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Editorial

Beyond Research Reporting Guidelines: How can the Quality of Published Research be Enhanced?

Published original research papers, regardless of the impact factor and standing of the journal, are often found to suffer from several shortcomings. At best, these papers junk the scientific literature, and at worst, misinform clinicians and researchers. The fact remains that they see the light of the day after escaping the layers of quality control mechanisms available in publishing today such as the double-blind peer review and multiple editorial checks. Partly, in an effort to address these issues, and to bring about some uniformity in reporting research designs, several evidence-based checklists such as the Preferred Reporting Items for a Systematic Review and Meta-analysis (PRISMA), Strengthening the Reporting of Observational Studies (STROBE), Meta-analysis of Observational Studies in Epidemiology (MOOSE), and Consolidated Standards of Reporting Trials (CONSORT) statements were developed for various research designs in the last two decades and are available on the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) network.[1]

Notwithstanding these positive developments, it is widely accepted that the dissemination of these guidelines has only modestly impacted the quality of medical research reporting. Recently, Song *et al*., in a study of nearly 500 randomized controlled trials (RCTs),[2] divided into pre-CONSORT (n = 285) and post-CONSORT (n = 214) era, found that the reporting of several essential steps in an RCT, including methods of randomization, allocation concealment, and blinding continued to be inadequate 20 years following the first publication of the CONSORT statement.[3] Specialty specific studies from obstetrics and gynecology and surgery have concluded similarly.[4,5] Even papers published in the most influential high-impact biomedical journals are not immune to deficits in reporting.[6] As for observational studies, experts have opined that it is unnecessary and may even be detrimental to insist on registered research protocols before publication and that simpler alternatives may need to be found.[7]

Though one may argue that there is inadequate dissemination of the reporting guidelines, the problems leading to poor quality of published research are far more complex and unlikely to be resolved solely with strategies aimed at raising awareness of the many reporting guidelines. Rather, what is required is a multipronged strategy that includes a nuanced understanding of the limitations of these guidelines and incorporates educational and statutory elements. A few strategies to this effect are outlined below:

1. *Promoting awareness, adoption, and a balanced understanding of reporting guidelines:* For starters, these guidelines are only intended to be a checklist for reporting and do not pre-empt issues in design or methodology. Therefore, they cannot be expected to be a solution for the garbage-in, garbage-out phenomenon in research. Nevertheless, a good understanding of what is eventually expected should, ideally, prompt researchers to address some of those issues at the initial stage itself. Focus group discussions with early career researchers may elicit barriers to guideline adherence and provide inputs to design appropriate remedial measures. Raising awareness of reporting criteria and their utility, through periodic thematic workshops, for all stakeholders may enhance guideline uptake. Research methodology workshops should devote an entire session for introducing research guidelines. Institutions should incentivize and popularize research papers that demonstrate good adherence to reporting guidelines. Nodal funding agencies such as Indian Council of Medical Research (ICMR) and Department of Science and Technology (DST) should design research process algorithms, along the lines of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) initiative[8] aimed at guiding young researchers to develop guidelines-compliant research protocols
2. *Registered research reports and publishing of research protocols*: Registering of research reports has taken a big leap in the last decade or so. In India, this trend is most obvious for clinical trials, probably owing to the insistence of many journals on prior registration of trials with the Clinical Trials Registry of India (CTRI) before publication.[9] Now, studies with any research design (observational/interventional) can be registered with the CTRI, though few authors bother with registering observational study protocols. Nearly a decade ago, an editorial in the

British Medical Journal (*BMJ*) had drawn attention to the need for registering research protocols for even observational studies, to enhance research transparency.[10] It is argued that this would reduce the problems of data dredging and selective reporting by researchers who may indulge in these undesirable practices for career advancement or financial gains. Sister journals of the *BMJ*, such as *BMJ Open*, as well as the *Lancet* have been publishing protocols of observational studies for quite a while now. However, it remains to be seen if the editors of smaller, upcoming journals would be willing to sacrifice potential submissions at the altar of research transparency by insisting on prior registration of protocols. Editors may also consider publishing research protocols in their journals to promote transparency and enhance quality. Protocol publishing can be one way to ensure that the study results eventually get published regardless of their direction. Editors too are often guilty of disfavoring papers with negative results, and protocol publishing may help in mitigating the publication bias that plagues biomedical research. If these measures are perceived to be resource intensive, a low burden alternative for editors would be to insist on a simple declaration of transparency by the corresponding author that the study hypothesis arose before the inspection of the data. Nevertheless, in the long run, a central repository of observational study protocols, akin to the clinical trial registry, would be highly beneficial for researchers in two ways: by enabling easier access to previous similar research and thus reducing duplication, and by providing an opportunity to build and improve upon previous work, with greater scientific value and impact

3. *Establishment of research oversight committees at both institutional and journal level*: It has been proposed that journals should consider appointing a qualified person to the post of a research ombudsman.[11] While the initial goal of such an appointment was mainly to put a lid on abuse of trust and power by journal editors,[12] in the current scenario, there is a felt need to confer a wider educational (about research integrity, protocols and guidelines) and consultancy (for research related queries) role for this watchdog. However, recognizing the limitations and potential workload issues, perhaps, journals and institutions should consider establishing an independent "research oversight committee" comprising chosen experts. This committee should have a composition that reflects the aims and scope of the journal. For instance, a journal with a focus on consultation-liaison psychiatry can have experts from medical, surgical, dental and nursing fields, apart from psychiatrists, to fully evaluate the issues of subject safety and quality. The remit of this committee could include education and consultancy as described earlier. However, it should also oversee whether manuscripts conform to standard reporting protocols and offer suggestions to this effect for erring authors
4. *Augmentation of editorial practices and guidelines:* This could include a requirement of publishing full table of findings as supplementary material online. This may address the problem of publication bias and cherry picking of data by the researchers. In addition, journals may mandate that the authors include responses to two questions at the end of an article; "What is known" and "What this study adds?" – a practice followed by few journals presently. Authors must specify their primary objective, and all other analyses done apart from this must be treated as exploratory. While exploratory analysis is exciting and has its own importance in contributing to hypothesis generation, the fact remains that they have to be treated as preliminary findings requiring further testing. To this effect, the practice of specifying certain analysis as "exploratory" in a paper will prevent wrong conclusions. Editors also need training in spotting data mining practices, and while rejecting such manuscripts, the editors must clearly specify the reasons so that the authors are better informed about the pitfalls of such practices
5. *Formation of a National Editors' Consortium*: A less commonly encountered but, nevertheless, significant issue is that papers rejected for lack of methodological rigor by one journal find their way into another journal of similar standing. If this has occurred due to a genuine reason, such as the author making a significant improvement in the paper based on the comments of the initial reviewer(s), then it can only be beneficial to science. Worryingly, more often, this phenomenon owes its occurrence to wide disparity in reviewing standards (which allows such articles to fall through the sieve). The obvious solution here seems to be reviewer training. However, a central repository or consortium where the review comments can be made accessible to all those who wish to see them can have dual benefits: first, it allows editors of various journals to access these comments for papers in the rejection-resubmission cycle and second, it will expose the predatory journals (where such articles may commonly end up) for what they are and what they stand for. Peer reviewers' time is a precious commodity and any step that augments the sanctity of this time-trusted quality assurance mechanism in scientific publishing should be given a serious thought by the powers that be. It is time the editors worked together and not in isolation for the advancement of science.

In summary, only a combination of strategies that target awareness, training, and sensitive enforcement can eventually enhance the quality of published research. While none of these methods may be sufficient on its own, the bottom line is that we have to constantly endeavor to find ways to improve the quality of published research and mere awareness raising may not suffice. Editors need to be vigilant, yet sensitive, in framing journal policies and dealing with transgressions. Scientific publishing is serious business that demands time, training and trust. Training is clearly required for all stakeholders including editors and peer reviewers, apart from researchers and junior investigators.

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Review Article

Women with Mental Illness – An Overview of Sociocultural Factors Influencing Family Rejection and Subsequent Institutionalization in India

Febna Moorkath, Mysore Narasimha Vranda, Channaveerachari Naveenkumar[1]

ABSTRACT

Background: Family abandonment and rejection resulting in homelessness are detrimental to women diagnosed with mental illness in India. A majority of the literature related to homelessness holds a western background, and women's homelessness in relation to mental illness is relatively unexplored in the Indian context. This review was conducted to understand the sociocultural factors influencing family rejection and to synthesize the living situation of institutionalized women with mental illness in India. **Methods:** Literature search in electronic databases (PubMed, Google Scholar), carried out using appropriate keywords, and a manual search in the library catalog. **Results:** As per the selection criteria, 19 reports, including original research articles and conceptual papers, were included and reviewed. **Conclusion:** There is a shortage of methodologically sound research in understanding the connection of mental illness–women homelessness–and the institutionalization scenario. This review highlights the necessity of shifting focus from institutionalization to innovative psychiatric rehabilitation strategies using the Mental Healthcare Act, 2017.

Key words: *Homelessness, institutionalization, psychiatric rehabilitation, women with mental illness*

Mental health is a crucial element in the overall concept of health, which equally strives toward the physical, emotional, social, and spiritual aspects.[1] The extent of prejudices and sufferings faced by the people diagnosed with mental health disorders has been demonstrated in research.[2] Considering the Indian social scenario from a patriarchal framework, women diagnosed with mental illness undergo a variety of gender-specific issues in individual, familial, and social facets.[3] This specific population has to face an unsupportive world while managing their inner disturbances caused by the various psychiatric symptoms.[4] The occurrence, manifestation, treatment, and outcome of mental disorders in women

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in India need to be understood in relation to the specific norms which act as guiding principles[5] in the society.

The stigma and discrimination in relation to mental health and their potential impact on marginalization are well documented in the literature, ranging from denial of opportunities to social and cultural exclusion.[6] In India, multidimensional poverty and the stigma associated with severe mental illness is pervasive; and for women, it is reported to be a strong indicator of poverty. The prevalent interaction between stigma, mental illness, and gender meant women in those conditions was more prone to be poor than men.[7]

The immediate family is primarily the care providers for people with mental illness in India.[8] However, the label of mental illness in relation to the female gender often creates difficulty in familial and marital contexts. It is impossible to evaluate the scenario of women in isolation; rather, it needs a comprehensive understanding of the different interacting social structures and cultural norms. The current review has represented the nexus of mental illness–family rejection–women homelessness–institutionalization specific to the Indian scenario. This review was an attempt to answer two main questions considering the Indian social climate:

1. What are the sociocultural factors influencing families to reject/abandon women members diagnosed with a mental illness?
2. What is the living situation of women placed in the shelter of care homes/psychiatric hospitals due to various psychosocial circumstances?

METHODS

Relevant studies and reports were identified through a combination of different electronic database and Internet searches, and cross-reference searches of retrieved documents. A systematic database search was conducted in PubMed and Google Scholar. A manual search in the library catalog and Google search to find out relevant reports that are not included in bibliographic retrievel systems was also carried out to find out any grey literature. The literature review process was carried out through literature searches, storing, making abstracts of retrieved documents, and synthesis.

Criteria for selection

Considering lacunae in published original articles in the intended area, other than peer-reviewed articles, relevant documents and reports of government or nongovernment organizations published in the English language available on the Internet were included in the review. Original articles included both quantitative and qualitative studies which focused on any of the components regarding women with mental illness–family rejection–homelessness–institutionalization.

Restricted vocabulary/search terms

The literature search was mainly focused on a two-tier strategy – an electronic search and a manual search. Keywords such as women with mental illness, marriage, stigma and discrimination, gender, patriarchy, homelessness, institutionalization, family rejection, shelter care homes, psychiatric hospitalization, psychiatric rehabilitation, along with women and India, Indian setting/context/society, and Indian culture were used to identify relevant literature.

RESULTS

Women with mental illness – sociocultural and familial response

Families' perception toward women with mental illness plays a critical role in the treatment and caregiving process. Indian families are tolerant of deviant behavior and at most times are ready to take care of the ill member.[9] However, cases of familial rejection and abandonment also seem to be rampant due to multiple reasons:

1. Helpless abandonment: This happens in a majority of families. Poverty, lack of support, inability to meet the cost of medications, inability to travel long distances for care, elderly caregivers, stigma, suboptimal living conditions, unsafe neighborhoods, and so on
2. Careless abandonment: It appears when the primary caregivers, especially parents, get old, and the other family members are not ready to shoulder the caregiving responsibility of the person with mental illness
3. Willful abandonment: It is the intentional dumping of the mentally ill family member by other significant relatives due to vested interests such and getting divorce and property.[4]

The marginalization of women is reported to be in three aspects: first is the female status, the second is the psychoses, and the third is the marital status (divorced/separated).[10]

Prevalent stigma (stereotypes, prejudice, and discrimination)

The stigma toward mentally ill women often leads to their marginalization, which in turn creates barriers to their recovery. Prevalent stereotypes spread negativity toward the mentally ill; the prejudice results in cognitive or affective responses like anger or fear toward such people, and this finally leads to discrimination, rejection, and avoidance from the

society.[11,12] Reported evidence from southern India has indicated that young women with schizophrenia are more vulnerable to discrimination within society.[13]

Indian families, marriage, and gender roles

The family is regarded as the nucleus of the Indian social system. Unlike the Western scenario, Indian culture follows a collectivistic attitude which places the family in the center of individual lives. Marriage for women in India, ideally considered being one time, is colored with social conformity and sanction. Hence, broken marriages due to mental illness shatter the lives of these women.[10] The marriage and familial roles are strictly gender-based, wherein men involve in active familial affairs, whereas women possess a marginal and passive role. Factors such as joint family system, patriarchy, marriage as a necessity, subservient status of daughters-in-law at home, preference for a male child, dowry, lower educational status of women, strict gender rules, and the primary roles of women being childbearing and nurturing have a major influence in the lives of women in India.[5] There is a strong inverse relationship between social position and health-related outcomes. Therefore, the social disadvantages experienced by Indian women prove that biological vulnerability effect is exponentially higher.[14] In India, where 90% of marriages are arranged by the families, the fact of mental illness in the case of female members heavily burdens them. Other factors such as poverty, deprivation, illiteracy, stigma, lack of community resources, domestic violence, family rejection, abandonment, and death of primary caregivers evidently result in homelessness of women with mental illness.[3,15]

A comprehensive report published by World Health Organization[16] elaborately explains the link between increased prevalence of mental health issues in women and their vulnerability in a patriarchal society. Women with mental illness appear to be at a particular disadvantage in India. Thara *et al*. mentioned in their study that such women were frequently sent back to their family of origin and their responsibility borne by their old parents. The women and the family experience social isolation and stigma.[10,17] They are abandoned mainly due to the negative attitude toward the illness rather than the illness itself.[10] Broken marriages and separation in the context of mental illness meant that many caregivers felt depression and sorrow and experienced a large amount of stigma within the society.[13]

Families abandon and reject their mentally ill members due to the taboo deeply rooted in shame.[18] In an unsupportive family environment, access to mental healthcare and maintenance of treatment remains a question. Neglect eventually leads to abandonment; as such, homelessness is the most common outcome for these women. Irrespective of the severity of the symptoms, this segment is considered to be the most marginalized and deprived of all human and civil rights.[19] A court-based study to analyze the judgments related to annulment and divorce in the background of mental illness revealed that in the Family Court at Pune, 85% of the cases were filed by husbands who alleged that their spouse was mentally ill. Among cases reaching the High Court, 95% were filed by male petitioners.[20]

The failure in gender role establishment seems to be interfering with the lives of women, more so in those with mental illness. Viewing from a gender perspective, decision-making and access to property allow for minimal involvement from women. For example, in the case of married and unemployed women, decision-making ability is restricted to the kitchen. Whereas men, despite any illness, are involved in every decision-making process. The women were denied property rights by the family due to the presence of psychiatric illness.[21] In the marital context, separation and divorce were reported more in female patients, predominantly those who were symptomatic or childless.[22] Evidence suggests that women are being deserted by their spouses without any maintenance support.[10]

Research underscores the fact that in most developing countries, the numbers of mentally ill women who become homeless seem to be increasing. This is due to the disorganization of the joint/extended family system and an increase in transportation facilities which cause such women to wander off to different places. Some families are even hostile and indifferent toward these women when sent back home.[22] This may be due to moralistic reasons and the stigma associated with the mental illness. The women abandoned by their family are often sent to institutional facilities for long-term care and protection.

Institutionalization and living conditions of Indian women with mental illness

In 2014, a report published by the Human Rights Watch (HRW), named "Treated worse than animals-abuses against women and girls with psychosocial or intellectual disabilities in institutions in India," created a good deal of discussion in both government and nongovernment platforms. HRW identified that stigma, discrimination, a lack of appropriate governmental community-based services, and a lack of awareness about facilities and available services for people with a disability often lead to institutionalization. The interviews with the respondents highlighted harsh realities like forced institutionalization, abuse in institutional care,

including neglect, physical, and verbal abuse, and involuntary treatment.[23]

Following this report of HRW, National Commission for Women and National Institute of Mental Health and Neuro Sciences (NIMHANS), Bengaluru (2016), conducted a study to address the concerns of women admitted to psychiatric institutions in India, to explore the clinical, social, cultural, and economic factors likely to affect the lives of women with mental illness admitted to mental health hospitals within the country. HRW's report selectively highlighted the abuse in Indian institutions. The study, however, reported reasonable satisfaction of women with mental illness regarding the facilities provided to them. On a closer examination, it has been concluded that many of these women came from difficult backgrounds deprived of basic facilities, and the availability of such facilities led to reasonable satisfaction among these women. In this report, women staying in some institutions expressed high level of dissatisfaction with basic amenities such as safe drinking water, facilities to sleep, rest, wash, and dry clothes.[4]

A study conducted in West Bengal by the Ministry of Health and Family Welfare in 2013, to form a draft policy for psychiatric rehabilitation of long-stay patients in state-run mental hospitals, revealed that out of five state-run psychiatric hospitals, four are overcrowded with long-stay patients who are stable or fit to be discharged; many being abandoned and the families not ready to shoulder the responsibility. The study also highlighted the need for strategic interventions to improve the condition of long-stay patients who have no one to care for them.[24]

The National Commission for Women (2006), in collaboration with Sane and Enthusiast Volunteers' Association of Calcutta (SEVAC), explored rehabilitation of female mentally ill in psychiatric hospitals in Kolkata. The study mentioned that the living conditions of people inside the psychiatric hospitals are very pathetic, even violating basic human rights. Physical torture and lack of humane care are the main flaws in these systems, and the report continued that some female patients were even kept naked due to several reasons. The study revealed that a majority of patients (60%) indicated poor quality of life and the study also identified that government infrastructures for the delivery of mental healthcare are inadequate for ensuring treatment compliance.[25]

CONCLUSION

It is clear from the current review that the sociocultural involvement in the lives of women with mental illness is visible in India. The available literature underscores the prevalent gender-specific explanations and their influence in the aftercare activities. There is a lack of evidence-based studies to explain the nexus of mental illness–homelessness–institutionalization. There is an alarming need to shift the focus toward community-based psychiatric rehabilitation rather than sticking to the conventional mode of institutionalization. In Mental Healthcare Act 2017, Chapter v, section 19, the right to community living is highlighted as one of the basic rights of people with mental illness, and it directs the Government to make necessary arrangement for establishing or supporting less restrictive community-based establishments. The Act also mentions Government support in free legal aid measures for abandoned people with mental illness to exercise their right to live in the family/home. The right to community living should be highlighted in the major platforms of research and policy initiatives to address the needs and concerns of the institutionalized and invisible population.

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Conflicts of interest

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Review Article

Eating Disorders: An Overview of Indian Research

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ABSTRACT

There has been sporadic research on eating disorders in India, with no published attempt to collate and summarize the literature landscape. Hence, the present narrative review aims to summarize Indian work related to eating disorders, discern current trends, and highlight gaps in research that will provide directions for future work in the area. Electronic search using the MEDLINE, Google Scholar, and PsycINFO databases was done to identify relevant peer-reviewed English language articles, in October 2018, using combinations of the following medical subject headings or free text terms: "eating disorders," "anorexia nervosa," "bulimia," "treatment," "epidemiology," "co-morbidity," "management," "medications," "behavioral intervention," and "psychosocial intervention." The data extracted from studies included details such as author names, year, from which of the states in India the work originated, type of intervention (for interventional studies), comparator (if any), and major outcomes. There is increasing research focused on eating disorders from India over the last decade, but it continues to be an under-researched area as evidenced by the relative paucity of original research. The cultural differences between east and west have contributed to variations in the presentation as well as challenges in the diagnosis. Hence, there is a need for the development of culturally sensitive instruments for diagnosis, as well as generating locally relevant epidemiological data about eating disorders from community and hospital settings.

Key words: *Anorexia nervosa, bulimia nervosa, eating disorder, India*

The earliest description of an eating disorder (ED)-like syndrome appears in a treatise by Morton (1694), under the section "Nervous Consumption," where the author talks about two adolescents who presented with loss of appetite, extreme fasting, weight loss, and their treatment and outcome.[1] Historical reports point to the existence of ED even in the 17th century, referred to as "holy anorexia." However, one of the first scientific reports of this condition, in the late 19th century, was by William Gull who is credited with coining the term anorexia nervosa (AN).[2] In India, the occurrence of ED was not reported until the late 20th century.[3] Perhaps, media-related glorification of "size zero" body type and culturally sanctioned drive for thinness, body shaming, and dissatisfaction have contributed to the recent upsurge of ED cases.[4-6] Traditionally,

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these parameters have been less of a concern in India than other countries.[4] Yet, another reason for the recent increase in the incidence of ED such as bulimia nervosa (BN) and binge eating disorder (BED) is more easy access to media outlets promoting unhealthy body types and higher socioeconomic status of people.[7,8]

Notwithstanding its increasing prevalence rates, ED continues to be an area that is under-reported and under-researched. There are several reasons why ED must be given increasing focus in health care research and policy planning in today's scenario. AN, a prototype ED, has the highest mortality rate among mental health disorders.[9,10] The economic and social impact of ED was estimated to be upwards of $15 billion (INR 1057.8 billion) in 2012, which is comparable to the productivity impact of anxiety and depression, estimated at $17.9 billion (INR 1262.3 billion) in 2010.[9] Though, relatively rare in the general population, the individual impact of ED can be quite debilitating and long-term treatments are often expensive. ED have high rates of psychiatric and medical co-morbidity.[9-12]

Though there has been sporadic research on ED in India, there has been no attempt to collate and summarize the literature landscape. We undertook the present narrative review with the objectives of summarizing Indian work related to ED, discern current trends, and highlight gaps in research that will provide directions for future work in the area. These would potentially answer key questions on the clinical presentation and trajectories of ED in our setting.

METHODOLOGY

Search strategy and study selection

Electronic search using the MEDLINE, Google Scholar, and PsycINFO to identify relevant peer-reviewed English language articles was carried out to include articles between April 1967 to October 2018. We used random combinations of the following medical subject headings or free text terms: "eating disorders," "anorexia nervosa," "bulimia," "treatment," "epidemiology," "co-morbidity," "management," "medications," "behavioral intervention," and "psychosocial intervention."

This being a narrative review and because research on ED in India is relatively sparse, we included all types of research reports, including case reports, to gain a true picture of the research landscape. The initial search yielded 84 articles. From the initial search, 39 articles were relevant and therefore selected for inclusion in the review. The full text of these articles was retrieved electronically. Additionally, the reference section of all articles was manually screened to identify potentially relevant articles. We only selected articles describing research from India. There was no restriction on the date of publication. Citation indexing services and gray literature such as conference proceedings were not included in the present review.

Data extraction

The data extracted from studies included details such as author names, year, from which of the states in India the work originated, type of intervention (for interventional studies), comparator (if any), and major outcomes.

RESULTS

A major part of the literature on ED from India is derived from case reports and case series (n = 24). In comparison, there are 15 original studies summarized in Table 1.

The earliest reports of ED date back to 1966. The case was of AN in a 42-year-old female with episodes of compulsive fasting for 2 years. The patient was treated with 100 mg chlorpromazine, 100 ml of 25% glucose with vitamin C 500 mg intravenously, 10 injections of liver extract 2 ml intramuscularly biweekly, and 9 sessions of electroconvulsive treatment. After 46 days of intensive pharmacotherapy and supportive psychotherapy, she showed improvement and was kept in close follow up.[3] Following this, there has been increasing reports of ED cases in the last two decades. Majority of the cases were of AN, especially restrictive subtype. The typical profile of cases described from India is of adolescent females,[26-31] belonging to Hindu religion,[29,31,32] and coming from an upper- or middle-socioeconomic background[26-29,31,33] In contrast, there are only four cases of male AN reported.[27,34] There is a single case report of AN described in a pair of monozygotic twins too.[35]

Cases of AN have been described in Indian adolescents belonging to Sikh religions, living in the United Kingdom.[34] The symptoms of AN were found to flare up after being teased by peers about weight which was followed by concerns about weight gain, in the majority of cases.[27,29] There is also a case of AN which had atypical features such as denial of fears of weight gain.[36] One report of disordered eating described a young female, in whom "not eating" was conceptualized as a resistance to the patriarchal system and this highlights the role of Indian sociocultural factors for developing an ED.[37]

Bradycardia, hypotension, anemia, and dyselectrolytemia have been reported at the time of presentation to a psychiatrist.[27,28,38] Wernicke–Korsakoff syndrome

Table 1: Summary of original studies on eating disorders in India

Authors	Subjects	Study settings	Sampling type	Assessment tools	Methodology	Major findings
King and Bhugra, 1989 Yamuna Nagar[13]	574 school girls aged between 14-23 years	Two schools and two colleges	Quota sampling	Hindi version of EAT-26	Abnormal eating attitude and behavior was assessed by a score of more than 20 on EAT-26	About 29% (*n*=167) had disordered eating or probable eating disorder
Srinivasan *et al*., 1995 Chennai[14]	Medical students Step1: 602 Step 2: 210	Medical college	Convenient sampling	EAT-40 BITE DSM-III criteria	Two step procedure Step 1: Screening of probable cases. They were defined as : Scoring >30 on 40-item EAT Scoring >10 on 33-item BITE Step 2: Clinical assessment and diagnosis of eating disorder as per DSM-III in all probable subjects as well as 1/3 of screen negative subjects selected by random sampling	About 28 students had scored more than cut offs as per EAT or BITE in Step 1 None of the subjects had syndromal eating disorder diagnosis on clinical evaluation About 14.8% subjects (*n*=31) could be diagnosed with syndrome of EDS, subsyndromal eating disorder
Srinivasan *et al*., 1998 Chennai[15]	Medical students Step1: 210 Step 2: 146	Medical college	Convenient sampling	SQ-EDSSQ -EDS) SRQ-20	Step 1: 15 item SQ-EDS was made based on the study by Srinivasan *et al*., 1995 on 210 subjects Step 2: The questionnaire was validated in another set of 146 students against 20-item SRQ-20	Among 210 subjects assessed individually, no criterion-based diagnosis of AN or BN could be made. About 14.8% of subjects were identified as having EDS which did not fit into any of the standard diagnostic criteria for major eating disorders In Step 2, none of the subjects could be diagnosed with AN, BN, or partial syndrome of AN or BN. About 11% of subjects were diagnosed with EDS
Mammen *et al*., 2007 Vellore[16]	Medical charts of 3274 patients attending child and adolescent psychiatry unit	Hospital child guidance clinic	Consecutive sampling	ICD-10	Retrospective chart review of patient records of consecutive children and adolescents availing. Child and Adolescent Psychiatry Unit services from 2000-2005. The case records diagnosed with eating disorder (F 50.0-50.9) as per the ICD-10 were reviewed by a psychiatrist	After chart review, 41 cases were identified. About 1.25% had an eating disorder. 85.4% (35 cases) had psychogenic vomiting. 14.6% (6 cases) had AN psychogenic vomiting (F: M=2:1.5) and AN (F: M=5:1) was predominantly seen in females. The mean age was around 11.2 (4.3) years. About 44% had psychiatric co-morbidity
Kurpad *et al*., 2010 Bengaluru[17]	*n*=73 outpatients of psychosis (schizophrenia/ psychosis NoS) on treatment	Hospital	Purposive sampling	Eating behavior questionnaire DSM-IV	Eating behavior questionnaire as well as DSM-IV criteria were used for diagnosing. BED in patients of psychosis	None of the patients had BED
Balhara *et al*., 2012 New Delhi[18]	*n*=97 female nursing students	Government nursing college affiliated with tertiary care hospital	Quota sampling	EAT-26, BSQ	Disordered eating attitude and behavior was assessed by a score of more than 20 on EAT-26. BSQ was used to assess attitude regarding body shape	About 4% (*n*=3) had disordered eating or probable eating disorder. A significant correlation was obtained between EAT-26 and BSQ
Chellappa and Karunanidhi, 2013 Chennai[19]	*n*=200 undergraduate female students	Five premier colleges affiliated to the University of Madras	Convenience sampling	EAT-26, State Trait Anxiety Inventory BDI	Abnormal eating attitudes were assessed by EAT-26. Anxiety and depression were assessed by the State Trait Anxiety Inventory and BDI, respectively	30% of students had abnormal eating attitudes. Participants in the abnormal eating attitude category had exhibited higher scores on depression and anxiety when compared to those with normal eating attitudes
Jugale *et al*., 2014 Bengaluru[20]	*n*=117 females aged between 20-25 years	Five professional college hostels	Convenience sampling	SCOFF	A score of 2 or more on the SCOFF questionnaire was used for diagnosing disordered eating. Score more than 2 on SCOFF signifies suspected eating disorder. Dental hygiene was assessed by dental professional	About 42.7% (*n*=50) had suspected eating disorders. They had a significantly higher prevalence of periomylolysis, dental caries, and tooth sensitivity

Contd...

Table 1: Contd...

Authors	Subjects	Study settings	Sampling type	Assessment tools	Methodology	Major findings
Upadhyah *et al*., 2014 Meerut[21]	*n*=120 females aged between 13-17 years	School	Convenience sampling	EAT-26	Disordered eating attitude and behavior was assessed by a score of 20 or more on EAT-26	Nearly 26.67% (*n*=32) had disordered eating
Ramaiah, 2015 Bellur[22]	*n*=172 medical students	Tertiary care rural medical college	Convenience sampling	EAT-26 BSQ	Disordered eating attitude and behavior was assessed by a score of 20 or more on EAT-26. BSQ was used to assess attitude regarding body shape	About 16.9% (*n*=29) had disordered eating. A significant correlation was obtained between EAT-26 and BSQ
Lal *et al*., 2015 New Delhi[4]	Indian patients of eating disorder=30 outpatient Australian patients of eating disorder (outpatients=30, inpatients=30) All patients were females of age range 1626 years	Private mental health clinics in India and Australia	Convenience sampling	QOL EDs questionnaire DSM-IV	The diagnostic profiles and the quality of life was assessed by the QOL EDs questionnaire Eating disorder was diagnosed as per the DSM-IV	No significant difference was noted in global ED-QOL score. Indians compared to Australian patients had: Higher beliefs that they overeat more frequently Similar frequency of restriction of food, vomiting, use of laxatives Lesser frequency of beliefs of fears of loss of control over intake of food and having preoccupations with the body or food intake
Singh *et al*., 2016 Manipal[6]	*n*=550 students	Pre-university colleges	Convenience sampling	EAT-26	The tendency to develop an eating disorder was assessed by a score of more than 20 on EAT-26	Nearly 31.09% (*n*=171) had affinity to develop eating disorder
Shashank *et al*., 2016 Mandya[23]	*n*=134 medical students	Tertiary care medical college and hospital	Convenience sampling	EAT-26 SCOFF	EAT-26 and SCOFF questionnaire was used to assess disordered eating attitude and behavior. Disordered eating was determined by a cut-off of 20 and 2 on EAT-26 and SCOFF, respectively	29.2% and 17.2% of students had disordered eating behavior as per EAT-26 and SCOFF, respectively
Gupta *et al*., 2017 Chandigarh[24]	*n*=250 medical students	Government Medical College	Convenience sampling	Hindi version of EAT-26 BSQ	Hindi version of 26 item EAT-26 BSQ was used to assess disordered eating attitudes and body shape attitude	Females scored significantly greater on dieting subscale of EAT-26 and BSQ. BSQ was found to be a significant predictor of eating disorder
Vijayalakshmi *et al*., 2017 Bengaluru[25]	*n*=241 medical students *n*=213 nursing students	Medical college	Convenient sampling	EAT-26 SCOFF Patient health questionnaire	SCOFF questionnaire was used to assess disordered eating behaviors Score more than 2 signifies suspected eating disorder	Males (45.4%) scored higher on the cut-off for SCOFF questionnaire compared to female (31.1%). Males (16.5%) scored higher on the cut-off for EAT-26 compared to female (8.7%)

AN – Anorexia nervosa; BDI – Beck's Depression Inventory; BED – Binge eating disorder; BITE – Bulimia investigatory test; BSQ – Body shape questionnaire; BN – Bulimia nervosa; DSM-IV – Diagnostic and Statistical Manual of Mental Disorders Version IV; DSM-III – Diagnostic and Statistical Manual of Mental Disorders Version III; EAT – Eating attitudes test; EDS – Eating distress syndrome; ICD-10 – International Classification of Diseases; QOL EDs – Quality-of-life for eating disorders questionnaire; SCOFF – Sick, Control, One-stone (14 lbs/6.5 kg), Fat, Food; SRQ – Self-report questionnaire; SQ-EDS – Screening questionnaire for eating distress syndrome

was the presenting symptom for a 39-year-old female who had AN from adolescence.[39] Surreptitious use of metformin, with episodes of hypoglycemia, was the presenting symptom in another case of AN in a 21-year-old female.[33] Though the nature of psychiatric co-morbidity has not been described, psychiatric co-morbidity was noted in all the cases of a case series.[27] Obsessive traits of symmetry and order,[32] obsessive compulsive disorder (OCD),[40] and major depressive disorder have been reported as co-morbidities.[33] Menstrual abnormalities and poorly developed secondary sexual characteristics have been noted in the majority of cases.[26-28,32,41]

There have been only five cases of BN reported till date.[42-46] Two of the cases were females: one was a 22-year-old medical student, with the onset of symptoms around 13 years of age, with binging and purging with isabgol husk and consumption of orlistat.[44,45] The other three cases were atypical, with an absence of concerns for body weight or body image, along with an absence of concurrent use of diuretics or laxatives in a 37-year-old male,[46] 15-year-old female,[43] and a 24-year-old female.[42]

Cases of ED have been described occurring co-morbid to physical illnesses such as systemic lupus

erythematosus[26] and secondary to traumatic brain injury[31] or due to an adverse drug reaction to zolpidem consumption termed as a nocturnal sleep-related ED.[47] Further, AN has been found to mask physical illnesses such as carcinoma.[48] Treatment described in these cases included comprehensive treatment involving mental health professionals and dieticians.[26,27]

Majority of cases were managed in the in-patient setting.[3,26,27] In AN, high-calorie high-protein diet has been advised, with careful monitoring for re-feeding syndrome.[26,27] In the 1960s, chlorpromazine and modified insulin therapy were the treatment options used.[3] Cyproheptadine in combination with chlorpromazine,[26] combination of cyproheptadine and olanzapine,[41] mirtazapine,[27] risperidone,[27] trazodone,[27] citalopram,[27] and fluoxetine at 20 mg/day[28] have been used for treatment of AN. Combinations of olanzapine and fluvoxamine or olanzapine and fluoxetine have been used in cases of AN with obsessive traits and OCD, respectively.[32,40] Sertraline[42] and fluoxetine at low dose of 20 mg/day[44] as well as at 80 mg/day[42] has been described in the management of BN, with good response.

