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Editorial

Translation or Development of a Rating Scale: Plenty of Science, a Bit of Art

Perhaps one of the greatest challenges in psychiatric research is the selection of an appropriate scale or measure to examine psychological constructs of interest. For a keen researcher, several questions at once spring to mind. What construct(s) does it measure? Does it have sound psychometric properties (reliability and validity)? Is it a screening or diagnostic tool? Is it valid for our setting and culture? Is it norm-referenced or criterion-referenced? Can the cut-offs suggested by the author be directly applied to our setting? Specifically, these questions assume relevance as there are several measures available for evaluating each construct.

Sometimes, a recent systematic review of available measures makes the job easier to choose a scale with good psychometric properties. However, the scale might not be available in regional languages, which is a necessity if it is a self-rated tool. In such situations, 'translation' of the tool using a standard protocol (e.g., the forward-translation and back-translation method of the World Health Organization [WHO])[1] may be required (Box 1). Also, some items of a given scale may not be culturally relevant. Consequently, some form of 'adaptation' of the items or format may be needed. At times, the need for adaptation only becomes apparent while translating a scale. Hence, 'translation and adaptation' of a scale is commonly used together. Furthermore, the psychometric properties of the translated or adapted scales may not be known and are required to be examined before they can be used in research, specifically during cross-cultural studies. More rarely, if the available scales do not meet the requirements of research or the constructs under investigation are not adequately captured by extant scales, there may be a need to develop a new psychological scale (Box 2). The steps involved in this process are different from that of translation and adaptation of an existing scale or measure (Box 3).

Translation and adaptation of existing scale

In this issue, Grover and Dua[2] have translated, adapted, and validated three scales on religiosity into the Hindi language. It is not uncommon to see simple translated versions of English language tools, without any validation, being used in research. These authors have used a standard method of translation by bilingual experts, followed by expert panel evaluation, then pretesting on 20 participants, and finally back-translation by independent bilingual experts. Although this sequence is somewhat different from the guidelines put forth by WHO, it follows the four standard techniques suggested by Brislin[3] to maintain equivalence between the original and translated measure: a) back-translation method, b) bilingual technique, c) committee or expert team approach and d) pretest procedure. Indeed, current approaches to translation have evolved from the Brislin's classic back-translation technique to include more bilingual and bicultural experts to generate a consensus on the final version.

The scales were administered to 132 respondents in the first round. This was followed by a second round of application of the same instruments, after 3-7 days, in either Hindi (n = 61) or English (n = 71). Given the short turnaround time between testing and retesting, memory effects cannot be ruled out. Also, as the same participants were used for all three scales, there is a possibility of respondent fatigue, which could have affected the results.

There was high correlation between the itemized scores on the Hindi and English versions of all three scales. This was indicative of good cross-language equivalence of these tools, which makes them suitable for use not only in the Indian setting but also for comparison with global studies. There are higher chances of type I error in this approach. However, p values less than 0.001 were found for all comparisons, indicating that such a risk is low in this case. Test-retest reliability, internal consistency, and split-half reliability of the Hindi version for all three scales were in the acceptable range. An interrater reliability exercise could have been a meaningful addition. Further, the sample predominantly comprised of urban residents with a minimum of ten years of formal education, limiting the generalizability.

Scale development

Singh *et al*.[4] developed the Comprehensive Satisfaction Index (ComSI) to assess levels of well-being, happiness, and life satisfaction among elderly individuals and examined its psychometric properties. The need for the scale was justified by citing the unique health demands in the elderly and the changing family milieu that has compromised the safety and security of this group. Notably, there is little theoretical discussion to support a strong conceptual foundation for the scale and the putative domain content. This assumes importance because a top-down or deductive process (where the review of literature serves as the guide for item generation) appears to have been followed for domain identification, and this approach has to be based on robust theoretical foundations.[5] Instead, the domain identification was done by a panel of three experts, and item generation was performed by three independent experts.

Subsequently, 5 independent experts performed a content validation exercise that led to the development of a 26-item tool. However, the details of the item pool generated and the number of the items that had to be removed are not stated. Furthermore, some items were modified and shaped following pretesting in 30 individuals and expert consensus. Whether these 30 individuals were drawn from the same target population of interest and whether they were part of the larger sample used in the same study (n = 260) are unclear. The assertion that the "feasibility" of the scale was assessed through the pilot sample could possibly mean validity, as pretesting is part of the process of establishing content validity.

Applying an item-response ratio of 1:10, responses of 260 rural subjects were obtained. Hence the scale may not be applicable to urban respondents in whom the underlying needs and issues are likely to be different. Apart from age, gender, and socio-economic status, other sample characteristics are not presented, thereby raising concerns regarding sample representativeness and generalizability.

Dimensionality of ComSI was assessed using principal component analysis,[6] a procedure similar to exploratory factor analysis. The sample was adequate for factor analysis; however, an inter-item correlation matrix (which allows identification of items that correlate poorly and thus be a source of error and unreliability)[7] was not performed. To identify the number of factors, only Kaiser criterion[8] of eigenvalue >1 was used. Using multiple methods (e.g., scree plot or Horn's parallel analysis)[9] could have increased the reliability.

Notably, item no 17 did not load onto any of the factors, indicating that the item may either not apply to the setting or need to be reworded as it was understood incorrectly by the respondents. Also, reliability statistics (internal consistency), a necessary pre-condition for validity, was not reported. Convergent validity was checked with the WHO Quality of Life (QOL) Scale, but discriminant and criterion validity were not examined.

Bedi and Varma[10] developed a new scale, Positive Temperament Inventory (PTI), to tap the positive temperamental attributes of Indian adults. There is a persuasive account of the relative neglect of positive emotionality in the extant literature. This and the unsuitability of Western instruments in Indian setting were key drivers for developing the scale. Domain identification and item generation were done through a deductive process[5] following a literature search, identifying items that represented the most relevant and common behaviours in the Indian setting and rewording them for cultural compatibility.

However, the semantics of the paper leaves room for some confusion. It is mentioned that "15 factors" were reduced to "6 factors" containing 6 items each (making it a 36-item scale), based on the opinion of 2 experts, because these 6 factors had more putative items related to positive temperament. However, this approach may have potentially excluded less frequent temperamental attributes.

Subsequently, exploratory and confirmatory factor analyses were carried out, separately, in two different but demographically similar samples. Convergent validity was assessed through the prosocial domain of the Strength and Difficulties Questionnaire (SDQ), while divergent validity was assessed through the correlations of factors with the neuroticism subscale of International Personality Item Pool (IPIP). However, the choice of SDQ to check validity is not appropriate because the age group intended to be covered by the SDQ (3-16)[11] and the PTI (18-80)[10] do not overlap.

The results of the two-stage factor analysis with sample adequacy, the goodness of fit statistics, and cut-offs for factor loading are explained well. Observed convergence between Kaiser criteria and scree plot, as well as good reliability statistics, adds certainty to the results. How two second-order factors (temperamental positivity and dynamic positivity) were arrived at using the correlation matrix of the four first-order factors was also explained adequately. However, the

Box 1: World Health Organization (WHO) protocol for scale translation

1. Forward translation: Translation to the target language by a bilingual individual aiming conceptual equivalence of the items
2. Expert panel: A bilingual expert panel identifies and resolves the discrepancies between the two versions.
3. Back-translation: Translation back to original language by an independent person not familiar with the measure
4. Pretesting: On target participants followed by in-depth interviews or focused groups to identify any unacceptable words or expressions.

Box 2: When to develop a new scale or measure?

1. When existing scales do not measure the intended construct or do not adequately cover key attributes of the construct of interest
2. When the existing scales do not address the needs of the intended target population, which may differ psychologically from the original population in whom the scale was validated
3. When existing scales have become outdated due to cultural, societal, or generational change, and there is a need for new measures that may better capture topical issues
4. When the adapted or translated version does not have psychometric or dimensional stability across culturally and linguistically different groups
5. When novel research hypotheses, involving new constructs, are propounded.

Box 3: Steps involved in scale development

1. Define the construct and the context: Based on literature review, consultation with subject experts and a sound theoretical foundation
2. Selecting response format: The scale format (e.g., Likert type) and number of response options are selected
3. Item pool generation: Generation of items that adequately sample the content domains of interest
4. Item evaluation: A panel of experts examine the quality and relevance of the items, which may be modified or refined based on their input
5. Pilot testing: This is done through an exploratory study in order to create a more parsimonious representation of the original items
6. Testing for psychometric properties: Reliability assessment includes internal consistency, split-half reliability, and test-retest reliability. The dimensionality of the scale is examined through exploratory and confirmatory factor analysis. Other validity measures include convergent, discriminant, and criterion validity.

omission of findings of the inter-item correlation matrix limits the understanding of prerequisites of factor analysis. This is particularly relevant because moderate correlations were noted between the first-order factors. Also, the inclusion of a self-selected sample points to a possible selection bias, which is not acknowledged in the paper.

To sum up, using culturally validated measures lends greater credibility to any research. From this perspective, it is gladdening to note the increasing research focus on developing and validating culturally compatible instruments. This will, no doubt, enhance good quality data from our settings and facilitate comparisons with global literature. The readers are advised to read the three articles discussed here thoroughly along with this editorial in order to understand the nuances involved in the development of a psychological measure, which can be aptly described as plenty of science and a bit of art.

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Original Article

A Focus Group Study of Indian Psychiatrists' Views on Electroconvulsive Therapy under India's Mental Healthcare Act 2017: 'The Ground Reality is Different'

Richard M. Duffy, Gautam Gulati[1], Vasudeo Paralikar[2], Niket Kasar[2], Nishant Goyal[3], Avinash Desousa[4], Brendan D. Kelly

ABSTRACT

Background: India's Mental Healthcare Act, 2017 (MHCA) greatly restricts the use of electroconvulsive therapy (ECT) in minors and bans unmodified ECT. Indian psychiatrists have raised concerns that these measures may deprive certain patients of life-saving treatment. This study describes the perspectives of Indian psychiatrists on how ECT is dealt with in the legislation. **Methods:** We conducted nine focus groups in three Indian states. We explored the positive and negative implications of the MHCA and discussed its implementation, especially in relation to ECT. **Results:** Many of the themes and concerns commonly discussed in relation to ECT in other jurisdictions are readily apparent among Indian psychiatrists, although perspectives on specific issues remain heterogeneous. The one area of near-universal agreement is Indian psychiatrists' affirmation of the effectiveness of ECT. We identified three main areas of current concern: the MHCA's ban on unmodified ECT, ECT in minors, and ECT in the acute phase. Two broad additional themes also emerged: resource limitations and the impact of nonmedical models of mental health. We identified a need for greater education about the MHCA among all stakeholders. **Conclusion:** Core concerns about ECT in India's new legislation relate, in part, to medical decisions apparently being taken out of the hands of psychiatrists and change being driven by theoretical perspectives that do not reflect "ground realities." Although the MHCA offers significant opportunities, failure to resource its ambitious changes will greatly limit the use of ECT in India.

Key words: *Electroconvulsive therapy, human rights, India, jurisprudence, mental health legislation*

Key Messages: *a) Indian psychiatrists have grave concerns about legislative restrictions on ECT and mental health resource limitations. b) There is a need for greater education about the Mental Healthcare Act, 2017 among all stakeholders, not least because failure to resource its ambitious changes will greatly limit ECT in India.*

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India has radically revised its mental health laws with the introduction of the Mental Healthcare Act, 2017 (MHCA). This legislation seeks to make India's mental health law concordant with the United Nations (UN) Convention on the Rights of Persons with Disabilities (CRPD) and, arguably, represents a paradigm shift toward rights-based, patient-centered mental health law.[1-3] Both the CRPD and the MHCA have proved to be controversial, and many psychiatrists are significantly concerned about the unfolding legislative changes.[4-7] One of the major areas of contention is electroconvulsive therapy (ECT).

The MHCA will impact the use of ECT in many ways. Involuntary admissions are being replaced by supported admissions (Sections 89--90), and while ECT can be given to supported patients, there are significant administrative and regulatory requirements. Section 95 of the new legislation bans unmodified ECT (i.e., ECT without anesthetic) and only permits ECT in minors with the consent of the guardian and Mental Health Review Board (MHRB). Section 94 bans ECT during emergency treatment outside of the hospital or in nonmental health establishments.

ECT is widely used in India. One survey of 66 hospitals identified almost 20,000 patients receiving over 110,000 sessions of ECT in a 1-year period, of whom more than half received unmodified ECT.[8] Psychiatrists have expressed concern that restrictions on ECT in the MHCA will deprive certain patients of life-saving treatments.[9,10] In contrast to the concerns of psychiatrists, many ethical issues have been raised about the practice of ECT in India and media portrayals have increased stigma.[11,12]

This study aims to describe the perspectives of Indian psychiatrists on how ECT is dealt with in the MHCA. Using focus group methodology, common themes relating to ECT and the new legislation are identified, examined, and explored.

METHODS

A focus group methodology was employed to explore mental health professionals' perceptions of the MHCA in general, with the intention of focusing more closely on specific issues as they emerged. Focus group methodology was chosen because the topics being explored are complex and tend to elicit complex opinions, and additional insights were to be gained from both the emotional content expressed in focus groups and from interactions during focus group discussions. Many of these subtleties are not amenable to quantitative approaches. Ethical approval was granted by Trinity College Dublin's School of Medicine Research Ethics Committee.

Population and sampling

Nine focus groups were conducted, in seven centers, in three states (one in Bihar, two in Jharkhand, six in Maharashtra) between November 2017 and November 2018. Sixty-one mental health professionals participated, including 56 psychiatrists. A purposive sampling method was adopted, and informants with high-level knowledge of the MHCA were sought from a wide range of backgrounds.[13,14] Focus groups were organized by key academics through existing local professional development groups. At locations where two focus groups were conducted, senior staff who were longer in practice were included in focus groups separate from other staff in an attempt to minimize group heterogeneity.[15] Groups were divided so that psychiatrists who had practiced for longer were interviewed in the same group, in order to reduce the effect of power dynamics within focus groups, as suggested by the Krueger and Casey.[16] Focus groups were mixed by specialty and subspecialty because most psychiatrists had multiple specialties, and specialty or sub-specialty did not affect the power balance within groups.

Focus groups

Focus groups consisted of six to ten individuals and lasted between 45 and 90 min. Written informed consent was obtained from all participants. All focus groups had one moderator who led the discussion and one to two observers who recorded who was speaking and documented nonverbal information. The questioning route (see Appendix) evolved out of extensive document analysis and the relevant published literature.[2,3,16-18]

Focus groups were audio-recorded and recordings transcribed. Nonverbal information was documented on paper by the observers during the focus groups and was coded when listening to the audio-recordings during the analysis phase of the study.

In terms of opening questions, focus groups explored participants' views regarding what they felt was positive about the new legislation, their concerns about the MHCA, what they felt needed to be done during the transitional phase, and what they would have done differently if they were writing the legislation themselves (see Appendix). With these questions as focus points, the moderator encouraged participants to examine emergent topics that they found especially relevant. The moderator and observer debriefed after each group in order to facilitate an iterative development of the questioning route as the study

progressed. Demographic and professional information was collected on all participants.

Data analysis

Focus groups were audio-recorded and recordings transcribed. Data were coded inductively and a conventional content analysis performed by two of the authors both independently and collaboratively in an iterative process.[19,20] Although the focus groups were initially thematically focused on the entire MHCA, ECT quickly emerged as a key theme early in the study, so, guided by this thematic development and consistent with focus group methodology, all data pertaining to ECT were analyzed for the present paper. Categories were identified and related categories incorporated into higher-order categories. Data were analyzed using NVIVO (Version 12.0).

