by altered mental states (n = 3), functional neurological disorder (n = 3), mania (n = 2), and depression (n = 1). Most of these cases were reported after the first dose of the vaccine (n = 10), and the age range of the sufferers varied from 18 to 74 years.[1] Considering that there is still limited data on the COVID-19 vaccination and psychiatric manifestations, we present a case of the unmasking of schizophrenia following COVID-19 vaccination with the Covishield vaccine.

CASE DESCRIPTION

A 40-year female, unmarried, post-graduate, and unemployed, who was premorbidly well adjusted, with no past or family history of mental disorder, with no history of COVID-19 infection, was vaccinated with 1st dose of COVID-19 vaccine (Covishield) in mid-2021. On the evening of the day of the vaccination, she started complaining of headache associated with palpitations and discomfort in the chest. On the same night, she was not able to sleep properly. From the next day, she was observed to be fearful and restless. On the second night, she was also unable to sleep and kept pacing throughout the night. From the next day, she started expressing fearfulness and suspiciousness. On the third day, she was seen by a psychiatrist, and a diagnosis of acute transient psychotic disorder was considered and started on tablet olanzapine 5 mg per day. However, her symptoms kept worsening, and from the fourth day, additionally started voicing delusions of persecution against her sister-in-law (i.e., planning to harm her) and reported commanding auditory hallucinations which were present for most part of the day, and were very distressing to the patient. These symptoms led to marked psychosocial dysfunction. Over the next ten days, the symptoms kept increasing, and she stopped olanzapine after a week due to weight gain (about 2 kilograms over 10 days) and sedation. The symptoms worsened despite being given olanzapine 5 mg/day surreptitiously for the next three months. Following this, she was brought to our setting.

After a detailed assessment a diagnosis of schizophrenia (as per the ICD-10 criteria) was considered. Her routine investigations in the form of hemogram, liver function test, renal function test, fasting blood glucose levels, lipid profile, thyroid function test, and neuroimaging in the form of magnetic resonance imaging of the brain did not reveal any abnormality. She also had no evidence from physical examination and investigations to support systemic lupus erythematosus, Wilson's disease, and porphyria. An autoimmune panel could not be done due to affordability issues and the local non-availability of the testing facility. She was given adequate trials of olanzapine and aripiprazole, with no significant improvement and intolerable side effects (excessive sedation, weight gain, and amenorrhea with olanzapine and no improvement with aripiprazole, although did not experience side effects). Later, she was started on clozapine and increased to the dose of 75 mg/day, with which she showed significant improvement in psychopathology and her functioning improved. She is currently on regular follow-up and maintaining well on clozapine 75 mg/day. The patient did not receive the second dose of the vaccine.

DISCUSSION

Previous case reports which have reported psychiatric manifestations following COVID-19 vaccinations have reported the occurrence of psychosis, mania, functional neurological symptoms, and depression.[1] However, all these reports have reported the short-term outcome of the association. As in the written case reports, in the index case, the psychotic symptoms emerged immediately after the first dose of the vaccine. In contrast to a previous report that documented the onset of schizophrenia after vaccination in a patient with premorbid schizotypal traits,[2] the index case did not have any such predisposing factor. The first psychotic breaks infrequently occur at this age, and our patient did not exhibit thought disorganization. Her predominant symptoms were auditory hallucinations and persecutory delusions, to which she demonstrated poor insight on initial evaluation.

The previous reports that have reported the occurrence of psychosis following vaccination have noted the emergence of symptoms on the day of vaccination to as late as 12 days.[3] In the index case, the signs emerged on immunization day and persisted for more than five months. In contrast to the previously reported cases, the index case developed long-term psychosis, which was resistant to antipsychotics and required clozapine. As per the Naranjo scale,[4] the score of the patient was 6 (previous conclusive reports: +1; adverse event appear after the suspected drug was administered: +2; Adverse reaction improve when the drug was discontinued or a specific antagonist was administered:

+1; No alternative causes other than the drug that could on their own have caused the reaction: +2), suggesting a probable adverse reaction.