The non-pharmacological therapy of ED included family therapy, cognitive behavioral therapy (CBT), supportive psychotherapy, contingency management, hypnotherapy, and play therapy.[26,27,29,31,42-44,49] High-frequency repetitive transcranial magnetic stimulation (rTMS) over the left dorsolateral prefrontal cortex was given as augmentation strategy in a 23-year-old female who earlier had only a partial response to antidepressants as well as atypical antipsychotics and CBT. rTMS was found to improve attitude toward body weight and body shape, with an improvement of weight.[38]

DISCUSSION

This review attempted to summarize the Indian research on ED. The literature is largely comprised of case reports, as noted in the previous reviews.[50,51] However, there has been an increase in the number of published original research articles over the last 5–6 years. There are no studies available which determined the prevalence of ED from the community setting. There is a single hospital-based retrospective review, which reported a prevalence of 1.25% for ED.[16] Of them, almost 85% had psychogenic vomiting and about 15% had AN. This is in contrast to the international literature, wherein the frequency of occurrence of BN and BED is more common than that of AN. A meta-analysis of 15 studies from various settings reported that the estimated lifetime prevalence of any ED was 1.01%, and those of AN, BN, and BED were 0.21%, 0.81%, and 2.22%, respectively.[52] BED had the highest point prevalence of ED, followed by BN and AN, among young females across China, Japan, Africa, and Latin America.[53] In comparison, in the Indian setting, there are no cases reported of BED, and only five cases have been reported of BN.[42-46] Further, the two-step assessment (initial screening by self-rated questionnaire, followed by assessment by semi-structured or diagnostic interview) is the standard procedure followed globally. However, there is a single study using the two-step procedure and found no cases.[14] Majority of the Indian studies used only the screening, self-rated assessment. The frequency of disordered eating/probable ED ranged from 4 to 45.4%.[18,25]

It is possible that subsyndromal ED cases may not be captured by a self-rated assessment. Two studies reported the prevalence of eating distress syndrome (EDS) to be 11% and 14.8%.[14,15] EDS refers to subsyndromal forms of AN or BN, with patients having distressing and conflicting thoughts about body shape and eating habits. EDS is characterized by strict dieting, and bingeing in a few cases, with no significant weight loss or behaviors such as resorting to severe measures of weight loss such as diet pills, starvation, purging, or vomiting.[14] However, there has been practically no Indian research on EDS in the last 20 years.

There are several methodological issues in Indian studies which need to be addressed. Firstly, many of the studies have employed convenient sampling on medical and nursing students.[14,15,18,22,24,25] This may lead to selection bias and such samples may not be truly representative of the population at large. However, this practice of studying medical students is popular worldwide. The rationale given to support this being the "stressful" nature of medical training, which could be a risk factor for ED.[54-56] But this may also imply that the prevalence rates obtained in these studies may be an inflated figure.

Secondly, in the measurement of the frequency of disordered eating, it was found to be higher as per the Sick, Control, One-stone, Fat, Food questionnaire (SCOFF) compared to the Eating Attitudes Test-26 item (EAT-26) questionnaire.[23,25] The frequency with SCOFF ranged from 17.2% in women to 45.4% in men, and the frequency with EAT-26 ranged from 4% to 31%.[6,18,24,25] Thirdly, there are limitations in the translation and implementation of the questionnaires in a setting like India that has such linguistic diversity. Though the EAT-26 questionnaire has been translated into Hindi, the cut-off score for the Hindi version has not been defined.[24] Also, the rationale for using the same cut-off of the English version in the Kannada version is not clear.[6] Hence, due

to cultural differences between the western and Indian settings, there is a definite need for the development of culturally sensitive scales for screening ED.

Culture bears a strong influence on the presentation of ED in India. One unique point noted in the Indian presentations of ED is relative lack of concern for body fat/shape. This has been termed as "Non-fat phobic" variant of AN.[50] This has been described in Hong Kong as well. In this form, food restriction is attributed to somatic complaints such as abdominal bloating, pain, and lack of appetite, rather than concern for body fat. Similar atypical features have been noted in cases of BN too from India. Also, the concept of EDS is in accordance with this concept.[50,57] Further, food restriction is culturally sanctioned in Indian culture when one is unwell, for "cleansing the bowel."[36] However, several recent studies show an association between perception of body shape and higher scores on EAT-26.[18,22,24] This could be explained by the ongoing rapid societal transitions in India and the increasing influence of western ideals.

At least 50% of patients with an ED are known to have a psychiatric co-morbidity, with depression being the most common.[58,59] In contrast, a few cases had syndromal co-morbidity.[27,40] The principles of management of ED adopted in India is similar to the west. Most reports of AN and BN describe using a combination of pharmacotherapy and psychotherapy. Selective serotonin reuptake inhibitors (SSRIs), second-generation antipsychotics, and cyproheptadine have been found to be effective for AN.[60] Patients with BN were treated with 20–80 mg/day of fluoxetine in the case reports.[42,44] In contrast, globally, a higher dose of SSRIs, especially fluoxetine, has been found to be effective in cases of BN.[61] Psychotherapeutic approaches used in the Indian setting, such as family-based therapy and CBT, therapy match global practices.[62]

To conclude, there is increasing research focus on ED from India over the last two decades. Lower prevalence of ED could be the reason for the relative paucity of studies. But, with the increasing impact of westernization of society, ED merit renewed focus. The cultural differences between east and west have contributed to variations in presentation as well as challenges in diagnosis. Hence, there is a need for the development of culturally sensitive instruments for diagnosis as well as generating locally relevant epidemiological data about ED from the community and hospital settings.

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There are no conflicts of interest.

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Original Article

Fear of Childbirth among Pregnant Women Availing Antenatal Services in a Maternity Hospital in Rural Karnataka

Avita Rose Johnson, Melvin Kumar G, Rosy Jacob, Maria Arul Jessie, Fabiyola Mary, Twinkle Agrawal, Vijaya Raman[1]

ABSTRACT

Background: Pregnancy, though joyful, may be a time of fear and anxiety. Twenty percent of pregnant women in developed nations report a fear of childbirth, and 6%–10% describe a severe fear that is crippling. This could lead to adverse maternal and fetal outcomes. Data on fear of childbirth among pregnant women are lacking in India and would help in incorporating measures to enhance routine antenatal care. **Methodology:** With the objective of documenting fear of childbirth and associated factors, a cross-sectional study was conducted in rural Karnataka among women availing antenatal care services, using a face-validated 30 item questionnaire developed by the authors which was then scored to determine fear of childbirth. **Results:** Of 388 women studied, 45.4% (176) had a fear of childbirth. The commonest fears documented were: not feeling confident about childbirth, being afraid or tense about the process of childbirth, fear of labor pains, and fear of cesarean section. Teenage pregnancy, nulliparity, primigravida status, and having no living child were significantly associated with fear of childbirth. **Conclusion:** Overall, 45.4% (176) of women had a fear of childbirth. It is important to identify and address the various fears of childbirth that women may have, as revealed by this study, with a view to providing information and reassurance to the mother, with the aim of improved maternal and fetal outcomes.

Key words: *Fear of childbirth, gravida, parity, pregnant women, primigravida*

Key messages: *It is important to identify and address the fears of childbirth that women may have before, during and after childbirth and it will help in better maternal and fetal outcomes.*

Motherhood and pregnancy are cherished moments in a woman's life. Pregnancy, for most women, should be a period of great happiness and fulfillment. However, giving birth to a child is one of the most intense experiences a woman can go through, so it is understandable that many women are nervous about

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childbirth. The fear of pregnancy is called tokophobia. It is defined as an intense state of anxiety which leads some women to fear childbirth and consequently to avoid pregnancy despite desperately wanting a baby.[1] With regard to childbirth, it is probably normal to experience some concern or anxiety.[2] Termination of pregnancy may be requested by women who suffer from tokophobia who dearly want a baby but are unable to understand their own aversion to parturition.[3] Twenty percent of pregnant women report fear of childbirth and 6%–10% describe a severe fear that is crippling.[4] An irrational fear of childbirth can affect the entire pregnancy, complicate labor, lead to difficulties in the mother–infant relationship, and to postpartum depression.[5] Data on fear of childbirth among antenatal mothers would help healthcare professionals to provide targeted psychological support to those mothers who require it and an opportunity to alleviate fears of childbirth during pregnancy itself, thereby improving maternal and fetal outcomes. However, this particular data is scarce in India, especially among rural women who contribute significantly to the country's population. Therefore, it was decided to assess the fear of childbirth among women availing antenatal care services in a rural area of South India.

METHODOLOGY

A cross-sectional study was conducted in a rural maternity hospital in Ramanagara District of South Karnataka between March 2016 and May 2016. The sample size was calculated to be 304, assuming a 24% prevalence of fear of childbirth among pregnant women as evinced from an Australian study[6] along with a 20% relative precision. All pregnant women availing antenatal services at the hospital were included, irrespective of gestational age. Pregnant women in labor were excluded. Consecutive sampling method was employed. Written informed consent was taken before administering a questionnaire. As there was no available validated questionnaire to assess fear of childbirth among pregnant woman in an Indian setting, it was decided to develop a questionnaire for this purpose. The process began with a review of the available literature, followed by qualitative in-depth interviews with pregnant women attending an antenatal clinic in a different village located in Bangalore Urban District. Fears regarding labor, birth, and after-birth were discussed and documented, and a draft questionnaire was formulated. This was then face-validated by three experts in the field of Psychiatry and Maternal Health and was piloted among 10 pregnant women after taking written informed consent, in the same village where the qualitative interviews were conducted. After a few final modifications, the final questionnaire recorded socio-demographic and obstetric details and a 30-item "Fear of Childbirth Questionnaire [Online appendix]," which had three parts documenting (1) fear before childbirth-11 questions, (2) fear during childbirth—13 questions, and (3) fear after childbirth—six questions. Response to each question had one of the three responses: agree, disagree, or neutral. A response indicating fear of childbirth received a score of 1 ("agree" was scored 1, disagree and neutral did not indicate a fear of childbirth so was scored as 0). Therefore, it was possible to score a total of 0 to 30 (where a higher score indicated greater fear). Cronbach's alpha was calculated to be 0.89, indicating a high level of internal consistency (reliability) of the questionnaire. This questionnaire was in the local language (Kannada).

The study was conducted after obtaining institutional ethics committee approval, and all the participants provided written informed consent before recruitment. Data was entered in a Microsoft Excel worksheet and analyzed using SPSS version 16. Descriptive analysis for socio-demographic and obstetric variables was performed using means, standard deviations, and proportions. For tests of association between fear of childbirth scores and socio-demographic and obstetric variables, Student's *t*-test and Analysis of variance (ANOVA) were used. Multiple linear regression was performed with the factors that were significantly associated.

RESULTS

A total of 388 antenatal women were included in the study. Most of the women belonged to the age group of 20–25 years, with the mean age being 22.9 ± 2.9 years [Table 1]. Most of the women belonged to Hindu religion, hailed from a joint family, and had studied till high school or beyond. Majority were homemakers, belonged to middle socio-economic class by Modified BG Prasad scale[7] and were in possession of a below poverty line (BPL) card. Mean age at marriage was 20.65 ± 2.36 years. Over half the women were primigravidae.

The "fear of childbirth scores" were divided into quartiles. Those with scores above the 50th percentile (score of 4 and above) were considered to have a fear of childbirth. The mean "Fear of childbirth" score was found to be 4.54 ± 1.91. Fear of childbirth scores were found to be significantly higher among teenage mothers, nulliparous women, primigravidae, and those with no living children [Table 1]. No significant association was found between fear of childbirth scores and religion, type of family, education, occupation, socio-economic status, previous history of stillbirth or abortion, or age at marriage.

Table 1: Association between Fear of Childbirth scores and various socio-demographic and obstetric variables

Socio-demographic and obstetric variables	Categories	*n* (%)	Mean "Fear of childbirth" score	*P*
Age in years		388	Correlation coefficient (*r*) = 0.104	*P*=0.041#
Religion	Hindu	337 (86.9)	4.51	*F*=1.20
	Muslim	29 (7.4)	3.52	*P*=0.302**
	Other	22 (5.7)	5.63	
Type of family	Nuclear	111 (28.6)	5.04	*t*=1.256
	Joint	272 (71.4)	4.34	*P*=0.210*
Education	Up to middle school	50 (12.9%)	5.76	*F*=2.12
	High school	149 (38.4%)	4.61	*P*=0.121**
	College and above	189 (48.7%)	4.16	
Occupation	Homemaker	355 (91.5%)	4.49	*t*=0.708
	Gainfully employed	33 (8.5%)	5.12	*P*=0.479*
Socioeconomic status	Upper middle	378 (97.4%)	4.5	*t*=0.429
	and Middle class	10 (2.6%)	5.2	*P*=0.668*
	Lower middle and Lower class			
Parity status	Nulliparous	242 (62.4%)	5.55	*t*=5.3
	Multiparous	146 (37.6%)	2.87	*P*=0.001*
History of previous stillbirth	No stillbirth Previous stillbirth	384 (384%)	4.51	*t*=-1.2
		4 (1%)	7.50	*P*=0.227*
History of previous abortion	No	337 (86.9%)	4.47	*t*=-1.2
	Yes	51 (13.1%)	5.37	*P*=0.195*
Gravida	Primigravida	218 (56.1%)	5.49	*t*=4.3
	Multigravida	170 (43.9%)	3.33	*P*=0.001*
No of living children	No living children	251 (64.7%)	5.62	*t*=6.13
	At least one living child	137 (35.3%)	2.56	*P*=0.001*

*Student's *t*-test, **ANOVA, #Correlation

Table 2: Multivariable linear regression: Adjusted factors for fear of childbirth

Variables	Coefficient of regression	*t*	95% C.I. for coefficient		*P*
			Lower	Upper	
Constant	8.31	7.89	6.28	10.4	0.01*
Age	0.25	0.52	-0.93	0.98	0.96
Gravida	0.55	0.60	-1.24	2.35	0.54
Para	1.63	0.95	-1.73	4.99	0.34
Living child	-5.12	-3.13	-8.34	-1.91	0.02*

*Statistically significant at Alpha = 5%

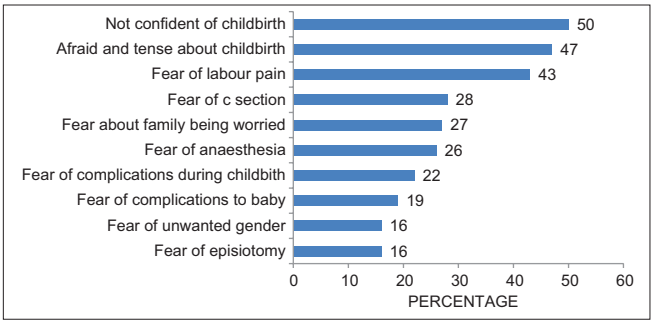

Figure 1: Top 10 Fears regarding childbirth

On performing multilinear regression, after adjusting for other variables, it was found that women with a living child were likely to have significantly lower fear of childbirth score as compared to women with no living children [Table 2]. Co-efficient of regression was −5.12 (−8.3 to −1.9). The most common fears regarding childbirth are presented in Figure 1. Not feeling confident about childbirth, being afraid or tense about the process of childbirth, and fear of labor pains were the most frequently mentioned fears. Women also mentioned the fear of cesarean section and episiotomy. Women anticipated not being able to take care of the baby by themselves during the postpartum period and not being able to breastfeed the baby properly. They also expressed a fear of becoming unattractive after birth.

DISCUSSION

An irrational fear of childbirth can affect maternal and fetal outcomes[5] and therefore, should be looked for and addressed during pregnancy. In this study, it was found that women had a fear of childbirth, fearing events that may occur before, during or after childbirth. An extensive review of the literature revealed no similar study from India. A few international studies on fear of childbirth have documented only the possible fears of events taking place during childbirth and have not addressed events occurring before or after childbirth. Therefore, it is difficult to compare the findings of our study with any other currently published studies. However, it is interesting to note that in an Australian sample of pregnant women, Toohill *et al.*[6] found the prevalence of fear of childbirth to be 24%. A similar study in Stafford, the UK by Hofberg *et al.* reported 20% of pregnant women with fear of childbirth.[3] Nieminen *et al.*, in Sweden,[8] reported a prevalence of 15.8% for fear of childbirth. In a cohort study conducted among Swedish women, the prevalence of fear of birth was 22% in mid-pregnancy and 19% in late pregnancy.[9]

These studies had used the Wijma Delivery Expectancy Questionnaire (WDEQ). WDEQ captures the fear of childbirth in terms of events during the actual childbirth and not events preceding or following it. Our study was able to capture a wide range of fears before, during, and after childbirth. However, it was beyond the scope of the present study to determine a cut-off score for fear of childbirth.

A study on the relationship between fear of childbirth and anxiety among Turkish pregnant women by Körükcü *et al.* found that 41.1% of pregnant women had a fear of childbirth.[10] This higher level of fear of childbirth in Turkey may be explained in a socio-cultural context, where women may not have been able to discuss their fears openly. Most studies have used the WDEQ as a screening tool for detecting a fear of childbirth. Internal consistency, i.e., Cronbach's alpha coefficient value, of WDEQ is 0.91 and 0.89 as reported in a few studies.[11,12] However, in the present study, a 30-item questionnaire was developed to document fears of childbirth in an Indian setting, encompassing the periods before and after childbirth, as well as during childbirth. Cronbach's alpha value of this questionnaire is 0.89 which indicates good internal consistency (reliability). A study on the fear of childbirth among primigravida in Kerala, by Jaju *et al.*, found that fear associated with childbirth was expressed by 17.7% women.[13] In the present study, primigravidae were found to have a significantly higher mean fear of childbirth score. But on multilinear regression, after adjusting for other factors, it was "having at least one living child" which was found to be significantly associated with a lower fear of childbirth score. The implication of this finding is that women who have no living child are more likely to have a fear of childbirth, and therefore, targeted interventions to this specific group are required during antenatal care to allay their fears. A wide variety of possible fears of childbirth has been documented in our study and were divided into three different parts, i.e. fear before childbirth, fear during childbirth and fear after childbirth. Before childbirth, the common fears about the period were fear of labor pain, fear of family being worried and fear of prolonged labor. Fears during childbirth were: not being confident about childbirth, being afraid and tense about childbirth, fear of cesarean section, fear of anesthesia and fear of episiotomy. After delivery, common fears about the period after delivery were fear of not be able to take care of her child by herself, not being able to breastfeed her child properly and fear of becoming unattractive. It is interesting to note that rural women had seemingly "medical" fears like fear of cesarean section, anesthesia, and episiotomy, which may be attributed to the rising education levels among rural women[14] as well as improved access to mass media. This finding is different from other studies done in Finland and Sweden, where women opted for cesarean section due to fear of labor pain. In a study conducted among women from Wangaratta & Örnsköldsvik, in Sweden found that women with a fear of childbirth prefer cesarean section and epidural anesthesia and had less positive feeling about being pregnant.[15] In a similar study conducted among 5,11,938 women in Finland found that fear of childbirth was the second strongest associated factor for major depression and women opted for cesarean section due to fear of labor pain.[16] In our study, we did not assess depression. It is evident in the present study that pregnant women have valid fears regarding childbirth, which need to be addressed. Considering the fact that routine antenatal care affords many opportunities for contact with pregnant women, fear of childbirth is something that healthcare professionals need to be aware of and should take steps to ensure that pregnant women receive adequate health education and counseling to allay these fears, in the view of better labor and perinatal outcomes. Partial medical knowledge about the procedures of labor might have increased the anxiety in pregnant women. Healthcare professionals should also consider these aspects during regular antenatal checkups.

Limitations

The pregnant women were not screened for any psychiatric illness or personality problems, the presence of which may have influenced the results. The tool used to screen for fear of birth was not a validated one. Reliability and validity of the questionnaire need to be checked in a larger population, and a cut-off score needs to be determined for fear of childbirth, which further research may be able to answer. But the strength of our study is the inclusion of the varieties of fears regarding childbirth which has not been earlier identified by other screening tools.

CONCLUSION

Overall, 45.4% of pregnant women in this study had a fear of childbirth. There was a significant association of fear of childbirth with lower gravida score, lower parity, lower number of living children, and a history of previous stillbirth. The most common fears regarding childbirth were: not feeling confident about childbirth, being afraid or tense, and fear of labor pains, cesarean section or episiotomy. Health care workers and professionals should be aware of the possible fears of childbirth that pregnant women may have, in order to identify and address these fears in the antenatal period. More research is required to explore the factors important to reduce the fear of childbirth.

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Conflicts of interest
There are no conflicts of interest.

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ONLINE APPENDIX

Fear of childbirth questionnaire

1. Sociodemographic details

1.1	Name	
1.2	How old are you now?	(Age in completed years)
1.3	Marital status	Married - 1 Separated/Divorced - 2 Widowed - 3 Unmarried - 4
1.4	Religion	Hindu - 1 Muslim - 2 Christian - 3 Others - 4 Pls specify
1.5	Phone number	
1.6	Education	Total no. of years of education (do not count pre-school)
1.7	BPL card holder	0….No 1….Yes
1.8	Occupation	1. Salaried 2. Self employed 3. Daily wage earner 4. Agriculturist 5.House wife
1.9	Total family members	
1.10	Total family income	In Rs/month
1.11	Type of family	Nuclear - 1 Joint/Three generation/Extended - 2
1.12	Age of husband	In completed years
1.13	Education of husband	Total no. of years of education (do not count pre-school)
1.14	Occupation of Husband	1. Salaried 2. Self-employed 3. Daily wage earner 4. Agriculturist 5. Unemployed

2. Obstetric details

2.1	Age at marriage (In completed years)	
2.2	Current Gestational age	
2.3	Obstetric Score: Gravida	
2.4	Para (no. of previous births)	
2.5	Abortions	
2.6	No. of living children	
2.7	No. of children who died	
2.8	No. of still births	
2.9	Was your present pregnancy planned?	1=yes, 2=No
2.10	Did you see anyone for antenatal care during present pregnancy?	Yes. 1 No. 0 (SKIP TO Q 3.1)
2.11	How many times in total did you receive antenatal care during your pregnancy?	No. of times. Don't know….99
2.12	How many weeks pregnant were you when you first received antenatal care for this pregnancy?	Less than 12 weeks…….1 More than 12 weeks…….2 Don't know. 99
2.13	Whom did you regularly see for a checkup for this pregnancy	Doctor. 1 Nurse. 2 Other (specify) ____
2.14	Where did you mostly go for antenatal checkups ?	Govt health facility ….1 Private health facility….2

3. Fear before childbirth

		Agree	Neutral	Disagree
3.1	I fear that I will go into labor much before my due date			
3.2	I fear that I will not have labor pains even after I cross my due date.			
3.3	I fear no one will be there to take me to hospital at the onset of labor			
3.4	I fear I may give birth at home or on the way to the hospital			
3.5	I fear that no doctor or nurse will attend to me when I reach the hospital			
3.6	I fear that my labor may be too long			
3.7	I fear labor pains			
3.8	I fear that I will feel lonely/helpless during labor			
3.9	I fear I may lose control over my bowel and bladder during labor			
3.10	I fear that I may have increased blood pressure during labor			
3.11	I fear that my family may be tensed and worried once my labor starts			

4. Fear during childbirth

		Agree	Neutral	Disagree
4.1	I feel afraid/tense thinking about child birth			
4.2	I feel happy/confident thinking about childbirth			
4.3	I fear that I may have some complications during childbirth			
4.4	I fear I may bleed excessively during childbirth			
4.5	I fear that I may die as a result of childbirth			
4.6	I am afraid of episiotomy			
4.7	I am afraid that I may have a caesarean section			
4.8	I am afraid of anesthesia during caesarean section			
4.9	I fear that my baby may have some complications during childbirth			
4.10	I fear I will give birth to abnormal child			
4.11	I fear that my baby may die during childbirth			
4.12	I fear that I may deliver a baby of an unwanted gender			
4.13	I fear I may not have enough money for the delivery			

5. Fear after childbirth

		Agree	Neutral	Disagree
5.1	I fear no one will be there to take care of me and my child during postpartum period			
5.2	I fear I will not be able to take care of my child by myself during postpartum period			
5.3	I fear I may not be able to breastfeed my child properly			
5.4	I fear of having pain during sex after child birth			
5.5	I fear I will lose my job, have to quit my job or stop working after the birth			
5.6	I fear I may become unattractive/fat after childbirth			

Original Article

Knowledge, Attitude, and Practice Regarding Contraception among Women with Schizophrenia: An Observational Study from South India

Bhuvaneshwari Sethuraman, Arun Rachana[1], Suja Kurian[1]

ABSTRACT

Background: Women with schizophrenia have needs beyond their mental health needs, such as those arising out of their gender, sexual, and reproductive functions. Very little is known about the knowledge, attitude, and practice regarding contraception among women with schizophrenia from India. **Materials and Methods:** Study among women with schizophrenia (in reproductive age group, having at least one living child, and currently staying with husband) from south India explored their knowledge, attitude, and practice of contraception. Adhering to observational design and ethical principles, data were collected using a semi-structured questionnaire. Modified National Family Health Survey-3 questionnaire and Positive and Negative Symptom Scale of Schizophrenia were also used. **Results:** Ninety-six women with schizophrenia participated. The mean age was 33.5 years [standard deviation (SD): 6.8 years], and the mean age of onset of schizophrenia was 29.2 years (SD: 6.2 years). Although nearly 90% had knowledge on at least one method of contraception, the mean total number of methods known was mere two. Out of 65 women who were practising contraception, 86.2% adopted female sterilization. The common reasons for not using contraception were wish for another child/son, lack of awareness, and fear of side effects. Unmet need for family planning was 14%. Informed choice of contraception was below 3%. There was statistically significant association between those who were currently using contraception and variables such as age 31 years and above, undifferentiated subtype of schizophrenia, and greater severity of schizophrenia. **Conclusion:** Although the majority had some knowledge about contraception, decision-making largely rested with others, and informed choice regarding contraception was poor. These could pose an obstetric risk on women with schizophrenia. Sociocultural and illness-related factors influencing contraception need to be explored.

Key words: *Contraception, family planning, reproductive health, schizophrenia, women*

Key messages: *Women with schizophrenia have low awareness about contraceptive methods, poor informed choices, and decision-making on contraception. There exists a need to empower women with schizophrenia on family planning. We put forward an argument to strengthen reproductive health education in the mental health setting.*

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Schizophrenia, with its variable prognosis, affects multiple domains of an individual's life. Women with schizophrenia have a better prognosis than men, which is partly attributed to a later age of onset, differences in gender-related roles, and lesser level of expectations on functioning from the family and society.[1-3] Women with schizophrenia are also found to have longer sexual relationships, higher rates of marriage, and more number of children than their male counterparts.[3,4] Women with schizophrenia thus experience needs beyond their mental healthcare, and it includes their reproductive health needs. The specific and unique sexual and reproductive needs of women with schizophrenia include those pertaining to a sexual relationship, marriage, pregnancy, delivery, breastfeeding, child rearing, birth control measures, and menstrual difficulties.[5,6] Exposure to psychotropic drugs, exacerbation of schizophrenia, and limited treatment options for schizophrenia in pregnancy and postpartum period complicate the obstetric care and illness outcome of women with schizophrenia.[7,8]

Gender-related roles pose specific challenges for married women. Increased rates of coerced and unprotected sex, unwanted and unplanned pregnancies, induced abortions, and difficulties in utilising antenatal health services are some of them.[6,9] Diagnosis of schizophrenia along with gender-related disadvantages cause significant emotional burden to women with schizophrenia. For example, compared with women without mental illness attending an outpatient department, a higher number of induced abortions and coercion of unwanted sexual contact were reported in women with schizophrenia or mood disorder.[10] These in turn increase the obstetric and perinatal complications among women with schizophrenia.[11] Deficits in parenting and child rearing skills may lead to children born to mothers with mental illness being reared by others.[6,12]

The disparity between fertility preferences of a woman and her fertility behavior is referred to as the unmet need for family planning and also as knowledge, attitude, and practice (KAP) gap. Unmet need for family planning is extensively studied nationally and internationally in community-living women.[13-17] Women, in general, have limited autonomy over their reproductive choices.[18,19] The National Family Health Survey (NFHS) done in 2015 in urban and rural areas of India revealed contraceptive practice in 53.5% of women belonging to the reproductive (15–49 years) age group.[14] The most common method adopted (36%) was female sterilization.[14] Unmet need for family planning and spacing of pregnancies were 10% and 5%, respectively, in the state of Tamil Nadu (NFHS-4), where this study was carried out.[15] Unmet need for family planning has been studied internationally in women with schizophrenia.[6,9] Women with schizophrenia perceive difficulty in planning and obtaining family planning methods and have poor knowledge about contraception.[9] Compared with women without schizophrenia, their capacity for decision-making regarding pregnancy and birth control is diminished.[6,9]

There is lack of Indian research on family planning among women with schizophrenia. To address this paucity of data from India, we studied the KAP of contraception among women with schizophrenia.

MATERIALS AND METHODS

Setting and participants

The study was carried out in the psychiatric department of a medical college in South India. The department is a tertiary care facility catering to the local population as well as those from other states of India. The department provides comprehensive psychiatric care on both outpatient and inpatient bases.

Participants were recruited from the outpatient clinic of the Department of Psychiatry. Tamil-speaking married women of age 18–45 years, with International Classification of Diseases-10 diagnosis of schizophrenia, and accompanied by a caregiver were screened for inclusion in the study. Women with at least one living child and currently living with husband were eligible to participate in the study. Postmenopausal women and women with a history of exacerbation of their illness or inpatient treatment during the preceding 3 months were excluded. Women with intellectual disability or sensory or cognitive impairment were also excluded.

Design and statistical analysis

To assess the objectives, (a) knowledge on contraception, (b) attitude toward contraception, and (c) practice of family planning measures among women with schizophrenia, we adopted an observational study design. The study proposal was approved by the Institutional Review Board of the Medical College (IRB no. 8486 dated 9/10/2013). The study was carried out from October 2013 to May 2015. Based on inclusion and exclusion criteria, consecutive eligible participants were recruited through purposive sampling. The questionnaire was administered among those who provided written informed consent. The first author collected the data using a semi-structured interview schedule.

Descriptive statistics were used to represent sociodemographic factors, illness-related factors, pregnancy, and family details. Variables on KAP were represented as mean (M) with its standard

deviation (SD) and/or frequency (*N* or *n*) with its percentage (%). Bivariate analysis was done using a comparison of means and Chi-square test; the findings were interpreted at a level of significance $P < 0.05$. For statistical analysis, SPSS software version 16.0 (SPSS Inc., Chicago, IL, USA) was used.

Assessment tools

Data on knowledge, attitude, and contraceptive practices were collected using a modified version of a questionnaire used in the NFHS-3.[13] To be relevant to the setting, certain questions were modified, such as providing more choices and deleting check questions. The questionnaire on contraception assesses (i) knowledge and its source, (ii) practice of contraception – current use, first use, and past use; complications, including pregnancy, on contraception; and any termination of pregnancy, and (iii) attitude toward using contraceptive methods – reasons for not using or using and reasons for delaying pregnancy. The severity of schizophrenia was rated using the Positive and Negative Syndrome Scale for schizophrenia (PANSS).[20]

RESULTS

Potential participants (124 married women with schizophrenia visiting outpatient clinic) were identified, of which 24 women met exclusion criteria. Of the rest 100 consecutive participants meeting the study criteria, 96 women provided consent. The mean age of participants was 33.5 years (SD: 6.8 years). The mean age of onset of schizophrenia was 29.2 years (SD: 6.2 years). The mean duration of schizophrenia was 4.5 years (SD: 3.9 years). The mean total PANSS score reflecting the severity of the condition was 38.7 (SD: 7.4). Table 1 provides further details on the participants' sociodemographic and clinical profiles.

Table 1: Sociodemographic profile and clinical profile of study participants

Sociodemographic variable	*n* (%)
Age (years)	
Upto 30	34 (35.4%)
31 and above	62 (64.6%)
Educational status	
Illiterate	7 (7.2%)
School education	71 (73.9%)
Graduation	18 (18.7%)
Place of residence	
Rural	66 (68.8%)
Urban	30 (31.2%)
Socioeconomic status	
Lower	61 (63.5%)
Middle	35 (36.5%)
Upper	1 (1.0%)
Religion	
Hindu	87 (90.6%)
Muslim	6 (6.3%)
Christian	3 (3.1%)
Employment status	
Unemployed	90 (93.8%)
Employed	6 (6.2%)
Clinical variable	***n* (%)**
Schizophrenia subtype	
Paranoid schizophrenia	64 (66.7%)
Undifferentiated schizophrenia	32 (33.3%)
Duration of contact with mental health services	
<5 years	77 (80.2%)
5-10 years	13 (13.5%)
More than 10 years	6 (6.2%)
Mode of treatment	
Only outpatient treatment	80 (83.3%)
Inpatient treatment at least once	26 (16.7%)
Self-reported treatment compliance	
Poor	18 (18.8%)
Misses occasionally	30 (31.2%)
Good	48 (50.0%)

Obstetric profile

The participants were married for a mean of 13.8 years (SD: 7.7 years). Eighty-one participants (84.4%) expressed a desire to have two or more children, wherein 70 participants (72.9%) had two or more children. Thirty-one participants (32.3%) had the last childbirth within the last 5 years, 27 participants (28.1%) between the last 5–10 years, and 38 participants (39.6%) more than 10 years ago. Seventeen participants (17.1%) reported that they had their delivery at home.

One out of every five participants ($n = 19$, 19.8%) had undergone medical termination of pregnancy in the past. Unplanned pregnancy was the leading cause for medical termination of pregnancy ($n = 11$), followed by medical reasons ($n = 3$) and reasons such as fear of having a female child, completed family, family wish, and financial reason ($n = 1$ each). In one patient, it was not possible to elicit any specific reasons.

Knowledge about contraception

Knowledge of any method of contraception was reported by 88.5% of the participants. About a tenth ($n = 10$, 10.4%) did not know of any method. Half of the participants ($n = 49$, 51%) had knowledge about more than one contraceptive method. Female sterilization, intrauterine devices, condoms, and oral contraceptive pills were the most commonly known contraceptive methods. The median number of contraceptive methods known per participant was two, ranging from zero to five. The knowledge of individual contraceptive methods among women in this study group is shown in Table 2.

Attitude toward the contraceptive practice

A majority of women (n = 65, 67.7%) in the study group were using a contraceptive method at the time of the study. Only three participants (4.6%) cited the presence of schizophrenia as the reason for adopting a contraceptive method. About one-third (n = 31; 32.3%) were not using any contraceptive methods at the time of the study. Many of the subjects had more than one reason for not using contraception. The reasons cited by participants for using and not using contraception are given in Table 3.

Nearly 15% of the participants (n = 14, 14.6%) were found to have unmet contraceptive needs, that is, KAP gap or wanting to avoid pregnancy but not using any contraceptive method. Among these subjects who had unmet contraceptive needs, many had reported multiple reasons for not using contraception. The commonly cited reasons were lack of awareness (8 of 14), not receiving any information (7 of 14), fear of side effects (5 of 14), and social reasons/opposition from the family (3 of 14). A majority of the participants (n = 57; 59.4%) felt it to be necessary to discuss with the treating doctor about contraception.

Among those who were current users, only 3.1% were ever told about other methods of contraception. Only 1.5% of current users were told about the side effects of the current contraceptive method being used. None of the current users were told what to do if there are side effects to current methods of contraception.