RESULTS

Three focus groups were carried out in December 2017 prior to formal commencement of the MHCA, and six were carried out during implementation in November 2018, although key elements of the legislation had not yet been implemented in practice at that point (e.g., MHRBs to review certain admissions had not yet been established). Three groups were conducted in stand-alone psychiatric hospitals, five at professional development meetings in psychiatric units in general hospitals, and one in an external professional development group.

Table 1 shows the demographic and professional characteristics of our focus group participants. In total, 61 individuals participated in the research. Fifty-six were consultant psychiatrists, and the others were senior clinicians or administrators.

Although the focus groups were initially focused on the entire MHCA, ECT quickly emerged as a key theme that arose spontaneously in all nine focus groups. While focus group methodology does not permit quantitative analysis of individual participants' views, all groups were supportive of ECT in general. One group stated that limitations on ECT were their greatest concern with the MHCA. Eight groups felt that the MHCA was negative for patients in terms of ECT, whereas one group welcomed the additional regulations and ban on unmodified ECT. Four groups strongly supported being able to give unmodified ECT; two did not express a clear consensus, and three supported the ban. Three groups held the view that ECT was totally banned in minors.

Three focus groups raised the issue of resource limitations in relation to ECT, noting that deficits in

Table 1: Demographic and professional characteristics of mental health professionals who participated in focus groups

	FG1	FG 2	FG3	FG4	FG5	FG6	FG7	FG8	FG9	Total
Number of participants	8	6	7*	6	6	6†	10	6	6	61
Male	87.5% (7/8)	83.3% (5/6)	85.7% (6/7)	33.3% (2/6)	100% (6/6)	66.7% (4/6)	100% (10/10)	66.7% (4/6)	50.0% (3/6)	77.0% (47/61)
Mean years of experience (range)	18.6 (5-39)	16.3 (8-33)	12.4 (8-25)	5.0 (0-16)	1.3 (.5-2)	17.8 (5-35)	17.7 (12-35)	16.2 (4-35)	19.0 (5-40)	14.2 (0.5-40)
Working in urban settings	100% (8/8)	50% (3/6)	85.7% (6/7)	100% (6/6)	100% (6/6)	100% (6/6)	100% (10/10)	100% (6/6)	100% (6/6)	93.4% (57/61)
Working in rural settings	12.5% (1/8)	50% (3/6)	57.1% (4/7)	0% (0/6)	0% (0/6)	16.7% (1/6)	30% (3/10)	0% (0/6)	0% (0/6)	19.7% (12/61)
Public practice	87.5%(7/8)	100% (6/6)	100% (7/7)	100% (6/6)	100% (6/6)	100% (6/6)	50% (5/10)	16.7% (1/6)	16.7% (1/6)	73% (45/61)
Private practice	25% (2/8)	0% (0/6)	0% (0/7)	16.7% (1/6)	0% (0/6)	33.3% (2/6)	90% (9/10)	100% (6/6)	83.3% (5/6)	40.1% (25/61)
General adult psychiatry practice	100% (8/8)	100% (6/6)	85.7% (6/7)	83.3% (5/6)	83.3% (5/6)	83.3% (5/6)	100% (10/10)	83.3% (5/6)	100% (6/6)	91.8% (56/61)
Liaison psychiatry practice	37.5% (3/8)	33.3% (2/6)	42.9% (3/7)	16.7% (1/6)	66.7% (4/6)	50.0% (3/6)	40% (4/10)	66.7% (4/6)	50.0% (3/6)	44.3% (27/61)
Academic psychiatry	25% (2/8)	100% (6/6)	71.4% (5/7)	50.0% (3/6)	83.3% (5/6)	0% (0/6)	30% (3/10)	16.7% (1/6)	16.7% (1/6)	42.6% (26/61)
Old age psychiatry practice	50% (4/8)	16.7% (1/6)	14.3% (1/7)	16.7% (1/6)	50.0% (3/6)	66.7% (4-6)	40% (4/10)	16.7% (1/6)	33.3% (2/6)	34.4% (21/61)
Forensic psychiatry practice	25% (2/8)	16.7% (1/6)	0% (0/7)	16.7% (1/6)	16.7% (1/6)	33.3% (2/6)	10% (1/10)	0% (0/6)	0% (0/6)	13.1% (8/61)
Child and adolescent psychiatry practice	50% (4/8)	50% (3/6)	28.6% (2/7)	33.3% (2/6)	83.3% (5/6)	33.3% (2/6)	30% (3/10)	33.3% (2/6)	16.7% (1/6)	39.3% (24/61)
Intellectual disability psychiatry practice	12.5% (1/8)	33.3% (2/6)	28.6% (2/7)	16.7% (1/6)	50.0% (3/6)	33.3% (2/6)	0% (0/10)	33.3% (2/6)	0% (0/6)	21.3% (13/61)
Addiction psychiatry practice	87.5% (7/8)	50% (3/6)	57.1% (4/7)	33.3% (2/6)	66.7% (4/6)	83.3% (5/6)	70% (7/10)	16.7% (1/6)	50.0% (3/6)	59.0% (36/61)
Inpatient work	75% (6/8)	100% (6/6)	100% (7/7)	100% (6/6)	100% (6/6)	83.3% (5/6)	100% (10/10)	33.3% (2/6)	83.3% (5/6)	86.9% (53/61)
Outpatient work	100% (8/8)	100% (6/6)	85.7% (6/7)	100% (6/6)	100% (6/6)	83.3% (5/6)	100% (10/10)	100% (6/6)	100% (6/6)	96.7% (59/61)

Clinicians were encouraged to tick all descriptions that applied to them. FG – Focus group. *Included the hospital's heads of nursing, social work, and occupational therapy, †Included one consultant anesthetist responsible for ECT in the hospital and the hospital's most senior mental health administrator, ECT - Electroconvulsive therapy

human resources necessitated the use of unmodified ECT in rural areas and that a paucity of trained staff and trained MHRB members might limit access to ECT in the future. Seven of the nine focus groups supported the use of ECT in minors and were very concerned about the limitations imposed by the MHCA.

Overall, ECT generated some of the most emotionally charged responses in the study. Four main themes emerged that directly related to ECT [Table 2] and two more emerged that were indirectly related to ECT [Table 3]. These six key themes are now each discussed in turn in more detail.

Themes directly relating to ECT

The benefits of ECT

The professionals we interviewed were highly supportive of ECT [Table 2]. They described their departments as "ECT friendly" and their use of ECT as "liberal". ECT was described as "life-saving" in two-thirds of the groups. They referenced many anecdotes in support of ECT but also talked about both published literature and local research. Many highlighted the severity of cases presenting to them and a long duration of untreated illness as justifying the need for ECT. They felt that many patients did not have other viable options:

> "Most of us have prevented suicide … with ECT, but now our hands are tied."

ECT in minors

The strongest opposition to the new legislation concerned the restrictions on ECT in minors; this topic often evoked angry statements concerning the MHCA. Many psychiatrists whom we interviewed practiced ECT in minors. Two subthemes emerged:

First, many psychiatrists stated that the MHCA prohibited minors from receiving ECT (although it can, in fact, be authorized). Some believed that this prohibition was in the MHCA, whereas others acknowledged that ECT in minors was possible but that administrative constraints would amount to a *de facto*

Table 2: Key themes and subthemes identified from focus groups directly relating to ECT

Theme	Subtheme	Key quotes
Benefits	Life-saving nature	"ECT is a life-saving therapy." "It works; it works wonders."
	Evidence base	"We have robust data to say that unmodified ECT is safer than modified ECT, which is safer than antidepressants." "We shared data from our institute that we have been using ECT for the last 60 odd years."
	Vignette or personal story	"Every time he has mania, the only thing he responds to is ECT … But in a manic phase, he will refuse. But after a couple of sessions of ECT, he comes back to himself. Nothing works with him except ECT."
	In severe cases	"We have to take permission from them [MHRBs], but the patient is violent and highly suicidal. It will take a lot, maybe three to four days."
Minors	Prohibition	"This Act doesn't allow it."
	MHRB role	"They have talked about minors. You need to go to the District Review Board; Fine if you win the review." "The Review Boards - Who knows what they're actually going to advise on, what they're actually going to do."
Unmodified ECT (i.e., without anesthetic)		"Even in a set up like this, we have serious problems getting an anesthetist because there is a paucity of anesthetists." "And we have not seen any significant problems with unmodified ECT. In fact, we can say that in many aspects it is better than the modified ECT."
Acute phase	Emergency treatment	"Of course, there are institutions and psychiatrists who do give ECT within the first 24 h; Now, under the [new legislation], that cannot happen."
	Early in admission	"That is our concern there: that ECT will be less used and particularly when there is a definite need in terms of emergency." "You can treat for 72 h, and we are not allowed to give ECT in those 72 h."

ECT - Electroconvulsive therapy, MHRB – Mental Health Review Board

Table 3: Key themes and subthemes identified from focus groups indirectly relating toECT

Theme	Subtheme	Key quote
Resource limitation	Professionals	"We are not able to give unmodified ECT. And again we have to beg for anesthetists."
	Infrastructure	"We need to improve the resources so that we can give those kinds of services." "People from remote places are visiting faith healers. First, they have to get the proper psychiatrist; That would be our first objective."
	Personal finance	'"In many private set-ups, if you had an anesthetist for the ECT, the expenses or cost of ECT will also be too much."
Non- medical models of mental health	Drafting legislation	"The Act was discussed here before going to Parliament. This draft was discussed, and there were a lot of protests. But it was dismissed by giving the reference of the United Nations' Convention on the Rights of Persons with Disabilities." "… Psychiatrists feel that their concerns, their viewpoints, have not been given as much importance as the views and opinions of other stakeholders like patients or care-givers and nongovernmental organizations."
	MHRBs	"Psychiatrists do not have proper representation on any committee, on any board." "Medical decisions should be left to medical people."
	Patients	"They [nongovernmental organizations and the anti-ECT lobby] are strongly against ECT. They have created lots of anger about ECT and these patients and families are rejecting ECT."

ECT - Electroconvulsive therapy, MHRB – Mental Health Review Board

prohibition. Second, many psychiatrists felt bureaucracy and MHRBs could greatly delay ECT in a minor.

Only one group saw any positive aspect to the limitation of ECT in minors. In that group, one psychiatrist mentioned that they felt that the new legislation offered a degree of protection:

> "I would prefer a judicial review rather than a police review."

Unmodified ECT

The prohibition of unmodified ECT also produced strong reactions, but there was less consensus on this issue compared to ECT in minors. The vast majority of psychiatrists reported never having delivered unmodified ECT; none currently delivered it. Many groups welcomed this prohibition, especially younger psychiatrists. The CRPD in general and its prohibition of torture or inhumane treatment in particular were quoted as a justification for the change.

Many psychiatrists argued against the prohibition, especially in emergency cases or circumstances in which muscle relaxants or general anesthesia might be unavailable or contraindicated. Some participants expressed a preference for unmodified ECT.

One focus group raised the issue of "anesthetist's availability and cost" as a major driver of unmodified ECT. They suggested that poorer families might opt for unmodified ECT. These views on unmodified ECT were more prominent in Bihar and Jharkhand, compared to Maharashtra. There was limited consideration given to the complications of unmodified ECT. Negative long-term complications were not discussed; instead, the psychiatrists focused on the implications of untreated illness.

ECT in the acute phase

The delivery of ECT in the acute phase was raised in many groups. Multiple focus groups stated that ECT could not be used in the emergency setting, especially in the first 72 h. This was another area where many psychiatrists were unclear about the legislation; that is, the understanding of "emergency treatment" in practice differed significantly from the MHCA itself (see Discussion).

Another issue concerned how long it will take MHRBs to make decisions and their suitability to make such decisions in the first place. The potential for the delay was of particular relevance in the acute phase. Some focus groups were also unclear about the use of ECT in an individual admitted on a "supported" basis and how "advance directives" and "nominated representatives" could be used and challenged.

Themes indirectly related to ECT

Resource limitation

Resource limitation was one of the most consistent themes in our study. It arose in relation to almost every topic in every focus group [Table 3]. There were particular concerns about the numbers of trained mental health professionals. Apprehension was also expressed that there was no capacity to train more staff. The lack of professionals related to ECT in several ways. For example, the lack of doctors and nurses prolongs the duration of untreated illness, increasing the severity of presentations.

Many psychiatrists reported that they did not have the resources to do the procedural work needed to deliver ECT. A lack of anesthetists was identified by three groups as a reason for requiring unmodified ECT. The lack of appropriate staff for MHRBs made the psychiatrists uncertain if they could carry out their role:

> "We have Review Boards where the people who will be there have no idea what mental illness is."

The current judicial infrastructure could also greatly delay treatment on occasions when MHRB decisions are challenged:

> "The resources are not available, and we are tied down by various laws and norms. They are good. Definitely, they are ideal. But first of all, the platform has to be ready to launch something which is big and ideal."

The limited financial resources of patients and families came up multiple times and was given as a reason for requiring unmodified ECT.

The impact of the nonmedical model on mental healthcare

This was another one of the most consistent topics that arose in our focus groups, and it was seen as impacting directly on ECT. Psychiatrists felt that parties with a social model of mental healthcare were exercising disproportionate influence at multiple levels, including during the drafting of the legislation. Focus group participants also raised concerns about the decision-making ability of the MHRBs as well as the ability of patients to make healthcare decisions themselves.

There was much concern about how the MHCA was drafted. One group described the drafters as "anti-psychiatry." Other groups stated that they and the Indian Psychiatric Society had limited involvement in the drafting. The role of nongovernmental organizations in drafting was extensively discussed.

Apart from the drafting of the new legislation, participants saw the role of nongovernmental

organizations as mixed: many highlighted benefits, but when it came to their influence on ECT in the MHCA, psychiatrists were more critical:

> "The nongovernmental organization lobby was very strong because everywhere outside of the hospital, a negative picture of ECT has been portrayed and they selectively, or maybe deliberately, undermined the positive effect of ECT."

There was an impression in many of the focus groups that the new legislation represents international rather than Indian standards and is "borrowed from established developed nations." Some described the MHCA as "un-Indian."

Psychiatrists were especially disturbed by how little influence they feel they will have on MHRBs:

> "When to give ECT, when not to give ECT — it's a medical decision. It should not be dictated by nonmedical people."

Concerns were raised about the scientific and psychiatric literacy of patients. The time constraints on Indian psychiatrists led some to feel that they would not have sufficient time to deliver the level of psychoeducation required to help patients to make fully informed treatment decisions. One focus group of psychiatrists expressed concern that there will be ongoing hostility toward ECT from nongovernmental organizations and that they will attempt to influence patients' advance directives to further limit ECT use. This was not a view commonly expressed, and it was challenged in the one group where it was brought up.

A repeated observation, from multiple groups, summed up the divergent perspectives of psychiatrists and legislators in relation to the new legislation:

> "The ground reality is different."

DISCUSSION

Overall, we found that many of the themes and concerns commonly associated with ECT in other jurisdictions are readily apparent among Indian psychiatrists, although perspectives on specific issues remain heterogeneous. The one area of near-universal agreement was Indian psychiatrists' affirmation of the effectiveness of ECT. There were three main areas of concern: the MHCA's ban on unmodified ECT, ECT in minors, and ECT in the acute phase. Two broad additional themes also emerged: resource limitations and the impact of nonmedical models of mental health. We identified a need for greater education about the MHCA among all stakeholders.