To conclude, it can be said that the COVID-19 vaccine can rarely unmask psychosis in some persons. However, because only a handful of cases of psychiatric manifestations following COVID-19 vaccination have been reported in the literature, the general public should not be hesitant to receive COVID-19 vaccination.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given her consent for her images and other clinical information to be reported in the journal. The patient understands that her name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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There are no conflicts of interest.

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Ethylenediaminetetraacetic acid-dependent pseudothrombocytopenia, presenting as spurious pancytopenia, associated with risperidone

Dear Editor,

There have been reports of risperidone-associated thrombocytopenia and pancytopenia.[1,2] Certain medications may also cause ethylenediaminetetraacetic acid (EDTA)-dependent pseudothrombocytopenia, which is a laboratory artifact due to *in vitro* agglutination of platelets, leading to spuriously low platelet counts (PC).[3] Psychotropic agents, such as moclobemide, olanzapine, valproic acid, and lurasidone, have been associated with pseudothrombocytopenia.[4,5] To the best of our knowledge, this is the first report of risperidone-associated pseudothrombocytopenia, which also manifested as spurious pancytopenia on some occasions. Written informed consent for this publication was obtained from the patient and her caregiver.

A 32-year-old drug-naïve lady presented with a 4-year history of symptoms suggestive of schizophrenia. In-patient care was advised due to unmanageable aggression. Her baseline investigations revealed hemoglobin (Hb) of 11.6 gm/dL, with serum Vitamin B12 levels 95.60 pg/mL (Normal: 197–771 pg/mL). The other investigations were unremarkable. Tablets risperidone up to 8 mg, trihexyphenidyl, and injectable vitamin B12 supplements were started.

Three weeks later, she developed dry skin over both feet with pruritus, leading to itching and petechial lesions. The dermatologist made an impression of asteatotic eczema and advised topical mometasone and paraffin, with which the lesions resolved. Considering the petechiae, a complete blood count (CBC) was done, which revealed pancytopenia (Hb: 8 gm/dL, total leukocyte count (TLC): 2400/μL, PC: 20,000/μL). As the patient did not have any significant clinical manifestation of pancytopenia, CBC was repeated to rule out laboratory error. The repeated sample revealed isolated thrombocytopenia, in addition to anemia present at baseline (Hb: 11.3 gm/dL, TLC: 4900/μL, PC:

31,000/μL). Peripheral smear revealed adequate PC present in clumps. A physician referral was made, who ruled out potential causes of thrombocytopenia, including malaria and dengue. Further, the CBC done in another laboratory was within normal limits. The details of the anticoagulant used for this CBC are not available. Pancytopenia was again revealed on day 32 (Hb: 6.6 gm/dL, TLC: 2200/μL, PC: 22,000/μL). This finding of pancytopenia on days 21 and 32 might be explained by EDTA-induced agglutination of erythrocytes and leucocytes along with platelets leading to pseudo-pancytopenia. The patient was closely monitored for any bleeding tendency and other physical symptoms/signs.

After 4 weeks, risperidone was cross-tapered with olanzapine due to inadequate response and completely stopped by day 35. Even though olanzapine has been shown to cause pseudothrombocytopenia in literature,[6] it was still considered mainly due to its efficacy and patient affordability. Pseudothrombocytopenia was also thought of as an idiosyncratic laboratory reaction, which might not necessarily reappear with olanzapine. CBC repeated after stopping risperidone revealed an upward trend, with counts reaching near the baseline on day 45 of inpatient care (Hb: 10.8 gm/dL, TLC: 6300/μL, PC: 320,000/μL). She was continued on trihexyphenidyl and vitamin B12 supplements even after risperidone was stopped. The improvement in blood picture after stopping risperidone while continuing the other medicines suggests that risperidone is the likely inciting factor. On applying the Naranjo adverse drug reaction probability scale,[7] a score of + 6 was obtained, signifying that the pseudothrombocytopenia could be a probable reaction to risperidone.