Out of the 73 women who were the first time users of contraception, 38 (52.1%) had undergone permanent sterilization, whereas the remaining 35 (47.9%) used temporary methods. Among these, 22 (62.9%) had discontinued their use of the temporary method. Reasons for discontinuing contraception were wanting another child (10 of 22, 45.5%), side effects (9 of 22, 40.9%), and other reasons (3 of 22; 13.6%). A majority of the group (49 of 73; 67.1%) had started using contraception for the first time when they had at least two children. In majority of instances, decision-making regarding the use of contraception for the first time was made by others. Decision-makers regarding the use of contraception for the first time are depicted in Figure 1.

Table 2: Knowledge of contraception among study participants, *n*=96

Contraception methods	Know (%)*
Female sterilization	72 (75.0%)
Male sterilization	2 (2.1%)
Oral contraceptive pill	26 (27.1%)
Intrauterine device/loop	40 (41.7%)
Injectable	5 (5.2%)
Implant	0 (0.0%)
Condom	29 (30.2%)
Female condom	1 (1.0%)
Diaphragm	0 (0.0%)
Rhythm method	6 (6.25%)
Withdrawal method	1 (1.0%)

*The total percentage is more than 100 because some participants have knowledge about more than one method

Table 3: Attitude toward contraception among study participants

Reason for current contraception use (n=65)	n (%)*
Small family norm	38 (58.5%)
Completed family	26 (40%)
Economic reasons	9 (13.8%)
Spacing	3 (4.6%)
Exacerbation of illness during pregnancy and postpartum	3 (4.6%)
Social reasons	3 (4.6%)
Motivation to use contraception	1 (1.5%)
Reason for not adopting contraception currently, n=31	**n (%)***
Lack of adequate awareness	11 (35.5%)
Fear of side effects	8 (25.8%)
Wants to have a male child/another child	14 (45.2%)
Did not receive information about family planning in mental health services	10 (32.3%)
Social reasons	3 (9.6%)
Not expecting to have sex	3 (9.6%)
Difficulty in planning ahead about contraception	1 (3.2%)
Difficulty in accessing family planning services	1 (3.2%)
Felt her view was not considered important by her family	1 (3.2%)
Inconvenient to use	1 (3.2%)

*The total percentage is more than 100 because some participants might be citing more than one reason

Contraceptive practice

Women were classified into three mutually exclusive categories with respect to their contraceptive use: those practicing contraception currently – "current users;" those who have used at any time – "ever users;" and those who never practiced contraception – "never users." Less than a quarter of the study group (n = 22, 22.9%) had never used contraception at any point of time.

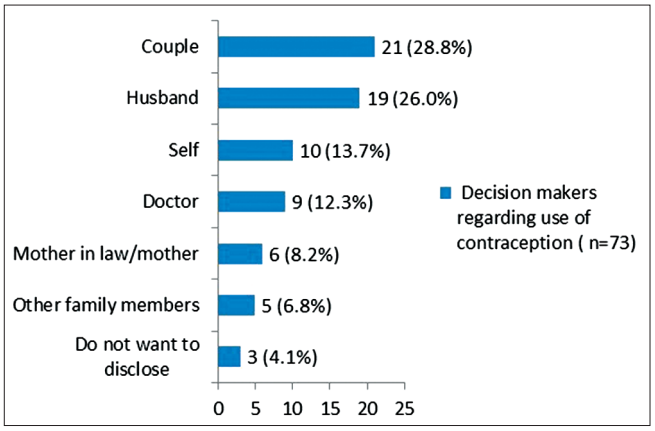

Figure 1: Decision-maker during first use of contraception among study participants, n = 73. *X*-axis: frequency of responses with percentage; *Y*-axis: decision-maker of contraception

Contraceptive use at some point of time (ever use)

Out of 96 women, 74 (77.1%) had used contraception at some point in time. A majority of them (n = 56, 58.3%) underwent sterilization. An intrauterine device was used by 15.6% (n = 15). Among the spouses of the women, 10.4% (n = 10) used condoms, and 3.1% (n = 3) underwent sterilization. Among ever users, rhythm method was practised by 3.1% (n = 3) of the couples and withdrawal method by another 3.1% (n = 3). None of them used female condoms, depot injections, or emergency contraception.

Current use of contraception

A majority of the women (n = 65, 67.7%) were using a contraceptive method at the time of the study. Duration of the practice of any contraceptive method was about 10 years (mean: 9.9 years, SD: 6.6 years). Prevalence of contraception was 26.9% among those with one child, 79.2% among those with two children, 93.3% among those with three children, and 100% among those with four or more children. Out of 65 women who were practicing contraception, the majority (n = 56, 86.2%) had adopted female sterilization. Intrauterine contraceptive device, male sterilisation, use of a male condom, rhythm method, and withdrawal were adopted by only a few (9 of 65; 13.8%) couples. No one was using methods such as oral contraceptive pills, injectable, implants, female condom, or diaphragm.

Association of the current use of contraception with sociodemographic and clinical variables

The mean difference in PANSS total score was statistically significant (P = 0.019) between those who adopted contraception (PANSS score 39.9) and those who did not (PANSS score 36.2). The results of bivariate analysis using Chi-square test are provided in Table 4.

DISCUSSION

The study identified low knowledge of contraception among the participants when compared with the state statistics. Knowledge on at least one contraceptive method was 88.5% in our study sample, whereas it was 99.4% in Tamil Nadu (NFHS-4).[15] Also, the mean number of contraceptive methods known to our study participants was only two when the mean number of contraceptive methods known to married women in Tamil Nadu was eight (NFHS-4).[15] This low knowledge in our sample was despite our participants being educated, having at least one child, and having higher contraception prevalence rate than the state average. In our sample, although a majority reported that they knew at least one contraceptive method, 11.5% of participants still reported lack of adequate awareness to decide upon contraception. It further revealed the lacunae in the transition from mere knowledge to

Table 4: Association of sociodemographic and clinical variables with the current use of contraception using Chi-square test

	Not using contraception	Using contraception	Chi-square value	*P*
Sociodemographic				
Age (years)				
Upto 30	17 (54.8%)	17 (26.2%)	7.551	0.006*
31 and above	14 (45.2%)	48 (73.8%)		
Place of residence				
Urban	10 (32.3%)	20 (30.8%)	0.022	0.883
Rural	21 (67.7%)	45 (69.2%)		
Education				
Less than high school	8 (25.8%)	15 (23.1%)	0.086	0.770
High school and above	23 (74.2%)	50 (76.8%)		
Socioeconomic status				
Lower	19 (61.3%)	42 (64.6%)	0.100	0.752
Middle and upper	12 (38.7%)	23 (35.4%)		
Clinical				
Type of schizophrenia				
Paranoid	26 (83.9%)	38 (58.5%)	6.098	0.014*
Undifferentiated	5 (16.1%)	27 (41.5%)		
Duration of schizophrenia				
<5 years	22 (71.0%)	41 (63.1%)	0.579	0.447
5 years and more	9 (29.0%)	24 (36.9%)		
Duration of contact with mental health services				
<5 years	25 (80.6%)	52 (80.0%)	0.006	0.941
5 years and more	6 (19.4%)	13 (20.0%)		
Mode of treatment				
Only outpatient	28 (90.3%)	52 (80.0%)	1.610	0.204
At least once inpatient	3 (9.7%)	13 (20.0%)		

*$P<0.05$

adequate awareness and the adoption of contraception among the participants.

Preconception counselling among those with psychosis aids in allaying women's anxieties and thereby preventing disease relapse, in enhancing women's emotional support, in timing pregnancy (i.e., not during a relapse period), in averting unplanned pregnancies and their consequences, in drug rationalization that are safe in pregnancy, in close monitoring of symptoms, in adopting appropriate contraception measures that would not impact the illness, and so on. Education and preconception counselling, which are possible in a mental health setting, will enable the patient to assess the risk–benefit ratio of conceiving a child in the future.[6,9,21] Recognizing these benefits, many existing guidelines have identified imparting knowledge regarding contraception and planning for the family as part of the clinical care.[9,21] However, there is an absence of adequate prepregnancy counselling in Indian psychiatric facilities.[7] Our findings endorse the idea that mental health facilities should give priority in discussing birth control measures, especially when more than half of the study participants expressed their willingness to discuss contraception with their treating psychiatrist. Furthermore, the impact of such an initiative in improving patients' knowledge can also be evaluated.

Our study revealed that attitude toward contraception among women with schizophrenia in our sample could be mediated by sociocultural factors. Nearly half of those who were not currently using contraceptives cited a desire to have a male child/another child as the reason for not adopting contraception. Family health surveys in India had long before identified the preference for sons in certain Indian states, which include Tamil Nadu. Citing the wish to have a male child or another child as a reason for not using contraception is a culturally sanctioned practice in India.[19,22] However, this reason of wanting to have a male child provided by our sample was different from the reasons for not using contraception in women with schizophrenia from the western world.[9,10,23] More than half of the women in this group were also noted to have discontinued their use of contraceptive practices after the initial use. This should be noted along with the high rates of medical termination of pregnancy in the study population being attributed to unwanted pregnancy. It had to be emphasized that unplanned pregnancy and its consequences carry significant risk in these vulnerable women.[6,11,24]

Only a little above one-third of women reported that they had a role in decision-making about contraception while they adopted contraception for the first time. Decision-making about the use of contraception in Indian women has been recorded to arise from within the family, especially in a joint household.[25] Less than half of the study population also noted that the decision about the first time contraceptive use was taken by the family members. In the extremes of Indian scenario, there were objections to contraceptive use from within the family.[26,27] This is in contrast with the person-centric approach of the West, where the role of the family in reproductive decision making is minimal. Markers of informed choice of family planning – users ever told about other methods, users told about side effects of current method, and users told what to do if there are side effects of the current method – were alarmingly low in our participants. This hard reality existed when NFHS-4 reported informed choice to be three-fouth among Tamil Nadu women.[15] The poor informed choices about methods of contraception and side effects cannot thus be completely attributed to cultural norms such as family-centric decision-making.[25] How does the presence of schizophrenia influence the informed choice of contraception is worth exploring. Our findings on decision-making and informed choices endorse the broader concept of women's mental health in India, wherein biological factors interplay with sociocultural factors.[28,29]

Fourteen percent of the sample reported unmet contraceptive need, whereas unmet contraceptive need in Tamil Nadu as per NFHS-4 was 10%.[15] The common reasons cited by our participants were lack of awareness, lack of information, and fear of side effects. These reasons were similar to those quoted by community-living women in India.[30] One of the consequences of unmet contraceptive need is unplanned pregnancy, which then leads to medical termination of pregnancy. Numbers of unmet contraceptive need, medical termination of pregnancy, and unplanned pregnancy reported in our sample agree with this argument. Sociodemographic factors such as education and socioeconomic status were found to influence decision-making on medical termination of pregnancy among Indian women with psychiatric illness,[31] thereby endorsing the role of social factors. A mental health professional can play a role in surrogate/assisted decision-making with beneficence and non-maleficence regarding the termination of pregnancy in women with major mental illness when the patient's threshold of autonomy and cognitive, evaluative, appreciative understanding of the problem is in question.[32]

The practice of contraception, evident by contraception prevalence rate, in our sample was 67.7%. This was higher than the NFHS-4 Tamil Nadu data for married with at least one child, which was 58.4%.[15] This difference becomes more relevant when we understand

that we expect higher rate in NFHS-4 sample than our study sample because NFHS-4 data are from women of a wider age group. Adoption of female sterilization among women (with at least one child) among our participants was comparable to NFHS-4 Tamil Nadu rate, 58.3% and 54.23%, respectively.[15] The trend of higher prevalence of female sterilization with an increasing number of children in this study is similar to the pattern seen in the community. Findings from our hospital-based sample thus matched findings from the community samples. However, sterilization as the major contraceptive practice in our sample was different from the practice reported from the West.[33] Again, sociocultural factors, especially gender-specific roles and family-driven choices in decision-making, might have influenced the practice of contraception among women with schizophrenia.[25] Factors influencing the majority of women with schizophrenia to choose permanent methods over modern reversible methods are yet to be studied in India. Since multiple factors, both personal and social, influence the practice of contraception among women,[34,35] whether such factors would have influenced the specific pattern of contraception practices in our sample need to be studied.

The association between age and contraception was expected: the higher the age, the greater the chance of adopting contraception. Other sociodemographic variables did not have an association with contraception use. The study did not reveal any association between clinical variables studied, except for the severity of schizophrenia and subtype of schizophrenia. These findings need further exploration.

The strengths of the study are we attempted to address a neglected side of healthcare, namely, reproductive health of women with schizophrenia. To our knowledge, this is the first study from India exploring KAP of contraception among women with schizophrenia. The study adopted a nationally valid tool (NFHS) for assessing the primary objective.

The limitations of our study are as follows: comparisons could not be done in view of the absence of controls, results cannot be generalized to community setting in view of hospital-based sampling, and results are not generated for subpopulations due to limited sample size. Further research covering limitations of our study are required to look at various factors influencing contraceptive behavior in women with schizophrenia.

CONCLUSION

Overall, our study brought out the following regarding contraception among women with schizophrenia: deficiencies in their knowledge, limitations in their awareness, possible sociocultural influences on their attitude toward contraception, and a low informed choice in spite of high contraceptive prevalence. Hence, we put forward an argument to strengthen reproductive health education in the mental health setting and study its impact on KAP. Our study results pave way for exploring the notion of sociocultural factors influencing contraceptive practice in women with schizophrenia and schizophrenia further complicating this practice. Such a notion, if proven, emphasizes that contraception is quite complex for Indian women when they suffer from schizophrenia.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Gender Variability of Perceived Stress and Negative Inferential Feedback in Depression

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ABSTRACT

Background: The role of negative inferential feedback and perceived stress in hopelessness depression is known. However, studies on their gender variability are lacking. The difference in various domains of negative inferential feedback and its impact on cognitive hopelessness, depression, and outcome of psychotherapy between men and women has been hypothesized. **Aims:** This study analyzed the difference in stress levels and hopelessness in the form of negative inferential feedback in depressed men and women. **Methodology:** In all, 35 men and 35 women suffering from depression were recruited. They were first assessed on the Hamilton's Depression Rating Scale, and their sociodemographical details were recorded. They were then administered the Perceived Stress Scale (PSS) and the Adaptive Inferential Feedback Questionnaire. **Results:** Perceived stress in depressed women showed a positive correlation with negative inferential feedback ($r = 0.39$, $P = 0.04$). Levels of depression were comparable in the two genders. Comparison between the two genders showed no difference in proportion across the levels of severity of depression ($\chi^2 = 5.44$, $P = 0.14$). Depressed women rated higher stress, mainly in the helplessness domain of the PSS ($P = 0.04$). Women were shown to have more negative inferential feedback and attribute their hopelessness to more stable and global causes when compared with men ($P = 0.04$). **Conclusion:** Depressed women perceive more stress and receive more negative feedback, than men, to negative life events. Women attribute their hopelessness to more stable and global causes when compared with men.

Key words: *Depression, hopelessness, inferential feedback, perceived stress*

Key messages: *Depressed women perceive more stress than depressed men. Depressed women also receive more negative inferential feedback from their social support as compared to depressed men, which leads them to attribute the cause of the stress to stable and global causes. These findings can help in planning better management strategies for depression, which could be gender specific.*

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Depression is a common and debilitating illness affecting many people.[1] While various theories of depression have been proposed, the one that has gained popularity in recent times is the expanded hopelessness theory. It is a stress-diathesis model which implicates a style or tendency to infer negative characteristics about the self, negative consequences for the future, and stable, global causes for negative events.[2] It implies that a negative life event (stress) and the inferential feedback received from friends and family based on the inferential style of the patient about the event (diathesis) lead to hopelessness and depression.[3,4] Inferential feedback can occur on a continuum ranging from adaptive to maladaptive.[3,4] Individuals with depressogenic inferential styles are likely to show increase in depressive symptoms following the occurrence of negative events. These depressogenic inferential styles have been described to be typically latent cognitive processes that are difficult to assess accurately.[5]

The expanded hopelessness theory explains four domains on which the inferential feedback is sought: *Globality of cause* – the negative event is likely to lead to other problems in a person's life; *Stability of cause* – the negative event is frequently going to lead to other problems in a person's life; *Consequences for the future* – the negative event is going to lead to a lot of other problems in the future, and *Implications for the self* – the person is responsible for the negative life event.[3] Depressive symptoms are more likely to occur when negative life events are attributed to stable (i.e., enduring) and global (i.e., likely to affect many outcomes) causes and viewed as important than when they are attributed to unstable, specific causes and are viewed as unimportant.[3] Thus, the four domains can be seen as constituents of the cognitions involved in hopelessness. Adaptive inferential feedback is a more precise concept of social support and can elucidate the protective or deleterious effects of adequate and inadequate social support, respectively.

Studies have documented differences between women and men with respect to symptom reporting, treatment seeking, coping style, and several neurobiological variables pertinent to depression.[6-9] Vulnerability to develop depression secondary to stress is different in the two genders. Women have been shown across many nations, cultures, and ethnicities, to be twice as likely as men to develop depression and experience stress.[10] Stress and depression have been shown to have a bidirectional relationship between cause and effect.[11] Several dimensions of stress, such as helplessness, distress, and coping, are relevant in understanding the pathophysiology of depression. Women have a lifetime prevalence for major depressive disorder of 21.3%, compared with 12.7% in men.[10-12] It has been hypothesized that the gender differences in depression could be possibly due to differences in vulnerability, negative inferential styles, and perceived stress. However, the evidence for this has been inconclusive.

The effect of gender norms on the quality of the psychotherapy experience remains poorly understood, despite considerable interest reflected in the clinical and research literature.[13] Much of the focus has been directed at examining whether patient gender or therapist gender has an important impact on the outcome of therapy.[13] Understanding the gender differences in the etiological mechanisms of hopelessness depression (a subtype of depression defined under the expanded hopelessness theory, chiefly characterized by retarded initiation of voluntary responses and sad affect) can help in understanding the effect gender may pose for psychotherapeutic outcome, as it shows the exact mechanisms involved in cognitive therapy for depression based on the negative inferential styles of the patient and can predict the feedback and outcome of depressive symptoms, chiefly hopelessness.[14] Previous researchers have shown women to have poorer outcomes in psychotherapy when compared with their male counterparts, whereas others have shown that men have a poorer outcome.[15,16] Cuijpers *et al*., on the other hand, have found gender to have no predictive role in response to psychotherapy.[17] Joshi claims that given the patriarchal nature of Indian society, there is a strong need for integrating gender discourse within existing counseling services in India.[18]

Thus, the following study was devised to understand the gender differences in perceived stress of a negative life event and the negative inferential feedback in patients with depression. The authors also correlated the levels of perceived stress and negative inferential feedback with depression in men and women.

METHODOLOGY

Procedure

This is a cross-sectional observational study. It was conducted in the psychiatry department of a tertiary care hospital. Ethical clearance was obtained from the Institutional Ethics Committee. A convenient method of sampling was used, and consecutive patients who were willing to participate in the study were included. Thirty-five male and 35 female age-matched consecutive patients, between the ages of 18 and 45 years, suffering from major depressive disorder as diagnosed by the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria, were recruited from the outpatient department. Patients suffering from other comorbid psychiatric or medical

illnesses were excluded. Age matching between male and female patients was done using the individual matching method. Patients were explained about the nature of the study, and written informed consent was obtained from them. After gathering their sociodemographic data, they were initially administered the Hamilton's Depression Rating Scale (HDRS) for severity of depression. They were subsequently administered validated versions of Perceived Stress Scale (PSS) and Adaptive Inferential Feedback Questionnaire (AIFQ), in their vernacular languages. Assessment of face validity of the scales was done for the population being studied. The scales were translated into Hindi and Marathi and later back-translated into English, and validation was carried out by a group of subject experts consisting of psychiatrists, psychologist, and psychiatric social worker, who found the validated versions of AIFQ and PSS appropriate for the population being studied.

Instruments

HDRS is designed to assess the severity of depression in patients already diagnosed with depressive disorder.[19] The total score is obtained by summing the score of each item, 0–4 or 0–2. For the 17-item version, scores can range from 0 to 54 with a rising severity of depression. Validity has been reported to range from 0.65 to 0.90 with global measures of depression severity.

AIFQ was developed as a measure of the inferential feedback a person receives following a stressful event.[3] The patients are asked to list a negative life event that was the most stressful for them in the last week. Then they are asked to list three significant individuals (social support) to whom they spoke about their stressor and how they felt after talking about it. The scale has a total of seven questions, where questions 4–7 address the feedback that they received and are rated on a 6-point Likert scale. A total inferential feedback score is calculated by summing the average scores of the type of feedback endorsed by each identified person on each domain of globality of cause (AIFQ1), stability of cause (AIFQ2), consequences for the future (AIFQ3), and self-implication (AIFQ4). Higher total scores indicate that the individual perceives receiving more negative inferential feedback, while lower total scores indicate the receipt of adaptive feedback.

PSS measures the degree to which situations in one's life are appraised as stressful. We used the 10-item version of PSS.[20] An exploratory factor analysis had revealed a two-factor structure measuring Perceived Distress or helplessness and Perceived Coping or self-efficacy.[20] Scores were analyzed on each subscale, and a total score was obtained. The test scores range from 0 to 40; the higher the PSS score, the more likely the individual will perceive that environmental demands exceed their ability to cope.

Statistical analysis

Statistical analysis was undertaken using SPSS version 20. Data were expressed as mean ± standard deviation. Correlation between stress, depression, and inferential styles was done using Pearson's correlation test. The difference in the proportion of depression and negative inferential feedback was done using Chi-square test of proportion. Gender differences were studied using unpaired *t*-test between males and females. A P value <0.05 after using Bonferroni's correction was considered as statistically significant.

RESULTS

Data from 35 men and 35 women who completed the structured proforma, HDRS, AIFQ, and PSS were considered for analysis. Table 1 shows the distribution of marital status, educational level, and socioeconomic status among males and females. There were no significant differences in the sociodemographic variables among the two genders. None reported a history of divorce/separation or death of the spouse.

Table 2 shows the comparison of scores on HDRS, PSS, and AIFQ among the two genders. Analysis of the severity of depression showed that men had a mean score of 15.31 ± 4.24 on HDRS, whereas women had a mean score of 16.63 ± 5.14. There was no statistically significant difference in the two groups as demonstrated by unpaired *t*-test ($P = 0.25$). Comparison of perceived stress between males and females by unpaired *t*-test showed that perceived stress was higher in females, and this difference was statistically significant ($P = 0.04$, $t = 2.06$). The difference was marked in the helplessness domain

Table 1: Distribution of marital status, educational level, and socioeconomic status among males and females

Sociodemographic variable	Depressed males (n=35)	Depressed females (n=35)	χ^2	P
Marital status	Married=30 (85.71%) Unmarried=5 (14.29%)	Married=32 (91.43%) Unmarried=3 (8.57%)	0.56	0.45
Education status (up to secondary level)	Yes=29 (82.86%) No=6 (17.14%)	Yes=28 (80%) No=7 (20%)	0.09	0.76
Socioeconomic status (as per modified Kuppuswamy's classification)	Upper middle class=15 (42. 85%) Lower middle class=20 (57.15%)	Upper middle class=13 (37.14%) Lower middle class=22 (62.86%)	0.23	0.63

Values expressed as n(%)

of perceived stress, and the self-efficacy domain did not show any statistically significant difference. A comparison of the AIFQ scores using the unpaired *t*-test showed that women had significantly more negative inferential feedback than men ($P = 0.04$) as per the total scale scores. The difference between the four domain scores varied. The domain of globality of cause had the most significant difference, being more in women ($P = 0.01$, $t = 2.61$). This was followed by stability of cause ($P = 0.02$, $t = 2.49$), which was also more in women than men. The other two domains did no vary significantly between the two groups.

Table 3 shows the proportion of grade of depression as classified by severity and the proportion of negative inferential feedback received among the two genders. Using Chi-square test, comparison between men and women showed no difference in proportion across the levels of severity of depression ($\chi^2 = 5.44$, $P = 0.14$). The proportion of depressed women receiving negative inferential feedback (0.40) was significantly greater than men (0.09) as analyzed by Chi-square test of proportion ($\chi^2 = 9.25$, $P = 0.002$).

Table 4 shows the correlation between depression, perceived stress, and negative inferential feedback among depressed men, while Table 5 shows the same correlation among women. Men only had a correlation between depression and perceived stress ($P = 0.03$), which was not significant after adjusting with Bonferroni's correction. However, women had a more significant correlation across all three scales. After using Bonferroni's correction, the correlation between PSS and AIFQ in depressed women was statistically significant ($P = 0.04$), indicating higher negative inferential feedback with increased perceived stress.

Table 2: Comparison of HDRS, PSS, and AIFQ scale scores among males and females

Variable being compared	Depressed males (*n*=35)	Depressed females (*n*=35)	Mean difference (95% CI)	*t*	*P*
Depression					
Severity of depression (HDRS score)	15.31±4.24	16.63±5.14	1.31 (−0.93-3.56)	1.17	0.25
Perceived stress					
Self-efficacy domain (PSS-S)	9.00±3.16	10.09±3.23	1.09 (−0.44-2.61)	1.42	0.16
Helplessness domain (PSS-H)	14.09±4.38	16.26±4.87	2.17 (0.04-4.38)	1.96	0.04*
Total perceived stress (PSS-T)	23.09±6.13	26.29±6.86	3.2 (0.10-6.30)	2.06	0.04*
Inferential feedback					
Globality of cause domain (AIFQ 1)	0.95±1.25	1.91±1.78	0.96 (0.23-1.69)	2.61	0.01*
Stability of cause domain (AIFQ 2)	1.01±1.32	1.93±1.72	0.91 (0.18-1.65)	2.49	0.02*
Consequences of future domain (AIFQ 3)	1.12±1.52	1.72±1.72	0.60 (−0.18-1.38)	1.54	0.13
Implications for the self-domain (AIFQ 4)	0.76±1.39	0.92±1.35	0.16 (−0.50-0.82)	0.49	0.63
Total maladaptive feedback (AIFQ-T)	3.84±4.8	6.59±5.94	2.75 (0.16-5.33)	2.12	0.04*

CI: Confidence interval; HDRS: Hamilton Depression Rating Scale; PSS-S: Perceived Stress Scale, self-efficacy domain; PSS-H: Perceived Stress Scale, helplessness domain; PSS-T: Perceived Stress Scale, total score; AIFQ: Adaptive Inferential Feedback Questionnaire; *Statistically significant

Table 3: Comparison of the proportion of grades of depression based on severity and proportion of negative inferential feedback received between males and females

Variable being compared	Proportion among males	Proportion among females	Difference (95% CI)	χ^2	*P*
Grade of depression					
Mild depression	0.31	0.37	0.06 (−15.64-26.89)		
Moderate depression	0.37	0.14	0.23 (−2.49-41.32)		
Severe	0.26	0.34	0.08 (−13.16-28.24)	5.44	0.14
Very severe	0.06	0.15	0.09 (−6.41-24.81)		
Negative inferential feedback received					
Negative inferential feedback	0.09	0.40	0.31 (0.11-0.48)	9.25	0.002*

CI: Confidence interval, *Statistically significant

Table 4: Correlation of HDRS, PSS, and AIFQ scores in depressed males

Variables being correlated	Coefficient of correlation (*r*) (95% CI)	*P*	Adjusted *P* (using Bonferroni's correction)
Severity of depression (HDRS) and perceived stress (PSS)	0.38 (0.05-0.63)	0.03*	0.08
Perceived stress (PSS) and Negative inferential feedback (AIFQ)	0.29 (−0.04-0.57)	0.09	0.25
Depression (HDRS) and Negative inferential feedback (AIFQ)	0.12 (−0.22-0.43)	0.49	1.00

*Statistically significant. HDRS: Hamilton Depression Rating Scale; PSS: Perceived Stress Scale; AIFQ: Adaptive Inferential Feedback Questionnaire; CI: Confidence interval

Table 5: Correlation of HDRS, PSS, and AIFQ scores in depressed females

Variables being correlated	Coefficient of correlation (*r*) (95% CI)	*P*	Adjusted *P* (using Bonferroni's correction)
Severity of depression (HDRS) and perceived stress (PSS)	0.35 (0.017-0.61)	0.04*	0.12
Perceived stress (PSS) and Negative inferential feedback (AIFQ)	0.39 (0.06-0.64)	0.02*	0.04*
Depression (HDRS) and Negative inferential feedback (AIFQ)	0.42 (0.09-0.66)	0.01*	0.06

*Statistically significant. HDRS: Hamilton Depression Rating Scale; PSS: Perceived Stress Scale; AIFQ: Adaptive Inferential Feedback Questionnaire

DISCUSSION

Depressed men and women differ in a number of important aspects that may alter the course of an affective disorder. Women, in general, tend to experience more stressful events in a lifetime than men.[21,22] Using the expanded hopelessness model, our study showed that stress generated in response to a negative life event is higher in women than men. Various mechanisms have been hypothesized to account for this difference. It could be the difference in their biology, primary social roles, or metacognitions. Other researchers have also shown a significant difference in distress scales among the two genders.[23,24] Even when women and men have similar psychopathology affecting them, women are more likely than men to perceive stress, possibly because of the differences in their biological responses to stressors, self-concepts, or coping styles.[10] On comparing the severity and grades of difference, it was found that both men and women had comparable scores on HDRS.

The expanded hopelessness theory hypothesizes that individuals with negative attributional styles are vulnerable to develop depression in the presence of negative life events.[2] The elaborated causal chain posits that negative events contribute to initial elevations of general negative affect. Cognitive vulnerability factors then moderate the likelihood that the initial negative affect will progress to full-blown depression. Increase in severity of depression can further lead to more negative life events and thus begin the causal chain again.[25] Our analysis reveals that depressed women use a more negative attribution style about a stressor than depressed men. Fourteen (40%) of the women received maladaptive feedback from their social support as opposed to only 3 (8.6%) of the men. Nolen-Hoeksema *et al*. had shown similar findings in adolescent women.[26]

Our study shows that depressed women tend to attribute the stressor to stable and global causes more than men, and this difference was significant. These attributional dimensions of stable-unstable and global-specific are crucial for understanding how negative life events may contribute to the formation of hopelessness.[27] In our study, women were shown to be using sentences like "the stressor is likely due to a cause that frequently causes problems" and also "the cause of the stressor will lead to problems in other areas of my life." Whereas depressed men used such statements less frequently. The implications of self and consequences of future domains did not show significant difference, indicating it does not vary differently in the two genders. The negative inferential feedback has been shown to depend on several factors including genetic susceptibility, social support, and personality factors, and further research should be undertaken to elucidate them.

This research also attempted to elucidate the correlation between the severity of depression, negative inferential feedback, and perceived stress. Our analysis found a significant correlation only between perceived stress and negative inferential feedback among depressed women. The other correlations were statistically insignificant. However, other researchers have demonstrated that a linear correlation exists between stress, negative inferential feedback, and severity of depression, which is in keeping with the model given by Abramson *et al*.[28-31] Thus, vulnerability of developing depression after exposure to a stressor is decided by the inferential feedback a person receives, which in turn modulates the level of perceived stress.

Relatively absent from the literature of psychotherapy is the issue of whether male and female patients respond similarly to different forms of psychotherapy or not. No research hitherto has described which forms of therapy may be most suitable for male or female patients. However, a number of writers have suggested that male and female patients may prefer or benefit more from different aspects of psychotherapy.[13] Ogrodniczuk *et al*. had suggested that women may need a greater focus on external problem-solving to counter a ruminative response style that amplifies vulnerability to depression, while men would benefit more with affective awareness.[13] The difference in cognitive vulnerability to hopelessness seen in women could account for a poorer outcome to psychotherapy.[15,16] Other researchers have similarly argued that female patients benefit more from an approach that considers external pressures.[32,33] This is in keeping with our finding of women having a more negative inferential attitude toward negative life events, which is stable and global. As our research also suggests them to have more helplessness and distress related to their perceived stress, they may refrain from

using more effective problem-solving coping strategies, as has been previously suggested.[34] This argument suggests that a supportive form of therapy may be more beneficial to female patients when compared with males. Male patients, on the contrary, do not possess such attributional styles and may benefit from affective awareness. Thus, they may prefer a form of treatment that provides them with a relationship that allows some emotional distance and sense of independence.[13]

Our study was not without limitations. Sample size was too small. Hence, we may not have been able to establish the correlation of depression, negative inferential feedback, and perceived stress to a robust extent. Moreover, after Bonferroni's correction, only one correlation remained significant. Only the face validity of the scales being used was carried out, and they were not validated for the population. Gender differences in negative inferential feedback were seen only in two domains, and even the self-efficacy domain of perceived stress did not show gender variability in this analysis, when compared with other data. A small sample size may account for this.

Our findings may necessitate a different psychotherapeutic approach in depressed women: one more focused on handling their attribution of cause of stressor. They should be directed to attribute it to unstable and more localized causes. This may reduce the severity of their depression, allay hopelessness, and facilitate an earlier and more robust response. Since hopelessness has been linked to higher suicide risk, this approach can help in reducing the risk of suicide in depressed women.

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Conflicts of interest
There are no conflicts of interest.

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Original Article

The Level and Sources of Stress in Mothers of Infants Admitted in Neonatal Intensive Care Unit

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ABSTRACT

Background: Hospitalization of a new-born child is stressful for parents. This study was done to determine the level and sources of stress in mothers of infants admitted in Neonatal Intensive Care Unit (NICU) and variance in stress by infant and maternal characteristics. **Materials and Methods:** Parental Stressor Scale for NICU was used as the primary outcome measure. Maternal socio-demography, maternal and infant characteristics such as gravidity, number of prenatal visits, perceived support from family members, perceived level of discomfort that the baby underwent, pregnancy and delivery complications, gestational age, sex, birth weight, length of NICU stay and ventilator support, and neonatal morbidity were also collected from maternal and infant hospital records. **Results:** Amongst these rural and poorly educated mothers, the appearance of the baby, sights and sounds of NICU environment were major sources of stress. Higher maternal stress was found to be associated with poor family support during pregnancy, mothers' perception of the baby's discomfort, lower birth weight of the baby, baby on ventilator, post-partum depression, and moderate to severe anxiety symptoms. Mothers who had higher levels of education and those with pregnancy complications were more stressed. **Conclusions:** Before designing remediation programs for parents, local demography and the predominant NICU stressors need to be kept in mind. Possibility of screening at-risk mothers by questioning them about perception of baby's discomfort needs to be evaluated further.

Key words: *Maternal stress, Neonatal Intensive Care Unit environment, parental role alteration, PSS-NICU*
Key messages: *Looks and behavior of the baby followed by parental role alternation were major sources of maternal stress. Higher stress was seen amongst mothers of Very Low Birth Weight infants and those needing ventilation. Lower education level may mitigate maternal stress.*

Hospitalization of a child in the Neonatal Intensive Care Unit (NICU) can be particularly stressful for the parents.[1] The effects may persist beyond the admission and influence later family functioning and parents' mental health.[2]

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Stress on the mother can be conceptualized using the 'Parental NICU stress model' which considers the following factors contributing to it:[3] (A) NICU environment stressors such as sights and sounds, babies' appearance and behavior, parental role alteration, and staff behaviors have a direct influence on the mothers' stress response. Parental role alternation means the impact of the admission on the parent-infant relationship, due to the nurses being the primary caregivers. (B) Factors influencing the parents' experience of the NICU environment are (1) situational factors (2) personal characteristics of the parent including depression and anxiety, and (3) personal resources.

Parental Stressor Scale: Neonatal Intensive Care Unit (PSS: NICU) has been widely used in the Western population to measure the parental stress response and environmental stressors due to the admission of the infant in NICU.[4] However, there are few studies in the Indian population.[1,5] A Ludhiana study (2011) conducted amongst 343 parents found baby appearance, followed by parental role alteration as the major sources of stress.[1] A Pondicherry study (2012) carried out amongst urban, homemaker, and educated group of mothers, reported parental role alteration followed by baby appearances as the major sources of stress.[5]

Sources of maternal stress may vary according to sociocultural population and the NICU environment; hence this study was done to determine the level and sources of stress in mothers of infants admitted in our NICU and variance in maternal stress by infant and maternal characteristics including depression and anxiety.