The idea that the MHCA completely prohibits ECT in minors is seen not just in our focus groups but also in general media.[21] In practice, it is indeed possible that delays in approval by a MHRB [Section 80 (4)] could result in *de facto* prohibition. This would accord with what many of the psychiatrists whom we interviewed felt would happen, and with the World Health Organization's (WHO) direction that ECT in minors should be stopped.[22]

The WHO is also seeking to ban unmodified ECT.[22] In 2012, the Indian Psychiatric Society, the Indian Association of Biological Psychiatry, and the Indian Association of Private Psychiatry released a position paper on unmodified ECT that questions its negative impacts and advocates for its use in exceptional circumstances.[23] Some of these topics emerged in our focus groups too, along with other arguments, such as the use of unmodified ECT to reduce costs for patients' families. There is now an extensive literature on this topic in the Indian literature.[23-26]

In 2018, following the new legislation, the Indian Psychiatric Society submitted a writ petition to the High Court of Mumbai, arguing that elements of the MHCA violate the right to equality and consequentially right to life of mentally ill people, as enshrined in the Constitution of India.[27] The writ argues that prohibition on unmodified ECT is not evidence-based and will significantly limit mental healthcare in India. This is consistent with the view that many Indian psychiatrists see unmodified ECT as a necessary therapeutic compromise in light of resource limitations, in order to treat the seriously mentally ill persons.

Our focus groups expressed considerable concerns about the MHCA's provisions relating to ECT in emergencies. Section 94 (3) of the legislation ("Emergency treatment") states that "nothing in this section shall allow any medical officer or psychiatrist to use electroconvulsive therapy as a form of treatment." This effectively bans the provision of ECT on an emergency basis. Section 94 (4), however, states that "the emergency treatment referred to in this section shall be limited to 72 h or till the person with mental illness has been assessed at a mental health establishment, whichever is earlier". As a result, it appears that the emergency period ends the following assessment in a psychiatric hospital and so – presumably – the ban on emergency ECT is no longer relevant because the "emergency" is then deemed to be over. Greater clarity is, however, needed on this point, as was repeatedly evidenced in our focus groups.

This issue – like virtually all issues raised in our focus groups -- is also linked with recurring concerns about resource limitations in Indian mental health services. There is strong evidence to support these concerns. In 2016, the *National Mental Health Survey of India,*

2015-2016 highlighted the burden of mental health problems in Indian society.[28] It estimated that 11% of Indian adults suffer from a mental disorder, with 150 million people in need of mental health interventions. In addition to large treatment gaps (up to 92% for some disorders), there are also variations in service availability across the country, with especially limited services in rural areas, although the picture is complicated by the practice of traditional medicine.[29,30] Financial resources are grossly inadequate, with less than 1% of the national healthcare budget spent on mental health. In addition, there are very significant human resource limitations.[29] These concerns all clearly informed the views of the psychiatrists in our focus groups.

Focus group participants were also deeply concerned about the impact of the nonmedical model of healthcare. Many of these concerns stem from the fact that the theoretical underpinnings of mental health legislation have been changed by the CRPD, especially in India.[1] Clearly, modern psychiatry needs to become increasingly rights based and patient centered if it is to accord fully with the CRPD. Interestingly, the drafting of the CRPD mirrored many of the tensions that are seen in the implementation of India's MHCA: strong, well-organized lobby groups pushed for the exclusion of any coercive practices, whereas medical professionals and other groups attempted to forge a more moderate course.[31,32]

In a fashion similar to what is happening under the MHCA with unmodified ECT, there were petitions right up until the last minute during the drafting of the CRPD for some emergency provisions to be included to allow forced interventions in extreme circumstances.[33] If Indian psychiatrists are concerned that the provisions of the MHCA are the narrow end of the wedge and that further limitations are to come, recent interpretations of the CRPD strongly affirm their concerns. In 2014, the Committee on the Rights of Persons with Disabilities, which interprets the CRPD, went even further by explicitly objecting to all coercive treatments, thus challenging a key aspect of mental health legislation in most countries (including India).[34]

Limitations

Our study would have been enhanced by a collection of complementary quantitative data to augment our focus group findings. Although we believe we reached theoretical saturation in our focus group data, our work was complicated by the evolving implementation of the MHCA during the study. Notwithstanding this fact, our sampling of a wide range of Indian psychiatrists revealed very consistent themes across our work. No new topics or themes arose in the later focus group that had not already emerged in earlier ones.

Our focus group participants would ideally have been randomly sampled from an extensive list of potential participants, from a wide range of Indian states. As a result, our sampling method may limit the generalizability of our findings. It could also be argued that individuals who agreed to participate in our study were not a representative sample, due to selection bias. Although our participants may represent a more outspoken cohort, they were by no means homogenous in their views on the new legislation, suggesting that we captured a good range of views in our work, despite any possible sampling limitations.

Even so, our sampling method might still affect generalizability because most of the psychiatrists who participated were working in urban settings (93.4%). These practitioners might have a different viewpoint regarding ECT compared to those practicing in rural settings where resources are very limited. Our findings need to be interpreted with this in mind. Future work could usefully address this issue by focusing on psychiatrists and other mental health practitioners working in rural settings.

At locations where two focus groups were conducted, senior staff who were longer in practice were included in focus groups separate from other staff, in an attempt to minimize group heterogeneity.[15] While this recommended technique has the benefit of reducing the effect of power dynamics,[16] it might also introduce bias. Future studies with groups of mixed seniority might yield different or additional insights in the future.

Three of the researchers involved in this work are not primarily based in India. This facilitates a position of equipoise at the focus groups, brings an international perspective to this work, and allows these authors to be more objective about their findings. However, it also necessitates input from India-based co-investigators and co-authors to provide an understanding of this legislation on the ground, as they do in this paper.

Finally, the study period for these focus groups was between November 2017 and November 2018, but some of the key elements of the new legislation were not implemented fully in practice during this period. While we sought to identify issues and problems prior to full implementation, it would nonetheless be informative to perform such focus groups following a full implementation. We hope to do so over the coming years as the legislation is rolled out.

CONCLUSION

The perspectives of Indian psychiatrists on ECT within the MHCA are very considered but also

heterogeneous. Their one area of near-universal agreement is their affirmation of the effectiveness of ECT. Key concerns relate to the legislation's ban on unmodified ECT, ECT in minors, and ECT in the acute phase. Two broad additional themes also emerged in our focus groups: resource limitations and the impact of nonmedical models of mental health, with a perception that theoretical perspectives are driving legislative changes that do not reflect "ground realities" in India. As a result, our work highlights both the problems with the MHCA and ECT at one level and misconceptions among mental health professionals at the other end.

Overall, India's MHCA is an ambitious attempt at rights-based, patient-centered mental health law and, for many reasons, it deserves close international attention.[35,36] The impact that it has on the use of ECT in India should be watched especially closely, as this pattern is likely to be repeated in many other countries as they reform their mental health laws over the coming years to better align with the CRPD.

Finally, while it has been important to describe the concerns of Indian psychiatrists as they face into the new legislation, it remains to be seen how this pioneering law will work out in practice. On the one hand, some of the concerns raised in our focus groups may prove disproportionate, but, on the other hand, unanticipated issues may arise. What is already clear, however, is that while the MHCA offers significant opportunities for Indian psychiatry, failure to resource its ambitious changes will greatly limit the use of ECT in India.

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Conflicts of interest
There are no conflicts of interest.

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APPENDIX: QUESTIONING ROUTE FOR FOCUS GROUPS

Phase		Question	Timing
Opening	1	Please tell us your name, where you practice psychiatry, and what you enjoy most when not practicing psychiatry.	15 min
Introduction	2	Please tell us about your use of mental health legislation.	10 min
Transition	3	When did you start to hear about the MHCA and what were your first impressions of it?	10 min
Key	4	What have you been pleased to see in the new MHCA?	15 min
	5	Do you have any concerns about the MHCA?	15 min
	6	How do you think the transition between the old Act and the new Act is being managed?	15 min
Ending	7	If you were writing the legislation, what would you have done differently?	10 min
	8	Is there any major area that we have not talked about today that you feel is very important concerning the MHCA?	10 min

MHCA – Mental Healthcare Act 2017

Original Article

Factors Associated with Alcohol Misuse among Indigenous Tribal Men in Wayanad: A Qualitative Study

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ABSTRACT

Background: Disproportionate level of alcohol misuse is reported among indigenous people all over the world. A few available studies from India also support higher alcohol misuse among tribal men, but the reason for it is largely unexplored. Thus, we explored the factors associated with alcohol misuse among indigenous tribal men in Wayanad, Kerala. **Methods:** Using a qualitative phenomenological method and purposive sampling techniques, we recruited seven tribal men with a history of alcohol misuse and 28 tribal promoters from the identified tribal colonies in Wayanad, Kerala, India. Data collection was done with a combination of focus group discussions and in-depth interviews. Thematic analysis was applied to the data for identifying core themes. **Results:** We identified the important trajectories of alcohol consumption among tribal men. They initiated alcohol misuse at a younger age due to parental influence, home environment, and peer pressure. Alcohol misuse associated with their traditional rituals and practices, exploitation of landlords, occupational factors, and saving habits. It caused a substantial burden to their spouses and children. **Conclusion:** Alcohol consumption often initiated in their young age was associated with socio-cultural rituals, practices, and exploitation.

Key words: *Alcohol misuse, indigenous population, tribe, Wayanad district*

Key messages: *Parental factors, home environment, peer factors, and early financial autonomy contributed to the initiation of alcohol use at a young age. Alcohol misuse among tribal men was associated with their traditional rituals and practices, exploitation of landlords, occupational factors, and saving habits.*

A disproportionate level of alcohol misuse has been reported among indigenous people all over the world,[1-3] and the burden of disease associated with alcohol misuse is almost double among them.[4] In India, indigenous people are known as scheduled tribes (STs), or Adivasis, and live as a group with distinctive social, cultural, historical, and geographical circumstances. Evidence from India also supports a high prevalence of alcohol consumption and

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smoking among indigenous tribes,[5,6] which is associated with a wide range of health and social problems, including violence, family breakdown, child neglect, loss of income, diverting income away from family needs, high morbidity, and early mortality.[4] The data derived from National Family Health Survey suggests alcohol use among 26% of the indigenous population, while the rate was just 9% among the non-indigenous population.[5] Higher substance abuse[6] and worse health status[7] among this group is inherently related with their socio-economic marginalization[5,8] and historical oppression.[9]

Wayanad is a home for one-third of the total tribes in Kerala. The Paniya, Kurichiya, Kuruma/Mullu Kuruma/Uraali Kuruma, Kattunaikan, and Adiya are the predominant tribal groups in Wayanad.[10] The tribes are backward in education, health, and living standard as compared to the general population.[11] Our experience and engagement in Tribal Mental Health Program in the district reflect high substance misuse among the tribes, especially alcohol and betel quid use. Evidently, indigenous ethnicity is the strongest predictor of higher alcohol misuse,[5] and the tribes have a different socio-cultural reason for substance misuse.[12] Nevertheless, the socio-cultural factors associated with such practices among tribes are less studied in India, with a few exceptions.[9,12-14] Even these available studies were either with tribes of Tamil Nadu,[14] quantitative in nature,[12] qualitative study of limited scope with pregnant tribal women[13] or only with Paniya tribes.[9] Thus we explore the factors associated with alcohol misuse among the indigenous tribal men in Wayanad.

METHODS

The study was conducted as part of a Tribal Mental Health Project, supported by the Department of Social Justice, Govt. of Kerala and District Legal Service Authority, Wayanad. The study is part of a larger project that got approval from the Institute's Ethics Committee. Informed consent was obtained from each study participant prior to their participation.

We used a qualitative phenomenological approach to explore alcohol misuse among the tribal men. The aim of the phenomenological approach was to deal with experiences and meanings and to capture as closely as possible how the phenomenon is experienced within the context in which the experience takes place.[15,16] The qualitative method was chosen as it best suits to capture the experience and voice of a marginalized group.[16]

Setting

The study was conducted in Wayanad District, located in the north-east of Kerala state. It has a population of 8,16,558. Scheduled tribes account for more than 18.5% of the total population of the district, while the state average of tribes is a meagre 1.5%. Among the scheduled tribe population of 4,84,839 in the state, 1,51,443 are from Wayanad.[10] Wayanad District consists of four community development (CD) blocks, namely Mananthavady, Kalpetta, Sulthan Bathery, and Panamaram, and has 25 Grama Panchayaths in total. The tribe population is spread across all the panchayats, although some Panchayaths like Thirunelly and Noolppuzha have a high concentration of the tribes. The low literacy of the tribes contributes to Wayanad district having relatively lower literacy rates than other districts of Kerala.

Population and sampling

The study population consisted with persons from Paniya, Kuruma, Adiya, Kurichyas, and Kattunaikan tribal groups. The Paniya is the dominant tribal group in Wayanad, and they are less educated and most marginalized. The majority of them are casual agricultural labourers.[17] Kurichiyas are one of the most developed tribes; Most of them possess some land, and they do agriculture for livelihood. The Kurumas are another dominant tribe in Wayanad, and most of them earn a livelihood through agriculture and cattle rearing. Some of them are working in government sector also. Kattunaikan is a primitive tribal group. They are experts in collecting honey and wax and prefer to live in the forest. The Adiya group was bonded labourers of landlords, and the majority of them are now agricultural workers.

Using purposive sampling technique, we selected seven tribal men with alcohol misuse and 28 tribal promoters for the study. The tribal men with alcohol misuse were identified from four tribal colonies in Mananthvady (Begur Paniya colony and Iruvaki Adiya colony) Panamaram (Marakkadavu colony) and Bathery (Ponkuzhi Kattunaikan Colony) CD blocks. The samples were selected from different colonies to have a representation of various tribal subgroups. The selected tribal men were adult who had used alcohol at least once in the past 30 days. The colonies selected for the study were very close to the Kerala-Karnataka border, and these places are known to have high substance misuse.

The potential tribal promoters were selected from the Tribal Extension Offices of Kappiset, Bathery, and Mananthavady. They were available in these places to attend their weekly review meetings. The tribal promoters are members of the tribal community who are appointed to function as facilitators in tribal areas for channelizing and extending the benefits of tribal development schemes to the STs. They also make a link between the ST beneficiaries and the local bodies.

All the promoters who were available consented to participate in the study.

Data collection

The data collection for this study was done through a combination of in-depth interviews and focus group discussions (FGD). The in-depth interviews were conducted with seven tribal men who had used at least once in the past 30 days, while the FGDs were with the tribal promoters.

The in-depth interviews were conducted by psychiatric social workers with experience in tribal mental health (first and second authors). The participants were interviewed in their homes at the identified tribal colonies. The in-depth interviews lasted 1-1.5 hours and were audiotaped. Observations and field notes were also used to record the interviews. Data saturation in qualitative research generally occurs between six and twelve interviews.[18] Thus we aimed at seven in-depth interviews in addition to the FGDs.

We conducted three FGDs with tribal promoters, and 28 promoters participated. The FGDs were also facilitated by the psychiatric social workers in tribal mental health and assisted by one Master of Social Work student (third author) and one MPhil trainee (fourth author). All FGDs were audio-recorded and lasted around two hours. We used a brief socio-demographic data sheet and an unstructured interview guide to facilitate in-depth interviews and FGDs. Separate interview guides were used for the in-depth interviews and FGDs. Probes were used when necessary. They were prepared based on a review of literature, discussion with experts in tribal projects, and also reflected our own experience in tribal mental health. The in-depth interview and FGD guides are provided as online only supplementary files.

Qualitative data analysis

The audio-taped in-depth interviews and FGDs were combined for an inductive thematic analysis.[19] Such combined approach would increase data richness and rigor in qualitative studies.[20] First, the researcher performed verbatim transcription. In this process, the audiotaped in-depth interviews and FGDs were converted into text, and the message was captured exactly the way it had been delivered. Second, the converted verbatim transcription and field notes were translated into English. The researcher systematically read the translated text several times to get familiarized with the data and to understand the in-depth meaning. Third, lists of codes were developed based on the reading of the data, and these codes were allocated to data through coding procedures, which helped to categorize and stratify the data in a logical way. Inferences and written comments were also made on the themes. The first author performed the thematic analysis, which was revised and fine-tuned with the suggestion of the remaining authors.