The exact mechanism of EDTA-dependent pseudothrombocytopenia is still unclear; however, it is hypothesized to be secondary to EDTA-dependent antiplatelet antibodies.[3] The trigger for the production of these antibodies is unknown and may arise in response to an unrelated antigen. When exposed to platelets, EDTA causes a conformational change in the membrane, resulting in the exposure of certain "neoantigens" to which these antibodies bind.[8] The antibody binding site of the GP IIb is normally hidden in the GP IIb IIIa complex, and the complex must dissociate before antibody binding may occur.[8] It is postulated that certain drugs may affect this dissociation,[8] and risperidone might be one of them. The antibody may then cross-react with platelets resulting in agglutination, thereby causing falsely low PC.[8] Several measures have been proposed to prevent getting these spurious readings, including recollection of blood using sodium citrate, CPT (Trisodium citrate, pyridoxal 5'-phosphate, and Tris), or calcium chloride/heparin as additives, keeping the sample at 37°C till the counts have been estimated.[3] It is important to delineate pseudothrombocytopenia from true thrombocytopenia to avoid unnecessary investigations and interventions.

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Setting the stage: A pilot analysis of reporting of study setting in two major Indian psychiatry journals

Sir,

Study setting refers to the physical, social, and cultural context in which the investigators conduct the research. An accurate and complete description of the study setting and location is critical to judge the applicability and generalizability of the findings.[1] Research setting description also finds mention in major reporting guidelines, confirming its importance.[1,2] However, few studies have evaluated the completeness of study setting reporting in Psychiatry. Previously, Andrade *et al*.[3] found that only 60%-70% of articles published in two Indian psychiatry journals provided information about study location; other aspects of study setting reporting were not analysed.

In this context, we examined reporting of the study setting in original articles published in two major psychiatry journals from India: the Indian Journal of Psychiatry (IJP), in publication since 1949,[4] and the Indian Journal of Psychological Medicine (IJPM), in publication since 1978.[5] We selected these journals as they have the longest publication history. In all original articles published in the two latest issues (May-June and March-April 2022 issues of IJP and May-June and July-August 2022 issues of IJPM) of these journals at the time of search (July 13, 2022), we examined the description of the study setting for its completeness; other types of articles were excluded irrespective of whether they reported original data or not.

After going through the relevant portions of the methods section, we categorized the description of the study setting in included articles as follows: no description, partial description, and complete description. Partial description was further subdivided into the following four subcategories: only the name of the setting or facility mentioned; only the level of care mentioned (primary/secondary/etc.); both the name and level of care mentioned but nothing more; and name, level of care, and some more (but incomplete) details mentioned. If the methodology described name of setting, level of care, and relevant details about the setting such as the catchment area and some characteristics of population being sampled, it was coded as a complete description. Literature search, data extraction, and coding were performed by a single author (N.V.) and cross-checked for accuracy by a senior author (V.M.). Discrepancies were resolved through mutual discussion till consensus; if necessary, all authors were involved in resolving conflicts.

We located 39 original articles and analysed 33; four articles were excluded as they were online surveys (where the setting data are limited and qualitatively different); two were excluded as they were subsequent papers from a dataset where the setting was already described in earlier papers. Of the 33 articles analysed, 19 were from IJP and 14 from IJPM. Twenty-five articles were from India while eight articles originated abroad. Most of the articles (n = 21) described the study setting partially; of these, most either described only the name of the setting (n = 8) or the level of care (n = 6). Eleven articles had no description of the study setting. Only one article described the study setting completely [Table 1].