SUBJECTS AND METHODS

A cross-sectional survey was conducted in mothers of infants admitted for >48 hours in a level 3 NICU. Over a period of 1 year, mothers of all consecutive admissions to the NICU were approached for inclusion in the study. Mothers who were unable to visit their babies in the NICU or whose babies succumbed during treatment were excluded. A trained NICU nurse conducted interviews with the mothers. She approached the mothers for an interview between the 6th to 8th day of admission. Data was also collected from maternal and infant hospital records. Approval was taken from the Institutional Ethics Committee, HM Patel Center for Medical Care and Education, Karamsad, Anand, Gujarat before the study. The survey was administered in the NICU after taking written informed consent of the mother.

Data collected consisted of:

(1) Maternal socio-demographic and other characteristics like gravidity, number of prenatal visits, perceived support from family members, perceived level of the discomfort that the baby is going through, pregnancy, and delivery complications
(2) Infant characteristics such as gestational age, sex, birth weight, length of NICU stay and ventilator support, and neonatal morbidity. Neonatal Morbidity Scale (NMS)[6] was used to evaluate the objective severity of morbidity in infants. The score is based on 20 of the most common significant problems seen in sick children, scored as none, mild, moderate, and serious based on anchors provided in the scale. From the first day of admission in NICU till discharge from NICU, neonatal morbidity score was calculated once daily. Cumulative neonatal morbidity was calculated from the daily scores
(3) Parental Stressor Scale: Neonatal Intensive Care Unit (PSS: NICU)[4] was used to measure maternal stress. It is a 46-item instrument that measures mothers' perceptions of stress within the NICU. The scale consists of four subscales that measure stress related to (a) sights and sounds of the unit (5 items), (b) appearance and behaviors of the infant (19 items), (c) impact on the mothers' role and her relationship with her baby (10 items), and (d) mothers' relationship and communication with the staff (11 items). It also has a general stress-level question that summarizes the mothers' overall feeling of stress related to having an infant in the NICU. The responses to the PSS: NICU are scored on a 5-point Likert scale from 1 (not at all stressful) to 5 (extremely stressful). If a mother reports an item as not being applicable, it would be scored 0. The overall stress metric was used in this study. Chourasia *et al*. have suggested arbitrary classification of the PSS: NICU mean score into high (4.0–5.0), medium (3.0–3.9), and low levels (1.0–2.9).[5] Gujarati version of PSS: NICU was developed using a translation-back translation methodology and pilot tested on 10 mothers before use for study purpose. The validity of contextually appropriate translation was checked before administration of the Gujarati version of PSS: NICU
(4) Edinburgh Postnatal Depression Scale (EPDS)[7] was used to evaluate depressive symptoms. The 10-item EPDS is a valuable and efficient way of identifying patients at risk for peri-natal depression. Mothers who scored above 12 are likely to be suffering from post-partum depression. It has previously been validated in Gujarati[8]
(5) Generalized Anxiety Disorder - 7 (GAD-7)[9] was used to evaluate anxiety symptoms. It is a 7-item scale, rated on a Likert scale from 0 to 3. Scores of 5, 10, and 15 are taken as the cut-off points for mild, moderate and severe anxiety, respectively. A previously translated version was used from the authors' site, but it has not been validated in this population.

PSS: NICU score (maternal stress) was the outcome variable. Variance in maternal stress with maternal and infant characteristics, cumulative neonatal morbidity, depression (EPDS score) and anxiety symptoms (GAD-7 score) was calculated. Descriptive statistics were calculated for demographics, Analysis of variance (ANOVA) was used to compare PSS: NICU mean score between various categories of maternal and infant characteristics, neonatal morbidity, depression, and anxiety at the univariate level. Pearson correlation coefficient was calculated for PSS: NICU mean score with maternal and infant characteristics and cumulative neonatal morbidity score. Backward regression analysis was performed to determine the factors influencing the stress at the multivariate level. The threshold for statistical significance was set at a *P* value of 0.05. The analysis was performed using STATA version 14.2.

RESULTS

One hundred and fifty-one mothers were recruited over a period of one year. The mean (SD) age of mothers was 25.47 (4.98) years. All mothers were married. Majority of them came from a rural background, were illiterate (11.2%) or had less than high school level of education (59.6%), and most of them were homemakers (90.7%). Forty-one percent of the mothers were primigravida, 76.4% reported more than five prenatal check-up visits, 53% reported pregnancy complications, and 55.6% delivered by normal labor. Most of the mothers (94.7%) perceived good family support during pregnancy; 41.1% perceived that their baby was suffering from severe discomfort.

Majority of the infants were premature (62.9%), and 75.5% weighed less than 2500 gm at birth. Seventy-five percent of the infants were males. Seventy-eight percent of the infants required ventilator support. Mean length of NICU stay for the infants was 21.5 days (range 8–75). Mean cumulative neonatal morbidity score for infants on the day of the interview was 20.97 (range 0–106).

The mean (Standard Deviation, SD) maternal stress level on PSS: NICU was 1.62 (0.47). The mean (SD) scores for sub-scales sights and sounds, baby look and behavior, parental role alteration, and staff behaviors were 1.98 (0.83), 1.45 (0.45), 1.76 (0.54), and 1.03 (0.12) respectively. "Tubes and equipment on or near my baby" (2.50) followed by "presence of monitors and equipment" (2.46) were stressors with the maximum score on the PSS: NICU. Thirteen percent of mothers had clinically significant depressive symptoms (EPDS ≥12). All mothers had anxiety symptoms (GAD-7 ≥5).

Variance in maternal stress with the infant and maternal characteristics at the univariate level is shown in Table 1. Higher maternal stress was found to be associated with poor family support during pregnancy, mothers' perception of the baby's discomfort, extremely low birth weight of the baby, baby being on ventilator, likely post-partum depression, and moderate to severe anxiety symptoms. Regression analysis revealed that education level ($P = 0.01$), perceived family support ($P = 0.01$) and baby discomfort ($P = 0.02$), baby being on ventilator ($P = 0.05$), EPDS scores ($P = 0.003$), and GAD-7 scores ($P = 0.03$) were significantly associated with PSS: NICU scores. The coefficient of determination of the model was satisfactory ($R^2 = 0.4$).

DISCUSSION

We have discussed our findings in light of the "Parental NICU stress model."[3] For this study, parental stress response was calculated using the overall stress metric (PSS: NICU mean score). The NICU environmental stressors are analogous with the four subscales of the PSS: NICU. Situational factors considered in our design were the perceived severity of the baby's illness, first look at the baby, and infant characteristics such as baby's sex, birth weight, gestational age, and need for ventilation. Personal factors included maternal age, past experiences such as gravidity and abortions, education, and family support.

The intensity of overall maternal stress (1.62) was in the low-level range (1.0–2.9 on a scale of 1.0–5.0) as compared to 3.78 in the Ludhiana study.[1] The Pondicherry study did not use the overall stress metric, and hence the overall maternal stress could not be compared.[5] Mean scores for the subscales sights and sound, appearance and behavior, parental role alteration, and staff behaviors were 1.98, 1.45, 1.76, and 1.03 respectively as compared to 2.55, 4.1, and 4.12, and not evaluated respectively in the Pondicherry study and not reported, 4.25, 3.64, and not reported respectively in the Ludhiana study.[5] A more recent study from Indore reported a moderate level of overall maternal stress 2.73 (2.04, 3.32, 3.74, 1.92 for the subscales listed as above).[10] Compared to the Indore study, our scores were significantly lower on all subscales (including staff behaviors) except sights and sound. Mothers in the Indore study had a mean age of 27.3 years, but only half were homemakers, and 27% were illiterate.

Lower stress levels in our population may be explained by parental resources (education, family support) and staff behavior. Lower education of the majority of

Table 1: Variance in maternal stress with maternal and infant characteristics

Variable	Group	*n* (%)	PSS: NICU score mean (SD)	*P*
Age (*n*=151)	18-25	87 (57.6)	1.60 (0.44)	0.456
	>=26	64 (42.4)	1.65 (0.49)	
Level of education (*n*=151)	Illiterate	17 (11.2)	1.36 (0.32)	<0.001
	Less than High School	90 (59.6)	1.56 (0.44)	
	High School	27 (17.9)	1.96 (0.48)	
	Graduate	17 (11.2)	1.65 (0.44)	
Gravidity (*n*=151)	Primigravida	62 (41.0)	1.60 (0.45)	0.672
	Multigravida	89 (59.0)	1.63 (0.48)	
Prenatal visits (*n*=148)	<4	35 (23.6)	1.73 (0.63)	0.200
	>=4	113 (76.4)	1.58 (0.40)	
Pregnancy complications (*n*=151) *	Reported	80 (53.0)	1.61 (0.44)	0.725
	Not reported	71 (47.0)	1.63 (0.49)	
Good family support in pregnancy (*n*=151)	Yes	143 (94.7)	1.59 (0.45)	0.004
	No	8 (5.3)	2.08 (0.53)	
Type of delivery (*n*=151)	Normal labor	84 (55.6)	1.56 (0.41)	0.103
	C-Section	67 (44.4)	1.69 (0.53)	
Mothers perception of baby discomfort (*n*=151)	None/Mild	89 (58.9)	1.47 (0.38)	<0.001
	Severe	62 (41.1)	1.83 (0.50)	
Baby gender (*n*=151)	Male	113 (75.2)	1.60 (0.44)	0.275
	Female	38 (24.8)	1.69 (0.53)	
Gestational age (*n*=151)	Extremely Premature	4 (2.7)	1.62 (0.39)	0.876
	Premature	95 (62.9)	1.63 (0.47)	
	Full term	52 (34.4)	1.59 (0.46)	
Birth Weight (*n*=151)	Average (2500 g)	37 (24.5)	1.69 (0.49)	0.003
	LBW (1500-2500 g)	59 (39.1)	1.52 (0.36)	
	VLBW (1000-1500 g)	48 (31.8)	1.60 (0.50)	
	ELBW (<1000 g)	7 (4.6)	2.17 (0.51)	
Baby put on ventilator (*n*=151)	Yes	118 (78.1)	1.67 (0.46)	0.013
	No	33 (21.9)	1.44 (0.44)	
Own a house (*n*=151)	Yes	120 (79.5)	1.65 (0.48)	0.080
	No	31 (20.5)	1.49 (0.38)	
EPDS (*n*=151)	Unlikely Post-Partum Depression (<12)	131 (86.8)	1.56 (0.45)	<0.001
	Likely Post-Partum Depression (≥12)	20 (13.2)	1.99 (0.43)	
GAD7 (*n*=147)	Mild (5-9)	131 (87.3)	1.56 (0.44)	<0.001
	Moderate-Severe (≥10)	16 (12.7)	2.07 (0.47)	

*Missing data were assumed as "not reported". EPDS – Edinburgh postnatal depression scale; GAD – Generalized anxiety disorder; LBW – Low Birth Weight; VLBW – Very low birth weight; ELBW – Extremely low birth weight; PSS: NICU – Parental stressor scale: Neonatal intensive care unit

our study population seems to be protective against maternal stress [Table 1]. While the Ludhiana study[1] did not report the socio-economic profile of their study population, Pondicherry study[5] was done amongst urban, homemaker, and a more educated group of parents. Majority of the mothers in our study reported good family support during pregnancy [Table 1]. However, those who reported poor support during pregnancy had higher maternal stress score. In our routine observations, we had noted that parents get help from various sources such as grandparents, friends, and neighbors during hospitalization, which may be instrumental in mitigating some of the parental stress.

The lower level may also be explained by the mitigating effect of staff behavior (PSS: NICU staff behavior subscale mean 1.03 on a scale of 1–5, where a lower score means favorable staff behavior). However, lower levels of staff behaviors may also be explained by giving of a socially desirable response to the questions on staff behaviors, as the interviews were conducted by one of the staff nurses.

Sights and sound of the NICU environment, followed by parental role alteration, were major sources of stress in our study. Consistent with these findings, 'tubes and equipment on or near my baby' (2.50) followed by 'presence of monitors and equipment' (2.46) were stressors with the maximum score on the PSS: NICU. The Ludhiana study[1] had found baby appearance, followed by parental role alteration, as the major sources of stress, and the Pondicherry study[5] had reported parental role alteration, followed by baby appearances, as the major sources of stress. While the major sources of stress may vary, the common thread in all three studies is the parental role alteration (the inability of the parent to care for the child, who is largely taken care of by the NICU nurse). So, remediation programs for parents should be designed keeping in mind the local demographic profile and

predominant stressors in that environment but should always have a component that addresses parental role alteration.

As expected, the mothers' perception of the baby's illness severity was strongly associated with their stress response. Single question screeners using mothers' perception of the baby's illness severity may be useful and practical to identify mothers in distress who require more staff support. An earlier study[11] had shown high patient to nurse ratio in Gujarat, making it pertinent to have brief instruments to screen mothers. Other situational factors such as the baby having extremely low birth weight (<1000 g) and the need for ventilator support were significantly associated with maternal stress response. Singer *et al*.[12] found that at 1-month post-delivery, mothers of very low birth weight (VLBW) infants had more psychological distress than mothers of term infants. They also recommended that follow-up programs should incorporate psychological screening and support services for mothers of VLBW infants in the immediate postnatal period, with a monitoring of mothers of high-risk VLBW infants.

Busse *et al*. found that amongst parents, PSS: NICU total score was significantly correlated with anxiety (r = 0.61), depression (r = 0.36), and sleep disturbance (r = 0.60).[13] We found that all the mothers had anxiety symptoms, but the majority had mild symptoms only. Twelve percent had moderate-severe anxiety symptoms, and about 13% of the mothers were likely to be having post-partum depression. It can be expected that without intervention, such symptoms may continue even after discharge from the hospital and may hamper mother-child bonding. This subgroup of patients would benefit from interventions as described above for mothers of VLBW infants.

Limitations of the study are that we have not considered many factors that could be part of the parental NICU stress model such as uncertainty about illness, concurrent life events, cognitive and financial resources, perceptions about support by staff, etc., Generalizability may be limited as there is a male bias in the study sample of neonates. Additionally, compared to previous studies, our interviews were conducted at different time points in the study. Also, mothers were not formally evaluated for major psychiatric disorders.

Conclusions: Looks and behavior of the baby, followed by parental role alternation, were the major sources of maternal stress, which is associated with significant psychological morbidity. Higher stress was seen amongst mothers of VLBW infants and those needing ventilation. Lower education level may mitigate maternal stress. Remediation programs for parents should be designed, keeping in mind the local demography and the predominant stressors but should always have a component that addresses parental role alteration. The possibility of screening at-risk mothers by questioning them about the perception of baby's discomfort needs to be evaluated further.

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Conflicts of interest
There are no conflicts of interest.

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Original Article

Training and Clinical Impact of Cognitive Behaviour Therapy Workshops in a Teaching Hospital in North India

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ABSTRACT

Background: Cognitive behaviour therapy (CBT) is an empirically supported psychotherapy with applications across psychiatric disorders. The demand for nonpharmacological interventions is increasing in the developing world. Unfortunately, existing resources are unable to cater to treatment and training needs. **Methods:** The aim of the current paper is to provide a description of the format of a series of CBT training workshops and their clinical impact in a psychiatric tertiary care center in north India. Over a period of nine years, nine training workshops were conducted. CBT concepts and skills sets were inculcated in faculty and student participants, using teaching strategies based on adult learning techniques. **Results:** The workshops resulted in a tremendous increase in the number of patients taken up for CBT. While therapeutic and training outcomes were not systematically assessed, the naturalistic outcomes (60 out of 85 patients completed therapy; improvement reported by >90% of the completers) are encouraging and showcase capacity building by means of CBT training in these workshops. **Conclusions:** CBT training workshops are an effective way to impart CBT skills and, therefore, to build CBT expertise in a resource-poor setting.

Key words: *Adult learning theory, cognitive behaviour therapy, outcome, training, workshop*

Key message: *Short-duration, recurrent CBT training workshops are an effective way of imparting CBT skills to practicing and trainee mental health professionals.*

CBT has a definitive role in the treatment of several psychiatric disorders.[1-3] In comparison to other forms of psychotherapy, CBT has certain conceptual and practical advantages. It is time-bound, is structured, and can be manualized.[4] Epidemiological studies from India suggest that more than 20% of the

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adult population in the community is afflicted with psychiatric disorders.[5] Increasing awareness about mental illnesses has led to an increased demand for nonpharmacological interventions such as CBT. Unfortunately, there is a shortage of therapists. There are less than 700 Clinical Psychologists registered with the Rehabilitation Council of India (http://rciregistration.nic.in/rehabcouncil/Report_StCat_Jdbc.jsp). Other mental health professionals, i.e., Psychiatrists and Psychiatric Social workers, have only limited exposure to CBT during training. Shortage of skilled human resources is considered a critical barrier in improving access to evidence-based psychological interventions in low resource settings.[6] A large number of patients who could benefit from the incorporation of CBT in their treatment continue to suffer disabling symptoms; this also results in over-reliance on polypharmacy, with its inherent limitations and adverse effects. There is, thus, an immense need for scaling up services for psychological interventions.

CBT has specific, delineable technical components that can be taught.[7] There is only one institute in India that runs a formal CBT training program. In this program, training in cognitive and behavioral therapies is offered through a 3-month clinical posting. Training programs, ranging in duration from a single day workshop to a 12-week systematic training, for mental health and non-mental health professionals, have been examined.[8-10] These highlight the feasibility and effectiveness of CBT training outside of academic curricula. There is room for methodological improvement and demonstration of cross-cultural applicability and utility. Beck *et al*.[7] proposed a two-stage CBT training model—a smaller group of master trainers/supervisors/researchers and a larger group of practitioners, ensuring the continuation of CBT provision and monitoring beyond the training period. Their model also stresses on the need for cultural adaptation of CBT and the use of Kolb's model of experiential learning.[11] Simplification in language, use of pictorial materials, use of local metaphors and phrases, in addition to drawing analogs from mythological/folk tales could be useful in cultural adaptation.[6] Experiential learning[12] is related to adult learning theory[13] which states that adults learn when the teaching program appreciates their existing knowledge and experiences and when their experiences are linked to the learning process. Active learning methods, including techniques such as brainstorming, demonstrations, role-playing, games, and case studies, are generally more useful than passive learning.

We organized a series of CBT training workshops in the Department of Psychiatry at a tertiary care hospital in north India. Even though a tertiary care hospital, there were no established services for CBT. The aim of the current paper is to provide a description of the format of the workshops and their clinical impact. The proposal for this paper was approved by the Institutional Ethics Committee.

METHODS

The workshops and training method

Frequency, duration, and spacing

Between 2007 and 2015, nine workshops were organized, i.e., one per year, each lasting two to three days, three hours in the afternoon on each day.

The trainer

A CBT practitioner (lead author) has been the expert trainer in these workshops. He received peer supervision from two CBT practitioners certified in the UK.

The trainees

Faculty members (Psychiatrists and Clinical Psychologists) along with postgraduate students in Psychiatry and Clinical Psychology attended these workshops. Participation in the workshops was voluntary. For all the participants, knowledge and exposure to CBT before the workshops were mainly from didactic lectures from their masters' coursework and from self-reading.

The training method

The instruction method adopted was a combination of didactic presentations alongside experiential learning. During a 2-day "pre-workshop," faculty members with some prior exposure to CBT conducted introductory sessions informed by theoretical principles described in reference books,[14,15] with lectures on topics such as the cognitive behavioral conceptualization of disorders and the evidence base for CBT. The workshops followed these introductory sessions. They were conducted in a teaching hall with the trainer and trainees seated in a circle. The format of the 3-day workshops is depicted in Table 1.

RESULTS

Each of the nine workshops was attended by 25–30 participants. Typically, 80% of the participants were postgraduate MD and MPhil students, and 20% were faculty members. While faculty members were able to attend multiple workshops over the course of nine years, postgraduate students attended on average 2-3 workshops, due to the tenure of their postgraduate program.

The workshops, drawing on principles of adult learning, used a variety of case-based discussions and demonstrations. Open group discussions, brainstorming, and role plays were often employed, whereas didactic

Table 1: Format of the 3-day CBT training workshops

Day	Agenda	Time	Technique
1	Familiarization with ongoing CBT work in the department	30 minutes	Open session with the faculty participants
	Ice-breaking with the group/introductions	15 minutes	A short game followed by trainees introducing themselves
	Assessment of prior learning and experience in CBT	30 minutes	Individual inputs from all trainees
	Learning targets for current workshop Role-play/demonstration/practice of CBT skills Homework assignment for trainees for next day	45 minutes+ 45 minutes	Individual inputs from all trainees; working in groups; role play
2	Inculcate skills related to practice and supervision of CBT in the select group	45 minutes	A separate session with faculty participants Case studies, Demonstrations, Brainstorming
	Feedback on the previous day	15 minutes	Individual inputs from all trainees
	Introduction/enhancement of CBT skills	45 minutes+ 45 minutes	Case presentations, Demonstrations by trainer, Roleplays
	Take home messages from the day and any additional inputs for the next day; agreeing on homework for the next day	15 minutes	Individual inputs (on a semi-structured proforma) from all trainees
3	Inculcate skills related to practice and supervision of CBT in a select group	45 minutes	A separate session with faculty participants Case studies, Demonstrations, Brainstorming
	Feedback on the previous day	15 minutes	Individual inputs from all trainees
	Introduction/enhancement of CBT skills	45 minutes+ 45 minutes	Case presentations Demonstrations by trainer Role plays
	Take home messages and learning from the workshop	15 minutes	Individual inputs (on a semi-structured proforma) from all trainees

CBT – Cognitive behavioral therapy

sessions and PowerPoint presentations were seldom used. On each of days 2 and 3 of the workshop, clinical cases were presented by pre-identified participants and discussed. On day 2, the trainer led group sessions—either small groups working on different aspects of the case or a larger group discussion. For each identified problem in the case, the trainer invited responses from the group. Each of the responses was then discussed, and the trainer provided constructive feedback. On day 3, the trainer supervised faculty participants in leading the group sessions. Discussions during the workshops were utilized to demonstrate communication skills and techniques. As an example, when a maladaptive thinking pattern was identified in a case, the trainer employed Socratic dialogue and guided discovery to help participants reach the most apt method to use for cognitive restructuring. The workshops provided opportunities for case-based learning and for developing a capacity for further self-learning.

CBT skills discussed

CBT skills were covered in the context of case studies on depression, generalized anxiety disorder, obsessive compulsive disorder, phobia, and panic disorder. General psychotherapeutic skills included patient selection and planning of therapy, collaborative agenda setting, handling dependency on the therapist, and termination and relapse prevention. Specific CBT skills included—5-area model, cognitive behavioral formulation, Socratic dialogue, guided discovery, thought record, correction of negative automatic thoughts, cognitive restructuring, exposure and response prevention, homework, and behavioral experiments.

Peer-supervision

The CBT workshops encouraged peer-feedback and supervision. Consequently, an additional key skill developed in the group was 'peer-supervision.' Peer supervision can provide an emotionally safe environment for therapists to identify and discuss shortcomings in their role and thereby improve patient care.[16] From the 5th annual workshop, a group of five faculty members in the department started weekly peer group meetings that lasted a couple of hours. Before each meeting, all members read up on a specific aspect of CBT and discussed it in the first half hour. This helped enhance theoretical knowledge. Therapy cases were presented and discussed, with one member by turn leading the discussion. Role plays were often used to troubleshoot. The peer-supervisory groups were a much-needed space for the beginner therapists to constructively handle their own stress arising from the multi-faceted challenges of the new arena they were stepping into.

Status of CBT practice in the department

The state of CBT practice saw a dramatic change since the first CBT workshop in 2007. The number of cases taken up for CBT went up from only six cases in 2008, to 85 cases in 2015. The majority of these cases were of obsessive compulsive disorder (36.5%), followed by depression (34.1%) and anxiety disorders (17.6%). All these patients were taken up for CBT following inadequate/no response to pharmacotherapy. Of the 60 patients (70.5%) who completed therapy sessions, a massive majority (91.7%) reported a good outcome (Clinical Global Impression-Improvement scale[17] rating 1 or 2) at the end of therapy. Pharmacotherapy was continued alongside CBT.

DISCUSSION

We have reported in this paper the training and clinical impact of a series of CBT training workshops conducted in a tertiary-care hospital in India. The key outcomes of these workshops were an increase in the number of people with exposure to CBT training, increase in the number of patients taken up for CBT, the development of a peer-supervisory group, and continued collaboration with the trainer to take this program further. In the absence of a formal academic curriculum for CBT training in our institution, it is heartening to note that a workshop model has been able to generate sufficient interest among the trainees and has led to the beginnings of clinical services for CBT in the department. CBT training or formal training in any form of psychological therapy is not yet mandatory for psychiatry training in India. In the workshops described herein, the trainees sought the training voluntarily and offered it to clients over and above their regular work, often working more their than contracted hours.

The training program has addressed some of the limitations of the previous work in this area. Continuous supervision has been identified as a key factor in positive training outcomes. Research has shown that distant supervision via technological means and peer-supervision are helpful where on-site expert supervision is not readily available.[6,7] Our training program has laid special emphasis on the development of a peer-supervisory group among faculty members, who can, in turn, provide individual supervision to students.

Earlier papers have reported the outcome of training only from the perspective of the trainees. However, as pointed out by Maunder *et al*.[8] trainees could be biased towards reporting positive outcomes for social-desirability or motivational reasons alone. In this paper, we have chosen to report the clinical impact of the training program in terms of the increase in the number of patients being offered CBT and the treatment outcomes. Over the nine years of this program, there was a 10-fold increase in patients taken up for CBT. The increase in the number of patients taken up for CBT is a reflection of the participants' interest in and theoretical understanding of CBT that was honed by the workshops. Our findings suggest that the CBT training program described in this paper was effective and that it is feasible to develop CBT skills in mental health professionals in similar resource-poor settings.

We are aware of the limitations of this paper. The CBT skills of the trainees have not been assessed formally by use of established rating scales such as Cognitive Therapy Scale-Revised (CTS-R).[18] The outcome of CBT in patients, assessed prospectively, is partly evidence of the efficacy of training in the practical sense. Moreover, all the patients taken up for CBT had not adequately responded to pharmacotherapeutic treatment alone. In this context the improvement at the end of therapy could be attributable to the introduction of CBT. We thought it important to report this work at this stage to share our experience and encourage similar training programs in other parts of the country. When compared to academic programs for CBT training in India, there obviously appears to be much lacking in terms of the hours and rigor of training. Further long-term evaluation and more formal outcome assessments of our training program can inform us about the shortcomings that need to be addressed. Audio- and video-recorded sessions are often recommended for monitoring and supervision of psychotherapy, and the absence of these in our work is a limitation. However, the development of a peer supervisory group would have partly addressed this limitation.

An earlier publication,[19,20] also based on these workshops, reported the feasibility of training mental health professionals, from a non-English speaking background, in CBT. We demonstrate how, even in a resource-poor setting, in terms of regular availability of trained CBT practitioner, CBT skills can be inculcated in faculty and students by means of yearly workshops, of short duration and utilizing adult learning models. The feedback from faculty participants and students has been encouraging, as has been the changing scenario of CBT practice in the department. Interestingly, the acceptability of the CBT model was good, considering that we used the same techniques used internationally. Thus, there were no apparent cultural barriers to the practice of CBT. Teaching methods in a diverse and growing field like psychotherapy need as much stringent attention and research as is being paid to pharmacotherapy and other treatment methods like brain stimulation. The evaluation of psychotherapy training programs has often been limited by small sample sizes, lack of external validity, and the use of pre-post designs without adequate control.[9] This has to change.

CONCLUSION

Capacity building is the need of the hour in mental health. Task-shifting approaches to service delivery, with supervisory arrangements, have been stressed as a key intervention to improve the state of service availability.[6] However, before we can task-shift, we need to have enough training capacity. Following Beck's two-stage training model, and in light of the positive impact of CBT training workshops, the stage is set for further systematic evaluation of these workshops by carefully designed clinical trials.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Knowledge and Attitudes toward Sexual Health and Common Sexual Practices among College Students – A Survey from Vellore, Tamil Nadu, India

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ABSTRACT

Background: Indian society is considered to have conservative attitudes regarding sex and is ambivalent about the concept of sex education. Previous reports suggest that a considerable proportion of Indian youth have inadequate sexual knowledge and hold a variety of sexual misconceptions. Methodological flaws limit the generalizability of some earlier studies. **Aims:** This study assessed knowledge and attitude toward sexual health and common sexual practices among college students in Tamil Nadu. **Methodology:** A total of 952 students from seven randomly selected colleges in Vellore district of Tamil Nadu participated in the survey. The survey questionnaire contained 51 questions on knowledge and attitude toward sexual health and common sexual practices and incorporated items from standardized questionnaires and additional questions suggested by a multidisciplinary group who work in the field. **Results:** Two hundred seventy-five students among those who completed the survey were women. Higher knowledge scores were associated with older age, male gender, being from a rural background, pursuing non-science streams, and being in postgraduate courses. Nonconservative attitudes were associated with older age, male gender, enrollment in non-science disciplines, discomfort with the family environment, and a religious family background. **Conclusions:** Sexual knowledge is inadequate and sexual misconceptions were widely prevalent in the population studied. School-based comprehensive sex education programs, which have been demonstrated to be effective in improving sexual health, could be used to deal with these lacunae in sexual health knowledge and attitudes.

Key words: *College students, sexual attitudes, sexual knowledge, sexual misconceptions, sexual practices*
Key messages: *Sexual knowledge is inadequate and sexual misconceptions are widely prevalent among the youth in India. Culturally sensitive and comprehensive sex education programs could be used to deal with these lacunae.*

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A positive, respectful approach to sexuality and relationships, with the possibility of having pleasurable and safe sexual experiences free of coercion, discrimination and violence, is essential for good sexual health.[1] Knowledge about sex and sexuality, and sexual attitudes and behavior are influenced by societal, cultural, environmental, and physical factors. Though the "Kamasutra" was composed in ancient India, Indian society is extremely conservative about sex and ambivalent about the concept of sex education. A considerable proportion of youth in India is reported to have inadequate knowledge, a variety of sexual misconceptions, and concerns about different aspects of sex.[2-4] This can, in turn, lead to unhealthy attitudes, unsafe sexual practices, and significant health consequences.

Most data regarding sexual health from India are from nonsystematic surveys and opinion polls that look at a superficial range of issues. Methodological flaws including problems in sample selection; improper design and content of questionnaires; and participation, recall and reporting biases limit their generalizability.[5] In this context, this study was planned to assess knowledge, attitudes, and sexual behavior among college students from Tamil Nadu.

METHODOLOGY

Study design: This was a descriptive study with a cross-sectional design.

Selection of colleges

A list of all arts and science colleges in Vellore district was obtained. Professional colleges were not included as the student population in these may not have been representative of the geographical region under study. Authorities of 14 randomly selected colleges of the 27 identified were approached for permission to conduct the study. The survey was carried out in all seven of the colleges who consented to participate. The colleges that did not participate in the survey did not differ from the ones that participated in location (urban/rural), the gender of the students (co-educational/men's/women's) or funding (public or private). As the required sample size was achieved with seven colleges that consented to participate in the study, no further colleges were recruited.

Participants

Details regarding the total number of classes in the college and the number of students in each class were collected. Classes were then randomly chosen using lots to obtain a total of at least 100 students from each college. Students aged 18 years and above who were able to read and write in English or Tamil were invited to participate in the survey and were provided the information sheet. The study questionnaire was given to those who provided written informed consent. The survey was conducted in the classroom, seminar hall, or auditorium of the college surveyed. Participants were seated in such a way as to ensure privacy. The questionnaire was self-administered and anonymous to encourage participants to respond as genuinely as possible. Practicing psychiatrists, fluent in the local language, were present during the administration to address any doubts and queries related to the questionnaire.

Survey questionnaire

A total of 105 questions were initially proposed for possible inclusion in the questionnaire. These were sourced from the Illustrative Questionnaire for Interview-Surveys with Young People[6] and a questionnaire devised by Martin S. Weinberg at the Kinsey Institute.[7] In addition, questions based on discussions with mental health professionals who routinely deal with sexual issues among the target age group were also included. These were evaluated by a panel of five experts (three men and two women) comprising of three psychiatrists, a psychologist, and a psychiatric nurse for suitability, relevance, and language. 51 questions that were selected were piloted among a group of 37 professionals, including psychiatrists, psychologists, psychiatric nurses, and general physicians who work in this field; further revisions were made based on their feedback. The finalized questionnaire was translated into Tamil independently by two people, back-translated into English by two persons, and the final consensus version was arrived at by all translators together. For those words which did not have precise or commonly used Tamil translations, the English equivalents were provided in brackets. Face and content validity of the questionnaire was established by the expert group as well as during the pilot study. Cronbach's alpha value calculated for the questions (knowledge and attitudes), which could be scored using the study sample, was 0.6. The alpha value is lower than what is acceptable, as only 22 items of the 51-item questionnaire were used in the calculation, and the questions used a dichotomous (yes/no) response format. A proforma was used to collect selected sociodemographic details. A score was calculated by giving a point for a correct response to each of the 13 questions that assessed knowledge. Higher scores reflect better knowledge. Similarly, a point was given for nonconservative responses (accepting of premarital romantic or sexual relations, not endorsing the concept of virginity till marriage, agreeing with medical termination when pregnancy is unplanned, not feeling that homosexuality is wrong, etc.) to the nine questions

which assessed attitude. Higher scores reflect less conservative attitudes.

Ethical considerations

Informed consent was obtained from all participants. The survey was anonymous and participants were asked not to identify themselves by name. The information collected was available only to the research team. The research protocol was approved by the Institutional Review Board and Ethics Committee.

Determination of sample size

The sample size was determined based on the findings from a previous study which reported prevalence rates for sexual knowledge, attitude, and practices.[4] The sample size for each of these was calculated and the largest sample size obtained was 941, assuming the prevalence as 2.7% for a forced sexual encounter, d = 1%, with 95% confidence limits and adjusting for 20% students whom we anticipated might withdraw consent or leave the questionnaire incomplete.

Data analysis

SPSS for Windows (version 16.0. SPSS Inc., Chicago, IL, USA) was employed for the analysis of data. Mean and standard deviation were calculated to describe continuous variables, while frequency distributions were used for categorical data. The Chi-square test, Pearson's correlation coefficient, and the Student's t-test were used to assess the significance of associations for categorical and continuous variables, respectively. A P value of less than 0.01 was considered as statistically significant. Linear and logistic regression was employed as multivariate statistics to adjust for common confounders. All variables with $P < 0.05$ in bivariate analyses were entered into the regression model.

RESULTS

Sociodemographic details

A total of 952 students completed the survey. The mean age of the participants was 19.39 years (SD – 1.34). The majority were male, single, and pursuing an undergraduate course in a science discipline [Table 1].

Sources of information

Participants reported that they acquired information regarding puberty, sex, and reproduction mostly from books, magazines, or videos (40.2% for males and 30.5% for females), friends (32% for males), and parents (23% for females).

Sexual knowledge

Half of the respondents were aware that a woman could become pregnant after puberty (51.7%) and about the legal ages for marriage and consent for sexual intercourse (50.1%). A total of 20% of males and 12% of females believed that a woman could get pregnant if sexual intercourse occurred during menstruation. The contraceptive measure that respondents were most aware of was the condom (46.6%), while knowledge about the other methods was less.