RESULTS

Table 1 shows that the majority of the tribal promoters in FGDs were female (82.1%), married (85.7%) and educated up to high school (50%) and belonged to Kuruma/Uraali tribe. Their average age (SD) was 35.21 (6.17) years. The tribal promoters received INR 9,625 as monthly salary, and they had been working as a promoter for the past 3.26 (3.26) years. Table 2 shows the socio-demographic details of the tribal men who participated in in-depth interviews.

Qualitative results

The trajectory of alcohol misuse

Tribes are exposed to alcohol at a very young age through various routes. First, the parents provide alcohol (smaller quantity) to their children during most of the festivals and special days. Eventually, they start liking it, and when they grow, they perceive that using alcohol is not a problem.

A Paniya tribal promoter said:

> "Many of our people drink alcohol regularly. They may even give it to their children on special occasions. Now this practice is being reduced, but is still prevalent in some families"

Table 1: Socio-demographic details of the tribal promoters in FGDs

Variables	Frequency (%)
Mean INR 9625 (same salary to all)	
Gender	
Male	05 (17.9)
Female	23 (82.1)
Marital status	
Married	24 (85.7)
Unmarried	01 (3.6)
Divorced/widowed	03 (107)
Education	
High school	14 (50)
Higher secondary	10 (35.7)
Under graduation or above	04 (14.3)
Tribe name	
Kuruma/Urali Kuruma	10 (35.7)
Paniya	05 (17.9)
Adiya	06 (21.4)
Kurichiya	05 (17.9)
Kattunaikan	02 (7.1)
Age	
Monthly salary	35.21 (6.17)
No. of years working as promoter	3.26 (3.14)

FGD - Focus group discussion

Table 2: Demographic and substance use details of the tribal men who participated in the in-depth interviews (*n*=7)

Respondents	1	2	3	4	5	6	7
Tribe name	Kuruma	Adiya	Adiya	Kattunaikan	Paniya	Paniya	Adiya
Age	28	57	38	35	27	40	40
Education	Higher secondary	Illiterate	Lower primary	Illiterate	Upper primary	Illiterate	Illiterate
Marital status	Unmarried	Married	Married	Married	Married	Married	Unmarried
Are you currently working	Yes	No	Yes	Yes	Yes	Yes	Yes
Nature of work (if applicable)	Office work	-	Daily wage	Petty shop	Daily wage	Collect medicinal plants from the forest	Daily wage
Frequency of alcohol use in the past 12 months	1-4 days a week	1-3 days a month	1-4 days a week	1-3 days a month	5-7 days a week	1-4 days a week	1-3 days a month
Age at time of first alcohol use	23		15	20	18	30	14
Any previous treatment for alcohol use	No	No	No	No	Yes, relapsed after six months	No	No
Do you smoke tobacco	Yes	No	Yes	Yes	Yes	No	No
Frequency of smoking	5-6 per day	-	20 per day	5-6 per day	4-5 a day	-	-
Age at first smoking	20	-	15	22	9	-	-
Use of betel quid	Yes	No	Yes	Yes	Yes	Yes	No
Cannabis use	No	No	4-5 times a month	No	No	No	No
Money spent on substances (INR)	1000	300	1500	750	6000	3600	500

Secondly, children get exposed to alcohol when parents drink at home. There is also a practice of 'family drink' where parents drink alcohol with their children.

By recollecting childhood experience, an Adiya tribe said:

> "Sometimes my parents give me alcohol when they drink….When they don't give, I used to steal…"

Thirdly, small children often make friends with elder children or adults who are already using alcohol. This friendship also influenced the initiation of alcohol consumption.

Finally, tribal children earn money as they work at a younger age. The early financial autonomy also contributes to their alcohol misuse behaviour.

A Kuruma tribal promoter said:

> "Many of our children don't go to school… They go and collect areca-nut or Amla fruit from the forest… They earn enough money to buy the substances"

Surprisingly, some parents served alcohol to their children with the expectation that in return, the children will bring alcohol for them when they are old.

Alcohol use as a ritual and custom

Alcohol use was widely accepted in the tribal community, and it was part of their culture. Alcohol consumption was related not only to the celebration of festivals such as Onam (a popular festival in Kerala) and Christmas but also to many important life events.

A Paniya tribal promoter said:

> "From birth to death, we celebrate all the special days with alcohol. You know, our funeral is celebrated with alcohol. We need to serve alcohol to the persons preparing the grave and those attending the funeral. If we don't serve it, it would be hard to get persons for such work"

There was also an event called "Pela chadangu," related to the funeral function in which a religious leader/priest visits the deceased person's home and graveyard to offer prayers and pujas for a peaceful rest of the soul. Alcohol is used at these events. Alcohol is an indispensable part of the tribal culture on many other important occasions too. For example, the meetings of prospective bride/groom and the fixation of marriage are also associated with alcohol misuse.

A Kuruma tribal promoter said: "We serve alcohol during the meeting of the prospective bride/groom. If the served alcohol is consumed, it indicates the willingness of the family for the alliance, and vice versa"

Furthermore, the parents of the prospective groom and bride are expected to offer alcohol for the neighbors and elders in the colony if a marriage is being fixed or confirmed.

Exploitation by landlords

For many years, the landlords (agricultural landowners) used to offer alcohol to the tribal men for the work. Eventually, the tribal men expected it from the workplace, and they were unwilling or demotivated to work if alcohol is not being served. As serving alcohol at the workplace was a tradition, some landlords who do not offer alcohol had difficulties in getting good

workers. It was also a general belief in the community that tribal men work harder if they are intoxicated. Thus, the landlords served an increased quantity of alcohol to the tribal men before they work. The tribal men themselves felt that alcohol would keep them energetic during the work hours.

A Kattunaikan tribe said:

> "I like to drink (alcohol) before work. It makes me energetic, and I don't feel the harshness of work if I am drunk"

In some instances, the landlords did not pay money or paid less for the tribal men as they deduct alcohol expenses from the wage. The tribal men agreed to such deals, as they wanted money, to a large extent, only for buying alcohol. A few of them used to spend balance wages too on alcoholic beverages. The exploitation by landlords was also observed in the form of differential treatment at the workplace for the tribal men and non-tribal men.

A tribal promoter said:

> "They (landlords) ask our people to work hard and more time in the land. They (tribal men) are less paid for the work. Nontribal men are paid higher than the tribes"

Occupational factors

Unemployment or seasonal employment was frequent among the tribal population. They are at high risk for alcohol consumption at the workplace due to the policies of the landlords; Ironically, being unemployed also contributed to alcohol misuse. The tribal houses are very close to each other as they live in a colony and the young men who do not have regular work gather and plan for a drink. Such peer group meetings, usually occurring in non-working days, contributed to alcohol misuse.

A tribal man said

> "We get only three- or four-days' work in a month. The rest of the time, we are simply sitting idle at home. So we (peers) plan for a drink from the morning. There is no other enjoyment for us here."

The employment and unemployment status reflected variably on alcohol misuse. For example, first, being unemployed and having less option to spend time productively contributed to alcohol misuse among the youngsters. Second, for many tribal men, the predominantly motivation for working was the fact that they can get alcohol from the landlord or buy it with their wages. Finally, many elder tribal men remained abstinent or consumed less simply because they do not have any job and consequently, no money to buy alcohol.

A 57-year-old Adiya man said:

> "I want to drink, but I don't have any money. My children earn money. Hence, they drink. Sometimes they offer me a drink."

Attitude towards savings

Most of the tribal men spend their entire income on alcohol. They do not save anything in cash/bank account or other assets and spend their wages on the same day itself. Since raw food (rice) is available free of cost for them from the government, they spend their earnings predominantly on alcohol and betel quid.

A Kuruama tribal promoter said:

> "Many tribal men opened a bank account for Mahatma Gandhi National Rural Employment Guarantee Act (MGNREGA) wages….But there are no savings in the account, and they withdraw the entire amount when they go to town"

(MGNREGA is a government program that provides at least 100 days of guaranteed wage employment, in a financial year, to every rural household whose adult members volunteer to do unskilled manual work.)

Surprisingly, most of the in-depth interview participants shared that they used to take food only once a day, despite it (rice) being available free of cost. This could be a result of prolonged substance misuse and dependence. The need for regular food intake was not perceived as very important.

The tribal men go for work at far-away places, and they come to their home only once or twice a month. They bring enough liquor when they come home, and they won't go for work until the stock is finished. Alcohol consumption often was contingent upon their earnings.

The burden on spouses and children

As male members spend almost all their wages on alcohol, the financial needs of the family are often met by the women of the household. Such situations demand tribal women to go for work to run the family, and this additional role, along with the existing housewife role, contributes to a high level of burden on them.

A female tribal promoter said:

> "We both work, but my husband does not give any money for the family. His wages are not even sufficient for his drinking, and at times he would ask money from me for the drink. I don't drink alcohol, and I use only betel leaf"

The parents are unable to perform parental duties if they have had 'drinks' in the previous night, which resulted

in the children being left uncared and unprotected. Children often missed school.

A tribal promoter said:

> "Many parents drink heavily. Hence, they wake up late in the morning. They don't go for work and also won't send their children to school"

DISCUSSION

The study revealed increased and hazardous alcohol consumption among tribal men, which is intertwined with their traditional rituals, historical exploitation, and socio-cultural backwardness. A previous quantitative survey on substance abuse among adult tribal men had reported a prevalence rate of 67%, which included a 49% rate for alcohol abuse.[21] Among tribal men alcohol consumption was often initiated at a young age through parental and peer routes and sustained by many socio-occupational and cultural factors which further cause a burden on the family. Severe alcohol misuse prevailed in the tribal community at Wayanad irrespective of their tribal sect, although the prevalence among some of the most socio-economically backward groups like Paniya and Kattu Paniya was relatively on the higher side. Socio-economic marginalization is a major reason for higher substance abuse among tribal men in India.[22]

We agree with the observation of previous researchers that culture shapes alcohol abuse.[23] The tribal men perceived alcohol use as a part of their culture, with high community acceptance,[13] although there were growing dissatisfaction and concern about it among the educated young tribes, especially the ones like the tribal promoters. However, the promoters themselves felt helpless and frustrated about this situation and anticipated no change in the near future. The substance abuse among their children was not even perceived as a major problem by the parents or the community people, maybe because of a lack of education and awareness. Similar to our findings, a previous study among the Paniya tribe had reported the employer's exploitation by providing alcohol as an incentive to attract tribal men to job.[9] In some cases, young Adivasis consumed alcohol first time from the workplace. This practice is not only a factor in initiating or maintaining alcohol consumption among tribal men, but also repeats the historical patterns of enslavement and exploitation.

Alcoholic beverages were easily accessible to our sample. One reason for this finding could be that we recruited people who lived close to the Kerala-Karnataka border. Although no illicit alcohol production was reported in the localities, Indian-made Foreign Liquor was available in the black market in the area, targeting the tribal youth. Many tribal youths from the study area availed alcohol from the Karnataka state by crossing the border through a river. Others availed it from the outlets of Kerala State Beverages Corporation, from the employer/landlords, or as a few did, from the local toddy shops. A study from Andhra Pradesh had found that tribes predominantly use locally prepared handmade liquor which is easily available,[22] while we found more use of Indian-made Foreign Liquor. The increased number of Kerala Beverages Corporation outlets in recent years could be a reason for this finding.

Our study also revealed many consequences, including the huge amount of money spent on alcohol, the burden on spouse and children, and less food intake as a result of increased alcohol consumption. Devastating consequences of alcohol abuse such as high mortality and morbidity, suicide,[4] family discord, and domestic violence[24] has been reported in studies with the indigenous populations.

The present study is one of the few which attempted to explore the socio-cultural factors influencing alcohol misuse among indigenous tribal men in India. The findings of the study have significance for initiating specialized de-addiction services, policies, and programs for the tribal men in Wayanad. The limitation of the study is that although we explored the real-life experience of alcohol misuse through in-depth interviews, the participants of FGDs were the tribal promoters who are not necessarily in alcohol misuse. Although they were rich sources of information on alcohol abuse of the tribal men, most of them lacked real-life experience of being in the phenomenon of alcohol misuse.

CONCLUSION

Parental factors, home environment, peer factors and early financial autonomy contributed to the initiation of alcohol use at a young age. The alcohol misuse among tribal men was linked with their tradition and culture, exploitation by landlords, occupational factors, and saving habits, which in turn resulted in a substantial burden on the spouses and children.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Prevalence of Adult ADHD Co-morbidity in Alcohol Use Disorders in a General Hospital Setup

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ABSTRACT

Background: Attention deficit hyperactive disorder (ADHD) symptoms persisting into adulthood can influence the course and outcome of alcohol use disorders (AUDs). A cross-sectional study was conducted to assess the prevalence of adult ADHD in patients admitted with AUDs in a general hospital setup. **Methods:** In this study, 100 consecutive inpatients with alcohol use disorder (AUD) were evaluated for the diagnosis of ADHD. Patients with AUD were assessed with Severity of Alcohol Dependence Questionnaire, Clinical Institute Withdrawal Assessment for Alcohol and Adult ADHD Self Report Scale. Among the subjects who screened positive for adult ADHD on ASRS, diagnosis of adult ADHD was confirmed using the DSM 5 diagnostic interview. Epi-Info Version 7.2 was used for data entry and analysis. Mann Whitney test and Chi-square test (or Fisher's Exact test) were used for statistical analysis. **Results:** Twenty-one subjects screened positive for adult ADHD. Among them, 19 subjects had a confirmative diagnosis of adult ADHD. Patients with adult ADHD comorbid with AUDs showed accelerated progression towards dependence, and early relapses. **Conclusions:** In all, 19% of treatment-seeking inpatients with AUDs have co-morbid adult ADHD. Regular screening of AUD patients for adult ADHD and addressing the psychopathology may improve the treatment outcome.

Key words: *Adult ADHD, alcohol use disorder, prevalence*
Key messages: *Adult ADHD is a common co-morbidity in subjects with alcohol use disorders.*

Attention deficit hyperactivity disorder (ADHD) is a neuro-developmental disorder characterized by core symptoms of inattention, hyperactivity, and impulsivity. ADHD persists into adulthood among the majority of the affected children.[1,2] However, with the increasing age, the symptom manifestation changes considerably: the hyperactivity decreases, while the inattention and impulsivity persist.[3] Studies around the world have shown that the prevalence of childhood ADHD in the

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general population ranges 5%-12% while the prevalence of adult ADHD ranges 2%-6%.[4-8]

The literature review indicates a bidirectional relationship between ADHD and substance use disorders (SUDs).[9] Earlier studies from the west showed a very high prevalence ranging from 35% to 70% for adult ADHD among individuals with SUD.[7] However, recent studies with improved diagnostic instruments indicate a prevalence rate ranging from 10.8% to 40.9%.[4-8] A recent meta-analysis reported the prevalence of comorbid ADHD at 23.1% among individuals with SUD.[4] Most studies to date have been on ADHD comorbidity among individuals with SUD as a whole or have focused predominantly on stimulant abuse. Very little data are available on adult ADHD comorbidity among individuals with alcohol use disorders (AUDs), particularly from the Indian population. A few studies have indicated that adult ADHD is comparatively low among individuals with AUD compared to those who use other substances.[8] Ohlmeier *et al*. reported that ADHD comorbidity among individuals with AUD had a lifetime prevalence of 23%, while only 8% had symptoms persisting into adulthood. Wood *et al*. determined that 33% of the AUD individuals have comorbid adult ADHD.[6,7] Kumar *et al*. reported 40% prevalence for adult ADHD among fishermen with alcohol-dependence, while in another outpatient-based screening study, Ganesh *et al*. reported that 21.7% of the SUD subjects screened positive for "highly likely ADHD."[1,10] Both the studies were done in South India and had used screening tools to check for ADHD in patients with AUD.