These findings, albeit from a small sample, suggest that description of the study setting is deficient in original articles published in two leading Indian psychiatry journals. Our findings should be viewed in the context of the varying significance of different aspects of the study setting for different types of studies. As an example, for epidemiological studies, physical and administrative aspects related to study location, such as country, city, village/panchayat distribution, and population demographics, assume significance as they can influence the baseline risk of the condition under investigation.[6] In contrast, for hospital-based randomized controlled trials, the physical and organizational aspects of the hospital, its catchment areas, issues with accessibility of services (such as lack of transport options), resources available in the hospital, average outpatient footfall, and patient workflow[7] are essential to report because it allows the readers to judge the relevance of the trial findings to their own setting. Table 2 provides a checklist of elements to be included when reporting study setting; authors should include all that is relevant to their study design.

A limitation of our analysis is the limited sample size of studies analysed. Nonetheless, given the high proportion of articles with deficits in reporting, it appears reasonable to conclude that reporting of study setting in leading Indian Psychiatry journals is deficient. Because study results and their interpretation are dependent on the study setting and because information from studies is often used to guide practice and policy, it is incumbent upon prospective

Table 1: Description of study setting in original articles analysed

Study setting	Articles (*n*=33)
Setting not mentioned	11
Setting mentioned but not described completely	21
Only name of the setting mentioned	8
Only level of care mentioned	6
Both name and level of care mentioned	1
Both name and level of care mentioned but description is partial	6
Setting mentioned and described completely	1

Table 2: Suggested elements of study setting reporting

Component	Specific elements to be reported
Place	Country, state, city, and village/block/panchayat area[†]
Institution or community	Name of hospital, level of care (primary/secondary/tertiary), village wards or panchayat blocks selected for study[†], average outpatient footfall, and brief patient workflow
Type of patients/ subjects	Inpatients, outpatients, or from community
Target population	Basic characteristics of population residing in the study catchment area (e.g., total population[†], predominant socio-economic status, and major occupation[s])
Catchment area	Areas from where the hospital or facility draws its clientele (e.g., neighbouring cities, villages or states)
Study dates[$]	Relevant dates, including periods of recruitment, exposure, follow-up, and data collection

[†]For community-based studies; [$]Included under study setting in study reporting checklists

authors to report the setting accurately and completely. We believe that journal editors should make it mandatory for authors to provide a full description of the study setting in submitted articles involving human or animal data; one way of achieving this is to mention this in the instructions to contributors section. In addition, study-reporting checklists should include more and specific details about the study setting, to guide authors better.

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Zolpidem dependence for self-medication in the management of tardive dyskinesia

Zolpidem is a short-acting imidazopyridine hypnotic agent, acting on the gamma-aminobutyric acid A ($GABA_A$) receptors. With a selective binding to the α1 subunit-containing $GABA_A$ benzodiazepine (BZ1) receptors, it has been proposed that it has less abuse and dependence potential compared to other benzodiazepines. However, there is growing evidence on the risk of zolpidem dependence. Multiple case reports have focused on the anxiolytic and stimulating effects of zolpidem dependence, especially among patients with a history of substance dependence. Zolpidem has also been reported to improve motor symptoms among patients with movement disorders, including tardive dyskinesia (TD). TD is a delayed effect of antipsychotic treatment and is characterized by involuntary, persistent, hyperkinetic, and irregular choreoathetoid movements. TD may cause severe distress and has negative effects on physical and psychosocial functioning. We present a case of zolpidem dependence for self-medication in managing TD.

Ms. A, a 45-year-old woman, had experienced long-term depression, fatigue, and insomnia since the age of 20. During her 20s, she abused alcohol, multiple hypnotics, and low-potency antipsychotics, including clotiapine 40–60 mg/day and *chlorpromazine* 50–100 mg/day, to cope with insomnia. TD developed across her face and neck and persisted into her late 30s. For the past five years, she had received zolpidem to treat her insomnia and reported that her facial and neck dyskinetic movements diminished shortly after zolpidem usage. She gradually increased the dosage from 20 mg/day to 500 mg/day in divided doses. She experienced anxiety, tremors, and increased severity of TD during periods of zolpidem withdrawal. The symptom score was measured using the Abnormal Involuntary Movement Scale (AIMS; 12 items, score: 0–4, a total score of 1–7, items: 0–28) during outpatient visits demonstrated a marked improvement from 10 to 2 shortly after zolpidem usage. The woman was hospitalized three times for abstaining from zolpidem and relapsed shortly after each discharge. Relapses occurred because the patient wished to alleviate TD symptoms after zolpidem usage.