The use of condoms (46.6%) and avoiding unprotected sexual intercourse (16.6%) were reported as the most effective ways of preventing HIV infection, with men considering the former to be more effective, while women considered the latter to be more useful. 22% of males and 9.4% of females stated that they would approach a traditional healer or local pharmacy rather than a medical practitioner for treatment of sexually transmitted diseases (STDs).

Awareness regarding the legal age of consent for sexual intercourse for males (χ^2 = 24.58, $P < 0.001$) and females (χ^2 = 36.22, $P < 0.001$) was better in men, while awareness regarding the `safe period' was better in women (χ^2 = 8.79, $P < 0.001$). Higher knowledge scores were significantly associated with male gender, postgraduate education, and married status [Table 2].

Attitudes regarding sexual behavior

While the majority of the participants disapproved of premarital romantic and sexual relationships even if monogamous, more of those who were in favor were men. Many considered virginity till marriage important. Several participants believed that having sexual urges before the age of 18 was harmful, that a frequency of sexual intercourse more than three times a week was harmful, and that semen loss could harm the body or result in sexual dysfunction [Table 3]. Higher nonconservative attitude scores were significantly associated with gender, the stream of study, and family environment [Table 2].

Sexual practices

Details of sexual behavior or practices are found in Table 4.

Masturbation

About a third of the respondents, men more than women, reported that they had masturbated at some time in their life, with a mean age of onset of 17.21 years (SD = 2.65). Factors significantly associated with masturbatory practice were greater age (t = 5.13, df = 739, $P < 0.001$), male gender (χ^2 = 56.64, $P < 0.001$), nonscience stream of study (χ^2 = 31.32, $P < 0.001$), and endorsement of the concept of 'virginity till marriage' (χ^2 = 18.03, $P < 0.001$). Those who believed that loss of semen damages health reported less masturbatory behavior (χ^2 = 6.60, P = 0.01). Higher scores on knowledge (t = -3.86, df = 776, $P < 0.001$)

Table 1: Sociodemographic variables

Characteristics	Overall (%) (*n*=952)*	Men (%) (*n*=662)	Women (%) (*n*=275)
Mean age in years (SD)	19.39 (1.54)	19.62 (1.63)	18.89 (1.16)
Religion			
Hindu	683 (71.7)	468 (70.7)	211 (76.7)
Muslim	171 (18)	153 (23.1)	15 (5.5)
Christian	64 (6.7)	19 (2.9)	45 (16.4)
Others	1 (0.1)	1 (0.2)	-
Place of residence			
Rural	509 (53.5)	377 (56.9	130 (40.3)
Urban	412 (43.3)	267 (40.4)	140 (50.9
Education			
Degree student	773 (81.2)	541 (81.7)	225 (81.8)
Postgraduate student	123 (12.9)	88 (13.3)	35 (12.7)
M Phil/PhD student	11 9 (1.1)	6 (1)	5 (1.8)
Discipline			
Arts stream	254 (26.7)	235 (35.5)	16 (5.8)
Science stream	546 (57.4)	301 (45.5)	242 (88)
Commerce stream	48 (5)	48 (7.3)	-
Marital status			
Single	886 (93.1)	626 (94.6)	254 (92.4)
Married	24 (2.5)	7 (1.1)	15 (15.5)
Divorced/separated/widowed	5 (0.5)	3 (0.5)	2 (0.7)
Fathers' education			
Educated up to higher secondary	630 (66.2)	438 (66.2)	186 (67.6)
Graduate	50 (5.3)	25 (3.8)	24 (8.7)
Postgraduate	14 (1.6)	9 (1.4)	6 (2.2)
Mothers' education			
Educated up to higher secondary	603 (63.3)	410 (61.9)	188 (68.4)
Graduate	23 (2.4)	11 (1.7)	11 (4)
Postgraduate	7 (0.7	3 (0.5)	4 (1.5)
Importance of religion to the person			
Very important	423 (44.4)	291 (44)	129 (46.9)
Important	267 (28)	179 (27)	85 (30.9)
Not important	75 (7.9)	144 (21.8)	49 (7.8)
Importance of religion to the family			
Very important	499 (52.4)	328 (49.5)	167 (60.7)
Important	287 (30.1)	195 (29.5)	88 (32)
Not important	75 (7.9)	71 (10.7)	4 (1.5)
Comfortable in the family environment			
Comfortable	655 (68.8)	426 (64.4)	225 (81.8)
Not comfortable	115 (12.1)	90 (13.6)	21 (7.6)
Neither	83 (8.7)	65 (9.8)	18 (6.5)
Restriction in the family environment			
Very strict	225 (23.6)	170 (25.7)	53 (19.3)
Strict	501 (52.6)	323 (48.8)	174 (63.3)
Not strict	95 (10)	57 (8.6)	36 (13.1)

*15 respondents did not mention their gender

and nonconservative attitudes (t = -6.35, df = 776, $P < 0.001$) were present in respondents who practiced masturbation.

Multivariate logistic regression revealed that masturbatory practice (age, gender, discipline of study, and attitude and knowledge scores were entered into the model) was associated with increasing age (adjusted OR = 1.17, CI = 1.05-1.3, P = 0.006), male gender (adjusted OR = 3.09, CI = 1.86-–5.14, $P < 0.001$), and higher score on non-conservative attitude (adjusted OR = 1.27, CI – 1.13-1.42, $P < 0.001$). Students in the science stream appeared to have lower masturbatory practice (adjusted OR = 0.69, CI = 0.49–0.99, P = 0.044).

Sexual intercourse

Thirty-five percent of the sample reported ever having had sexual intercourse. The average age of first sexual intercourse was 21 (SD = 2.68) years for females and 19.11 (SD = 3.41) years for males. Less than one-tenth of the respondents reported an oral or anal sexual experience. More men than women had a sexual experience through relationships developed on social networking sites.

Male respondents (χ^2 = 16.97, $P < 0.001$), older people (t = 2.15, df = 806, P = 0.032), those who perceived their family environment as uncomfortable (χ^2 = 6.49, P = 0.011) and those who

Table 2: Association of knowledge and attitude scores with selected sociodemographic details

Characteristics	Attitude score Mean (SD)	*t*/*r* (*P*)	Knowledge score Mean (SD)	*t*/*r* (*P*)
Age	-	0.109 (0.001*)	-	0.240 (<0.001**)
Gender				
Males	4.5 (1.62)	9.52 (<0.001**)	4.94 (2.22)	7.89 (<0.001**)
Females	3.41 (1.54)		3.73 (1.92)	
Place of residence				
Rural	4.17 (1.69)	0.42 (0.677)	4.73 (2.23)	2.13 (0.03*)
Urban	4.22 (1.64)		4.42 (2.14)	
Education				
Undergraduate student	4.2 (1.69)	0.03 (0.98)	4.49 (2.17)	-3.83 (<0.001**)
Postgraduate student	4.19 (1.6)		5.28 (2.34)	
Discipline				
Science stream	4.01 (1.64)	-4.57 (<0.001**)	4.41 (2.12)	-3.43 (0.001*)
Non-science stream	4.55 (1.6)		4.94 (2.24)	
Marital status				
Single	4.2 (1.66)	0.41 (0.68)	4.58 (2.19)	-2.08 (0.04*)
Ever married	4.07 (1.65)		5.45 (2.38)	
Fathers education				
School educated	4.28 (1.66)	0.92 (0.358)	4.65 (2.15)	2.42 (0.016*)
College educated	4.08 (1.65)		3.98 (1.84)	
Mothers education				
School educated	4.22 (1.64)	0.47 (0.636)	4.58 (2.11)	0.44 (0.658)
College educated	4.37 (1.94)		4.4 (2.25)	
Importance of religion to the person	4.14 (1.63)			
Important	4.4 (1.72)	1.93 (0.054)	4.56 (2.19)	0.81 (0.419)
Not important			4.7 (2.16)	
Importance of religion to the family				
Important	4.16 (1.65)	-3.49 (0.001*)	4.57 (2.17)	1.01 (0.314)
Not important	4.85 (1.65)		4.84 (2.45)	
Comfortable in the family environment				
Comfortable	4.15 (1.63)	-2.34 (0.020*)	4.56 (2.22)	-1.20 (0.230)
Others	4.46 (1.7)		4.77 (2.05)	
Restriction in the family environment				
Not strict	4.18 (1.55)	0.17 (0.866)	4.69 (2.26)	0.49 (0.623)
Others	4.21 (1.66)		4.58 (2.18)	

t=*t* value on Independent *t*-test; *r*=Pearson's correlation coefficient. *$P<0.01$ **$P<0.001$

Table 3: Sexual attitudes and misconceptions

Sexual attitudes	Overall (%) (*n*=952)*	Men (%) (*n*=662)	Women (%) (*n*=275)
Approves premarital romantic relations	428 (45)	353 (53.3)	68 (24.7)
Approves premarital sexual relations when in love	193 (20.3)	171 (25.8)	19 (6.9)
Approves premarital monogamous sexual relations	325 (34.1)	270 (40.8)	50 (18.2)
Women should be virgins till marriage - Agree	779 (81.8)	549 (82.9)	221 (80.4)
Men should be virgins till marriage - Agree	698 (73.3)	494 (74.6)	197 (71.6)
Approves medical termination when pregnancy is unplanned	327 (34.3)	259 (39.1)	62 (22.5)
Homosexuality is wrong - Agree	555 (58.3)	407 (61.5)	142 (51.6)
Social networking causes promiscuity - Agree	693 (72.8)	499 (75.4)	187 (68)
Sex education should be mandatory - Agree	574 (60.3)	384 (58)	181 (65.8)
Sex is important in life - Agree	818 (85.9)	598 (90.3)	208 (75.6)
Using condoms reduces pleasure - Agree	413 (43.4)	312 (47.1)	95 (34.5)
Sexual misconceptions			
Nightfall is a normal phenomenon - Agree	486 (51.1)	442 (66.8)	35 (12.7)
Semen loss can cause serious damage to the body - Agree	435 (45.7)	371 (56)	57 (20.7)
Semen loss can cause sexual dysfunction - Agree	445 (46.7)	366 (55.3)	72 (26.2)
Retention of semen improves stamina or physical health - Agree	425 (44.6)	354 (53.5)	63 (22.9)
Sexual urge before 18 years of age is harmful - Agree	657 (69)	462 (69.8)	184 (66.9)
The size of the penis should be at least six inches for satisfactory sexual intercourse - Agree	274 (28.8)	236 (35.6)	32 (11.6)
Sexual intercourse more than three times a week is harmful - Agree	539 (56.6)	402 (60.7)	131 (47.6)
Sexual intercourse during menstruation is harmful to the man - Agree	613 (64.4)	444 (67.1)	162 (58.9)

*15 respondents did not mention their gender

Table 4: Prevalence of reported sexual behaviors among the respondents

Sexual behavior	Overall (%) (*n*=952)*	Men (%) (*n*=662)	Women (%) (*n*=275)
Masturbation			
Prevalence	315 (33.1)	284 (42.9)	26 (9.5)
Frequency/month (mean with SD)	7.9 (20.71)	8.36 (21.53)	1.38 (0.72)
Mean age at initiation in years (SD)	17.21 (2.65)	17.18 (2.61)	17.73 (3.14)
Sexual intercourse			
Prevalence	339 (35.6)	269 (40.6)	65 (23.6)
Frequency/month (mean with SD)	2.24 (1.43)	2.46 (1.46)	1.73 (1.21)
Mean age at initiation in years (SD)	19.49 (3.35)	19.11 (3.41)	21 (2.68)
Oral sexual experience	87 (9.1)	66 (10)	19 (6.9)
Anal sexual experience	43 (4.5)	36 (5.4)	6 (2.2)
Sexual experience through social media	47 (4.9)	41 (6.2)	5 (1.8)
Homosexual behavior			
Fantasies	86 (9)	67 (10.1)	17 (6.2)
Acts	197 (20.7)	163 (24.6)	29 (10.5)
Coercive sexual behavior			
Victim	137 (14.4)	116 (17.5)	19 (6.9)
Perpetrator	108 (11.3)	98 (14.8)	8 (2.9)
Paraphilic behavior or fantasy			
Any paraphilic fantasy	125 (13.1)	112 (16.9)	12 (4.4)
Any paraphilic behavior	208 (21.8)	180 (27.2)	26 (9.5)
Any paraphilic behavior or fantasy	247 (25.9)	217 (32.8)	28 (10.2)

*15 respondents did not mention their gender

did not feel the need to preserve virginity till marriage in men ($\chi^2 = 26.48, P < 0.001$) or women ($\chi^2 = 13.23$, $P < 0.001$) were more likely to have had a sexual experience. Other significantly associated factors were a favorable attitude toward premarital romantic relations ($\chi^2 = 20.67$, $P < 0.001$), premarital sexual relationship when in love ($\chi^2 = 31.92$, $P < 0.001$), premarital monogamous relationship ($\chi^2 = 20.76$, $P < 0.001$), and absence of worries about the harmful effects of semen loss ($\chi^2 = 9.24$, $P = 0.002$). Higher knowledge ($t = -2.63$, df = 847, $P = 0.009$) and nonconservative attitude scores ($t = -6.47$, df = 847, $P < 0.001$) were present in respondents who reported having had sexual relations.

On logistic regression analysis, the likelihood of having had sexual intercourse (age, gender, attitude, and knowledge score were entered into the model) was associated with male gender (adjusted OR = 1.46, CI = 1.02–2.08, $P = 0.040$) and higher nonconservative attitude scores (adjusted OR = 1.28, CI = 1.15–1.41, $P < 0.001$).

Homosexual experience

Homosexual experiences were reported by 20.7% and fantasies by 9% of the participants. Mutual masturbation was the most commonly reported homosexual experience. Males ($\chi^2 = 13.18, P < 0.001$), students from nonscience streams ($\chi^2 = 7.51$, $P = 0.023$), and married respondents ($\chi^2 = 33.24$, $P < 0.001$) reported more same-sex experience. Those who perceived nocturnal emissions as a normal phenomenon ($\chi^2 = 20.77$, $P < 0.001$) or had favorable attitudes toward premarital romantic relations ($\chi^2 = 17.53$, $P < 0.001$), premarital sexual relationship when in love ($\chi^2 = 49.03$, $P < 0.001$) or premarital monogamous sexual relationship ($\chi^2 = 11.97$, $P = 0.003$) reported more homosexual experiences. Students who reported homosexual behavior had higher scores on nonconservative sexual attitudes ($t = -3.99$, df = 741, $P < 0.001$). Multivariate logistic regression revealed that homosexual experience (gender, discipline of study, marital status, attitude, and knowledge score were entered into the model) was associated with male gender (adjusted OR = 2.54, CI = 1.45–4.45, $P = 0.001$) and higher score on nonconservative attitudes (adjusted OR = 1.2, CI = 1.06–1.36, $P = 0.005$). Marriage seemed to reduce reported homosexual behavior (adjusted OR = 0.09, CI = 0.038–0.25, $P < 0.001$).

Coercive sexual experiences

A total of 14% of participants reported that they had experienced a coercive sexual act, while 11.3% reported being the aggressor in a forced sexual encounter.

Paraphilic behavior or fantasy

A total of 19% of the respondents reported a paraphilic behavior or fantasy, more males (24.6%) than females (6.5%).

Factors that were significantly associated with paraphilic behavior were male gender ($\chi^2 = 33.31$, $P < 0.001$), studying in a nonscience stream ($\chi^2 = 11.59$, $P = 0.001$) and not feeling comfortable in the family environment ($\chi^2 = 15.23$, $P < 0.001$). Students who reported a paraphilic behavior or fantasy had higher knowledge ($t = -4.99$, df = 950, $P < 0.001$) and

nonconservative attitude scores (t = -10.31, df = 950, $P < 0.001$).

DISCUSSION

Sexual attitudes and behavior are complex and influenced by physiological, psychological, social, and cultural factors. In conventional Indian society, discussions regarding sex are not encouraged. This leads to ignorance and lack of awareness, misconceptions, biased attitudes, psychological conflicts, low self-esteem, distress, and high-risk behavior. A lack of knowledge can also make an individual vulnerable to physical or sexual abuse, unethical treatment practices and result in unsatisfactory interpersonal relationships.

Though sexual health is considered an important contributor to overall health and wellbeing, it has been largely ignored, both at the individual and public health level. This survey attempted to assess the knowledge, prevailing attitudes, and beliefs toward sexuality and common sexual practices among college students.

Sexual knowledge

Knowledge and awareness about sexual health among youth have been reported to be inadequate the world over and especially in the developing countries.[8] This survey found that the majority of participants cited their friends as their main source of information regarding sex. This could also partly explain the high rates of sexual misconceptions noted in this survey, as wrong information is likely to be circulated among the peer group. Similar findings have been reported in previous studies from this region.[9] It is interesting to note that the internet and visual media have replaced many traditional sources of information in this age group.[10] This suggests that these media can be useful to disseminate information and awareness among the youth.

Despite the many intervention programs that have targeted the youth, this study highlights the inadequacies in knowledge regarding reproductive physiology, the legal age in India for consent for sex, pregnancy and contraception, STDs, and available reproductive health services.[2,4,11,12] Poor knowledge regarding these issues can lead to serious medicolegal complications, high-risk behavior, and its consequences.[11,13-15]

Sexual attitudes

Attitudes toward sexuality are generally colored by the sociocultural milieu. However, they may be startlingly different from those that are traditionally expected.[12] Many young people are comfortable with the notion of premarital romantic and/or sexual relationships, signaling a shift from an earlier largely conservative attitude, toward a more liberal and `Western' outlook.[16-18] The concept of 'virginity till marriage', considered the norm in traditional Indian society, also appears to be gradually changing.[17,18]

Many participants believed that condoms reduce pleasure during sexual intercourse, which could result in a reluctance to use them.[19,20] Attitudes about medical termination of pregnancy and homosexuality reflected the traditional religious and sociocultural views of this region that appear to be unchanged despite the recent legal rulings and debates on the topic.[21]

Despite the widely prevalent traditional view that disapproves of sex education programs in schools, it was encouraging to note that the youth in this sample felt it is an essential component of education. Such an attitudinal change could augur well for the nation, as it has been demonstrated that school-based comprehensive sex education programs are one of the most effective strategies for improving sexual health.[22-24]

A small proportion of participants in this survey did not feel that sex was an important aspect of life; these were mostly women and married individuals. This may be a statistical limitation as single respondents vastly outnumbered married subjects; it is possible that women and married subjects may consider sex less of a priority in the midst of their other responsibilities and may consider other aspects in a relationship to be more important rather than the `romantic' and sexual aspects.[25,26] Men and nonscience students seemed to have more permissive attitudes regarding premarital romantic relationships and sexual intercourse; the former finding has been reported earlier.[2,4]

Sexual misconceptions

Similar to previous reports,[27-31] the common sexual misconceptions we found were the beliefs regarding semen loss and retention on the body and mind, and beliefs regarding the frequency and age of initiation of sexual intercourse. Individuals resort to a variety of interventions[29,30] in response to these beliefs, which at times may be more harmful than helpful.[31] Science students, with presumably better awareness, were found to have a lower prevalence of sexual misconceptions as compared to others. Unlike earlier reports, marriage did not seem to reduce the prevalence of misconceptions.

Sexual behavior

The average age for initiation of sexual intercourse was later for women than men, similar to earlier reports.[11] Women were more likely to be celibate than men, as

expected. The more restrictive the home environment was perceived to be, the higher the likelihood of having had sexual intercourse, suggesting that the sexual behavior is in defiance to the controlling atmosphere at home.

One-third of the respondents practiced masturbation, in contrast to previous reports where the prevalence was estimated to be around 80%.[18,32,33] The locally prevalent beliefs about the ill-effects of masturbation may be a deterrent to the practice.

The prevalence rates of homosexual behavior, homoerotic fantasies, and nonconsensual sexual behavior were slightly higher than reported previously.[15,32] About one-fourth of all respondents reported some form of deviant sexual behavior, with men reporting more of these than women, similar to earlier findings.[34] Public health initiatives to identify and deal with people with such behaviors are required in view of the high prevalence and the distress they cause to the victims and maybe the individuals themselves.

Importance of sexual surveys in the youth

Young people are unable to discuss their sexual concerns freely in India due to cultural taboo. Family members and healthcare practitioners focus on health and functioning, and sexual concerns are routinely avoided. There is a lack of political will for effective public health initiatives, which further worsens the situation. Thus, sexual worries remain unresolved, leading to distress, unsafe behaviors, psychiatric morbidity, and poor quality of life.

Strengths and limitations of the study

Few systematic surveys have assessed sexual knowledge, attitude, and behavioral patterns among college students in this part of India. The sample size obtained was sufficiently large to extrapolate the conclusions of the study to college students in the region. The questionnaire was designed to obtain adequate information without being too lengthy. Social desirability bias was addressed by keeping the survey anonymous.

However, given the sensitive nature of the topics explored, it is still possible that participants might have felt unable to express their views freely. There are no well-defined criteria or norms to determine normal sexuality and attitude toward it, as these are influenced by a complex interplay of individual and cultural expectations and can change over time. It is possible that use of open-ended questions may have yielded more information.

Recommendations and future directions for research

Further research is required to better understand the cultural aspects, beliefs, and practices regarding sexuality among the youth. A culturally sensitive approach is required to develop validated tools and appropriate sex education modules for India.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

The Effectiveness of a Brief Psychological Intervention for Patients with Diabetes-Related Distress

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ABSTRACT

Background: Diabetes-related distress (DRD) is the negative emotional and psychological reaction to living with diabetes mellitus (DM). DRD has been reported to affect glycemic control and self-management practices adversely. Limited research is available on the effectiveness of psychological interventions for DRD. We aimed to study the effectiveness of a brief psychological intervention for patients with DRD. **Methods:** The findings of a targeted brief psychological intervention conducted for patients with DRD, as a part of psycho-endocrinology liaison services in a general hospital, are reported. Details regarding the assessment and intervention given were collected from the patients' records. Forty-one patients with DRD diagnosed using Diabetes Distress Scale (DDS) were given the single session intervention consisting of brief diabetes education focusing on physical activity and medication adherence, relaxation techniques, and illness-specific problem-solving strategies. Effectiveness was assessed using change in Clinical Global Impression-Severity (CGI-S), patient-rated visual analog scale, brief physical activity questionnaire, and medication adherence at baseline and 2-month follow-up. **Results:** Analysis using Wilcoxon signed rank test found a significant change in the follow-up scores on all the assessment scales. **Conclusions:** The study highlights the benefits of brief intervention for reducing DRD, thus reducing the emotional burden of living with DM.

Key words: *Depression, diabetes mellitus, diabetes-related distress*

Key messages: *Single session intervention incorporating education regarding lifestyle changes, medication adherence, relaxation techniques and problem solving therapy was found to reduce diabetes-related distress and improve diabetes self-management practices.*

As per the International Diabetes Federation, diabetes mellitus (DM) affects more than 425 million people globally.[1] India currently has the second highest number of people with DM, which has affected more than 72 million people, making this a major

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public health challenge.[1] DM treatment includes diabetes self-management practices along with pharmacological management. It would result in the patient making major lifestyle modifications such as regular blood glucose monitoring, physical activity, dietary modifications, and medication adherence. This would have a major impact on daily functioning in general and can potentially pose an immense emotional burden on the patient, thereby increasing the risk of developing mental health issues like depression and diabetes-related distress (DRD). DRD is the negative emotional and psychological reaction specific to living with DM, including feeling overwhelmed by DM self-management practices and long-term medication, concerns of DM-related physical complications, and perceived lack of support from family members.[2] Depressive symptoms and DRD have been the most commonly reported psychiatric co-morbidities in DM and have been associated with poor glycemic control and impaired self-care practices.[3,4] The Diabetes Attitudes Wishes and Needs (DAWN2) study, which surveyed 8,596 DM patients across 17 countries, reported that psychological issues are a major source of distress for patients with DM, and DRD, reported by 44.6% of the patients, was found to be the most common concern.[5] There are also reports, both cross-sectional and follow-up, that DRD, rather than depression, affects outcomes in DM by affecting adherence and self-management practices.[6-8] However, the studies ascertaining the effect of mental health issues in DM have produced conflicting results with regards to their prevalence and actual effect on glycemic control, due to wide variations in study methodology.

Therapeutic strategies such as cognitive-behavior interventions, mindfulness-based therapies, and problem-solving strategies have been shown to improve diabetes self-management and mental health issues associated with DM. Most of the research has focused on depression in DM.[9,10] Research on intervention strategies for DRD has been limited. Problem-solving strategies have been reported to independently improve both diabetes self-management and DRD.[11,12] Research on the use and impact of these strategies to improve DRD in clinical settings is sparse. We aimed to study the effectiveness of a brief psychological intervention for patients with DRD as part of an interdisciplinary liaison-service between endocrinology and psychiatry departments. We hypothesized that the brief psychological intervention would improve illness severity and improve diabetes self-management practices on follow-up.

METHODS

The findings from a chart review of patients who received targeted brief psychological intervention conducted as a part of the psycho-endocrinology services in a tertiary care teaching hospital are reported here. As part of this service, DM patients receiving outpatient treatment in the department of endocrinology were referred to the psychiatry outpatient services by the treating endocrinologist when mental health concerns were suspected. A detailed assessment with a specific focus on mental health aspects of DM was done by the psychiatry team, including a psychiatry nurse, for such referred patients, and appropriate management plans were formulated. A brief psychological intervention was provided only to patients with DRD (N = 41) (without axis I psychiatric disorders). The details regarding the assessment and intervention were systematically recorded in the patient's clinical records. The collection of data from the patients' clinical records was done after the approval by the institutional ethics review board. This reporting of data of human subjects is in accordance with the latest amendment of the Declaration of Helsinki. Patients had consented verbally for the ratings to be done. Since the information is derived from the clinical records of the service, written informed consent is not available.

The patients were assessed with the following instruments as a part of the clinical service. MINI version 5.0 was used to rule out major axis I psychiatric disorders.[13] Diabetes Distress Scale (DDS), a 17-item, self-reported scale which measures DRD experienced over last month, was employed to detect DRD.[2] It is a Likert scale with the score of each item ranging from 1 to 6. It has four subdomains assessing emotional burden, regimen-related distress, physician-related distress, and interpersonal distress. Patients with a mean item score of ≥3, indicating moderate distress, were considered for the intervention.

Brief physical activity questionnaire is a two-item scale assessing moderate and vigorous physical activity.[14] A total score of ≥4 indicates that the patient is sufficiently active. Adherence to medication for the previous month was assessed using a Likert scale of 1-5, and a cutoff point of 3 was used to indicate good medication adherence.

The effectiveness of the intervention was assessed using the clinician-rated Clinical Global Impression-Severity (CGI-S). In addition, patient-rated visual analog scale (VAS) from 1 to 10 was used for subjective reporting of symptom severity by patients. CGI-S, VAS, brief physical activity questionnaire and adherence to medication was assessed at baseline and 2-month follow-up, by psychiatry nurse.

The DM patients receive diabetes education and dietary advice in the endocrinology department by diabetes

educators as part of routine clinical care. Patients who were diagnosed with DRD received a brief psychological intervention by a trained psychiatry nurse, consisting of brief diabetes education focusing on physical activity and medication adherence, relaxation techniques, and illness-specific problem-solving strategies. Feedback related to the specific DRD domain involved was given to the respective patients. Problem-solving strategies involved identifying the challenges faced in DM self-management and impact of DRD. It also included helping the patients to set realistic goals and to weigh the pros and cons of each and enabling them to develop a plan to improve DM self-management and distress. Brief psychological intervention was a single session of 45-60 minutes on the day of the referral. All the components of the intervention were used in all the patients.

RESULTS

Out of 41 patients in the sample, 25 were females (60.9%), 33 (80.5%) were married, and 19 (46.3%) had >10 years of formal education. The mean (±SD) age was 44.63 ± 14.76 years and the mean duration of illness 77.12 ± 60.72 months (median = 94 months; range = 0.16-192). The mean body mass index (BMI) was 25.34 ± 3.96 kg/m^2. The mean DDS total score was 2.40 ± 0.56 (median = 2.35; range = 1-4.30). Among the various sub-domains of the DDS, emotional burden was present in 29 patients (mean score = 3.49 ± 1.14), regimen-related distress was present in 16 patients (mean score = 2.67 ± 1.04), interpersonal distress was present in 10 patients (mean score = 1.90 ± 1.27), and physician-related distress was present in 2 patients (mean score = 1.29 ± 0.59). Fifteen of the patients were on oral hypoglycemic medications, 19 were on insulin injections, and seven were on a combination of the two.

Table 1 shows the baseline and 2-month follow-up score of CGI-S and VAS. The baseline and follow-up scores of brief physical activity questionnaire and medication adherence Likert score were available for 35 patients.

DISCUSSION

The results suggest that brief psychological intervention in a clinic-based population was effective in improving psychological distress of patients with DRD. The intervention also succeeded in improving DM self-management practices like physical activity and medication adherence which were examined in a subset of the sample.

The key components of the brief psychological intervention chosen for this study were illness-specific problem-solving strategies and relaxation techniques. There is emerging evidence that problem-solving therapy can benefit patients having DRD and impaired DM self-management practices.[11,12] Patients with good problem-solving skills have been found to have better DM self-management practices.[15] Problem-solving-based self-management training for DM has been found to be feasible and beneficial even when adapted for socially disadvantaged patient populations having lower literacy rates.[16] It thus gives this therapy technique a greater clinical utility in a clinic-based population as shown by the results of this study.

Relaxation techniques like breathing practices have been known to be effective in reducing stress and mood and anxiety symptoms.[17,18] It has also been found to be beneficial in reducing stress in medical disorders such as hypertension, cardiovascular conditions, and cancer.[19] Deep breathing techniques have been shown to improve cardiac autonomic modulation, which is usually impaired in DM patients.[20,21]

The most common DDS sub-domain in our study population was related to the emotional burden of living with DM. Hence, the effectiveness of an intervention involving deep breathing and illness-based problem solving further adds to the existing literature on the benefits of these strategies in reducing the distress in the population having a high frequency of emotional burden. In addition, the intervention was also shown to significantly improve DM self-management practices such as physical activity and medication adherence. There is sparse literature regarding interventions for DRD done in clinical settings. This study from a clinic setting demonstrates the effectiveness of brief psychological intervention for DRD as part of routine patient care. Single session therapies will have greater utility in resource-constrained settings such as those in India where the population of patients attending the clinical

Table 1: The baseline and two months follow up scores of distress severity and other measures

Scale	Baseline score	Follow-up score	Wilcoxon signed rank test
CGI-S (*n*=41)	4.76±0.99	2.49±1.23	*Z*=−5.43 (*P*<0.001)
VAS (*n*=41)	7.76±1.16	3.54±2.16	*Z*=−5.47 (*P*<0.001)
Brief physical activity questionnaire (*n*=35)	2.60±2.72	4.71±2.92	*Z*=−3.21 (*P*=0.001)
Medication adherence (*n*=35)	4.28±1.15	4.89±0.53	*Z*=−2.47 (*P*=0.014)

CGI-S–Clinical Global Impression-Severity; VAS–Visual analogue scale

services is large. The study highlights the need for management of mental health issues in DM patients, an oft-neglected area in routine DM management.

The major limitation of our study is that it is based on the clinical records of a liaison service. The follow-up data for medication adherence and brief physical activity questionnaire was available only for 35 patients. The absence of a control arm without the intervention is a limitation. However, this report provides real-world data examining the "effectiveness" of such an intervention. A systematic prospective study including a control group would have been superior. Since the study was conducted in a tertiary hospital-based setting, its utility in general community settings is difficult to comment at present. Even though DDS was employed to detect DRD at the baseline, we have not used it during the follow-up assessment. This would have helped in understanding the improvement in specific symptom domains. CGI-S and VAS were easy to administer in a busy clinic-based setting. Since both these scales were used, it was possible to ascertain the clinician's judgment of severity and the patients' subjective report of severity at the baseline and follow-up.

The brief nature of this intervention makes it an effective tool for clinical practice in busy settings involving a large number of patients. Since the intervention was done by a trained psychiatry nurse, this can be generalized to resource-constrained settings. In conclusion, there is a definite need to address DRD in routine clinical settings. Systematically conducted controlled studies are required to test the efficacy of a brief intervention for DRD. The mental health needs of DM patients are often not addressed. A systematic inter-disciplinary liaison service will further enable in early detection and treatment of mental health comorbidities which can ultimately improve DM treatment outcomes. Furthermore, this will enable in providing more comprehensive treatment for DM patients.

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There are no conflicts of interest.

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Original Article

Correlation of Cognitive Resilience, Cognitive Flexibility and Impulsivity in Attempted Suicide

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ABSTRACT

Context: Impaired cognitive flexibility and resilience and increased impulsivity are presumed to underlie an attempt of suicide. There is, however, a paucity of research examining their relationship in those who attempted suicide. **Aims:** To know the correlation of cognitive flexibility and resilience and impulsivity in attempted suicide. **Materials and Methods:** Two hundred seventy subjects with suicide attempt (s) were assessed with sociodemographic and clinical proforma, cognitive flexibility scale (CFS), cognitive resilience scale (CRS), and Barratt impulsiveness scale (BIS-15). **Statistical Analysis Used:** Descriptive statistics, linear regression model. **Results:** Mean scores on CFS, CRS, and BIS-15 were 44.93 (SD ± 2.50), 4.49 (SD ± 0.25), and 36.13(SD ± 2.13), respectively. On linear regression analysis, BIS-15 nonplanning had statistically significant negative correlation with CFS and CRS scores, and BIS-15 attention had a positive correlation with CFS and CRS scores. CFS and CRS scores were positively correlated. **Conclusions:** In attempted suicide, cognitive flexibility and resilience are interrelated positively and inversely associated with impulsivity (nonplanning and inattention).

Key words: *Attempted suicide, cognitive flexibility, cognitive resilience, impulsivity*

Key messages: *High levels of cognitive flexibility, cognitive resilience and impulsivity are present in attempted suicide. Cognitive flexibility and resilience are not protective in the presence of high impulsivity.*

Resilience is a trajectory that starts from the presence of significant risk or adversity to the achievement of positive adaptation or outcomes[1] or demonstration of a relatively good outcome, given exposure to adverse circumstances.[2] Research on resilience has received increased interest over the years, particularly among those involved with policy and practice in relation to its potential impact on health, well-being, and quality of life. This inclination is because of moving away from "deficit" models of illness to understanding healthy development, despite the risk and focusing on strengths rather than weaknesses.[3] Literature reveals that about 25-84% of the general population is reasonably resilient.[4]

Cognitive resilience is the capacity to overcome the negative effects of setbacks and associated stress on cognitive function or performance.[5] Recently, this

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has been a topic of interest for psychological research. Previous studies have used this term in reference to aging and related disorders, cognitive functions,[6] or genetic risk.[7] So far, no study has examined cognitive resilience in attempted suicide, although, resilience, in general, seems to play a mitigating role in the ideation of suicide in depressive and anxious individuals.[8] Indirect evidence suggests impaired cognitive resilience in attempted suicide.[9]

Cognitive flexibility is the ability to adapt the cognitive processing strategies to face new and unexpected conditions in the environment.[10] It is the awareness of other alternatives and options in a situation, willingness to be flexible and to adapt to a situation, and the belief that one has the ability to be flexible.[11] In other words, cognitive flexibility is the ability to switch cognitive sets to adapt to changing environmental stimuli. Cognitive flexibility is positively correlated with problem-solving skills, coping with problem-solving oriented stress, and decision-making;[12] these are impaired in patients with suicidality.[13,14] Cognitive inflexibility enhances vulnerability to suicidal thinking by mediating greater brooding rumination and hopelessness.[15,16] Indirect evidence suggests a lower level of cognitive flexibility among nonwestern population.[17]

Impulsivity comprises of a wide range of actions that are poorly conceived, prematurely expressed, unduly risky, or inappropriate to the situation and those that often result in undesirable outcomes,[18] such as swift action without forethought or conscious judgment, behavior without adequate thought, and the tendency to act with less forethought than most individuals of equal ability and knowledge.[19] The ability to control our impulses is fundamental to day-to-day social functioning, and impairment predisposes to untoward events.[20] A significant proportion of suicides and attempted suicides are committed impulsively.[21,22] Elevated impulsivity facilitates the transition from suicidal thoughts to suicidal behavior[23] and interventions aimed to address impulsivity may reduce further attempts of suicide.[24] There is a paucity of research on impulsivity in suicide in India. Only one research by Menon *et al*, revealed a positive association of impulsivity and severity of intent in attempted suicide.[25] However, the study included subjects with parasuicide, diluting the accuracy of inferences to be made out of the findings.