With a paucity of studies on adult ADHD comorbidity among individuals with AUD in the Indian population, the current study was planned by using standardized diagnostic tools. In this study, the primary aim was to determine the prevalence of adult ADHD among subjects with AUD using diagnostic interview method according to DSM 5. Second aim was to compare the characteristics of alcoholism in subjects with and without adult ADHD co-morbidity.

SUBJECTS AND METHODS

Study design

This was a cross-sectional study conducted in a semiurban-based medical college hospital. All subjects admitted to the deaddiction ward with an index diagnosis of AUD were recruited for the study. A total of 100 patients who were consecutively admitted in the deaddiction ward between March and December 2017 were included in the study after taking the informed consent. The inclusion criteria were as follows: (1) Meeting the diagnostic criteria for AUD according to DSM 5; (2) Age between 18 and 60 years; and (3) Subjects consenting for participation in the study. Exclusion criteria were as follows: (1) Having other SUD except nicotine dependence; (2) Being admitted primarily for another major psychiatric disorder; and (3) Having intellectual disability. Subjects with intellectual disability were excluded by clinical interview method. All subjects admitted for alcohol deaddiction underwent both pharmacological and psychosocial interventions as part of the treatment protocol for managing withdrawal states and relapse prevention.

Procedure

After obtaining the approval from the Institutional Ethics Committee, patients meeting the above criteria were recruited into the study. All patients admitted to the deaddiction ward were clinically interviewed by the attending Consultant Psychiatrist. Patients presenting with an index diagnosis of AUD according to DSM 5 and consenting for the study were recruited. Following admission to the deaddiction ward, the patients underwent an assessment with SADQ to assess the severity of alcoholism and CIWA scale to monitor the withdrawal symptoms.[11,12] Patients were applied adult ADHD Self-Report Scale (ASRS) after completion of detoxification and the CIWA score being <9.[13] Those patients who screened positive on ASRS were taken up for diagnostic confirmation using DSM-5 Clinical Interview.[14] ASRS is an instrument used for screening adult ADHD and consists of two parts, A and B. The scale was applied in English and Urdu forms which have been validated and translated by the World Health Organisation. The diagnostic confirmation of ADHD was done using DSM 5 by clinical interview method. The diagnostic criteria for adult ADHD was made according to DSM 5 when (1) patients had at least five of the inattention or hyperactivity and impulsivity symptoms; (2) several of symptoms were present prior to the age of 12 years; (3) symptoms occur in more than two settings; and (4) symptoms cause social and occupational dysfunction. Further, the diagnosis was made only in those not being admitted for manifestations of other major psychiatric disorders. The primary investigator was trained in applying Structured Clinical Interview for DSM-5 disorder - Clinician version (SCID-CV-5) prior to the study.

Statistical analysis

Centre for Disease Control and Prevention (CDC) software Epi Info Version 7.2 was used for data entry and analysis.[15] For the purpose of analysis, the sample was divided into two groups: one group consisted of AUD with comorbid ADHD and the other group only AUD. Chi-square test (or Fisher's Exact test) was used to identify the difference among the subgroups regarding categorical variables, and

Mann-Whitney U test was used to compare the two groups on continuous variables. Benjamini-Hochberg procedure was applied to reduce false discovery rates. The individual *P* values were compared with the Benjamini-Hochberg critical value with a false discovery rate of 5%.

RESULTS

Socio-demographic details

All subjects were males, with the mean age being 40.68 years. Majority of the subjects had an education above the high school level, and one-third of them were graduates. The sociodemographic details are described in Table 1.

Table 1: Socio-demographic details of the study subjects

	Subjects with ADHD (*n*=19)	Subjects without ADHD (*n*=81)
Age (years)*	32.52 (SD=6.67)	42.59(SD=8.59)
Gender		
Male	19	81
Female	0	0
Religion		
Hindu	16	73
Muslim	2	6
Christian	1	2
Education		
No formal Schooling	1	4
Up to Middle School	1	13
High School	3	20
Pre-university	8	17
Graduation	6	27
Employment status		
Unemployed	7	6
Unskilled/semiskilled	1	18
Skilled	6	29
Business	3	11
Government service	2	17
Marital status		
Married	12	71
Unmarried	7	9
Widowed	0	1
Background		
Rural	10	41
Urban	9	40
Deaddiction treatment (prior to current admission)	15	66

*$P<0.001$. ADHD: Attention deficit hyperactivity disorder

Clinical characteristics

Among the 100 subjects, screening for ADHD using ASRS was positive in 21 subjects. Among the 21 ASRS positive patients, DSM-5 diagnostic interview confirmed the diagnosis of adult ADHD in 19. Of these 19 subjects with ADHD, eight subjects had a predominantly hyperactive/impulsive presentation; two had predominantly inattention subtype, while nine had a mixed presentation. A family history of alcoholism was present in 64 subjects of the total sample, which was not statistically different ($P = 0.9$) between subjects with and without ADHD. Psychiatric comorbidity was observed in 16 of the total subjects. Five subjects with ADHD had other psychiatric co-morbidity, which included two subjects with bipolar disorder in remission, one with delusional disorder, one with mild depressive disorder with anxious distress, and one with unspecified anxiety disorder. ADHD subjects had a higher risk of having a comorbid psychiatric disorder with an odds ratio of 2.26.

Characteristics of Alcohol use in subjects with and without ADHD

Mean age of subjects with ADHD was 32.52 years (SD = 6.67) and those without ADHD was 42.59 years (SD = 8.59), and the difference was statistically significant ($P < 0.001$). Mean age of first exposure to alcohol was 20.84 (SD = 3.53) and 22.9 years (SD = 5.70) for subjects with and without ADHD, respectively. Though there was early exposure to alcohol in subjects with ADHD, the difference was not statistically significant. Mean age of regular use of alcohol was 25.1 (SD = 5.52) and 28.5 years (SD = 6.95) for subjects with and without ADHD, respectively. The difference in mean age of onset of craving, tolerance, withdrawal symptoms, loss of control, salience and early morning use were

Table 2: Characteristics of alcoholism in subjects with ADHD and without ADHD

Characteristic of Alcoholism	Subjects with ADHD (*n*=19)	Subjects without ADHD (*n*=81)	*P* (Mann Whitney U test)
Age of first exposure to alcohol (years)	20.84	22.9	0.154
Age of regular use (years)	25.10	28.50	0.054
Age of onset of craving (years)	24.79	28.51	**0.035**
Age of development of tolerance (years)	25.89	29.85	**0.034**
Age of onset of withdrawal symptoms (years)	26.71	30.34	**0.038**
Age of development of loss of control (years)	26.78	32.51	**0.006***
Age of onset of salience (years)	27.31	33.33	**0.004***
Age of onset of early morning use (years)	29.81	36.25	**0.003***
Alcohol use in units per day	23.52	20.56	**0.026**
SADQ score	37.79	32.56	**<0.001***
Longest abstinence from Alcohol (days)	43.63	148.37	**0.029**

Bold values: $P<0.05$. *significant after applying Benjamini-Hochberg procedure for controlling false discovery rate. ADHD: Attention deficit hyperactivity disorder

statistically significant ($P < 0.05$). The pattern of alcohol use in subjects with ADHD when compared with subjects without ADHD has been described in detail in Table 2.

Average consumption of alcohol prior to admission in subjects with ADHD was 23.52 units per day, and in subjects without ADHD it was 20.56 units per day. There was a higher consumption of alcohol in the group with ADHD, and the difference was statistically significant ($P = 0.024$). The SADQ score for subjects with ADHD was 37.79 while that for those without ADHD was 32.56, and the difference was statistically significant ($P \leq 0.001$). The mean longest abstinent period prior to admission was 43.63 days for those with ADHD and it was 148.37 for those without ADHD, while in only those with history of deaddiction treatment the mean longest abstinence was 32.73 days and 110.59, respectively. The differences were statistically significant with $P = 0.029$ and $P = 0.021$, respectively.

DISCUSSION

Adult ADHD was seen in 19% of patients with AUDs and was associated with rapid progression towards dependence pattern of use of alcohol. The AUD patients in this study were recruited from an inpatient de-addiction ward in a hospital which caters to both rural and urban population. Data available with respect to adult ADHD in patients with AUDs is limited and most studies conducted are with SUDs in general. Our findings indicate that adult ADHD is common in patients with AUDs and that there is a need to evaluate for the same. AUD has a higher prevalence compared to other SUDs in India,[16] and hence the present study throws more light on the comorbidities of AUD in India.

On screening with ASRS, 21% ($n = 21$) of the subjects were positive for ADHD. After applying a diagnostic interview using DSM 5 in these subjects, ADHD diagnosis was confirmed in 19% ($n = 19$) of the subjects. Tartar *et al*. and Johann *et al*. reported that 19.9% and 21.3%, respectively, of their subjects with alcohol dependence were determined to have adult ADHD.[17,18] The findings from the current study are similar to the above studies on AUD patients. The predominant presentation of the subjects with ADHD in the study was of combined ($n = 9$) and hyperactive/impulsive ($n = 8$) types. These ADHD symptoms predispose an individual to have AUDs due to higher impulsivity.

In the current study, subjects with AUDs comorbid with ADHD were younger compared to the rest of the patients. The time of the first experience of alcohol to the time to regular use of alcohol was earlier in patients with ADHD when compared with patients without ADHD. The findings from the current study are similar to earlier studies in India and from other countries.[1,2,4] Subjects with ADHD had a relatively faster progression of the disease process. This is reflected in the significantly earlier age of onset of craving, higher amount of alcohol use, tolerance, withdrawal symptoms, salience, and early morning use among these patients in the current sample. Further, the subjects with ADHD had significantly higher severity of alcoholism compared to those without ADHD. Subjects with ADHD consumed a significantly higher amount of alcohol compared to the rest of the sample. These findings are similar to the findings by Matthys *et al*. and Arius *et al*.[5,9]

Patients with AUDs with comorbid adult ADHD had early progression towards dependence this might indicate common pathophysiology involving higher impulsivity and executive dysfunction affecting the outcome of AUDs. The subtype of patients of AUDs comorbid adult ADHD fall in the category of Babor's classification of type B subjects, who were characterized by early onset, a more rapid course, more severe symptoms, and poorer prognosis.[19] Whether comorbid ADHD with AUD is a subtype of AUD requiring aggressive management needs to be considered and evaluated in further studies.

The severity of alcohol use was high and the time to relapse was shorter in patients with ADHD, both of which are indirect indicators of higher severity of alcohol use in them. Further, this underlying pathology increases the dropout rate from the treatment process.[6] This is reflected in the current study finding that subjects with ADHD had shorter abstinence period compared to those without ADHD even after taking treatment. Wilens *et al*. reported that patients with ADHD had lower remission rates and longer duration of substance use.[5,6,20]

Patients with ADHD were at higher risk of developing another psychiatric disorder, with the odds being as high as 2.26 compared to subjects without ADHD. Oortmerssen *et al*. and Wilens *et al*. studying SUDs also reported higher psychiatric comorbidity among subjects with ADHD.[21]

Limitations

The present study was of cross-sectional design, and all patients in the study were recruited from an inpatient deaddiction ward with a diagnosis of severe AUD according to DSM 5. Hence, the data are limited in generalisability towards patients with mild

to moderate AUD attending deaddiction services. Adult ADHD diagnosis was confirmed by clinical interview method using DSM 5, and no structured diagnostic instruments were used for making adult ADHD diagnosis. Presence of childhood ADHD symptoms was not assessed. Clinical assessments were done using DSM 5 by interview method only, and structured assessment for other psychiatric morbidity, including personality disorders, was not done. Presence of childhood ADHD was not assessed. Finally, all patients in this study were males. Although this reflects the clinical scenario observed in India in a general hospital setup, it is a known fact that AUD is prevalent among the female population in a community set up.

CONCLUSION

Overall, the present study confirms high ADHD comorbidity in subjects with AUD and show that these subjects have a more severe course with early relapses. AUD subjects with ADHD were younger, had faster progression towards regular use of alcohol, and a higher amount of alcohol consumption. The subjects with comorbid ADHD have a history of an early relapse. Hence, all patients should be evaluated for ADHD and interventions should be initiated for the underlying ADHD along with treatment for AUDs. Further, medications like atomoxetine need to be considered in the management, while more trials are needed to confirm the benefits of the same.[22,23] Alcoholism being a significant problem in the Indian population, we need to evaluate all patients for comorbid ADHD and more research is required in these disorders in Indian samples.

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Conflicts of interest
There are no conflicts of interest.

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Original Article

Use of Filter Paper to Measure Alcohol Biomarkers among Opioid-Dependent Patients on Agonist Maintenance Treatment: A Community-Based Study

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ABSTRACT

Background: Harmful Alcohol use is frequent among opioid dependents patients undergoing agonist maintenance treatment. The objective assessment of harmful alcohol use can be done using laboratory measures of serum biomarkers. For community-based patients, there is often a requirement of an alternative method due to lack of onsite laboratory services. The aim of the study was to examine filter paper as a matrix to measure serum biomarkers of harmful alcohol use. **Methods:** The initial phase involved standardization of the filter-paper-based assay. Conditions were optimised for extraction and estimation of alcohol biomarkers (Aspartate Aminotransferase; AST, Alanine Aminotransferase; ALT, Gamma Glutamyl transferase; GGT and Carbohydrate Deficient Transferrin; CDT) from the filter paper. For clinical validation, serum samples were collected from community clinics. Biomarker levels obtained from both the methods were correlated using linear regression analysis. Limits of agreement between the two methods was estimated using the Intraclass Correlation Coefficient (ICC). **Results:** The extraction of enzymes (AST, ALT and GGT) from filter paper was carried out using the substrate buffer available with the reagent kit (Randox, UK). CDT was readily extracted from filter paper using deionised water. Serum biomarker levels measured from samples collected from community clinics correlated well with filter paper extracted levels (ICC 0.97-0.99). More than 90% of alcohol biomarker levels were recovered from the filter paper matrix using this method. **Conclusion:** Filter paper has the potential to be used as a matrix to objectively measure alcohol biomarkers among opioid-dependent patients from community settings lacking onsite laboratory facilities.