The misuse and dependence on zolpidem has drawn increased concerns. Studies have reported various symptoms of zolpidem dependence including sedative effects, euphoric sensations, exaltation, and anxiolytic effects.[1] However, this is a very rare case report that a patient developed high-dose zolpidem dependence for self-medicating antipsychotic-induced TD. Although the etiology of TD was unclear and we relied primarily on the patient's self-reported history, we suspect that the patient's symptoms of dyskinesia developed due to previous abuse of low-potency antipsychotics for hypnotic effects. Rapid alleviation of movement symptoms may have precipitated her self-medication of zolpidem and her dependence on the drug.

Various reports have mentioned the effectiveness of zolpidem in ameliorating involuntary movements in blepharospasm and advanced Parkinsonian-associated dystonia, dyskinesia, and akinesia.[2-4] One possible hypothesis is that GABAnergic neurotransmission and neuroprotective and antioxidant effects are involved. Zolpidem has a structure similar to that of melatonin and can mimic its properties, such as its role in alleviating jetlag and its antioxidant effect. Research has demonstrated that chronic zolpidem treatment in rats with antipsychotic-induced orofacial dyskinesia prevented the progress of orofacial dyskinesia, the increase in oxidative damage, and the decrease in catecholamine neurotransmitter levels.[5] The benefits in treating movement disorders may also be related to the GABAergic action of zolpidem on the output structures of the basal ganglia. In addition to the direct drug effects on the basal ganglia and associated structures, the anxiolytic influence or placebo effect of zolpidem may contribute to the beneficial effects of zolpidem on TD. Further research should be conducted on the mechanisms of zolpidem that reduce the severity of neuroleptic-induced TD.

Although some treatments are available, managing severe TD is still challenging for clinicians. First-generation antipsychotics have a higher risk of resulting in TD and have largely been substituted with second-generation antipsychotics that carry a relatively lower risk of doing so. However, off-label use of antipsychotics is still common in clinical practice, which may put patients at risk of developing TD. Thus, the best treatment approach should avoid unnecessary antipsychotics and use the lowest effective dose of second-generation antipsychotics for a relatively short period. Our report indicates the risks of zolpidem dependence and the misuse of antipsychotic drugs, particularly among patients with underlying chronic insomnia, mood disorders, and a history of medication misuse.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given her consent for her clinical information to be reported in the journal. The patient understands that his name will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

Author contributions
CYF: literature search, data analysis, and writing; HWL: data analysis, data interpretation, and writing; CHC: literature search, data interpretation, and final approval of the version.

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Dissociative disorder presenting as self-injurious behaviour: A unique presentation of factitial dermatitis

To the Editor,

Factitial dermatitis (FD) is a psychiatric disorder reported in 3% of dermatology patients.[1] A 12-year-old boy presented with a history of episodes of abnormal facial sensations, abnormal body movements, and spontaneous skin lesions for 2 years. Complaints of facial tingling sensation started after a difficult class test. It occurred for 10-15 mins, relieved on pressing the face, and resolved spontaneously. Later he started having dissociative seizures. After a few months a spindle-shaped, non-itchy erosion appeared on the anterior thigh fully formed and healed with applying ointments. Similar lesions reappeared in crops of 5 10 located in accessible areas of the body [Figure 1]. Investigations were inconclusive, and multiple treatments failed. Symptoms exacerbated during school reopening. The child also had anger outbursts when his demands were refused or when insisted to rejoin school. A Family history of chronic skin condition in uncle was present. The child was pressurized by his father for academics and occasionally punished. Fulfillment of demands by extended family members would reinforce his demanding behavior.