The relationship between impulsivity, cognitive flexibility, and resilience is unknown. Impulsivity affects executive functions and hence may influence cognitive flexibility.[26] Indirect evidence suggests a positive association of low impulsivity (attentional performance) and cognitive flexibility,[27,28] whereas inflexibility may enhance impulsivity.[12,15,16,29] A similar trend seems to be true for cognitive resilience as well.[9,30-32] However, resilience appears to have a reciprocal relationship with flexibility.[12,33] There is a dearth of research and a knowledge gap as to how these variables are related. This understanding may help to formulate management and preventive interventions and aid further research, especially as suicide is a global concern.

Keeping in view of the paucity of research in this area, and with the above background, this study was conducted to know the correlation between impulsivity, cognitive flexibility, and resilience among patients with attempted suicide, with the hypothesis that cognitive resilience and cognitive flexibility are positively interrelated and negatively related to impulsivity.

MATERIALS AND METHODS

This hospital-based cross-sectional study was conducted at the outpatient department of psychiatry in Jagadguru Sri Shivarathreeswara Medical College Hospital after approval from the institutional ethics committee. The department conducts a suicide prevention program, and patients are referred from medical and surgical departments for intervention after recovery from an attempted suicide. Participants were recruited while attending department of psychiatry, by purposive sampling method, after obtaining informed consent. Out of 311 patients screened, 270 met selection criteria. Inclusion criteria were a history of suicide attempt within 1 month, aged 18-65 years, of either gender. A suicide attempt was defined for our study as "self-inflicted, potentially injurious behavior with a nonfatal outcome for which there is evidence of intent to die".[34] Participants were excluded if they were unable to provide the required information; had intellectual disability, terminal illness, or dementia; or if psychotic symptoms were present. All participants underwent psychiatric and medical evaluations by a psychiatrist and a physician, respectively. The participants were further evaluated with the assessment tools in the following order:

1. Sociodemographic and clinical proforma- This proforma covered age, gender, marital status, occupation, religion, socioeconomic status, residence, the method of suicide attempt, and family history of suicide
2. Cognitive flexibility scale (CFS)- The scale was developed by Martin and Rubin in 1995 to assess cognitive flexibility.[11] The CFS is a 12-item self-report scale that measures aspects of cognitive flexibility considered relevant for effective interactions and communication on a 6-point Likert scale (strongly disagree to strongly agree). Each item on the scale consists of a statement dealing with beliefs and feelings about behavior. The CFS

had high-internal consistency (α = 0.76-0.77), good concurrent and construct validity, and high-test--retest reliability (r = 0.83) over 2 weeks.[11] The scale has been used in the Indian population previously.[35] Kannada translated and validated version of the scale was used for this study

3. Cognitive resilience scale (CRS)- This scale was developed by Smith MA in 2015.[36,37] Items of the scale are statements dealing with beliefs and feelings about behavior. This 10-item scale has five possible response ranging from strongly disagree = 1 to strongly agree = 5. To avoid a response bias, reverse scoring is done for item 2, 4, 5, 6, and 8. The score is obtained by adding up all 10 item scores, divided by 10. A higher score indicates better resilience. This scale predicts optimism about the future, life-goal tracking, satisfaction with productivity and effectiveness, and living according to core values. This self-administered scale can be administered in less than 10 min and has acceptable reliability and validity. In this study, Kannada translated and validated version of the scale was used
4. Barratt impulsiveness scale (BIS-15) - The BIS-15 was first developed by Spinella (2007) and is available in many languages, including Indian languages.[38] Items are scored on a 4-point scale from rarely/never, occasionally, often, and always/almost always. Some of the items are reverse scored to avoid response bias. The BIS-15 items score ranges from 1-4. Item numbers 1, 4,5,7, 8, and 15 are scored reverse. The scale can be administered in 10 min. The scale has three domains namely attention, motor, and nonplanning. Internal consistency was 0.793, and test-retest reliability was 0.80. This scale has been used in Indian population.[39,40] For this particular study, Kannada translated and validated version of the scale was used.

Data was analyzed using SPSS version 22. Descriptive statistics was used to describe sociodemographic and clinical characteristics. Assessment of the association of impulsivity with cognitive flexibility and cognitive resilience was done using linear regression model. Statistical significance for all tests was $P = 0.05$.

RESULTS

The majority were male, married, educated (nongraduate), Hindus, of low socioeconomic status, from a rural background, and without a family history of suicide or current psychiatric diagnosis [Table 1]. Mean of age, CFS score, CRS Score, and BIS-15 score were 41, 44.93, 4.49, and 36, respectively [Table 1].

On multiple linear regression analysis ($R^2 = 0.102$, df = 3, F = 10.120, $P = 0.001$), when CRS score was the dependent variable and subscales of BIS were the independent variables, 10% of the variance in the score of CRS was accounted for by subscales of BIS, with regression parameters to be 10. CRS score had a statistically significant association

Table 1: Sociodemographic and clinical feature

Variables	Frequency	Percent
Gender		
Male	187	69.3
Female	83	30.7
Marital status		
Single	77	28.5
Married	193	71.5
Education		
Uneducated	69	25.4
Primary	57	21.1
Middle	43	16.0
High school	59	21.9
Higher secondary	28	10.4
Graduate	14	5.2
Occupation		
Skilled	16	5.9
Semiskilled	108	40.0
Non-skilled	122	45.2
Unemployed	24	8.9
Religion		
Hindu	242	89.6
Non-Hindu	28	10.4
Residence		
Rural	217	80.4
Urban	53	19.6
Socioeconomic status		
Low	235	87.0
Middle	35	13.0
Method		
Organophosphorous compound	181	67.0
Aluminium phosphide	37	13.7
Potassium nitrate	14	5.2
Hanging	16	5.9
Phenyl	2	0.7
Medication overdose	20	7.4
Family History of suicide		
No	240	88.9
Yes	30	11.1
Psychiatric diagnosis		
No	253	93.7
Yes	17	6.3
	Mean	**Std. Deviation**
Age	41.41	16.70
CFS[1] score	44.93	2.50
CRS[2] score	4.49	0.25
BIS[3] score	36.13	2.13
BIS- non-planning	12.75	0.96
BIS- motor	10.82	0.69
BIS- attention	12.55	1.10

1 – Cognitive Flexibility Scale, 2 – Cognitive Resilience Scale, 3 – Barratt Impulsiveness Scale

with BIS-15-nonplanning (β = −0.23, t = −3.61, *P* = 009) and BIS-15-attention (β =0.30, t = 4.36, *P* = 001) [Table 2].

On multiple linear regression analysis (R^2 = 0.102, df = 3, F = 10.120, *P* = 0.001), when CFS score was the dependent variable and subscales of BIS were the independent variables, 10% of the variance in the score of CRS was accounted for by subscales of BIS, with regression parameters to be 10. CFS score had a statistically significant association with BIS-15-nonplanning (β = −0.23, t = −3.61, *P* = 001) and BIS-15-attention (β =0.30, t = 4.36, *P* = 001) [Table 3].

In linear regression analysis (R^2 = 1.000, df = 1, F = 5.029, *P* = 001), the score on CRS was entered as the dependent variable and CFS score was the independent variable. The variance (10%) in the score of CRS was accounted for by CFS score, with all regression parameters to be 5. There was a statistically significant positive association between CRS and CFS scores (β = 1.000, t = 2.24, *P* = 001) [Table 4].

Table 2: Relationships of BI and CR

	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	4.09	0.26		15.31	0.001
BIS -nonplanning	−0.06	0.017	−0.23	−3.61	0.001
BIS-motor	0.02	0.023	0.08	1.25	0.211
BIS-attention	0.06	0.016	0.30	4.36	0.001

Dependent Variable: CRS score; R^2=0.102, df=3, F=10.120, *P*=0.001 (BIS – Barratt Impulsiveness Scale), BI – Barratt impulsiveness; CR – Cognitive resilience

Table 3: Relationships of BI and CFS

	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	40.91	2.67		15.31	0.001
BIS -nonplanning	−0.60	0.16	−0.23	−3.61	0.001
BIS-motor	0.29	0.23	0.08	1.25	0.211
BIS-attention	0.68	0.15	0.30	4.36	0.001

Dependent Variable: CFS score; R^2=0.102, df=3, F=10.120, *P*=0.001 (BIS–Barratt Impulsiveness Scale, CF–Cognitive Flexibility), BI – Barratt impulsiveness

Table 4: Relationships between cognitive flexibility and cognitive resilience

	Unstandardized Coefficients		Standardised Coefficients	T	Sig.
	B	Std. Error	Beta		
(Constant)	1.15	0		0	1.000
CFS Score	0.100	0	1.000	2.24	0.001

Dependent Variable: CRS score; R^2=1.000, df=1, F=5.029, *P*=0.001 (CFS–Cognitive Flexibility Scale)

DISCUSSION

This study aimed to examine the correlation between cognitive resilience, flexibility, and impulsivity. Elevated impulsivity and impaired cognitive function have been reported in attempted suicide.[13,15,16,41] Although positive association of impaired cognitive flexibility and severity of illness has been reported in gambling and obsessive compulsive disorder, there is hardly any literature on the relationship of impulsivity with cognitive flexibility and cognitive resilience among those with attempted suicide, and to the best of our knowledge, this is the first study to examine the relationships between these variables.[42,43]

In this study, the nonplanning domain of impulsivity was negatively, and attention was positively, associated with cognitive flexibility. This was statistically significant. There appears to be a close but negative association between cognitive inflexibility and impulsivity. Impulsivity may directly or indirectly hamper executive functions that determine cognitive flexibility.[26] Moore and Malinowski reported a positive association of attentional performance and cognitive flexibility in the general population.[27] Loyo *et al.* found a problem in inhibitory control in social contexts, together with subtle alterations in executive functions, in patients with suicidal tendency.[28] Presence of cognitive inflexibility may mediate suicidal ideation, increased brooding rumination, and hopelessness.[15,16] This may further enhance impulsivity.[29] Similarly, impaired cognitive flexibility may adversely affect problem-solving skills, coping with stress, and decision-making, and may augment impulsivity.[12]

Another finding of this study was a statistically significant negative association of impulsivity with cognitive resilience. Impulsivity is reported to be inversely relate with resilience in general population.[30] Similarly, attention impulsivity and nonplanning impulsivity have been reported with low levels of resilience in bipolar disorder,[31] but no literature is available comparing these variables in attempted suicide. Indirect evidence suggests an impaired cognitive resilience in attempted suicide.[9,32] Since impulsivity adversely affects the factors contributing to resilience such as cognitive appraisal, locus of control, perception of predictability, and control, it can be stipulated that resilience is directly or indirectly impeded by impulsivity.[5]

We found an absolute correlation between cognitive flexibility and cognitive resilience. There appears to be a reciprocal relationship between these variables. Cognitive flexibility positively mediates nonaggressiveness

and tolerance, belief in social self-efficacy and problem-solving skills, coping with problem-solving oriented stress, and decision-making, and hence strengthens cognitive resilience.[12] On the other hand, resilient individuals are able to spontaneously generate new strategies in-action that support response to regular disturbances and potentiate cognitive flexibility.[33] We observed high scores on CFS (mean = 44.93 ± 2.54) and CRS (mean = 4.49 ± 0.25). Absolute correlation between variables is uncommon. It suggests that an increase of one standard deviation in the corresponding independent variable entails an increase of one or more than one standard deviation in the dependent variable. It can occur legitimately (though it poses a problem in interpretation) if there is a very high R^2 or very low standard error, particularly when predictor variable is single and is highly interdependent or correlated.[44]

It is of interest that in attempted suicide (as observed in this study), high resilience and flexibility appear to be nonprotective. It may be likely that impulsivity (as observed in this study, BIS-15 mean score = 36.13 ± 2.13) may have played a bigger role. There is an indication that impulsivity adversely affects resilience and flexibility (e.g., self-regulatory deficits, decision-making impairments).[30,45] On the other hand, there is indirect evidence that lack of flexibility (e.g., premeditation) and resilience (e.g., negative urgency, cognitive appraisal) are potential risk factors for suicidal behavior.[16,46] Thus, impulsivity may take a leading role and nullify the protective effects of resilience and flexibility.

It may be concluded that in attempted suicide, cognitive flexibility and resilience are positively interrelated and inversely associated with impulsivity (nonplanning and inattention). The findings imply that cognitive resilience, flexibility, and impulsivity should be assessed in attempted suicide and addressed appropriately. The findings of this study should be cautiously interpreted as study population were hospital- patients, and the study had a cross-sectional design and had no control group. Further research is needed to address these limitations to make the findings applicable to the general population.

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Original Article

Deficits in Theory of Mind and Emotional Awareness in Somatoform Disorders

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ABSTRACT

Introduction: Emotions develop from a less differentiated to a highly differentiated level, and their arrest at a lower level is hypothesized to result in somatization. The present study aimed at investigating the Theory of Mind and emotional awareness in patients with somatoform disorders. **Materials and Methods:** Twenty patients with somatoform disorders, along with 20 healthy controls matched for age, sex, and education, were recruited after obtaining informed consent. Assessments included semi-structured proforma for sociodemographic and clinical details; Scale for Assessment of Somatic Symptoms (SASS) for somatic symptoms; and Patients Health Questionnaire (PHQ) to assess somatic symptoms, depression, and anxiety. Emotional awareness was measured using the Levels of Emotional Awareness Scale (LEAS), in which the participants had to provide descriptions of feelings of self and the other person in 20 imaginary situations. The responses were scored using a standardized manual. The Theory of Mind was measured using the Social Cognition Rating Tool in Indian Settings (SOCRATIS). **Results:** The two groups did not differ on any demographic parameters. Patients with somatoform disorders scored significantly lower on emotional awareness (t = -3.74; $P < 0.001$) and the Theory of Mind (t = -3.56; $P < 0.001$). The above differences remained significant even after controlling for comorbid depressive and anxiety symptoms. **Conclusion:** Patients with somatoform disorders are likely to have Theory of Mind and emotional awareness deficits independent of mood states. Future studies are needed to assess whether these deficits are trait- or state-dependent and whether they are cause or effect.

Key words: *Emotional awareness, somatization, somatoform disorder, Theory of Mind*

Key messages: *Patients with somatoform disorders are more likely to have emotion awareness deficits. These deficits seem to be independent of the mood states.*

Somatoform disorders are common psychiatric disorders characterized by distressing, persistent, medically unexplained physical symptoms. The disability caused by them is comparable to that caused by major depression or anxiety disorders.[1,2] The ability to identify and represent different emotions has been a subject of investigation in somatoform disorders in the last few years. One of the best known theories was described by Sifneos who described "alexithymia" as an inability to perceive and describe emotions

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sufficiently.[3] Alexithymia interferes with a person's ability to deal with emotionally related mental contents and interaction with others.[4] People with alexithymia have a decreased ability to engage in abstract thinking, to elaborate their emotions, and to appreciate the possibility of psychological attribution of their physical symptoms, which might result in somatization.[5] However, various measures of alexithymia were noted to be affected by negative affects like anxiety and depression, which are the most common comorbidities with somatoform disorders.[6,7] In addition, there was a very little correlation between different measures of alexithymia, sharing only 2–9% of their variances.[8] This led to the formulation of a new theory: emotional awareness.

Emotional awareness is defined as the ability to describe one's own feelings and to evaluate the feelings of others.[9] Emotional awareness was postulated to develop from a less-differentiated level of experiencing emotions as physical sensations to a more differentiated state where one has the ability to perceive greatly differentiated emotions of others while remaining unbiased by one's own emotional state. Hence, emotional awareness is able to better describe and quantify the deficits, namely ability to elaborate emotions, appreciate other's emotions as opposed to alexithymia, while remaining unaffected by negative affect.[9]

The Theory of Mind (ToM) concept is described as the ability to infer the mental states of others and the ability to determine one's actions.[10] The above is also known as the cognitive ToM, to differentiate it from the affective ToM, which was used to describe the ability to infer the feeling of others.[11] ToM deficits have been noted in multiple disorders like autism, schizophrenia, and borderline personality disorder. Patients with the above disorders have also been found to have high alexithymia scores.[12–17] Hence, it appears that those with alexithymia probably have a difficulty in understanding one's as well as others' thoughts/feelings, which would result in maladaptive ways of regulating emotions.

Studies which looked into emotional awareness, alexithymia, and ToM in patients with functional disorders have provided varied results. Studies carried out with three comparison groups, namely conversion disorders (n = 29), functional somatic syndromes (n = 30), and medically explained disorders (n = 30), without any matching, did not find any significant difference between the groups in terms of emotional awareness or cognitive ToM.[18,19] In studies which had age-, sex-, and education-matched healthy controls (n = 30), there were significant deficits among patients with somatoform disorders (n = 30) with regard to emotional awareness, cognitive ToM, and affective ToM.[20,21]

Cultural factors are known to play a role in the degree of alexithymia and the prevalence of medically unexplained physical symptoms.[22–26] Similarly, ToM and emotion recognition are also influenced by one's culture.[27–29] The current study sought to extend the previous findings by using culturally validated tools to examine emotional awareness and ToM in patients with somatoform disorders. We hypothesized that patients with somatoform disorders would have deficits in emotional awareness and ToM compared to healthy controls.

MATERIALS AND METHODS

Subjects

Twenty patients with a clinical diagnosis of somatoform disorders as per the ICD-10 were recruited from the outpatient services of a tertiary psychiatry center, National Institute of Mental Health and NeuroSciences (NIMHANS) in Bangalore after obtaining informed consent. The inclusion criteria were: age between 18 and 60 years, able to read and write English or Hindi, and providing informed consent. The exclusion criteria included comorbid substance abuse or dependence within the past 6 months, history of cognitive impairment, and a current diagnosis or past history of psychosis. The selection was done on the basis of convenience sampling.

Twenty healthy controls were recruited from attenders of patients coming to NIMHANS, friends of the researchers, and the hospital staff. They were matched for age (±5 years), gender, and educational level. Subjects were included after obtaining informed consent and following inclusion criteria: age between 18 and 60 years, no identifiable Axis I diagnosis (ruled out through a clinical interview by the investigator), and no family history of psychosis in first degree relatives.

The sample size was estimated, based on a previous study,[20] to be 30 in each group. However, only 20 in each group could be recruited in the duration of the study.

Assessment of psychiatric symptoms and disease parameters

Patient Health Questionnaire-Somatic, Anxiety and Depressive Symptom (PHQ-SADS) was used in both the groups to screen for somatoform, anxiety, and depressive disorders and to assess the severity of somatoform disorders, anxiety, and depression. It is a self-report questionnaire comprising of the following modules:

PHQ-15 somatic symptom scale, PHQ-9 depression scale, and Generalized Anxiety Disorder (GAD-7) anxiety scale. It was designed primarily due to the frequent overlap of depressive, anxiety, and somatic symptoms in the patient population.[30] Scale for Assessment of Somatic Symptoms (SASS) was used to measure the somatic symptoms and their severity in the somatoform group.[31] Hindi Mental State Examination (HMSE), an adaptation of MMSE (Mini Mental State Examination), was used to rule out any cognitive deficits in the study subjects.[32]

Outcome measures

Levels of Emotional Awareness Scale

Levels of Emotional Awareness Scale (LEAS) consists of 20 scenarios involving two people: self and the other. Subject has to answer, "How would you feel?" and "How would the other person feel?" Each of the scenarios receives a score of 0–5, depending on the degree of differentiation in using emotional words and differentiating self-emotions from others. A glossary of words was created to ensure uniformity in scoring.[33] The vignettes try to evoke four basic emotions, namely anger, fear, sadness, and happiness. Some scenarios provide an opportunity for ambivalence regarding emotions in self and other.[33] LEAS appears to be more specific in measuring a change in emotional awareness, unlike Toronto Alexithymia Scale (TAS-20) which is affected by negative affect.[34] The scale has high internal consistency, inter-rater reliability, and test–retest reliability. Internal consistency reliability ranges from a coefficient alpha of 0.75–0.88, and inter-rater reliability ranges from 0.81–0.99.[35] The scenarios in LEAS need to be modified to accommodate cultural differences, as responses can be influenced by the cultural regulation of affect.[36] Hence, the scale was applied to all the study subjects after adapting it to the Indian settings.

ToM scores

Social Cognition Rating Tool in Indian Settings (SOCRATIS) has been validated in the Indian sociocultural context to assess social cognition in patients with schizophrenia. Only the ToM domain was used in the current study. These tests had good content validity, discriminant validity, and known groups validity.[37] ToM was assessed at three levels (first order, second order, and higher order) using false-belief stories/tasks adapted to the Indian context. The list of tasks used was:

1. First-order ToM – Shanti–Ravi story
2. Second-order ToM – Ice cream man story
3. Two metaphor-irony comprehension stories
4. Faux-pas recognition stories (two faux pas and three non-faux pas control stories).

The proportion of correct responses (range 0–1), calculated from the ToM stories and metaphor-irony comprehension stories, were averaged to calculate a ToM index (ToMI). Faux pas composite index (FPCI; range 0–1) was calculated based on the subject's ability to correctly identify situations with and without social blunders, and correctly answer the clarifying questions.[37] A combined index called the ToM Composite score (ToMCI), that gave equal weightage to scores on ToM tasks and faux-pas recognition stories, were calculated as an average of ToMI and FPCI.

Procedure

The study was carried out after obtaining ethical clearance from the Institutional Ethics Committee. A qualified psychiatrist assessed the patient for overall psychiatric morbidity, and patients with somatoform disorders were screened by the primary investigator for the study. The 20 scenarios of LEAS were modified to adapt them to the Indian settings, and expert validation was carried out with the help of six experts from the Departments of Psychiatry and Clinical Psychology. In the modified version, 9 scenarios were the same as the original LEAS, 10 scenarios had minor modifications, and 1 scenario had a major revision in accordance with cultural norms. Subsequently, modified scenarios and glossary of words were translated to Hindi using standard procedures for translation as per the World Health Organization.[38]

(The modified scenarios will be available on request from the authors). LEAS was scored according to the instructions from the manual and using the glossary of words which were translated for Hindi speaking subjects.[35] ToM was administered with the help of a software which displayed the scenarios and recorded the responses of the study participants.

Statistics

Data were expressed using descriptive statistic: mean and standard deviation (SD) for continuous variables, and frequency and percentage for categorical variables. Chi-square test and independent *t*-test were used to compare the group differences between the various measures. Analysis of covariance (ANCOVA) was done to compare the group differences between various measures after controlling for depression and anxiety. Correlations between ToMCI, LEAS, and somatoform symptom severity (PHQ-15 somatic symptom scale) were assessed using the Pearson's product moment correlation coefficient.

RESULTS

The mean age (±SD) was 36.5 ± 9.3 years for patients with somatoform disorders and 36.7 ± 9.9 years for

healthy controls. The mean duration of education was 9.1 ± 4.9 years in patients with somatoform disorders and 11.2 ± 5.3 years in healthy controls. There were 10 women each in the patient and control groups. There was no statistically significant difference between patients and healthy controls in terms of age, gender, education, marital status, background, or socioeconomic status [Table 1].

The mean duration of illness in patients with somatoform disorders was 9.9 ± 7.6 years. The mean total score on SASS was 18.4 ± 5.3. The mean scores on PHQ-15, GAD-7, and PHQ-9 in patients with somatoform disorders were 8.8 ± 1.9, 5.4 ± 3.2, and 4.8 ± 2.4, respectively, which was significantly higher from those of healthy controls [Table 2]. The most common subtype was the undifferentiated somatoform disorder (n = 12 of the somatoform group) followed by persistent somatoform pain disorder (n = 6 of the somatoform group). Three subjects in the patients group had hypertension and one had diabetes mellitus.

LEAS scores

As hypothesized, patients with somatoform disorders had significantly lower scores on the LEAS than the healthy controls, with a large effect size (Cohen's d = 1.2, $P < 0.001$) [Table 3].

ToM scores

The ToMCI was found to be significantly lower in patients with somatoform disorders compared to healthy controls. The effect size of the difference was 1.1 [Table 3].

Patients had significantly higher scores of depression and anxiety as measured by PHQ-9 and GAD-7, respectively [Table 2]. ANCOVA was conducted to test whether the above differences between the groups remained significant after controlling for depression and anxiety. The group differences in the LEAS scores remained significant after controlling for GAD-7 [F (1, 37) = 21.5, $P < 0.001$] and PHQ-9 [F (1, 37) = 1 2.1, $P < 0.001$]. The group differences in ToMCI scores also remained significant after controlling for GAD-7 [F (1, 37) = 17.5, $P < 0.001$] and PHQ-9 [F (1, 37) = 18.5, $P < 0.001$] [Table 4].

When only the patients were included, LEAS (r = 0.2, P = 0.3) or ToMCI (r = 0.2, P = 0.3) did not statistically correlate with PHQ-15. Similarly, when the healthy controls were analyzed separately, LEAS (r = −0.03, P = 0.8) or ToMCI (r = −0.2, P = 0.3) did not correlate with PHQ-15. When PHQ-15 scores were considered for the entire group (n = 40), LEAS (r = −0.4, P = 0.008) and ToMCI (r = −0.4, P =0.006) correlated negatively with severity of somatoform disorder as measured by PHQ-15. As hypothesized, LEAS also correlated positively with ToMCI (r = 0.5, $P < 0.001$).

DISCUSSION

The primary aim of the study was to assess the ToM and emotional awareness in patients with somatoform disorders, using culturally validated tools.

This study showed the presence of significant emotional awareness deficits in patients with somatoform disorders compared to healthy controls, and thus, replicates the findings from previous studies that had effect sizes (Cohen's d) ranging from 0.53–0.95.[20,21]

This study also showed the presence of significant deficits in ToM in patients with somatoform disorders. The ToM domains of SOCRATIS measures predominantly cognitive ToM than the affective ToM. The deficits in cognitive ToM in patients with somatoform disorders, compared to healthy controls, have been noted previously in two studies where it was assessed using the Frith-Happé animation task.[20,21] However, cognitive ToM measured using the Mental State Stories (MSS) and Frith-Happé animation task was not statistically different between patients with somatoform disorders and medical controls. The affective ToM, measured using the emotional content of animation tasks, has been found to be deficient in patients with somatoform disorders compared to healthy[20] as well as medical controls.[18] However, affective ToM, measured using the Reading the Mind

Table 1: Sociodemographic details of patients with somatoform disorders and healthy controls

Variables		Somatoform disorder (n=20)	Healthy controls (n=20)	t/χ^2	P
Age (in years)	Mean	36.7	36.7	0.02	0.98
	Standard deviation	9.3	9.9		
Education (in years)	Mean	9.1	11.2	−1.3	0.18
	Standard deviation	4.9	5.3		
Females	n (%)	10 (50)	10 (50)	0	1
Married	n (%)	14 (70)	13 (65)	0.12	0.73
Below poverty line	n (%)	13 (65)	7 (35)	3.6	0.06
Urban background	n (%)	15 (75)	13 (65)	0.47	0.49

in the Eyes Test, was found to be not different between patients with somatoform disorders and medical controls.[18,19] The reasons for the disparity in the results could be due to the difference in tools used to measure ToM, the sensitivity of tools in detecting subtle deficits, the severity of somatoform disorder, as well as a tendency to over-mentalize and type of controls used. For instance, Frith-Happé animation task is more sensitive in detecting mentalizing deficits, compared to false-belief tasks used in the SOCRATIS.[39]

Together, the above findings suggest that patients with somatoform disorders have difficulty in inferring mental/emotional states of others as well as themselves. This deficit might result in experiencing implicit manifestations of emotional arousal, characterized by physiological and behavioral components, rather than a conscious experience of the emotion itself. Further, this may exacerbate interpersonal difficulties which are commonly found in patients with somatoform disorders.[40] The interpersonal difficulties, in turn, might contribute to the maintenance of somatic distress.

Comorbid depression and anxiety are common in somatoform disorders.[6] Hence, we tried to investigate the effects of depression and anxiety on the deficits in ToM and emotional awareness in somatoform disorders. In our study, the group difference in ToM and LEAS persisted even after controlling for comorbid depression and anxiety symptoms.

Table 2: PHQ-15, GAD-7, and PHQ-9 scores in patients with somatoform disorders and healthy controls

	Somatoform disorder (n=20)		Healthy controls (n=20)		t	P
	Mean	SD	Mean	SD		
PHQ-15	8.8	1.9	1.9	1.2	12.9	<0.001
GAD-7	5.4	3.2	1.3	1.2	5.4	<0.001
PHQ-9	4.8	2.4	1.4	1.5	5.2	<0.001

PHQ – Patient health questionnaire; GAD – Generalized anxiety disorder

Table 3: LEAS and ToMCI scores in patients with somatoform disorders and healthy controls

	Cases		Healthy controls		t	P	Cohen's d
	Mean	SD	Mean	SD			
LEAS	43.9	10.3	54.5	7.2	−3.7	<0.001	1.181
ToMCI	0.6	0.2	0.8	0.1	−3.5	≤0.001	1.124

LEAS – Level of emotional awareness scale; ToMCI – Theory of mind composite index

A number of studies have also found that LEAS scores are independent of the prevailing mood of the subject.[21,34,41] Similarly, affective ToM deficits in the patients with somatoform disorders group, compared to the medical group, also persisted after controlling for negative affect.[18] Studies using self-report scales like the Toronto Alexithymia Scale (TAS) have reported frequently association of alexithymia with negative affect states like depression.[42,43] One of the drawbacks in self-report measures of alexithymia is the possible underreporting of deficits, as it is not necessary that the individuals are aware of the same. As LEAS measures a similar construct but in an implicit manner, it might have an advantage over the self-report measures.

This study also found that LEAS and ToM may have a negative correlation with severity of somatic symptoms, which has been demonstrated in a large study (n = 249) where LEAS scores and symptoms improved post 6 weeks of in-patient treatment, independent of negative affect.[34] Our finding is, however, in contrast to another cross-sectional study (n = 60) that found no correlation of ToM or LEAS with symptom severity.[21] It is also important to note that similar finding was not found when we attempted correlation within each group, probably due to lower statistical power. Hence, it is unclear at this point whether these deficits are a state or a trait factor.

This study has its limitations, with the first being a small sample size. No structured interview schedules were utilized to diagnose somatoform disorders or other comorbidities. Only expert validation was done for LEAS. The cross-sectional design allows only associations to be made and not causality. It may also have limited external validity, as the study population was recruited from a tertiary care center. There is also a probability of interviewer and selection bias, due to sampling methods and lack of blinding. Despite its limitations, the important strength of the study is the use of culturally validated tools to assess emotional awareness and ToM which is greatly influenced by one's culture.

The present study provides evidence for deficits in ToM and emotional awareness in patients with somatoform disorders, evaluated using culturally validated tools. Longitudinal studies are needed to establish causality, and controlled trials are needed to assess if interventions targeting these deficits have any therapeutic benefits.

Table 4: Analysis of covariance with LEAS and ToMCI as dependent variables after controlling for GAD-7 and PHQ-9

	Patients		Healthy controls		Group effect with GAD-7 controlled (F)	GAD-7 effect (F)	Group effect with PHQ-9 controlled (F)	PHQ-9 effect (F)
	Mean	SD	Mean	SD				
LEAS	43.9	10.3	54.5	7.2	21.5***	6.2*	12.1**	0.9
ToMCI	0.6	0.2	0.8	0.1	17.5***	4.5*	18.5***	5.0*

*P<0.05, **P<0.01, ***P<0.001. LEAS – Level of emotional awareness scale; ToMCI – Theory of mind composite index

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Conflicts of interest
There are no conflicts of interest.

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Brief Research Communication

Self-Reported Anger: Vulnerability for Risky Behaviors in Two-Wheeler Riding Young Men

Rajesh Kumar, Paulomi M. Sudhir, Rajeev J. Michael, Manoj K. Sharma, Neelima Chakrabarty[1], Seema Mehrotra

ABSTRACT

Objectives: Aggressive driving and road accidents are major concerns in the public health sector. This study aimed to explore risk to aggressive and risky behaviors on the road in two-wheeler riding young men. **Methods:** The study comprised 433 young male two-wheeler riders from an urban city of India. A two-wheeler riding survey that captured subjective perception of difficulty in managing anger in general, easy provocability to anger, and aggressive and risky behaviors on the road, and Negative Mood Regulation (NMR) scale were administered. **Results:** Of the 433 participants, 83 (19%) reported experiencing problematic anger in general, whereas 175 (40.42%) did not endorse experiencing problematic anger. Based on this, two groups were formed, namely, problematic anger-present group and problematic anger-absent group. The problematic anger-present group reported high score on easy provocability to anger, difficulty in controlling anger, specific motives related to riding fast than usual, and severity of aggressive responses to frustrating situations while riding, and low score on NMR scale. Statistical analysis revealed a significant difference between the groups. **Conclusion:** This study highlights the relevance of assessing subjective perception of problematic anger in two-wheeler riding young men. This has implications for designing interventions for enhancing road safety.

Key words: *Aggressive driving, anger, negative mood regulation, road rage, two-wheeler riding*

Key messages: *(a) Assessment of subjective perception of difficulty in managing anger in general could be very useful for understanding the aggressive and risky driving behaviours. (b) The study highlights the potential utility of identification of problematic anger and addressing the same. (c) Difficulty in managing anger in general and negative mood regulation. (d) Findings have implications for designing interventions aimed at minimizing risky driving behaviours and enhancing road safety.*

Aggressive driving or driver aggression is one of the contributing factors for road accidents, and it has emerged as one of the major concerns in the public health sector.[1] Aggressive forms of behavior on the road can be categorized into (i) aggressive behavior in which the intention is to cause physical and/or

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psychological harm or damage to oneself, other road users, or property and (ii) aggressive behavior in which there is no intention to harm others but the behavior appears to be risky.[2] Another term which is often used interchangeably in place of aggressive driving is road rage, and it broadly refers to driving-related aggressive behaviors on the road.[3]

There is an unprecedented growth in the number of two-wheeler riders and bicyclists worldwide and in India, as two wheelers and bicycles offer cost-effective and convenient means of transportation.[4,5] As a result, riders and pillion riders of two-wheelers and bicyclists are one of the most vulnerable groups with respect to road traffic accidents.[4,5]

Individual factors such as trait anger or difficulty to manage anger could be one of the important factors for aggressive driving behaviors on the road.[6,7] Similarly, an individual's coping ability, particularly the ability to regulate one's emotion, may contribute significantly to an aggressive expression on the road. It has been found that drivers who have high anger use less adaptive coping strategies compared with those with low anger.[7] In this context, one's beliefs about having the ability to overcome or alleviate a negative mood state, also known as negative mood regulation expectancies,[8] could be an important variable from a research perspective. Literature suggests that difficulty in managing anger may increase the probability of risky or aggressive behaviors, whereas effective emotion regulation is associated with safe driving behaviors.[9] Research also indicates that age and gender are other important variables in aggressive driving. It is reported that driver violence is more prevalent in male and young drivers.[1,10]

However, there is a paucity of research exploring driver anger and its contribution to aggressive driving in two-wheeler riding young men. This study was aimed at examining the extent to which self-report of difficulty in managing anger in general (self-perceived problematic anger) is associated with aggressive and risky riding behaviors in two-wheeler riding young men. In addition, the differences in negative mood regulation efficacy between individuals reporting problematic anger versus those not reporting problematic anger were also examined.