Key words: *Agonist maintenance, Alcohol biomarkers, community clinics, filter paper, opioid dependents*
Key messages: *Alcohol biomarkers can be measured efficiently from filter paper. The developed method may help to frequently assess the health status in patients undergoing maintenance treatment from community clinics.*

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Opioids are a major class of problem drugs, which cause significant disease burden and deaths worldwide.[1] A national survey among a treatment-seeking Indian sample reported the use of opiates as a primary drug of abuse in 26%,[2] which has risen to 53% in recent studies.[3] Long-term treatment with agonists like methadone and buprenorphine is the standard treatment available in India.[4] Patients undergoing agonist treatment frequently consume alcohol in a hazardous or dependent pattern.[5,6] This leads to adverse impacts like interactions with agonist medication, non-adherence, increased risk of fatal overdose, hepatotoxicity, and impairments in quality of life.[7] Hence, strategies to address the same become important, not only in dealing with alcohol-related problems but also in improving the treatment outcomes.[8]

Besides routine screening through self-reporting as measured by a standardized questionnaire, clinicians also need objective tools to assess the extent and pattern of alcohol use. Some of the traditional, inexpensive blood biomarkers such as aspartate aminotransferase (AST), alanine transaminase (ALT) and gamma glutamyl transferase (GGT) can be instrumental in identifying subjects with alcohol use problems. However, these biomarkers lack specificity, especially for harmful levels of use.[9] The relatively newer biomarker carbohydrate-deficient transferrin (CDT) has an important clinical value of being more sensitive to alcohol consumption *per se* rather than the effects of liver disease. The value of CDT increases at daily ethanol consumptions ranging from 40-80 g for a duration of 2-3 weeks. CDT also has sensitivity almost equal to that of GGT but is more specific.[10,11] Combining CDT and GGT tests for assessment of patients with alcohol use disorders gives a higher sensitivity (85%) than either of the assays alone.[12]

However, one of the challenges related to assessing biomarkers in clinical settings is to manage the logistics of sample collection and transportation to the laboratory. Transportation of samples to a central lab involves extra work of packaging, transportation, and labelling. Thus, it is expensive and tedious and involves problems like spillage and breakage.[13] An alternative sampling method is often looked for to carry out field-based studies. Recently, the use of filter paper for the transport of samples has gained popularity for resource-poor settings.[14,15] The use of filter paper for the collection and storage of serum has many advantages, including ease of collection and transportation. Serum samples collected on filter paper has been reported to efficiently measure various biochemical analytes, including AST and ALT.[16,17]

The study facility is a national level tertiary care treatment center for drug dependence, which is involved with various community-based projects and programs (including treatment and surveillance programs) at many places all over India. One of the challenges faced by the center is to provide support for laboratory needs in remote or densely populated areas where the facilities for performing laboratory test by a properly trained staff and in an established laboratory may not be available on the spot. The option is often that of a centralized laboratory carrying out all the investigations.

Thus, it was deemed worthwhile to explore the use of filter paper as a matrix to transport serum samples from community settings to measure alcohol biomarkers among opioid-dependent patients on agonist maintenance treatment.

METHODS

The study was carried out in a tertiary care treatment centre for substance use disorders. Ethical issues were addressed by maintaining the confidentiality of the subjects and obtaining consent before enrolling in the study. Ethical permission was obtained from the Institute Ethics Committee. The study was carried out in two phases. The first phase involved the optimization of conditions for extraction, recovery, and analysis of biochemical markers for alcohol use from serum spotted and dried on to filter paper. The second phase was the clinical validation of the standardized filter paper method.

Phase 1: Optimization

Estimation of enzymes

Estimation of AST, ALT and GGT was carried out from serum samples in chemistry analyzer AU 480 (Beckman Coulter), using reagents from Randox Laboratories, UK.[18] The levels obtained in direct serum samples were compared with their corresponding serum samples spotted on to filter paper.

Extraction and estimation of enzymes from filter paper

The serum-based calibrators for AST, ALT and GGT (139, 133 and 139 U/L) and controls level 1 (38, 36, 48 U/L) and level 2 (179, 123, 169 U/L) were used. A single drop of serum corresponding to 20 uL was spotted on to Whatman filter paper (903) in a non-absorbent surface. The filter disc was dried at room temperature (24-30°C) and kept at 4°C overnight. Extraction was carried out in the whole 20 uL disc. The disc was cut down to small pieces and the reagents were tried out for their extraction efficiency. Estimation of all the enzymes was carried out in chemistry analyzer AU 480 (Beckman Coulter) by small modifications in the protocol.

Direct serum estimation of CDT

A quantitative, sandwich enzyme immunoassay technique was used to measures CDT from serum samples.[19] The assay was performed by ELISA (Enzyme-Linked Immuno-Sorbent Assay) technique (Tecan GENios ELISA reader, Austria GmbH, Austria), using Magellan software. The procedure was followed as per the protocol provided by the manufacturer (Cusabio, USA). The concentration of CDT was determined using the professional software "Curve Expert" to make a standard curve from the web (www.cusabio.com). The levels obtained in direct serum samples were compared with their corresponding serum samples spotted on to filter paper.

Extraction and estimation of CDT from filter paper

Filter paper standards were prepared by spotting (20 uL) serum-based standard with CDT concentrations of 0, 50, 100, 350, 800 and 1600 ng/ml. After drying, the filter disc was kept at 4°C. The extraction conditions were standardized using various buffers under different conditions, and CDT measurement was carried out in the elute to estimate the recovery from filter paper.

Phase 2: Clinical validation

The study was carried out in three community settings lacking laboratory facilities. Samples were collected from patients attending community clinics run by the centre for the treatment of substance use disorder in three localities of Delhi (a distance of 20 to 40 km from the laboratory). The inclusion criteria for the study were: males aged between 18 to 60 years, diagnosed with opioid dependence (ODS as per ICD-10) by a trained psychiatrist and maintained on opioid agonists for at least three months, self-reporting regular alcohol use for the past three months. Those with a file diagnosis of co-morbidity (other substance abuse or dependence except tobacco, or axis 1 psychiatric comorbidity) were excluded.

A total of 45 participants meeting the selection criteria were included. After obtaining informed consent and clinical data, a blood sample (2 ml) was drawn in serum separator vacutainers. Clinical assessment included a semi-structured questionnaire for recording socio-demographic variables (age, gender, marital status, education, and employment) and clinical variables (alcohol use, OST [opioid substitution therapy] duration, compliance, and side effects). The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST), developed for the World Health Organization, was also used for early identification of substance use disorders.[20]

The blood samples were transported to the laboratory on the same day. Serum was separated by centrifugation at 2500 rpm for 15 minutes. The analysis of serum enzymes (AST, ALT, and GGT) was carried out on the same day. Serum was spotted on Whatman filter paper 903 as per the standardized conditions, and the remaining sample was stored at -20°C for CDT estimation as per the standardized conditions. The alcohol biomarkers levels measured from direct serum were compared with filter paper levels.

Statistical analysis

Descriptive statistics was employed to present the socio-demographic and clinical variables as number (%). The quantitative variables are summarized as mean with standard deviation (SD). The relationship between the biomarker levels obtained from serum and corresponding filter spots collected simultaneously were assessed using linear regression analysis. Intraclass correlation was calculated to estimate the limits of agreement between the two methods. The data were analyzed using IBM SPSS statistics 2015, version 20.0.

RESULTS

Patient characteristics: Sociodemographic and clinical details

All the participants were diagnosed with opioid dependence syndrome and maintained on OST with sublingual buprenorphine for varying length of time, with a mean (SD) of 40 (54.8) months. The mean age of the patients was 37.04 (10.7) years. Three-fourth (n = 33) of the patients were married, 22% (10) were unmarried, and only 4% (2) were either divorced or widower. One-fourth (11) of the patients were just literate, one-fourth (11) were either graduates or had acquired higher education, 30% (13) had studied up to 12th standard, and for the rest of the patients, the information was unavailable. More than 70% (34) of the patients were employed, 18% (9) were either self-employed or doing business, and two patients were unemployed.

Self-reported alcohol use was present in 60% of the patients on a weekly basis, followed by daily and monthly use [Table 1]. All the subjects were using tobacco, and almost half of them were cannabis users. When the patients were asked about their OST compliance, one third reported very regular use (more than 24 days/month). More than 90% denied any craving for opioids.

Extraction and estimation of biomarkers from filter paper

The extraction of serum enzymes (AST, ALT, and GGT) was effectively carried out in their respective substrate buffers. The levels obtained from quality controls compared well with their respective filter extracted

values. The extraction of CDT from filter paper serum spots was found to be optimal using distilled water. The optimal conditions for extraction of alcohol biomarkers (AST, ALT, and GGT and CDT) were standardized in filter paper spots [Table 2].

Clinical validation for measurement of biomarkers of harmful alcohol use from filter paper

Figure 1 shows the levels measured from direct serum and their corresponding filter paper spots. The values of all the biomarkers measured from direct serum correlated well with their corresponding filter paper levels [Table 3].

DISCUSSION

Harmful alcohol use is one of the common comorbidities associated with opioid-dependent patients on agonist maintenance treatment. This study was planned to objectively assess harmful alcohol use among opioid-dependent patients from community setting using filter paper as a matrix to measure alcohol biomarkers.

Table 1: Clinical profile of the subjects/patients (*n*=45)

Clinical Profile	Number (%) (*n*=45)
Pattern of alcohol use	Daily: 10 (22)
	Weekly: 28 (63)
	Monthly: 7 (16)
Use of other substance	Cannabis: 20 (45)
	Tobacco: 45 (100)
Medication compliance*	Very Regular: 34 (76)
	Regular: 3 (6.5)
	Irregular: 2 (4.5)
	Not known: 6 (13)
Craving for opioids	Present: 3 (7)
	Absent: 42 (93)
Buprenorphine side effect	Present: 4 (9)
	Absent: 41 (91)
WHO ASSIST Score#	Moderate risk: 75.5 (34)
	High risk: 24.5 (11)

*Very Regular (>24 day/month), Regular (15-24 day/month), Irregular (>15 day/month). #Moderate risk (11-26), High risk (27 and above), ASSIST - Alcohol, Smoking and Substance Involvement Screening Test

Routinely measured liver enzymes AST, ALT, and GGT were studied to assess the harm associated with alcohol use while CDT was included as a biomarker of alcohol use.[9,10] In community or field-based settings, the use of filter paper is associated with several advantages like ease of collection and transportation.[15] The standardization of the filter paper method was carried out as per our early reports.[16,17] Extraction of liver enzymes was efficiently carried out in their respective buffers, and the levels were measured using chemistry analyzers. Automation of the filter paper method in this study has made it adoptable and feasible.[21] CDT was found to be efficiently extracted from dried serum spots using water. Earlier, CDT estimation from dried blood spotted filter paper was reported using the electrophoresis method.[22] The present method developed for total CDT measurement is simple and fast, with one step extraction from dried serum.

The levels of biomarkers as measured in direct serum correlated well when compared with serum spotted onto filter paper. The recovery of biomarkers from filter paper was more than 90% for all the enzymes, using automated chemistry analyzer. For CDT, the recovery remained 89%, using a manual enzyme-linked immunoassay method. The two methods correlated well, with more than 0.95 ICC values. Filter paper has the potential to be used as a matrix to transport and measure alcohol biomarkers from field-based community studies. Previous studies from our group and other authors also reported filter paper as a reliable matrix for biochemical measurements.[13-17]

Table 2: Standardized conditions for alcohol biomarkers measurements from filter paper

Biomarker	Serum spot volume	Extraction agent	Extraction Condition	Estimation condition (volume µl)	Instrumentation
AST, ALT and GGT	20 µl	200 µl substrate buffer	Vortex briefly. Spin at 4000 rpm for 1 min. Repeat twice	Sample: 10 R1: 125 R2: 25	Chemistry analyzer
CDT	10 µl × 5 spots	300 µl water	1-h extraction at 37°C with brief vortexing	50	ELISA Reader

AST – Aspartate aminotransferase, ALT – Alanine aminotransferase, GGT – Gamma gutamyl transferase, CDT – Carbohydrate deficient transferrin, R1 – Reagent 1, R2 – Reagent 2

Table 3: Comparison between levels of alcohol biomarkers measured from direct and filter paper method

Alcohol Biomarker	Direct levels Mean (SD)	FP levels Mean (SD)	Recovery %	R^{2}*	ICC# (*P*)
AST	50.07 (81.9) (U/L)	49.9 (83.47) (U/L)	99	0.95	0.97 (0.001)
ALT	59.57 (56.57) (U/L)	53.2 (57.13) (U/L)	96.5	0.98	0.99 (0.001)
GGT	51.89 (61.70) (U/L)	49.9 (60.69) (U/L)	96.2	0.99	0.99 (0.001)
CDT	531.84 (518.88) (ng/ml)	474.95 (495.16) (ng/ml)	89	0.99	0.99 (0.001)

*R^{2} Goodness of fit in linear regression between two variables. #ICC Intra class correlation between two variables. AST – Aspartate aminotransferase. AL + T – Alanine aminotransferase, GGT – Gamma gutamyl transferase, CDT – Carbohydrate deficient transferrin

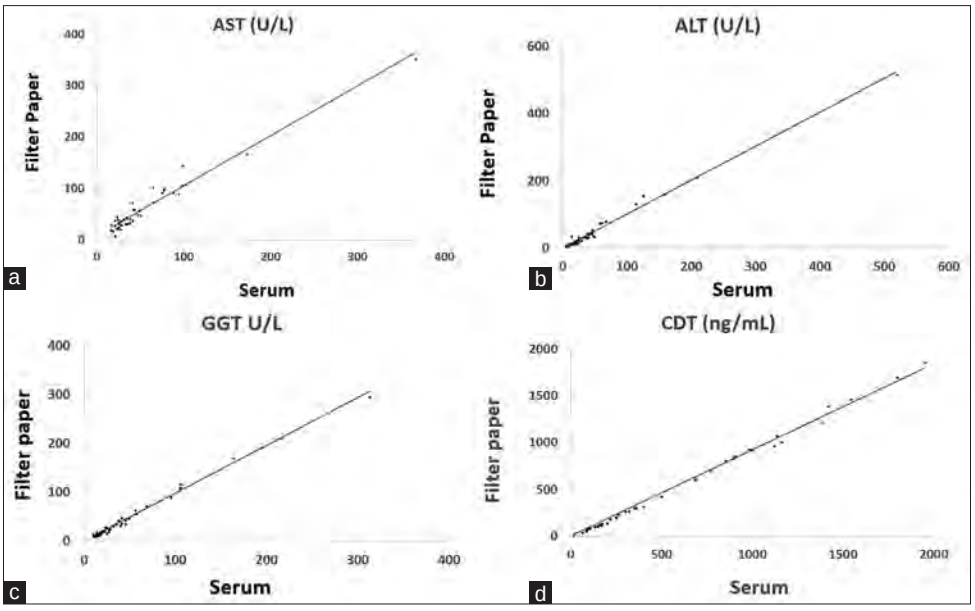

Figure 1: (a-d) Relationship in paired samples (n = 45): Regression curve for alcohol biomarker levels obtained from filter paper as compared with levels in direct serum. Each Individual values represent the mean of duplicate samples. AST: Aspartate aminotransferase, ALT: Alanine aminotransferase, GGT: Gamma gutamyl transferase, CDT: Carbohydrate deficient transferrin

The clinical profile of the subjects indicated alcohol use in a majority (85%) of the opioid dependent patients either on a daily or weekly basis. Previous literature had reported diverse rates of alcohol use in patients on agonist maintenance, mostly methadone.[6] However, there is very limited literature on the rates of alcohol use among buprenorphine-maintained patients,[23] especially from India.[8] Tobacco use was observed among all the subjects included in the study, while cannabis use was found in 45% of patients. Alcohol and tobacco are the substances most commonly used together, because of their shared neurobiological mechanisms augmenting each other's rewarding effects.[24] Previous literature had reported cannabis use among the opioid-dependent population in Indian settings.[25] While interpreting the results in treatment settings, caution should be maintained as the effect of concurrent tobacco and heavy alcohol use may alter liver enzymes.[26] However, cannabis use *per se* has no effect on liver function.[27]

Buprenorphine is one of the most widely used opioid agonist medications in India. Compliance to buprenorphine, without any side effect, among more than 90% of the study patients is in accordance with recent reports.[28] The clinical profile of the patients showed 34% of subjects with moderate ASSIST scores and the remaining 11% with high-risk scores. These results indicate the importance of an objective screening of these patients for harmful alcohol use on a regular basis.

At the same time, the study has a few limitations. The study was planned in a routine clinical setting, and therefore, more recent and specific alcohol biomarkers were not assessed. The liver enzymes assessed for alcohol use have limitations in terms of sensitivity and specificity. The number of samples included was determined on the feasibility of sample collection from a community setting on a pilot basis.