He was diagnosed as a case of Mixed Dissociative Disorder with Factitial Dermatitis (F44.7 with L98.1) as per ICD-10.[2] Bullying, corporal punishment in school, and learning disability were excluded. The child expressed his scholastic worries. He desired admission to an English medium school which was not feasible for his family. He had difficulty controlling his anger and desires. His lesions were exacerbated in the ward when his wish for a smartwatch was deferred by his father. He also developed transient vision loss modeled on another patient. The child could not recall the manner of skin lesion formation. However, his demands were clearly linked to its appearance. The European Society for Dermatology and Psychiatry (ESDaP) requires FD as a diagnosis only where external incentives are absent.[3] This child was motivated by his demands. Concurrent dissociative disorder and external gains for self-injurious behavior highlight this atypical case of FD.

The family was psychoeducated about the diagnosis, and it being a manifestation of unresolved mental conflicts and not any serious dermatological illness as presumed, with evidence.

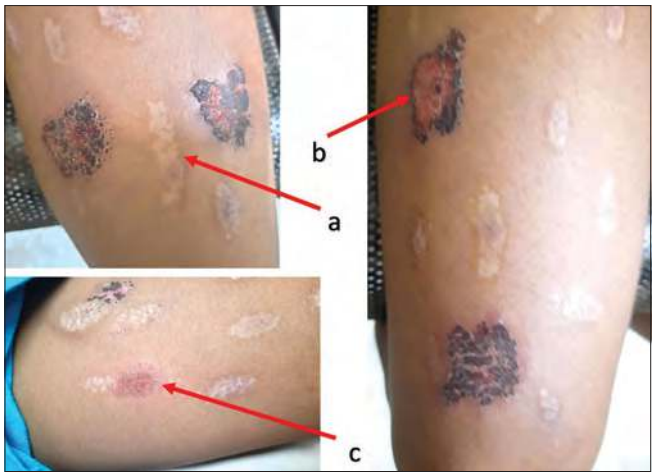

Figure 1: Images of the child's thighs revealing multiple skin lesions (scars, scabs and erosions). (a) Oldest scars are spindle shaped about 2 3 cm × 1 cm long. (b) Four recent scabbed lesions are black colored of uniform square shape of 3 × 3 cm and equally spaced (c) Three smaller spindle shaped erosions with exudate, edema and redness. All lesions have a well defined margin and minimal signs of inflammations. Similar lesions were present on lower abdomen, left are more than right and extensor part of wrist

We started Sertraline 25 mg for self-harm and Risperidone 0.5 mg for emotional dysregulation and impulsivity.[4] Anger control techniques, and breathing relaxation exercises were taught and activity scheduling was done. Coping skills were enhanced. Reducing sick roles, open discussion of demands, and consistent parenting were explained to the family. Earlier confrontation of factitious behavior was advocated but presently, non-confrontation has the advantage of maintaining rapport and achieving remission.[1,4] Assessment of the familial, social, educational life, temperament, parenting style, marital discord, abuse, child's adjustment, and reaction to disease was done.[4,5] FD is the patient's defense in dealing with stress, stripping them of it without solving the real issue or coping skills training results in new symptoms.[1,4] In 2 weeks, his lesions reduced, and his anger was regulated. He acknowledged the correlation of stress with symptoms and in 1 month, he rejoined school. Informed consent of the father and assent of the patient was taken for this report.

Considered 'manipulative' behavior, FD is a cry for help; the result of dysfunctional coping during psychological conflict. Treating FD requires control over wanting to know 'how it occurred'and resentment towards patient while empathizing and guiding the patient towards a normal life.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the legal guardian has given his consent for images and other clinical information to be reported in the journal. The guardian understands that names and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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