METHODS

Participants and procedure

The study used convenient sampling. The sample comprised 433 young male two-wheeler riders, undergraduate and postgraduate students, from Bengaluru city, recruited from nine colleges, including governmental and private colleges. Ethical approval was obtained from the Institute Ethics Committee. Permission for sample recruitment was obtained from the head of the college. Written informed consent was obtained from all participants.

Measures

Demographic data sheet

A demographic data sheet was prepared for the study to document demographic information and to document variables related to two-wheeler riding (e.g. total years of two-wheeler riding and riding frequency).

Two-wheeler riding survey

A two-wheeler riding survey was developed as per the need of the study and considering the nonavailability of tools in the Indian context. Domains and items were constructed on the basis of three focus group discussions that involved college students and a literature review. The items were reviewed for content validation by three mental health professionals having more than 15 years of clinical service, and their suggestions were taken into account in finalizing the survey items. The survey items captured various aspects related to two-wheeler riding. The items pertaining to the present study objectives are briefly described below.

Participants' perception of managing anger as a problem, in general, was assessed with a discrete response-type item having three options ("yes," "no," and "cannot say"). Provocability to anger on the road and difficulty to control anger while riding were assessed by two items having a 4-point Likert scale, ranging from "Not at all," scored as 1, to "Very much," scored as 4. Response to frustrating situations on the road was assessed by 11 items related to verbal and nonverbal aggressive expressions, with a 4-point Likert scale format. The items were preceded by a general stem, "When I feel irritated or angry on the road I tend to …" (e.g., sound my horn repeatedly, give an angry look at the other driver who caused me irritation). These items together formed a scale with good internal consistency and reliability (Cronbach's alpha = 0.75). Furthermore, factors associated with riding fast than usual were assessed using a checklist with eight options, while perceived motives for riding fast than usual (in terms of seeking specific emotional states by fast riding) were assessed using five items (e.g., to get relief from anger, to get a sense of joy), 4-point Likert scale, ranging from "Never true for me," scored as 1, to "Nearly always true for me," scored as 4.

Negative Mood Regulation efficacy scale[8]

The Negative Mood Regulation (NMR) scale has 30 items, with a 5-point Likert rating designed to measure generalized expectancies for alleviating

negative mood.[8] This scale has been tested for its psychometric properties in an Indian study, and internal consistency and reliability of the scale were found to be 0.87 (Cronbach's alpha).[11]

Data analysis

Data were analyzed using Statistical Package for Social Sciences, version 15 for Windows (SPSS-15, SPSS Inc., Chicago, USA). Descriptive statistics, independent *t*-test, Chi-square test, and Mann–Whitney rank *U* test were applied to examine demographic variables and to compare the two groups of those with problematic anger and those without problematic anger.

RESULTS

Sample characteristics

The sample size of two-wheeler young men riders was 433. Participant's age ranged between 17 and 26 years with a mean of 20.21 years [standard deviation (SD) =1.63 years]. Participants were predominantly undergraduate students [344 (79.6%)], and only 89 (20.4%) were postgraduate students. The mean number of years of education was 14.67 years (SD = 1.17 years). On an average, the participants had about 5 years of two-wheeler riding experience (mean = 4.62 years, SD = 2.85 years), and the majority [355 (82%)] reported riding two-wheelers almost daily to a few days in a week.

Subjective perception of problematic anger, in general, was assessed on a single self-reported item, "Do you feel that managing anger is a problem for you in general?" with three options (i.e., yes, no, and cannot say). Of 433 participants, 83 (19.71%) reported "yes," whereas 175 (40.42%) reported "no," and 175 (40.42%) reported "cannot say" to this item. Two groups were formed based on the participants' responses: (i) the problematic anger-present group (i.e., those who reported "yes," $n = 83$) and the problematic anger-absent group (i.e., those who reported "no," $n = 175$). These groups were compared on various factors related to aggressive driving behavior as described below.

Self-report of provocability to anger and difficulty in managing anger on the road

The problematic anger-present and problematic anger-absent groups were compared on 4-point, self-reported item about easy provocability to anger on roads ("I'm easily provoked to anger while riding two-wheeler") and difficulty in managing anger while riding ("I find it difficult to control my anger while riding"). Forty percent ($n = 33$) of the participants in the problematic anger-present group, whereas only 9% ($n = 16$) participants in the problematic anger-absent group, reported considerable to high provocability to anger, and statistical analysis revealed a significant difference between the groups [$\chi^{2df-3} = 63.94$; $P < 0.001$ (two-tailed)].

Similarly, 39.6% ($n = 33$) participants in the problematic anger-present group and 11% ($n = 20$) in the problematic anger-absent group reported considerable to high difficulty in managing anger while riding, and there was a significant difference between the groups [$\chi^{2df-3} = 45.41$; $P < 0.001$ (two-tailed)].

Expression of anger to frustrations on the road while riding

We compared the mean score of problematic anger-present group and problematic anger-absent group on the scale capturing aggressive responses to frustration when riding. The results showed a significant difference between the two groups [$P < 0.001$ (two-tailed); problematic anger-present group = 21.19 ± 5.89 and problematic anger-absent group = 18.48 ± 5.01 (mean ± SD)]. Figure 1a shows the significant differences between the groups on the items of this scale such as (i) give an angry look at the other driver, (ii) speed up to frustrate the other driver, and (iii) thoughts of taking revenge.

Perceived factors associated with riding fast than usual

There was a significant difference between the problematic anger-present and problematic anger-absent groups on topmost reasons which they perceived as factors for riding fast than usual. Figure 1b shows that the problematic anger-present group reported riding fast than usual due to being in a negative mood state such as anger or feeling sad. Similarly, the problematic anger-present group reported riding fast to seek relief from anger or feeling upset [Figure 1c].

Negative mood regulation efficacy

The group reporting problematic anger, in general, had lower scores (mean rank = 90.56) compared with problematic anger-absent group (mean rank = 125.12) on NMR scale. Shapiro–Wilk test was applied to check the normal distribution and it was found to be not normally distributed. Mann–Whitney *U* test revealed that there was a significant difference between the two groups ($P = 0.01$) indicating a lower efficacy in negative mood regulation in the problematic anger-present group.

DISCUSSION

The results indicate that participants who reported experiencing problematic anger in general also reported having easy provocability to anger, difficulty in controlling anger, and a lower efficacy in negative mood regulation. These findings have implications for behaviors such as aggressive driving and road rage which

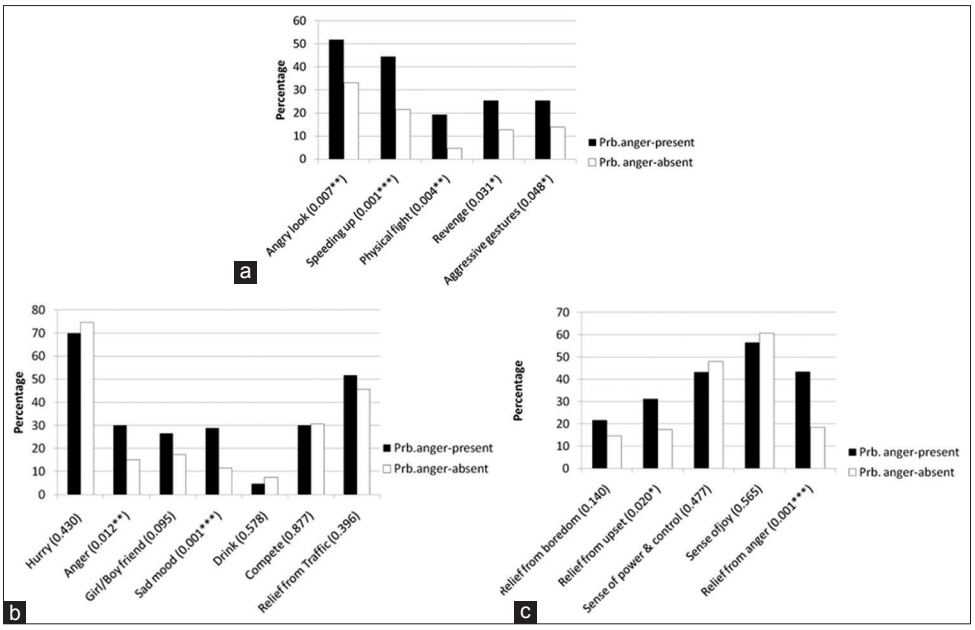

Figure 1: (a) Responses to frustrating situations on road. (b) Factors for riding fast than usual. (c) Motives for riding fast than usual. ***$P < 0.001$, **$P < 0.01$, *$P < 0.05$ (Two tailed); Prb.anger-present – Problematic anger-present group, Prb.anger-absent – Problematic anger-absent group

may place the riders as well as others at risk. Road rage is a rising problem that is seen in the context of traffic density,[1] and such tendencies may likely place such individuals at higher risk than those who are able to regulate negative emotions and are not easily provoked. Studies have reported a significant difference between drivers who are high or low in anger.[7,12] Individuals with low-trait anger are generally calmer when encountering provocative and annoying situations, whereas high-trait anger individuals tend to get easily provoked and lose control in the face of such situations.[13]

According to trait-state anger theory,[14] individuals with high anger trait when compared with low anger trait differ in several dimensions, for example, becoming angered by a wide spectrum of situations/events, experiencing anger more frequently and intensely, expressing anger in less adaptive ways, and experiencing more negative consequences. Furthermore, low NMR expectancies in the problematic anger-present group could suggest a higher level of anger and distress as well as difficulty in mood regulation compared with problematic anger-absent group. One study has reported that having difficulty in emotion regulation was associated with risky driving and vice versa.[9] This is particularly more important in the case of a young driver who may experience intense emotion and may have a relatively high probability of accidents.[15] Hence, it is necessary that one should have the ability to regulate negative mood.

This is further supported by the findings that participants in the problematic anger-present group reported greater use of aggressive and less constructive forms of expressing their anger in response to commonly occurring and their personally most provocative situations on the road, for example, angry look to the other driver and thinking about taking revenge. These findings are in line with several other studies that demonstrate a relationship between driver anger and risky behaviors.[7,12,16] Similarly, difficulty in negative emotion regulation may result in expressing negative emotion toward others and at times, more maladaptive behaviors on the road. Studies have shown that drivers with higher levels of anger use less adaptive coping methods.[7,14,16] Hence, difficulties in emotion regulation may increase the likelihood of aggressive or risky driving behaviors on the road.[9]

This study revealed that problematic anger-present group reported to speed up or ride fast than usual to get relief from anger and sadness. It is reported that negative emotions such as anger and sadness may lead to risky riding/driving behaviors such as stronger acceleration and speeding.[17] Several factors may cause the driver to accelerate speed in a state of anger. For example, drivers with high trait anger were found to be riding fast when they face an impediment.[18,19] Anger may also influence risk perception.[19] Negative emotions may produce more errors related to vehicle control and slower braking reaction time, and impairment in attention and concentration.[9,17] Furthermore, personal characteristics play an important role in experiencing emotions and influencing driving/riding behaviors. For example, younger drivers tend to experience more anger than older ones.[6,20]

CONCLUSION

Findings from this study have preventive implications for road safety. Individuals with high anger are prone to risky riding and accidents. These individuals may benefit from education about vulnerability to risky behaviors and negative consequences, and from addressing anger through interventions that target emotion regulation and adaptive coping skills. This may help them in dealing with provocative situations and in reducing risky riding behaviors on the road, and that, in turn, has implications for reducing incidents of clashes and accidents.

This study has a few limitations. A single item was used for dividing the sample into problematic anger-present group and problematic anger-absent group. The study excluded 40% of the sample who reported "cannot say" on this item. The instrument used has not been validated except for face validation, and the psychometric properties are not known. Objective data (e.g., accident/injury records) and pillion-riders' report to supplement self-report could enhance the robustness of the findings. The study was limited to college-going youth in an urban context. Further studies can help in examining the generalizability of the findings to youth in other settings and age groups. Its limitations notwithstanding, the study has several implications for future research and practice.

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Conflicts of interest

There are no conflicts of interest.

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Viewpoint

Revisiting Postgraduate (PG) Psychiatry Training in India

(Transcript of the Panel Discussion Held on 26th October 2018 at Annual Conference of Indian Psychiatric Society South Zonal Branch, Held in Tirupati)

The training that students receive today will have an impact on the professionals and society of tomorrow. To make them better psychiatrists, there should be an ongoing effort to improve the psychiatry training that postgraduates receive. The panel discussion involved three experts from different states and working backgrounds to discuss this important topic.

1. It is frequently pointed out by many that postgraduate training in psychiatry these days is mainly focusing on pharmacotherapy; psychosocial assessment and intervention are ignored; or in many centers, patients are referred to the concerned specialist, and there is little training happening.

Dr. Varghese Punnoose: Before one jumps in for a criticism of the prevailing medical model, it has to be acknowledged that this approach has some definite advantages. It has brought more accuracy in diagnosis and precision in pharmacological management. It has made psychiatry in line with other medical specialties bringing in more respect among peers. It has attracted young medical professionals to psychiatry who otherwise feel burdened by the psychological jargon and turned away by psychotherapeutic skills demanded of them. There is increasing evidence that the medical model has also contributed to stigma reduction. But too much of medical model has made psychiatry less mindful.

During the assessment, contextual factors should be given its due. While emphasizing the primary role of biological factors; psychosocial factors such as causative, precipitating, or perpetuating influences should also be considered.[1] Personal history, family history, and premorbid personality should be thoroughly assessed to understand the person who is under evaluation. The famous adage by William Osler "It is important to know the diagnosis, but it is more important to know the person who has got the diagnosis" is particularly true for psychiatry and should be the guiding principle in training psychiatry residents.

Interventions should not be confined to a prescription of pharmacological agents. Referring the patient to a psychologist and limiting the role of the trainee psychiatrist to pharmacological treatment alone is a sin. Psychological interventions by the trainee psychiatrist should be planned, documented, supervised, and evaluated for every patient.[2] It is an unfortunate situation that many PG training departments do not have a clinical psychologist or a social worker. The reason for this big lacuna is that the Medical Council of India (MCI) regulations do not mandate it. This has to be corrected urgently. The boundary issues with clinical psychologists or Rehabilitation Council of India (RCI) should not be a block for urgent steps in this direction. Till such permanent solutions emerge, the faculty in psychiatry themselves should provide hands-on training for the trainees. Human resource scarcity for psychotherapy training should be tackled by steps like student exchange programs or focused workshops.[3] Feasibility of examining the psychotherapy skills of the trainee in a separate practical examination is worth considering.

Absence or relative lack of psychological approach and interventions by psychiatrists is one of the major reasons for dissatisfaction with psychiatric services. Psychiatrists of the future should be equipped with the skills to meet the expectations of the evolving society.[4]

Dr. Kannan: There have been tremendous strides made in the fields of neurobiology and psychopharmacology. It is natural that psychiatry as a branch of medicine should focus on psychopharmacology. But what we need to understand better is the dynamics between psychiatry and the psychological sciences. The evidence-based medical methods and modern psychiatric classification had over the past few decades removed the psychological model of illnesses and the reliance of psychiatry on social sciences significantly. However, recently there is increasing recognition of the role of psychological-based understanding and therapeutic interventions such as CBT in the management of psychiatric illnesses. A multidisciplinary approach is advocated. The past few decades have seen a gradual recession in the processes of teaching psychotherapeutic techniques. We need to have more systematic programs to restart the processes.

The situation has started to improve, and there is an increased interest in nonpharmacological treatment options now.

Dr. Ashok: The number of departments that have introduced PG program in the last decade and the increase in the number of seats mean that there is more than twice the number of PGs now compared to about two decades back. The newer departments also do not have an adequate number of psychologists. The psychologists who do stay on with PG departments are often overburdened with clinical work. And find it harder to focus on supervisory roles and actively participate in PG training. Having them on rounds can be difficult too. This impacts on PG training and builds a vicious cycle of reduced exposure to nonpharmacological interventions. The MCI does not even specify the need for psychologists in the training team. It does specify a social worker (SW), but these posts are often filled with Masters in Social Work (MSWs) who may not actively participate in PG training. The universities recommend but do not make it mandatory to score psychological assessments or psychotherapy notes. There is also a need to get psychologists and psychiatric social workers (PSWs) to get pragmatic and flexible about what should the training in therapies for psychiatry PGs constitute. The teachers have to feel that it is important to focus on the psychological and psychosocial aspects and model for the students. This is the most crucial. The Indian Psychiatric Society (IPS) should encourage and support the newly evolved Indian Teachers of Psychiatry (IToP) group and build groundswell support for bringing such focus in training programs. The faculty should work with universities to develop M.Phil programs in their institutions and help bring about more exposure to psychological aspects through joint programs with psychologists.

2. All of us are seeing more and more child cases in practice; would it be desirable to have a mandatory child case in the final examination.

Dr. Varghese Punnoose: One short case from child psychiatry should be mandatory for PG clinical examination. Unless there is an examination, the training in child psychiatry will not be taken in a serious manner by the faculty and trainees. Acquisition of core competencies in assessment and interventions in child patients should be ensured for every candidate.

Dr. Kannan: We are witnessing the initial phases of child psychiatry emerging as a separate subspecialty within psychiatry. However, there is a huge need for child psychiatric services which cannot be met by subspecialists. The MCI norms make it mandatory for all teaching centers to have a separate child psychiatry clinic. The Tamil Nadu Dr. MGR Medical University guideline prescribes 4 months of clinical rotation in child psychiatry and also permits students to be posted to higher institutes for specialty training.[5] There is an increasing trend to include one child psychiatry case as part of the short case presentation during examinations even though it is not a mandatory requirement. Objective structured clinical examination (OSCE) scenarios invariably include a child psychiatry station. In this context, it is definitely implementable to include a mandatory child case in the final examination. Such inclusion would not only give a greater legitimacy for candidates to practice child psychiatry but also give a boost to child psychiatry training in India.

Dr. Ashok: This is absolutely necessary. Every department should carve out a role in child psychiatry for one of its faculty members and encourage them to gradually take more time on this. They should gradually focus on submitting detailed case summaries and also arranging case conferences in child psychiatry. However, if the numbers of child cases seen are very few, there should be an active liaison with centers where these services are more established. Having a child case in the examinations should be a rule than an exception, and the case needs to be formal child psychiatry case than a purely developmentally impaired child. There has to be a formal evaluation of competency with regard to interviewing children and parents (latter with regard to parenting) in examinations and not just ask a few questions on developmental anomalies to cover child psychiatry topic.

3. De-emphasis of descriptive psychopathology and case taking being more of a checklist exercise.

Dr. Varghese Punnoose: The categorical systems of diagnostic classifications (DSM and ICD), use of rating scales, and emphasis on criteria-based diagnosis have taken away the understanding of "what is actually happening in the patient's mind" from today's PG training programs. The practice of narrating an exhaustive list of "negative history" at the end of the history of presenting illness is an example of this mechanical symptom checking.[4] The symptom checklist approach deprives the trainee of understanding of the pain suffered by the patient with depression or the appreciation of the devastation of various mental functions in schizophrenia. In short, this leaves the trainee less empathetic. Emphasize on psychopathology should be brought back in training and the candidate's competence to elicit and describe psychopathology should be given due credit in PG examination.

Dr. Kannan: It is now recognized that the widespread use of classificatory systems and structured protocols has had a deleterious effect on the training of residents in interview techniques and descriptive psychopathology. This has been described in excellent clarity by Anderson where she states that since the publication of DSM-III in 1980, there has been a steady decline in the teaching of careful clinical evaluation that is targeted to the individual person's problems and social context and that is enriched by a good general knowledge of psychopathology.[6] The simultaneous booming of psychopharmacology and disillusionment with psychoanalysis has also compounded the decline. The currently prominent "diagnose by criteria and treat with medication" approach removes the focus from psychopathology.

We have always maintained that a good and open clinical interview is the gold standard against which structured clinical interviews are tested and designed. But as the use of structured checklists and criteria becomes more widespread among trainees and teachers, there is, unfortunately, a proportionate fall in the soft skill set needed to conduct an open clinical interview, leading to more reliance on superficial approach to criteria-based diagnosis with inadequate phenomenological understanding which becomes a vicious cycle.

Classificatory systems discourage clinicians from getting to know the patient as an individual person because of their dryly empirical approach leading to loss of empathic skills.

Psychopathology precedes nosology. We need a careful description of symptoms and experiences before we can know whether any diagnoses exist, and which ones.[7] Criteria include only some characteristic symptoms of a given disorder. They were never intended to provide a comprehensive description. As greater reliance is placed on criteria-based approaches, students typically do not recognize other potentially important or interesting signs and symptoms that are not included in the criteria. This is reflected in the increased use of Not Otherwise Specified categories and the failure to recognize atypical presentations.

The decline in the use of a diagnostic formulation and increasing use of case summaries are also reflective of these changes. Encouraging trainees to attempt diagnostic formulation exercises could counter the ill effects of overdependence on criteria-based diagnostic approaches. Encouraging use of a biopsychosocial approach or a pluralistic approach in case formulations as suggested by Ghaemi would definitely bring different perspectives into the mind of the trainee while interviewing a patient; enrich doctor–patient communication and treatment alliances.[8]

There is an increasing recognition that the evidence-based medical model may not be well suited for the management of many of the maladies of the 21st century which have their roots in individual lifestyles, societal structures, and economic policies. This has led some to advocate for interpersonal medicine.[9] Greater focus on psychopathology will put us in line with this trend.

Dr. Ashok: One needs to be pragmatic too. At least the weekly case conferences should focus on detailed psychopathological exploration. The PG needs to be formally quizzed on a psychopathological understanding of the case. This training should include comfort in asking questions across domains of functioning, attitude, and clinical negotiations. The skill to match definitions even as one engages in a free-flowing interview with the patient should be continually focused across all three years. IPS should arrange specific workshops in this regard.

4. Future of DPM courses and its current utility.

Dr. Varghese Punnoose: DPM has not lost its relevance in India. There may be logic in discontinuing DPM course in the national institutes, but it should be continued in other medical colleges. The special quota for candidates from general health services may be restricted to these seats. Fresh MD holders with high academic aspirations may not opt for rural and community services and locum jobs. At the same time, there are many in general practice who would like to take up a specialty like psychiatry in the middle of their career. A 2-year full-time clinical training in psychiatry, without the hassles of bringing out a thesis, may attract many such clinicians into the fold of psychiatry. This might be a solution for the relative human resources shortage in rural India.

Dr. Kannan: The diploma courses are the products of a bygone era in medical education. Most countries have shifted to a model where there is a single exit examination after clearing which a particular degree is awarded. Anyone can appear for the exit examination if they have undergone the minimal prescribed clinical training by resident training programs in approved centers. In India, there has been a slow but progressive shift in government policy to discourage diploma courses and encourage degree courses. Initially, the regulations that held that any institute that was approved to admit degree students could admit twice the number of diploma students were withdrawn. The criteria in terms of staffing and infrastructure for both degree and diploma courses

are the same now, thus disincentivizing institutions from beginning new diploma programs. Permissions for new diploma courses are not allowed as per current PG regulations. In addition, the government has now introduced a mechanism for surrendering diploma seats in existing institutes in lieu of degree seats subject to approval.[10,11] The parliamentary standing committee on health has recently recommended making diplomates with an additional 2 years of experience in teaching colleges eligible for academic promotions provided they have completed a thesis work in accordance with norms.[12] The ball is now in the court of the MCI to decide on the proposal. It must be noted that a similar request by the government was previously rejected by the MCI on the grounds that the diploma course was shorter and did not involve doing a thesis.[13]

Dr. Ashok: It may need to be retained in order to meet the needs of District Mental Health Program, etc., This can be all government sponsored in each state from among the doctors in service.

5. MCI PG requirements include museum, fixed and specified specialty clinics, room square feet! But ignoring many important aspects.

Dr. Varghese Punnoose: If the MCI mandates something, it is done. If some facility fails to find a place in the MCI checklist, it is never done. In short, facilities are provided only to serve MCI requirements. Unfortunately, many MCI requirements are anachronistic and illogical. I would like to cite a few such wants in MCI requirements.

a) MCI does not mandate even a single clinical psychologist in PG training departments. The managements, including governments, do not appoint a psychologist unless mandated by MCI. This results in a situation where a candidate can become a psychiatrist without ever being exposed to clinical psychological assessments and interventions[14]
b) MCI has some requirements like "psychomotor clinic." Nobody knows what it is! (Maybe a clerical error for the psychosomatic clinic)
c) MCI should revise its requirements to keep with advances in the field of psychiatry. There should be more emphasis on ensuring the qualitative aspect of PG training than its obsession with physical requirements.[15]

Dr. Kannan: The UG and PG training subcommittees of the IPS can work to produce a model curriculum, examination system, and minimum requirements for postgraduate training that is more appropriate for psychiatric training. One must recognize that the requirement of a museum though seemingly absurd is very much applicable for courses like anatomy and pathology. Therefore, any recommendation that is made must be in the language of extant government regulations. Special clinics are envisaged as a means of imparting specialized training to postgraduates. It is advisable to have functioning clinics for de-addiction, suicide prevention, family counseling, child psychiatry services, geriatric, and neuropsychiatry in all teaching hospitals. Governmental agencies are associated with red tape and only sustained liaison efforts and advocacy by professional bodies can be effective in changing policy.

Dr. Ashok: The MCI not only emphasizes poorly defined requirements but also omits specifications with regard to key issues such as forensic psychiatry training, exposure to child cases, and negotiations. There is a clear need for recommending changes to the MCI. The IPS has to take such issues on priority. Having a psychiatrist as a key person in the MCI system currently is a great opportunity to move things forward.

6. Neurology training is on the decline and consultation liaison training is picking up. Your views.

Dr. Varghese Punnoose: The conventional neurology training can be of little help to the future psychiatrists. The typical neurology case for PG examination is stroke. The focus in neurology training and neurological examination should shift to cognitive assessment, skills to interpret neuroimaging and EEG, and rehabilitation. The core competencies needed for psychiatrists practicing in general hospital settings, private practice, and community are different. They should have the skills needed to assess, manage, and engage in useful liaison with internists, gastroenterologists, cardiologists, rheumatologists, orthopedicians, dermatologists, and so on. So the training should focus more on liaison psychiatry than conventional neurology.

Dr. Kannan: The recent decades have seen a general decline in interspecialty interaction and different specialties' function as islands. The advent of high-resolution neuroimaging has in many ways lessened the need for achieving a high competence in clinical neurology not only for psychiatrists but also for physicians and even neurologists themselves. Within neurology, there is a comparatively greater focus on basic CNS pathology and lesser focus on higher mental functions and soft signs which is of more interest to psychiatrists. Wherever there is a possibility of organicity, imaging is done, and both psychiatric and neurologic consultations are obtained. This is more in line with western trends. However, one must remember that the World Psychiatric Association

institutional program on the core training curriculum for psychiatry recommends a minimum of 6 months of rotation in clinical neurology and medicine for trainees.[16] A 6-month training is also required by certain international fellowship examinations.

Though there is lesser training in other disciplines, the culture of today with increased accountability and medico-legal risk has ensured that specialists stick to their own discipline and obtain a liaison consultation even though they may be competent in another field. This has, in turn, led to increased liaison consultations in the management of delirium, fitness, detoxification, and toxicology.

Dr. Ashok: There is a general decline in neurology training of psychiatrists. The replacement of neurologists with psychiatrists themselves for the examinations has certainly had its downstream impact on the approach to training. Consultation-liaison psychiatry training needs to get much more specific in its approaches. Liaison rounds may be more relevant than didactic lectures. Here again, undue focus on MRI and EEG should be replaced by clarity in differentiating organic from other psychiatric syndromes. Collective involvement of neurology in psychiatry services is more important than postings to neurology alone. Such initiatives need to be taken by all psychiatrists in medical colleges. Challenges around this have to be directly explored and academic responses generated under the aegis of the IPS.

7. Do we need to change the assessment methods for the postgraduates?

Dr. Varghese Punnoose: The current pattern of PG examination has no uniformity across the country. The emphasis on the long case in psychiatry is perhaps the only unifying aspect. I would like to make the following suggestions:

a) The number of candidates examined in a single day should not exceed four
b) There should be uniformity across the nation – regarding the number of long and short cases, the relative marks awarded, OSCEs, ward rounds, pedagogue sessions, and viva
c) More importance should be given for continuous internal assessment, than a single exit assessment. The institutions or universities should evolve transparent mechanisms to address any grievances by the candidates regarding the assessment of their performance in internals
d) Consider bringing back the Part 1 Examination for basic sciences
e) More objectivity should be brought in the division and award of marks in the practical examination so that the candidate should not be a victim of the examiner idiosyncrasies.

Dr. Kannan: All over the world, there is a shift from case presentation and other unstructured methods like viva to continuous performance evaluation protocols and OSCE settings for assessing the achievement of competency in medical training. The key to the accurate implementation of OSCE is the simulated patient. Trained actors or recruited patients are used for this purpose. Similarly, examiners must also be familiarised with OSCE protocols.

Unstructured examination settings like case discussion can provide an index of the depth of clinical knowledge of a candidate in a particular case, while OSCE can be used to compare the performance of different candidates in the same setting. Conventional examination patterns may be suited for postgraduate examination, whereas OSCE is better suited for undergraduate-level assessments. Soft skills like communication can be tested in OSCE settings. Balanced examination protocols with equal weightage for both unstructured and structured sections and a prescribed passing minimum in each section would be ideal. The long case and viva can constitute the unstructured section. Spotters may be incorporated into the viva or eliminated. The short case can be incorporated into the OSCE with at least 10 stations allowing competencies in multiple domains to be tested.

Dr. Ashok: I do feel a more dynamic year-round performance record with regular feedbacks should become a larger portion of the certification process. IPS can mandate how often peers should evaluate the candidate during his/her training. This can be through city/district-wide conferences or even on invitation. The sanitized assessment headings for scoring in the MD exams (IPS PG guidelines) – history/Mental State Examination/physical findings and so on need to be superseded by clearer processes such as clarity of reasoning, sensitivity in interviewing patients, ability to integrate information, technical knowledge, and ethical planning of interventions. IPS can help prepare a system on training teachers in such evaluations in collaboration with Departments of Medical Education.

8. Thoughts on research training to our postgraduates.

Dr. Varghese Punnoose: The research training in centers other than big institutes are far from satisfactory. The faculty who are guiding the research work of the trainees themselves must undergo continuous training and certification. There should

be a research methodology training workshop after the first 3 months of PG training; then only the candidates should be required to submit their protocol. There should be ongoing supervision of the research project.

Dr. Kannan: There is an increased focus on research as part of training in postgraduation. In addition to thesis work, presentation in conferences and publications has been made mandatory. Training in basic sciences also includes biostatistics. Additional training in statistics and statistical software could be provided in a workshop format to all trainees. Departments must have regular research review meetings to monitor progress and provide inputs.

Dr. Ashok: Overall, the structure is adequate because of the dissertation. Only a few institutions have courses on research methodology, ethics of research, and so on around the time of synopsis submissions. IPS can step in here and make such for a more widely available. Protocols with timelines for the dissertations should be developed by each department to reduce chances of late submissions. Taking part in another study may be encouraged. Students should be encouraged to publish their own dissertation data without waiting for final examinations.

9. The number of faculties has been reduced by the MCI. Colleges are sticking to the minimum standard. How is it affecting the functioning?

Dr. Varghese Punnoose: The managements (including government) make sure that the faculty should not exceed the minimum stipulated by MCI. Any additional faculty is considered as a luxury. In psychiatry, the most important resource needed for training is experienced faculty. The quality of psychiatric services and training can be ensured only if adequate faculties are there to provide quality services (clinical and teaching). So the number of faculty should be revised depending on the workload – the number of out-patients (OP), in-patients (IP) strength, consultation work, specialty clinics, medico-legal work, teaching activities, and research projects. This important point has to be driven to the decision-makers in MCI/managements/governments.

Dr. Kannan: The number of minimum faculty required for UG and PG courses has been decreased for all specialties. The justification cited is that this is inevitable in view of staff shortage in the country. The implementation of these changes at a time when the flow of specialists is increasing raises doubts about lobbying by private medical training centers. Adverse staffing ratios will definitely impact on both patient care and level of supervision and training. Emphasis on quantity and dilution of norms will definitely lead to erosion of quality.

Dr. Ashok: The minimum standards are with regard to teacher–student ratios. This is necessary to increase mental health professionals. However, the teachers can use this opportunity to emphasize more detailed assessments and discuss them, as there would be more residents in the department. With more working residents, the department can organize more postings for them in places where complementing facilities are available (outside the campus). Otherwise, the model of doing minimal clinical work (with more residents) and just reading from books will get strengthened inadvertently.

10. Having a separate psychiatry paper in MBBS; will it help doctors take up psychiatry as postgraduation and change the mental health treatment scenario in the country?

Dr. Varghese Punnoose: Psychiatry should be a separate paper in the MBBS curriculum with a separate examination – theory and practical. The posting in psychiatry in UG course should be at least 6 weeks. Till such decisions are taken by the MCI, the following interim measures can be considered:

a) In addition to the existing 2 weeks' training in the 4th semester, an additional 2 weeks' training may be given in the 7th semester
b) Vertical integration with physiology, community medicine, forensic, pediatrics, and pharmacology lecture classes in the respective semesters
c) At least four general clinics in the final year
d) Minimum 80% attendance in psychiatry posting (for all specialty postings) should be mandatory to appear for university examination
e) The marks obtained in the end posting examination in the 4th semester and the 7th semester should be considered for calculating the internal assessment mark in general medicine.

Dr. Kannan: This issue has been discussed *ad hominem*, and there is no doubt that including a separate paper for psychiatry is definitely required. The same has been recommended by many authors. The recently revised MBBS curriculum[17] for 2019 does not make that shift; however, many common mental illnesses go undiagnosed. Primary care physicians trained in psychiatry are the way forward. Greater exposure to psychiatry during undergraduation will kindle interest in some students to take up the field.

Dr. Ashok: This is an ongoing issue. A report on undergraduate (UG) psychiatry training held under

national IPS is being prepared. By and large, there is a need to actively engage UGs in psychiatry training, and much depends on the available faculty and their skill sets. By encouraging the UG teachers of psychiatry group that has been evolving, IPS can build a bottom–up support for training UG teachers in carrying out their training roles more effectively.

CONCLUDING REMARKS

Many important aspects of psychiatry training in India have been covered in the discussions.

- To give importance to psychosocial assessment and management along with the growing interest in neurobiology
- Child psychiatry training needs improvement
- Descriptive psychopathology and interviewing skills should not be sidelined
- There seems to be still some scope to continue with DPM course
- MCI regulations and requirements should be more practical
- Neurology training of psychiatry postgraduates is on the decline
- There is a need for continuous assessment
- Research training has to be enhanced
- A separate paper of psychiatry for MBBS would help in providing better mental health services.

Our training program needs to be constantly evaluated and improved in view of the constant changes in social, economic, legal, and technological areas.[18] Rules when formed should include all major stakeholders especially the teachers. Evaluation needs to be more structured and objective. A uniform pattern of training and examination for the entire country would remove many inequalities.