However, the results of the study can be applied to any drug treatment community setting. This study advocates the need for routine use of objective methods to corroborate with patients' self-report during a clinical judgment. Future studies comprising more specific alcohol biomarkers, from multiple settings, are warranted.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Drug use among Teenagers and Young Adults in Bhutan

Kinley Wangdi[1,2], Tshering Jamtsho[3]

ABSTRACT

Background: Use, possession, and illegal transactions of controlled substances have increased in recent years in Bhutan. This study aimed to determine the national prevalence of ever drug use and identify its associated factors amongst teenagers and young adults. **Methods:** This study was conducted using data from the National Health Survey 2012 of Bhutan. The outcome variable of interest was ever drug use in teenagers and young adults. The questionnaire was developed following the WHO STEPwise approach to surveillance of non-communicable diseases (STEP). Univariate and multivariate logistic regression were performed to identify correlates of ever drug use. **Results:** The prevalence of ever drug use among teenagers and young adults was 3.2% (n = 672). The factors associated with ever drug use were: being men; being single; being in age group of 18-24 years; having a primary school, high school, monastic, university, or diploma education; being technicians or salespersons; feeling always lonely; having ever consumed alcohol, and having ever smoked. **Conclusion:** Compared to the other countries in the WHO South-east Asia region, the prevalence of ever drug use in Bhutan is low. Use of other substances, including smoking and alcohol use, was associated with ever drug use. For greater effect, drug use prevention strategies should include prevention of smoking and alcohol use.

Key words: *Bhutan, correlates, ever drug use, National Health Survey*

Key messages:

- *Prevalence of ever drug use in Bhutanese teenagers and young adults is low*
- *Drug use is associated with risky lifestyles such as smoking and alcohol use*
- *Drug prevention strategies should target these lifestyle-related risk factors.*

In 2016, the World Health Organization (WHO) estimated that 5.6% (270 million) of people between 15 and 64 years used drugs at least once in their lives.[1] Drug use can lead to dependence and require treatment. During the same period, one in nine people who use drugs (11%) were estimated to be suffering from drug use disorders, which translates to 30.5 million cases.[1]

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Globally, drug use contributes 2% of cause-specific disability-adjusted life-years (DALYs) for young people aged 10-24 years.[2]

Drugs are used for several reasons including experiment out of a sense of curiosity, excitement or rebellion, socializing, enhance an activity and alleviate the depressed mood, and reaction.[3-5] Drug use is associated with many harmful effects on both physical and mental health.[6-8] The cost to the community and society of drug abuse is colossal.[9] Drug abuse has a significant impact on healthcare services, public services, and the criminal justice system. A large part of the health care budget is spent on treating drug addiction.[10] Drug abusers are estimated to commit 36 million drug-motivated crimes each year, which financially accounts for 90% of the total cost to society.[11] In addition, individuals and families are affected through the loss of productivity and unable to earn income.[12]

With the rapid modernization of the country in the past five decades, Bhutanese society has gone through many changes during this period. This transition was characterised by rising disposable income levels and cultural changes with exposure to the outside world through television and the internet.[13] Further, demographics are changing rapidly as young people in particular move to towns for work, education, and entertainment.[14-16] Rising migration and divorce rates often result in a fraying of ties to traditional settings, leading to growing substance abuse that compounds the problem, particularly with school dropouts. In 2017, Thimphu Police registered 287 cases in connection with drug abuse, possession, and illegal transactions of controlled substances that led to the arrest of 596 people, the highest in recent years.[17]

Despite this societal transformation, there is a paucity of systematically analysed in-depth studies representing the national prevalence of drug use and its correlates. Therefore this study attempts to present the national prevalence of drug use amongst teenagers (12-17 years) and young adults (18-35 years),[18,19] and correlates associated with it.

METHODS

Study site

The study was undertaken in the small Himalayan Kingdom of Bhutan. It has an area of approximately 38,394 km^2, and the population was 735,553 in 2017. Bhutan is divided into 20 administrative districts and 205 sub-districts. Around 62.2% (452,178) of the population live in rural areas and practice subsistence farming. The altitude ranges from 75 m on the southern border with India to more than 7000 m in the Himalayas.

Study design

This is a retrospective analysis of secondary nationally representative data of the National Health Survey (NHS 2012) conducted nationwide in 20 districts of Bhutan in 2012. The survey sample was calculated to provide a reliable estimate of indicators using a census sample frame from the Population and Housing Census of Bhutan 2005 (PHCB 2005).[20]

Correlates of drug use

The participants for this study were teenagers and young adults. The outcome variable of interest was self-reported ever use of drugs. Independent variables were self-reported covariates collected using the WHO STEPwise approach to surveillance of non-communicable diseases (STEP) based questionnaire.[21] These included sex, age (13-17, 18-24 and 25-34 years), marital status, education level, occupation, urban-rural residence, ever consumed alcohol, ever smoked, and feeling lonely. A "standard drink" is the amount of ethanol contained in standard glasses of beer, wine, fortified wine such as sherry, and spirits, and it contains roughly 8-13 grams.

Statistical analysis

All analyses were done by appending sample weights to the individual data. Univariate logistic regression was undertaken to select the variables at the significance level of $P < 0.2$. The selected variables were fitted into the multivariate model to identify significant covariates. A value of $P \leq 0.05$ was considered significant. A goodness-of-fit test was undertaken to measure the adequacy of the final model. The analysis was performed using the SVY module for complex samples of the statistical package STATA version 15 (Stata Corporation, College Station, TX, USA).

Ethical approval

The ethical approval to use the NHS 2012 data was given by the Research Ethics Board of Health (REBH), Ministry of Health, Bhutan (REBH/Approval/2018/075).

RESULTS

Socio-demographic characteristics of those who had ever used drugs

Of the study participants, 93.8% (631) were men, and 3.2% (673) reported ever using drugs. Most drug users were in the age group of 18-24 and 25-35 years, with 46.0% (309) and 38.6% (260), respectively. Nearly 61% (398) were high school educated, followed by university-educated at 24.9% (163), and 68.3% (460)

were single. The commonest occupation groups were service and sales workers, farmers and unskilled, and managers and professionals at 39.6% (118), 35.0% (104) and 22.3% (67), respectively. 71% (479) and 80.1% (542) ever drank alcohol and ever smoked. There was an equal proportion of drug users from urban and rural areas. More than half (350) of the drug users were never lonely [Table 1].

Factors associated with ever drug use

Multivariate analysis found that men are ten times more likely to be ever drug users than women, adjusted odds ratio (aOR) =10.18 (95% CI, 5.22, 19.86). The participants in the age groups of 18-24 years were 48% [aOR = 1.48 (95% CI, 1.07, 2.067)] more likely to be ever drug users compared to participants in the age group of 25-35 years. Those who were singles were 59% more likely than married people to be ever drug users, aOR = 1.59 (95% CI, 1.17, 2.15). Education of all levels was associated with ever drug use than no education. Blue-collared workers, including technicians and sales workers, were 58% more likely to be ever drug users than farmers, aOR = 1.58 (95% CI, 1.15, 2.16). Those who always felt lonely were nearly 9.6 times more likely to use drugs than those who never felt lonely, aOR = 9.6 (95% CI, 2.94, 31.41). Participants who ever drank alcohol were 89% more likely than those who never drank alcohol to ever use drugs, aOR = 1.89 (95% CI, 1.37, 2.60). Those who ever smoked were 11.6 times likely than non-smokers to be a drug user, aOR = 11.59 (95% CI, 8.27, 16.24) [Figure 1 and Table 2].

Table 1: Sociodemographic characteristics of the study population and every drug user

Characteristic	Total (%)	Ever used drugs (%)
Sex		
Women	11,126 (54.8)	42 (6.2)
Men	9,170 (45.2)	631 (93.8)
Age group		
13-17	5,405 (26.6)	104 (15.4)
18-24	6,083 (24.0)	309 (46.0)
25-35	8,808 (43.4)	260 (38.6)
Education		
No formal education	4,493 (24.8)	16 (2.5)
Non-Formal Education	1,714 (9.5)	9 (1.4)
Primary school	2,522 (13.9)	51 (7.8)
High school	7,680 (42.4)	398 (60.7)
Diploma/Certificate	187 (0.9)	5 (0.8)
University	1,142 (6.3)	163 (24.9)
Monastic education	374 (2.1)	14 (2.1)
Marital status		
Single	10,109 (49.9)	460 (68.3)
Married	9,514 (46.9)	207 (30.8)
Divorced/separate	590 (2.9)	6 (0.9)
Widow	66 (0.3)	0 (0)
Occupation		
Clerical/farmer/unskilled	4,114 (58.3)	104 (35.0)
Army	266 (3.8)	9 (3.1)
Manager and professionals	582 (12.1)	67 (22.3)
Service and sales worker	1,807 (25.6)	118 (39.6)
Monks	20 (0.3)	0 (0)
Ever used alcohol		
No	13,760 (67.8)	192 (28.7)
Yes	6,531 (32.2)	479 (71.3)
Ever smoker		
No	17,729 (87.3)	131 (19.4)
Yes	2,567 (12.7)	542 (80.6)
Urban		
No	14,318 (70.5)	339 (50.4)
Yes	5,977 (29.5)	334 (49.6)
Lonely		
Never	13,764 (67.9)	350 (52.2)
Rarely	2,486 (12.3)	122 (18.2)
Sometimes	3,868 (19.1)	180 (26.9)
Always	162 (0.8)	18 (2.7)

DISCUSSION

There had been limited studies on ever drug use in Bhutan, and this is the first study in teenagers and young adults using nationally representative data. The national prevalence of drug use amongst teenagers and young adults was 3.2%. The correlates for drug use were being men, in the age group of 18-24 years, being single, having a higher education, blue-collar workers, feeling always lonely, having ever consumed alcohol and having ever smoked.

The prevalence of drug use among teenage and young adults in Bhutan is lower than in the region.[22-24] This could be attributed to the strict laws against the trafficking of drugs in Bhutan. Secondly, most or all drugs are ferried from India, and there are police check posts that deter from importing drugs into the country. However, getting drugs into the border towns of Bhutan

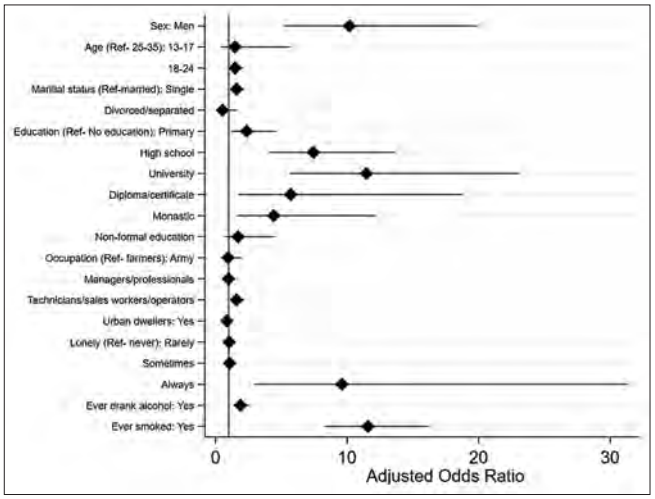

Figure 1: Forest plot of the adjusted odds ratio of correlates of ever used drugs

Table 2: Univariate and multivariate logistic regression analysis with risk factors for ever drug users

Variables	Unadjusted correlates			Adjusted correlates		
	OR	CI	*P*	OR	CI	*P*
Sex						
Women	Ref			Ref		
Men	19.49	14.24, 26.67	<0.001	10.18	5.22, 19.86	<0.02
Age group						
25-35	Ref			Ref		
13-17	0.64	0.51, 0.81	<0.001	1.47	0.38, 5.73	0.58
18-24	1.76	1.49, 2.08	<0.001	1.48	1.07, 2.06	<0.001
Marital Status						
Married	Ref			Ref		
Single	2.14	1.81, 2.53	<0.001	1.59	1.17, 2.15	0.003
Divorced/separated	0.46	0.20, 1.04	0.06	0.53	0.17, 1.62	0.266
Education						
No education	Ref			Ref		
Primary	5.67	3.24, 9.93	<0.001	2.37	1.20, 4.66	0.01
High school	15.03	9.14, 24.71	<0.001	7.44	4.06, 13.64	<0.001
University	45.77	27.37, 76.54	<0.001	11.47	5.69, 23.10	<0.001
Diploma/certificate	8.85	3.27, 24.00	<0.001	5.70	1.39, 18.71	0.004
Monastic	10.42	5.03, 21.56	<0.001	4.42	1.61, 12.15	0.004
Non-formal educated	1.43	0.63, 3.25	0.39	1.71	0.64, 4.58	0.29
Occupation						
Farmers	Ref			Ref		
Army	1.38	0.70, 2.73	0.36	0.95	0.45, 2.00	0.89
Manager/professional	3.25	2.37, 4.47	<0.001	0.98	0.64, 1.51	0.94
Technician/sales worker	2.69	2.05, 3.52	<0.001	1.58	1.15, 2.16	0.004
Rural-urban						
Rural	Ref			Ref		
Urban	2.44	2.09, 2.85	<0.001	0.86	0.65, 1.15	0.32
Lonely						
Never	Ref			Ref		
Rarely	1.98	1.61, 2.45	<0.001	1.03	0.72, 1.47	0.86
Sometimes	1.88	1.56, 2.25	<0.001	1.06	0.75, 1.50	0.72
Always	4.88	2.96, 8.03	<0.001	9.6	2.94, 31.41	<0.001
Ever used alcohol						
No	Ref			Ref		
Yes	5.57	4.70, 6.60	<0.001	1.89	1.37, 2.60	<0.001
Ever smoked						
No	Ref			Ref		
Yes	36.05	29.62, 43.87	<0.001	11.59	8.27, 16.24	<0.001

OR – Odds ratio; CI – Confidence interval; Ref – Reference group

from India is easy as the international border with India is open, with free movement of people.[25]

In this study, higher education was associated with drug use. This finding differs from that of other studies that reported education as a protective factor against drug use.[26-28] This observation in Bhutan could possibly be due to the influence of television and the Internet amongst the educated lot. However, it would be worthwhile to study the reasons for this association.

Drug use was more among men; similar findings have been reported in other studies.[24,28-32] Men are generally known to undertake risky lifestyle behaviour. The teenagers and young adults were at higher risk of ever using drugs than 25-35-year-old participants. This is particularly concerning for Bhutan because more than 50% of the Bhutanese population is younger than 25 years.[33] Existing studies have found a high correlation between adolescent drug abuse and becoming a problem drug user in the adulthood.[34] These aspects should be taken into account in drug prevention strategies.

As in other published literature,[35,36] we found that ever drug use is associated with other substance use, including smoking and alcohol use. Earlier studies have shown that those who use alcohol in the early teenage years are more likely to use drugs later in life.

Therefore, delaying the use of alcohol can also prevent drug use in teenagers.[37] Alcohol use in Bhutan is socially acceptable and the prevalence is one of the highest in the region.[38] Therefore, drug use prevention should be done in conjunction with prevention of alcohol use.

Choki *et al*. reported that unemployment was associated with psychoactive substance use by psychiatric patients in Bhutan.[30] In our study, blue-collared workers were more likely to use drugs than farmers. This difference could be partly explained by the study sample. The current study is based on the nationally representative study sample, while the other study was based on those admitted to the national referral hospital.[30]

The findings of this study have to been interpreted in light of some limitations. The causal relationship between ever drug use and its correlates cannot be concluded due to the cross-sectional nature of the study. Secondly, the lifestyle reported in this study was self-reported, so there could be recall bias. Thirdly, risky lifestyles such as smoking could be under-reported due to the influence of social desirability. Fourth, this study did not identify the different types of drugs that were used. Lastly, these data are rather old, and there could have been changes to the trends. Despite these limitations, this is the first study on the prevalence of ever drug use and its correlates among adolescents and young adults using nationally representative data. Therefore, the findings from this study can be useful in developing national preventive strategies in Bhutan.