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Planning Statistical Analysis: Wrong and Right Approaches Explained Using an Entertaining Example from Everyday Life

Chittaranjan Andrade, Nilesh B. Shah[1]

ABSTRACT

Inferential statistical tests are used to examine hypotheses in research data but can also be applied to information in everyday life. Using data from a cricket tournament as an example, this article describes a plausible but wrong plan of analysis and explains what a correct method of analysis might be. Testing a hypothesis that was set after visual inspection of data or indiscriminate analysis can both result in false-positive conclusions. Making incorrect assumptions in statistical tests will also result in incorrect conclusions. Statistics is not merely about crunching numbers. It is also about knowing how to plan and execute the analysis.

Key words: *Chi-square goodness-of-fit test, data mining, expected frequencies, false-positive errors, plan of analysis, primary hypothesis, probability*

Twenty-two persons participated in a game in which they tested their ability to predict the outcomes of cricket matches (n = 60) during the course of the Indian Premier League (IPL), 2019. There were 59 matches played; 1 was washed out due to rain. Among the 22 participants, 1 dropped out after predicting the outcomes of four matches.

On all occasions, the participants made predictions on the morning of the match, before the start of the match; that is, in a uniform way. The participant with the highest prediction accuracy correctly identified the outcomes of 37 (63.8%) of the 58 matches for which she had offered predictions.

A question that might be asked is whether this participant had foresight that was greater than what could be accounted for by chance. Consider: each match had only two teams contesting, and so assuming that there are only two outcomes possible for a match, she had a 50:50 chance of being right, or a 29:29 chance

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for her 58 attempts. However, she actually scored 37:21; that is, 16 (76%) more predictions that were right than wrong.

A Chi-square test was applied to examine the goodness of fit for the observed frequencies of 37:21 versus the expected frequencies of 29:29. The Chi-square value was 4.41 (df = 1), and the *P* value was 0.036. In other words, the participant appears to have had statistically significant foresight.

There are flaws in this approach to the analysis and in the actual analysis as well. Readers are invited to consider what these flaws might be before reading the rest of this article.

AN *A PRIORI* PLAN OF ANALYSIS

In research, ideally, the primary and secondary hypotheses and the plan of analysis should be outlined in advance.[1] It is particularly fallacious to do a study and to then test the statistical significance of an association only because the association "looks significant" on visual inspection of the data. This is because random variations in values in a sample may create what appear to be meaningful associations, although these associations are absent in the population from which the sample was drawn. Hence, applying statistical tests after spotting such "associations" in a sample may identify relationships that are statistically significant in that sample alone; the relationships may not be significant in other samples drawn from the same population and may not exist in the population.

In the IPL example, the precognition of the participant who scored 37/58 was tested statistically only because she had the best prediction score. She was not *a priori* chosen for testing. If some other participant had performed better than her, then that participant would have been tested. In other words, by visual inspection of the results, the best-performing participant, whoever s/he might have been, would have been selected to examine whether his or her prediction accuracy was statistically significant. If statistical significance was confirmed, it would only be because it was fated to be so; that is, because that performance had been chosen specially, after looking at the data.

If the statistical plan must be outlined in advance, can we plan to test *every* participant's prediction accuracy against a 50:50 expected frequency of their being right versus wrong? No. This is because such a plan of analysis has no hypothesis; rather, it is a data mining exercise in which everything is tested in the hope that something will turn out to be statistically significant. As already explained, there are random variations in the data in all samples, and some of these variations may throw up spurious associations. When a large number of statistical tests are performed, spurious associations are more likely to be picked up. That is, many of the statistically significant results in data mining exercises may be false-positive (Type 1) errors.[2]

This does not mean that it is always wrong to test hypotheses that are set after examining the data, or that we should never embark on data mining exercises. However, this does mean that when we perform such analyses, we must be aware of the risk of false-positive findings that are due to how and why the hypotheses were set, or how the analysis was planned and executed. Therefore, in these situations, the results of such analyses must be considered hypothesis-generating, not hypothesis-confirming. Based on the results of the IPL example, we might hypothesize that the participant who was studied does have foresight and that her prediction abilities may merit prospective study as a primary outcome in another context.

A SUGGESTED PLAN OF ANALYSIS

So, what might be the correct approach to the analysis of the IPL data? One possibility is to calculate the percentage of correct predictions for every participant, including the one who dropped out after four guesses. The distribution of these percentages is expected to be normal. Outliers in this distribution, defined, for example, as those whose prediction accuracy is two or more standard deviations away from the mean, could be hypothesized to be either very good or very poor at prediction. With this taken as the hypothesis-generating study, the abilities of outlier participants can be tested in a subsequent hypothesis-confirming study.

Importantly, good or poor prediction ability does not necessarily mean good or poor precognition; it could also mean good or poor knowledge and good or poor ability to apply this knowledge in the field of cricket. Precognition refers to extrasensory powers, whereas knowledge and the application thereof describe conscious cognitive attributes and processes.

THE EXPECTED FREQUENCIES

In the example of the participant for whom the Chi-square goodness-of-fit results were computed, the observed frequencies for the test were 37 and 21 for right and wrong predictions, respectively. It was assumed that because her predictions could have been either right or wrong, she had a 50:50 chance of being right, and that the expected frequencies for right and wrong predictions, therefore, would be 29 and 29. This assumption is wrong. It cannot be assumed that her

predictions were based on chance. It is almost certain that she had at least a passing awareness of which teams were playing and which team had better players. She would also almost certainly have known the outcomes of previous matches, and this knowledge of current form would have guided her predictions for subsequent match outcomes. So, the expected frequency for correct answers would almost certainly have been >29 and not 29.

This applies to all the participants; so, most, if not all, of the participants could be expected to have a prediction accuracy of above 50%. Because different participants would have different degrees of knowledge and different abilities to apply this knowledge, the distribution of prediction accuracy would still be expected to be normal. The mean of this distribution could be taken as the expected frequency for prediction accuracy if a Chi-square goodness-of-fit test is planned.

AFTERNOTE

Assume that cricket is a game of chance and that the expected frequencies for right and wrong predictions are truly 50:50. Did the participant who correctly predicted the results of 37 out of 58 matches exhibit precognition? To answer this question, we must phrase it in a different way: Assuming that the outcome of each match is random (50:50), like the toss of a coin, what is the probability that somebody would correctly predict 37 outcomes out of a total of 58 matches?

Probability is calculated as the number of favorable events divided by the total number of events. The number of favorable events is 37 correct predictions out of 58 matches; this number can be obtained in 58C37 possible ways. The total number of events is all the possible numbers of correct predictions, which can be obtained in 58C0 + 58C1 + 58C2 … +58C58 ways. The quotient of the two numbers provides the required probability.

What if, instead, we wish to calculate the probability that somebody will correctly predict the outcomes of at least 37 random-outcome matches instead of exactly 37 matches? The numerator here becomes 58C37 + 58C38 … +58C58; the denominator remains the same. Online permutation and combination calculators are available to perform these otherwise laborious calculations quickly.

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Letters to Editor

A Case of Frontotemporal Dementia Presenting as Nicotine Dependence and Carbohydrate Craving

Sir,

Frontotemporal dementia (FTD) is a progressive dementing condition characterized by selective degeneration of the frontal and anterior temporal lobes that causes a profound alteration in character and social conduct, in the context of relative preservation of perception, spatial skills, praxis, and memory.[1] FTD is not a rare disorder and is often misdiagnosed. FTD patients make up about 10% of all patients with dementing diseases.[2,3] Because FTD is usually a presenile onset disorder, among dementia patients with age at onset of less than 65 years, FTD accounts for approximately 20% of neurodegenerative dementias.[4] Core behavioral features of the Consensus Criteria are impaired social interactions, impaired personal regulation, emotional blunting, and loss of insight.[1] A characteristic feature of FTD is behavioral disinhibition, which can be manifested by substance use. As per our literature review, a few cases of behavioral variant FTD reported with substance abuse, but none of them reported a female patient presenting with nicotine dependence and showing significant improvement in these behaviors with antipsychotic medications.

CASE REPORT

A 72-year-old female was brought by her son with 2 years history of excessive use of tobacco in the form of *gutkha* (chewable tobacco), around 12–15 packets/day. This was a new onset symptom, which the family members did not notice until it increased to five to six packets per day and the patient started repeatedly demanding money to purchase tobacco. Once the family found out about this repeated use of tobacco, they started restricting her access to money. Within a year, family members noticed that the patient started to steal money and even sell small household items, including her grandson's mobile phone. She used this money to purchase tobacco packets. When family members questioned her activities, she would get irritable and abusive toward them, which was described as against her usual personality. Another new onset behavior that the family noted was that she was eating sugar in increased quantities. She would mix half a glass of sugar in water and drink it and add sugar to everything she eats. She would drink around 3–4 l of milk per day and eat 8–10 raw eggs. The family also noticed disinhibited behaviors like changing clothes in inappropriate places and being abusive toward everyone. Gradually, the patient started being forgetful about minor issues, repeatedly asking for food even after a meal, and blaming family members of taking away her things, which she had misplaced.

Physical examination revealed no significant findings, with stable vitals and systemic examination being within normal limits. On mental status examination, the patient was not cooperative and showed disinhibited behavior, occasional irrelevant speech, irritable affect, paranoid delusions, and immediate and recent memory deficits. After the initial history and mental status examination, the differential diagnoses of FTD, Alzheimer's dementia, and late onset psychosis were considered.

Routine blood investigations revealed increased thyroid-stimulating hormone (10.8 mU/l) and triglyceride (250 mg/dl) levels. Magnetic resonance imaging (MRI) of brain [Figure 1] showed significant atrophic changes in bilateral frontal and medial basal temporal lobes (right > left side) and perisylvian cortex. Mini Mental Status Examination score was 13 out of 31, which is suggestive of moderate cognitive impairment. Her attention was arousable, but concentration was not well sustained. Bender Gestalt Test (BGT) revealed difficulties in visual–motor integration, in discriminating visual stimuli, and in shifting attention from the original design to what is being drawn, features suggestive of significant visuoconstructive deficits. Her impaired concentration could have played some role in these BGT results. The test also showed memory disturbances and difficulties in concentration and comprehension. A final diagnosis of frontotemporal dementia behavioral variant (bvFTD) was made as per the International Consensus Criteria,[5] and the other two differentials were ruled out based on the history, examination, and investigation findings. The MRI findings played a key role in confirming the diagnosis.

The patient was started on quetiapine tablet 50 mg/day and the dose was gradually increased to 200 mg/day over a period of 2 weeks. A tablet preparation containing

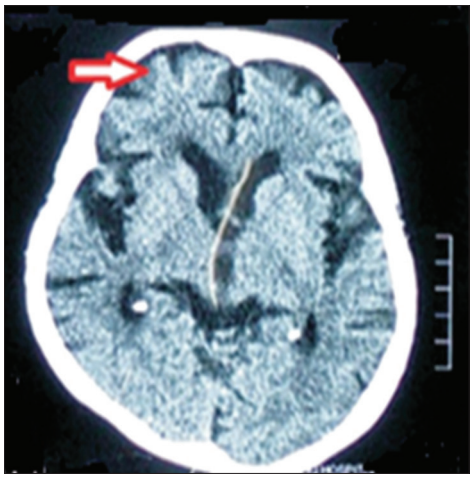

Figure 1: MRI brain section showing atrophic changes in bilateral frontotemporal regions (more on the right compared to left, indicated by an arrow)

both donepezil 5 mg and memantine 5 mg was started and then changed to a tablet preparation containing both donepezil 5 mg and memantine 10 mg. The patient was also started on rosuvastatin tablet 10 mg and thyroxine tablet 50 mcg after liaising with a physician. Psychoeducation for family members regarding the nature, course, and prognosis of the illness and the need for treatment was done. Over a period of 4–6 weeks, the patient showed significant improvement in her behavioral symptoms, mainly the craving for nicotine and carbohydrates and the irritability. No disinhibited behaviors were noted. The patient is on regular follow-up with the clinical team, with no significant behavioral problems but gradually progressing cognitive deficits.

DISCUSSION

The above case description and investigation findings helped us make the diagnosis of bvFTD. A literature review showed a few case reports of FTD presenting as pure psychiatric syndromes. One of the cases presented with persistent paranoid delusions.[6] Another case presented with clear schizophrenic symptoms and was treated with antipsychotics for a few years.[7] Another case presented with pathological gambling.[8] In another case report, where a case of frontotemporal lobar dementia whose presentation was consistent with bipolar affective disorder with psychosis in addition to ongoing substance abuse and the illness was refractory to treatment for bipolar disorder, the authors emphasized the need for the clinicians to consider differential diagnoses in manic and psychotic symptoms resistant to polypharmacy.[9]

Nucleus accumbens, part of the ventral striatum and the mesolimbic pathway, which are the reward pathway of the brain,[10] are responsible for addictive and reward-seeking behaviors. Atrophic changes in these areas can be implicated in these behaviors in patients with FTD. A study, which looked at the anatomical correlates of reward-seeking behaviors in bvFTD, revealed a significant correlation between primary reward seeking and atrophy of the right ventral putamen extending into the right pallidum. The authors concluded that these behaviors are caused, at least in part, by abnormal reward processing.[11]

Several medical and environmental risk factors such as traumatic brain injury, hypertension, hyperlipidaemia, and tobacco use might be associated with FTDs.[12] Hence, a thorough evaluation of the patient, as was conducted in our case, is mandatory. Our review of the literature did not reveal any reports of FTD with female patients presenting with nicotine dependence as one of the important presenting symptoms, especially in the Indian context.

When it comes to the treatment of the substance use behaviors, a case report highlights how topiramate led to improvement in the drug-seeking behaviors.[13] In our patient, the use of quetiapine along with donepezil and memantine led to significant improvement in the drug dependence and other behavioral problems within 4–6 weeks. The effective use of quetiapine along with the anti-dementia medications for the treatment of drug dependence in bvFTD has not been reported earlier. In the geriatric population, any late-onset behavioral symptoms should always raise a suspicion of neurodegenerative disorders, especially with an increase of substance abuse or dependence among the elderly population; one of the etiological factors for substance abuse in the elderly could be FTD. The main purpose of reporting this case is to highlight the varied presentation of a neurodegenerative disorder in an elderly woman and how early diagnosis and appropriate treatment can lead to good improvement in these behavioral symptoms and improve the quality of life in 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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Dysmorphic Delusion and Olanzapine-Induced Postpartum Dermatosis in a Case of Schizophrenia

Sir,

Olanzapine has been used widely to control psychotic symptoms in patients with schizophrenia, bipolar disorder, and aggression associated with other psychiatric disorders. Weight gain and hyperglycemia are the most serious side effects of olanzapine in long-term treatment.[1] Olanzapine is one of the preferred drugs among atypical antipsychotics for short-term use.[2] However, we encountered an acute dermatological adverse drug reaction (ADR) of olanzapine in a patient with dysmorphic delusion.

CASE REPORT

A 25-year-old lady, Mrs. G, P_1L_1, 6 months postpartum, presented with a 1-year history of hallucinatory behavior, hostility toward family members, disorganized behavior, and poor bonding with a physically healthy

infant. During 6 months of the postpartum period, she became socially aloof, muttering to self, not sleeping at nights, and holding a false belief that her face has turned ugly, in the absence of any visible facial skin changes. On mental status examination, poor cooperation, difficulty in establishing rapport, poverty of speech, second person auditory hallucinations, which patient refused to elaborate, and dysmorphic delusion were established. She was diagnosed with undifferentiated schizophrenia and treated by a psychiatrist with risperidone 6 mg/day for 3 months, without much improvement. When she came to our hospital, considering a failed response to treatment, risperidone was cross tapered with oral olanzapine up to 20 mg per day over 1 week. During 3 weeks of inpatient care, an improvement was noted in hallucinations, self-care, and bonding with the infant.

However, there was development of non-pruritic, non-erythematous, self-limiting papulopustular (acneiform) skin eruptions over the face, which worsened with increasing dosage of olanzapine. Despite reduction in other psychotic symptoms, the patient continued to hold the dysmorphic delusion that her face is ugly, and unfortunately, it appeared self-validating because of the recent development of acneiform eruptions.

There was no history of self-mutilation, skin excoriation, hair picking, or exposure to known allergens, and hence, diagnoses of self-induced dermatosis (acne excoriation) and hypersensitivity reaction were ruled out. Her blood glucose level, autoimmune workup, thyroid, liver and renal functions were found to be within normal limits. Her menstrual cycles were regular.

The diagnosis of olanzapine-induced acneiform dermatosis was considered after a dermatology consultation. A cognitive behavioral therapy approach was used to tackle dysmorphic delusion. The patient was reassured about probable cosmetic adverse effects of olanzapine. Her belief was shaken slowly through a course of five therapy sessions targeting overgeneralization as a main cognitive distortion. This was accompanied by disproving her beliefs by comparing pictures and mirror reflections, reassuring about the reversibility of acneform eruptions, and video feedback with the infant. Olanzapine was continued after risk-benefit analysis and shared decision-making with patient and caregiver.

DISCUSSION

Some of the common facial dermatological conditions during the postpartum period include dry skin, hormonal acne, spider veins, and post-pregnancy-melasma. Skin eruptions in the perinatal period are considered as dermatoses of pregnancy.[3] A broad group named pruritic urticarial papules and plaques of pregnancy and polymorphic eruptions of pregnancy are two distinct conditions that constitute 0.5% of total cases.[4] However, till now, only six case reports have described dermatoses during the post-partum period,[5] which include lesions that are pruritic, erythematous, and inflammatory in nature. The earlier reports also highlight facial sparing and occurrence during the immediate post-partum period.[6]

In contrast, acneiform dermatosis in our case was non-pruritic, non-erythematous, restricted to facial skin, and developed around the sixth month postpartum. None of the previous reports had described the postpartum onset of acneiform dermatoses on exposure to olanzapine. Skin rash,[7] pustular eruptions,[8] hypersensitivity syndrome,[9] acneform eruptions,[7] and pellagroid skin eruptions have been reported with oral olanzapine preparation[10] in non-postpartum cases. Pathological findings have confirmed the nature of the skin eruption after olanzapine exposure[11] in non-postpartum cases.There is no previous case report describing postpartum acneiform dermatosis with olanzapine exposure in schizophrenia. This case is interesting because the coincidental appearance of acneiform facial eruptions after treatment with olanzapine seemed to reinforce and consolidate the earlier dysmorphic delusion held by the patient.

The exact mechanism of olanzapine causing skin eruptions is sparsely studied. It is hypothesized that olanzapine acts through neurotrophic factors which work in sync with the neurohormonal system. In addition, it is possible that olanzapine alters the androgen sensitivity of end-organ sebaceous system, which is responsible for sebum formation and acneiform eruptions. In future, we need to study the exact mechanism of this adverse effect as olanzapine being one of the state of the art atypical antipsychotics, the cosmetic side effects should not limit its use. Moreover, such drug-induced dermatological adverse effect of antipsychotics can be challenging in patients with dysmorphic facial delusions.[12] Points in favor of our diagnosis were previous conclusive reports of olanzapine-induced dermatoses, the appearance of ADR after the introduction of olanzapine, dose-related severity of dermatosis, and the absence of alternative causes for dermatosis. With a Naranjo Nomogram score of 6, this case highlights acneiform facial dermatosis as a probable ADR of olanzapine.

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

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Euprolactinemic Galactorrhea with Paroxetine: Exploring the Missing Link

Sir,

Selective serotonin reuptake inhibitors (SSRI) are a group of antidepressants used in psychiatric conditions such as major depressive disorder, obsessive compulsive disorders, anxiety disorder, sexual disorders, etc. Paroxetine is an SSRI which also has concomitant norepinephrine reuptake inhibitory properties. Sexual dysfunctions including loss of libido, anorgasmia, and erectile dysfunction are the frequently described adverse effects with the use of SSRIs including paroxetine. Iatrogenic hyperprolactinemia causing galactorrhea has been described with the use of SSRIs such as sertraline, escitalopram, fluoxetine, and paroxetine.[1] However, galactorrhea in the context of a euprolactinemic state with the use of paroxetine is rarely cited, without any clear explanation of the underlying pathophysiology.[2,3] We report a woman who was treated with paroxetine when she developed galactorrhea despite having normal serum prolactin levels. We also attempt to postulate the possible neurobiological explanation for this presentation.

A 35-year-old married woman presented to the psychiatry outpatient department with complaints of a "ball of air" that is felt to move around in her abdomen for the last 9 years, in a fluctuating pattern characterized by periodic exacerbations and remissions. She would often speak of harboring a major abdominal condition that led to doctor shopping and multiple investigations on demand over the last 9 years but with little benefit. She was also found to be having low mood, anhedonia, prominent depressive cognition, insomnia, and loss of appetite for the last 2 months.

She was provisionally diagnosed with hypochondriacal disorder with secondary depression. She was started on Tab. paroxetine and maintained on a dose of 25 mg/day. After 2 months, on follow-up, there was a substantial reduction in her somatic preoccupations along with improvement in her mood state. She, however, complained of whitish milky discharge from both her nipples for the last 2 weeks, which was not present earlier. She had otherwise normal menstrual cycles without any use of oral contraceptives and had no recent pregnancy or lactation for the last 6 years after her only child was born. She also had no local chest infections or trauma recently. We suspected either a local breast pathology or an endocrinal/pituitary cause for the presentation.

Fine-needle aspiration cytology (FNAC) examination with a specimen of breast discharge revealed findings suggestive of galactorrhea, while mammogram of both breasts revealed focal segmental branch duct dilatation without obvious intraductal growth bilaterally (Breast Imaging Reporting and Data System or BIRADS II), and both these pointed to galactorrhea.[4] Routine blood investigations (complete hemogram, renal and hepatic function tests) were normal. An endocrinological profile was done, which revealed normal thyroid function tests and, surprisingly, normal morning serum prolactin level (7.22 ng/mL). Brain imaging (MRI brain) ruled out any central pituitary cause of such a presentation.

Paroxetine was stopped, and she was prescribed nortriptyline 25 mg/day. Follow-up after 2 months revealed a significant reduction in the galactorrhea. However, there was worsening of her mood state and hypochondriacal concerns. We planned to re-challenge her with paroxetine 25 mg/day afresh, and this again resulted in a re-emergence of galactorrhea after 3 weeks of the re-challenge. Paroxetine was again stopped and finally she was maintained on Cap. venlafaxine 75 mg/day, which resulted in improvement of her psychiatric symptoms, with no further recurrence of galactorrhea. Venlafaxine was chosen in view of its efficacy in hypochondriacal and somatic symptoms and also its less propensity to cause hormonal side effects.[5]

Iatrogenic galactorrhea has been reported with the use of most SSRIs, including paroxetine. However, isolated galactorrhea with the use of paroxetine, with a normal menstrual cycle, in the context of a euprolactinemic state, is a rare clinical presentation.[2] In our case the patient developed galactorrhea after around 6 weeks of continuous intake of paroxetine 25 mg/day, which waned off after discontinuing it and re-emerged upon re-challenge. The causality was further strengthened by the findings in FNAC, mammogram, and MRI brain. We applied the Naranjo Adverse Drug Reaction Probability Scale[6] that yielded a score of 6, suggesting "probable" causality due to paroxetine.

Reports of galactorrhea due to paroxetine are available in the literature [Table 1]. It has been found to start within a few weeks to months of starting paroxetine and has been associated with both normal and raised serum prolactin levels. However, the current finding of iatrogenic galactorrhea in an euprolactinemic state needs to be understood from a neuroendocrinological perspective.

Paroxetine-induced galactorrhea can be understood by probable serotonergic inhibition on the dopaminergic neurotransmission mediated through two different pathways. The first is the presynaptic inhibition of tuberoinfundibular dopamine release by serotonergic receptors, and the second is through direct stimulation of hypothalamic postsynaptic serotonergic receptors that leads to the release of prolactin-releasing factors such as vasoactive intestinal polypeptide and oxytocin, which in turn leads to hyperprolactinemia.[3] However, in both these cases, serum prolactin will be raised since both these involve "dopamine-dependent" pathways.

The biological basis of an iatrogenic euprolactinemic galactorrhea state remains elusive, though two mechanisms can be proposed to explain the finding.

Table 1: Published literature on paroxetine-induced galactorrhea

Authors	Paroxetine dose (mg/day)	Duration of paroxetine treatment before onset of galactorrhea (weeks)	Serum prolactin level
González *et al*., 2000[7]	40	16	Not mentioned/assessed
Bhattacharya *et al*., 2010[3]	25	6	Normal
Sertcelik *et al*., 2012[2]	60	2	Normal
Gulati *et al*., 2014[1]	75	11	Raised
Evrensel *et al*., 2016[8]	20	28	Raised

There are reports suggesting nondopaminergic involvement, where iatrogenic euprolactinemic galactorrhea has been implicated through thyrotropin releasing hormone hyper-responsiveness. Such a mechanism for galactorrhea was earlier proposed for escitalopram.[9] Paroxetine being of similar chemical class as escitalopram can probably produce a euprolactinemic galactorrhea state through this mechanism. The other postulate is that it might be due to the isomeric variation of prolactin. Prolactin has different isomers, i.e., small, big, and big-big, having differences in bioactivity and immunoreactivity. Macroprolactinemia is a rarely cited condition in which there is a proportionately higher level of the big-big isomeric fraction. Elevation in the levels of macroprolactin, which is impermeable to the capillary membrane, can present with symptoms of galactorrhea with normal serum prolactin, though a literature search did not reveal any such isomeric change induced by paroxetine. Macroprolactinemia can also be associated with autoimmune thyroid conditions.[10] A search for a possible autoimmune thyroid condition can be beneficial for this patient.

The exact causality of the finding is difficult to ascertain, though this report tries to highlight that paroxetine use can rarely cause galactorrhea which possibly involves a nondopaminergic explanation and clinicians need to be vigilant about the emergence of such symptoms.

Declaration of patient consent

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Meningomyelocele on Exposure to Clozapine During Perinatal Period

Use of antipsychotics in pregnancy is based on a risk-benefit analysis. Clozapine is generally used in treatment-resistant schizophrenia, and it is often less used in pregnancy. Safety of clozapine is not well studied in pregnant women. We report a case where a woman on clozapine along with folic acid supplementation gave birth to an infant with neural tube defect (NTD).

Clozapine readily crosses the placenta and is found in amniotic fluid and fetal blood.[1] A few case reports and case series have reported macrocephaly, floppy infant syndrome, cardiac arrhythmias, and neonatal seizure as teratogenic effects of clozapine.[2,3] We report a rare case where an NTD was detected in a new-born exposed to clozapine during the antenatal period.

CASE HISTORY

A 30-year-old woman, who had a weight of 60 kg and height of 160 cm (BMI 23), was on clozapine 225 mg for more than 2 years for treatment of schizophrenia. She was found to be pregnant after four months of amenorrhea while on clozapine 225 mg, haloperidol 2.5 mg, and multivitamin tablets (containing vitamin A 2500 IU, vitamin D3 200 IU, vitamin B1 2 mg, vitamin B2 2 mg, vitamin B6 0.5 mg, niacinamide 25 mg, calcium pantothenate 10 mg, vitamin C 50 mg and 0.2 mg of folic acid). She was symptomatic even on the regime.

Following the detection of pregnancy, clozapine was stopped, and she was on haloperidol 10 mg/day for 15 days. As the schizophrenia symptoms were worsening, within a month, clozapine was restarted and maintained at 150 mg/day.

On ultrasonography in the fifth month and at term, fetal ventriculomegaly was noticed. As her symptoms were manageable on clozapine 150 mg/day, it was continued until delivery. At the 36th week, she developed gestational diabetes and was treated with insulin.

At term, she delivered a male baby. During labor, the baby had shoulder dystocia and had a low Apgar score at one and nine minutes. At birth, the baby weighed 3.49 kg, the height was 46 cm, and the head circumference was 34.5 cm. The baby had a lumbar swelling and was diagnosed to have lumbar meningomyelocele, an open NTD [Figure 1]. The baby was admitted in the intensive care unit for further care.

DISCUSSION

This case is one where an NTD is detected on in-utero exposure to clozapine. NTD on exposure to olanzapine, another atypical antipsychotic, has been reported.[4]

In our case, the mother was on 225 mg/d of clozapine and 2.5 mg/d of haloperidol throughout her first trimester, a critical period of organogenesis. Neural tube formation occurs between the third and fourth weeks of embryogenesis.[5] Failure of closure within this period results in NTD. In a study of 11 cases who were on clozapine, two babies had congenital anomalies: one had craniosynostosis and gastroschisis, and the other baby had horseshoe kidney.[6] Macrocephaly has been reported with clozapine and olanzapine.[2]

According to the National Birth Defect Prevention Study, risk factors for NTDs include family history of NTD, obesity, pregestational diabetes, low folate, and anticonvulsant use: Together, these factors account for less than 50% of NTD.[7] Folic acid has been observed to be critical in neural tube development. Our patient, the mother, was on multivitamin supplementation containing 0.2 mg of folic acid, for about two years until her pregnancy was detected. Hence, a deficiency of folate is less likely. There are studies which have shown that vitamin supplementation during the periconceptional period reduces the risk of NTD (OR >=1.7), while folic acid supplementation was slightly more protective against spina bifida.[8]

Figure 1: Swelling over the lumbosacral region

Overweight is a risk factor for NTD. It is known that atypical antipsychotics cause weight gain, and low serum folate levels, along with overweight, may put infants of women with clozapine at high risk for NTD.[9] Amount of overall weight gain during pregnancy and serum folate levels are not available for this patient. Maternal diabetes is also a risk factor for NTD. This case had no diabetes before conception and was diagnosed to have gestational diabetes at the third trimester.

Clozapine is less studied in pregnancy or animal studies. NTD may be an effect of clozapine interfering in organogenesis. Clinicians must be vigilant about such cases. Further prospective studies are warranted to determine the safety of clozapine in pregnancy. Clozapine should be used only in difficult cases and in such situations, monitoring should be ensured.

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Comorbid Bipolar Disorder and Benign Joint Hyper Mobility Syndrome (BJHS): More than a Mere Coincidence?

Sir,

Benign Joint Hypermobility Syndrome (BJHS) is thought to be an inherited connective tissue disorder with an autosomal dominant pattern, clinically characterized by hypermobility and pain in multiple joints in the absence of systemic rheumatologic

disorder.[1] There is no consensus on whether this as an independent disorder or a milder variant of well-known Ehler-Danlos syndrome (type-III).[1] Although perceived as a rare condition, BJHS is common, with a prevalence of 5%-38% depending on age, sex, and race.[2] The syndrome appears to be due to an abnormality in collagen or the ratio of collagen subtypes. Mutation in the Fibrillin gene has also been identified in families with BJHS, and recently, mutations in a non-collagenous molecule, Tenascin-X, have also been identified in a subset of patients with BJHS.[1] An increased prevalence of psychological disturbances, such as anxiety, depression, agoraphobia, panic disorder, and attention deficit hyperkinetic disorder (ADHD) has been found in patients with BJHS.[1,3] Here, we describe a young male with BJHS comorbid with bipolar affective disorder (BPAD). To the best of our knowledge, BPAD comorbidity in BJHS has not been reported till date.

We report a 29-year-old male patient, an unmarried graduate, referred by the neurologist who was treating him for pain in multiple joints for more than a year. The patient had the first episode of depression at 21 years of age, followed by another episode within 4 years. Recently, he had manic episode followed again by depression and was treated with lithium carbonate 800 mg/day, olanzapine 5 mg/day, and escitalopram 2.5 mg/day. He was referred to us due to a partial response to the current treatment with persistent social withdrawal, suspiciousness, and reduced sleep and appetite. Mental status examination revealed referential and persecutory delusions, thought broadcasting, and depressed affect. His physical examination had several significant findings. He had marfanoid habitus such as tall stature, upper segment less than lower segment (<0.89 ratio) and arm span to height ratio of 1.20 (normal value is <1.05). He had hypermobile joints with a Beighton score of 6 [Figures 1-4]. Neurological and cardiovascular examinations were within normal limits. He was diagnosed with BJHS according to Brighton criteria: Beighton score of >4 and arthralgia for longer than 3 months in four or more

Figure 1: Passive dorsiflexion of the metacarpophalangeal joint to 90°

Figure 2: Forward flexion of trunk with knees extended and hands touching the floor

Figure 3: Hyperextension of the elbow beyond 90° (neutral)

Figure 4: Apposition of the thumb to the flexor aspect of the forearm

joints.[4] He had no history of drug or alcohol abuse. His mother was diagnosed with BPAD. He did not have any relative with BJHS. No abnormality was detected in his routine biochemistry and hemogram screen. We raised olanzapine up to 10 mg/day and stopped escitalopram. During the next follow-up after 2 weeks, he reported improvements in his symptoms.

This case illustrates the co-occurrence of BPAD with psychotic features in the presentation and BJHS in a male with a family history of BPAD but not of connective tissue disorders. Our patient had a significant disability due to the BJHS that he seldom played with friends and rather stayed back at home most of the time during his adolescent age. He presented with a history of predominantly depressive episodes with a single manic episode and responded well to a combination of lithium and olanzapine.

BJHS has a well-known association with psychological problems. A recent meta-analysis exploring the relationship between BJHS and psychological distress found greater perceptions of fear and more intense fear among patients with BJHS.[5] Furthermore, they have a higher probability of demonstrating agoraphobia, anxiety, depression and panic disorders than those without BJHS. Studies have observed a higher prevalence of autism spectrum disorders, BPAD, ADHD, depression and attempted suicide among patients with hypermobility syndromes (including different variants of Ehler-Danlos syndrome) when compared with matched controls.[1,6] A relationship was determined between five potentially pathophysiologically linked domains: anxiety disorders, joint laxity, chronic pain disorders, immune dysfunction, and mood disorders.[7] A recent study exploring psychiatric and somatic phenotype of BPAD with co-morbid anxiety disorder found hypermobile joints in 41% of the sample, and it was significantly associated with somatosensory amplification.[8] The commonly used medications for these symptoms, such as antidepressants for anxiety symptoms and steroids for pain symptoms, can have a negative impact on the course of BPAD. Hence, clinicians need to be careful in managing patients with BJHS at risk for BPAD.

The pathophysiology by which BJHS precipitates various psychiatric disorders is not yet clear. This could partly be due to the fear and anxiety associated with potential re-injuries. Moreover, the disease load in BJHS can contribute to poor quality of life and an increased risk of depression and suicide attempt.[2] However, such explanations could not clarify the association between BJHS and BPAD, a progressive, chronic, and episodic psychiatric disorder with multifactorial etiology and strong heritability. BPAD occurring in association with BJHS may be attributed to psychosocial stressors secondary to BJHS or maybe a chance association.

Another possible etiological link between BJHS and BPAD seems to be genetic. Recent evidence suggests that BPAD arises not merely due to neurotransmitter imbalances — rather, it is the result of an impaired synaptic modulation and neural plasticity in crucial pathways that mediate cognitive and affective functions.[9] It can be hypothesized that mutation in the fibrillin gene may predispose patients with BJHS to neurodevelopmental abnormalities which may manifest as psychiatric disorders such as BPAD. A recent genome-wide association study based on single-nucleotide polymorphisms also indicated that polymorphic FBN1 increases the susceptibility to BPAD.[10] Though BJHS is not considered primarily an inflammatory condition, a recent analysis of electronic medical records showed its association with autoimmune/inflammatory disorders.[11] As neuroinflammation is being recognized as an important mediator of the etiopathogenesis of BPAD,[12] the possibility of a shared inflammatory process needs consideration.

In conclusion, our case highlights the co-morbidity of BJHS with BPAD. Such co-occurrences of heritable disorders help us to further understand the neurobiology of both the disorders, especially the role of genes associated with BJHS and the role of connective tissue proteins, in the pathophysiology of BPAD.

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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