CONCLUSION

Compared to other countries in the WHO South East-Asia region, the prevalence of ever drug use among teenagers and young adults in Bhutan is low. Other substance use, including smoking and alcohol use, was associated with ever drug use. Drug use prevention strategies should include smoking and alcohol prevention for greater effect.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Nomophobia: A Mixed-Methods Study on Prevalence, Associated Factors, and Perception among College Students in Puducherry, India

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ABSTRACT

Background: As more people are utilizing smartphones, nomophobia is also on the rise. Several Indian studies have revealed nomophobia among young adults. The severity of nomophobia and related behaviors is underrated and often go unnoticed in India. **Methods:** The sociodemographic characteristics, smartphone usage pattern, and perceived ill-health related to smartphone usage of the participants were obtained using a semistructured questionnaire. Twenty-item Nomophobia questionnaire was used to assess nomophobia. In-depth interviews were conducted among students with moderate and severe nomophobia scores. **Results:** Among the 774 participants, 23.5% had severe nomophobia scores. Older age, male gender, duration and frequency of smartphone usage, use for social networking, checking without reason, and checking smartphone after waking up in the morning were significantly associated with nomophobia. The in-depth interview showed attributes of addiction among the students, like dependency and compulsive behavior. Students also experienced anxiety and frustration when they had to part with their smartphones. **Conclusion:** A sizable minority of the students had signs of severe nomophobia, distinct patterns of usage, and misperceptions regarding health and their usage pattern.

Key words: *In-depth Interview, nomophobia, smartphone addiction, young adult*

Key messages: *In collaboration with educational institutions, health professionals should take appropriate steps to find individuals with behaviors suggestive of smartphone addiction and nomophobia and ensure that they are given sufficient information and education about nomophobia and similar technology addictions.*

Nomophobia is thought to be a trend in only developed and technologically advanced countries; however, it is also identified in India by psychiatrists, particularly in adolescents and adults who are addicted to smartphones.[1,2] Nomophobia refers to discomfort, anxiety, nervousness, or anguish caused by being out

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of contact with a mobile phone.[3] Studies conducted in various regions of India have shown addictive behaviors related to smartphone use among young adults.[4-6] Even so, the severity of nomophobia and related behaviors is underrated and often goes unnoticed in India, because smartphone usage is widely considered an ordinary and necessary behavior. Smartphones can be used for a variety of purposes: call, texts, paying bills, making online transactions, etc. In such a scenario, identifying deviant behavior becomes an almost impossible task.

Ownership of a smartphone at an early age and increased hours of usage per day are identified as triggering factors for addictive behaviors.[7] Young adults keep their smartphones nearby even when they are sleeping.[8] Studies, done on students pursuing professional study courses, have found varying proportions of individuals affected with nomophobia.[4,6-9] Social networking media such as WhatsApp and Facebook are promoting factors for spending more hours on smartphones.[5,10] There are no awareness about nomophobia and its effects among the vulnerable population.[11] Anxiety related to the inability to use a smartphone or constant checking of the phone for notifications is often ignored as symptoms of possible addiction.

Nomophobia, if not identified and corrected at the earliest phase possible, can emerge as a significant public health issue in the coming years. Even though some quantitative studies[4,5,7,9,12] on such behavior are available in India, there is a lack of in-depth understanding of the perception and attitude that lead to nomophobia. More critical studies are required to gain more knowledge about the patterns and perception about nomophobia and, thus, fill the lacunae in the existing literature. In this context, the current study was carried out to estimate the prevalence and factors associated with nomophobia and to understand the perception of young adults about excessive smartphone usage, through qualitative methods.

SUBJECTS AND METHODS

This is a mixed-method study, with both a cross-sectional analytical and a qualitative descriptive component, conducted among undergraduate students aged 18 years and above.

Sample size

Assuming the prevalence of nomophobia among college students as 38%,[13] an absolute precision of 4%, 95% confidence level, and a design effect of 1.2, the sample size was calculated as 679. After adding a non-response of 10%, the final sample size was estimated to be 754. The actual sample achieved at the end of the data collection was 774.

Sampling technique

Puducherry has six government and four government-aided Arts and Science colleges. Two colleges from each category were randomly selected. Students from second and third year were selected for the study. To account for the difference in student strength of the colleges, 263 students from college A, 353 from college B, 65 from college C, and 73 from college D were required based on proportion. Cluster sampling was done, considering a class as a cluster in each college. The number of students in each class of the four colleges ranged from 33 to 64, and there were 10 to 20 classes in each college. Hence, for the sampling of students, a total of 19 classes were selected from all four colleges, with eight classes from college A, six from college B, two from college C, and three from college D. The classes to be studied were selected randomly (through lottery method) until the adequate sample of students were covered in each college. All students in each selected class were included in the study.

Data collection

Necessary scientific and Institutional Ethics Committee approvals were obtained for conducting the study. Prior permission was obtained from the Directorate of Higher and Technical Education, Puducherry and the Principals and the respective Heads of the Departments of each college, before commencing the study. A pretested, self-administered, semistructured questionnaire was used to collect the participants' sociodemographic characteristics and smartphone usage pattern. Socioeconomic status was assessed according to Modified BG Prasad's scale for socioeconomic class (2018).[14] Nomophobia Questionnaire, a twenty-item validated scale, was used to assess nomophobia scores.[15] It has questions under four main domains. The score obtained in each of the twenty items, measured with a Likert scale, is totaled to get a final score for each participant. These scores are divided into four categories, based on which the severity of nomophobia is determined. The scores below 20 are considered as the absence of nomophobia, 21 to 60 as mild, 61 to 100 as moderate, and 101 to 140 as severe nomophobia.

The questionnaire was forward-translated from English to Tamil independently by two bilingual translators. Discrepancies between the two versions of the questionnaire were resolved after discussion between the investigator and the translators. Then, the questionnaire was back-translated into English. Following that, changes were made by experts and the translators, after reviewing the translations, in

order to ensure clarity. Pilot testing was done among 30 respondents. They were asked to explain their understanding of the questionnaire and the answers they gave, to make sure that the original and the translated versions of the questionnaire had the same meaning. Cronbach's alpha of the translated version was found to be 0.87.

After class arrangement, the students were explained about the study procedure in Tamil, and written informed consent was obtained. Twenty-one students who did not own a smartphone were excluded. The questionnaire was distributed to all the students in the selected classroom at a single point of time. The questionnaires were identified by unique ID numbers. The filled questionnaires were collected back after 30 minutes.

For the qualitative component of the study, students with moderate or severe nomophobia were identified for conducting In-depth Interviews (IDI). The scores were totaled each day before the afternoon, and unique ID numbers with moderate and severe scores were traced on the same day. One unique ID among these was selected randomly. The interviews were conducted on the same day as the questionnaire was administered. Individuals with moderate nomophobia were also considered for the interview, as several selected students with severe nomophobia did not consent to participating in the interview. Out of a total of 15 students approached for the IDI, six consented to participate. The students were briefed about the procedures for the interview, and then, the willing participants were invited to participate in an IDI which was audio-recorded. Interviews were conducted until the information reached a saturation point.

Statistical analysis

The variables assessed were age, gender, and socioeconomic status of the participants, duration and frequency of smartphone usage, the purpose of maximum smartphone usage and its context, checking smartphone without any reason, perceived ill-health due to smartphone usage, and checking smartphone as soon as waking up in the morning. Prevalence of nomophobia was summarized as percentages with 95% confidence interval. Linear regression analysis was done to find the significant independent variables associated with nomophobia. A p value of less than 0.05 was considered statistically significant.

For the qualitative component of the study, audible data was transcribed verbatim on the same day of the interview. Thematic analysis of the interviews was done. This was followed by familiarizing ourselves with the data and generating initial codes. Themes were named and defined. During the familiarizing phase, phrases and sentences were highlighted. Codes were generated under each theme. Themes were identified as the unit of analysis. Inferences were drawn, and meanings were derived from the data.

RESULTS

Thirty forms were found to be incomplete. Sociodemographic characteristics of the participants are depicted in Table 1. Duration of smartphone usage was found to be 3–6 hours in nearly half of the participants (52.1%), and 19% of the participants even reported using their smartphone for 7 hours and more per day. Nearly half of the participants (48.6%) checked their phones at least 4–6 times per hour. Social networking and music were found to be the most used utilities in smartphones, with an almost equal proportion of the participants reporting it as the purpose of maximum usage (20% and 22%, respectively). Smartphone use was found to be maximum during leisure time (46.6%), followed by the time before sleeping (31.7%). Around 65% of the students admitted that they sometimes check their smartphones without any particular reason. Half of the participants (51.5%) reported that others have told them that they were using their smartphones too much. Nearly 38% felt that their smartphone use was hampering their academic performance, and 55% said that they check their smartphones as soon as they get up in the morning. Out of 774 responses from participants, the highest proportion of perceived ill health effect due to smartphone use was reported for headache (23.6%), followed by eye strain (21.8%). No perceived ill health was reported by 106 respondents [Table 2].

Table 1: Sociodemographic characteristics of college students (n=774)

Variables	Frequency (%)
Age (in years)	
18	368 (47.5)
19	278 (35.9)
20	106 (13.7)
More than 20	22 (2.9)
Gender	
Male	319 (41.2)
Female	455 (58.8)
Residence	
Urban	482 (62.3)
Rural	292 (37.7)
Socioeconomic Class#,*	
Class I (INR 6574 and above)	402 (70.1)
Class II (INR 3287-INR 6573)	130 (22.6)
Class III (INR 1972-INR 3286)	35 (6.1)
Class IV (INR 986-INR1971)	7 (1.2)

*Some data missing, #Modified B G Prasad's scale for socioeconomic class (2018)

Table 2: Smartphone usage characteristics of the college students (*n*=753)

Variables	Frequency (%)
Duration of smartphone use per day (hours)*	
2 and less	210 (28.9)
3-6	379 (52.1)
7 and more	138 (19.0)
The frequency of checking smartphone per hour*	
Three times and less	220 (31.0)
4-6 times	345 (48.6)
Seven times and more	145 (20.4)
Purpose of maximum usage	
Calls	170 (22.6)
Social Networking	165 (21.9)
Music	152 (20.2)
Texting	107 (14.2)
Video	81 (10.8)
Browsing the Internet	54 (7.2)
Camera	24 (3.1)
The context of maximum usage	
Leisure time	351 (46.6)
Before sleeping	239 (31.7)
On the bus	55 (7.3)
At college	51 (6.8)
While walking	48 (6.4)
While eating	9 (1.2)
Checking the phone without any reason*	
Never	175 (23.3)
Sometimes	488 (64.9)
Always	89 (11.8)
Perception of ill health due to smartphone usage	
Headache	183 (23.6)
Eyestrain	169 (21.8)
Neck pain	139 (18.0)
Disturbed sleep	129 (16.7)
No perceived ill health	106 (13.7)
Fatigue	48 (6.2)
Perception of overuse by others*	387 (51.5)
Perception of phone use hampering academic performance*	286 (38.1)
Checking smartphone first thing in the morning*	418 (55.7)

*Some data missing

Out of 774 respondents, nine had no nomophobia, 161 (20.8%) had mild nomophobia, 422 (54.5%) had moderate nomophobia, and 182 (23.5%) had severe nomophobia.

Linear regression [Table 3] showed that older age, male gender, increased daily duration of smartphone usage, frequency of checking smartphone, using a smartphone for social networking and texting, checking smartphone without reason, and checking smartphone immediately after waking were significantly associated with nomophobia. The adjusted R-square of the model was 0.26, implying that these variables predicted 26% of the variance in the nomophobia score, which was significant ($F = 26.68$, $P < 0.001$).

In-depth interviews

Four main themes were drawn from the interviews: Perception about smartphone usage, facilitating factors for smartphone usage, controlling factors for smartphone usage, and nomophobia and addiction. The codes corresponding to each theme are mentioned along with the statements in Table 4.

Perception about smartphone usage

The participants considered smartphones to be an absolute necessity and an escape route from boredom or stressful situations. They also found a sense of belonging from its use.

Two participants admitted that they were ashamed to take an old phone (button phone) with them when their smartphone was undergoing repairs. This showed a tendency to be accepted as normal among others because the participants felt inferior when others had a smartphone and they did not. This was included under the code of social desirability. They also associated having a smartphone with a sense of independence.

Some participants expressed the view that a gadget like a smartphone was very important to stay up-to-date with the current trends and changes and technology. They perceived smartphone use as something very normal and habitual because it is used for almost everything in their daily lives, even checking the time.

Facilitating factors for smartphone usage

Participants were motivated to increase their usage due to unlimited access to information, user-friendliness, convenience, Internet availability, and a sense of connectedness to others while using a smartphone.

There was also an urge to reply back when others text as it was considered a common courtesy (communication etiquette).

Participants expressed that they were eager to check their smartphones for any message or call notifications if they were not able to access their smartphones for a while (Anticipation of calls/texts). They also believed that talking through a smartphone can be equivalent to face-to-face interactions.

Controlling factors for smartphone usage

Participants reported restrictions from family, security concerns while using social media, health problems attributed to long hours of smartphone usage, missing out on family time, and conditional access (specified data limit or talk time in the given package which cannot be exceeded by the user) by the service providers as limiting aspects of their smartphone usage.

Table 3: Linear regression analysis of the factors associated with nomophobia

Variables	Beta coefficient	95% CI for Beta	*p* value
Constant	-19.08	-56.55-18.40	0.318
Age	3.98	1.98-5.97	<0.001
Gender (male)	3.58	0.27-6.89	0.03
Frequency of checking smartphone per hour	0.59	0.16-1.03	0.008
Duration of smartphone use per day (h)	0.84	0.42-1.26	<0.001
Purpose of maximum usage*			
Texting	5.68	1.05-10.30	0.02
Social Networking	5.56	1.66-9.45	0.005
Checking smartphone without reason**			
Always	18.65	12.82-24.49	<0.001
Sometimes	11.72	7.74-15.69	<0.001
Checking the smartphone immediately after waking up in the morning	8.78	5.29-12.26	<0.001

Adjusted *R* - 0.26*Reference-Watching videos **Reference-Never CI-Confidence Interval *P* significant at <0.05

Nomophobia and addiction

When the participants were not able to use their smartphones for even a short time, they would feel the urge to check it for any notification. Another participant expressed concern that once they start using, they will scroll through their smartphone even though they are not looking/working for anything specific (loss of control).

The participants conveyed that they felt sad when they forgot their smartphone at home or when they had to give it for repairs. They said that parting with their smartphones was impossible.

They reported experiencing an irrational fear when they forgot their phones at home or when they were waiting for their friends to reply back to them. This factor is an important aspect of nomophobia.

Smartphone use among participants was so rampant and pervasive that they felt the necessity to have it with them at all times, even while having food. This could be considered a characteristic of addiction because some of them are even going back home from college just to get their smartphone. Even though they realize that it will be safe at home, they had difficulty in adjusting to an environment without their smartphones. In the absence of their smartphones, they also had trouble finding alternate sources to look for information.

DISCUSSION

Prevalence of Nomophobia

The prevalence of severe nomophobia in the present study was 23.5%. Similar proportion has been reported from Kerala (23%)[16] and Odisha (21%).[17] Alahmari *et al.*[18] found a prevalence of 22% for severe nomophobia among undergraduate students in Saudi Arabia. These similar findings might have been due to the cultural similarities in the study settings where parental supervision and social etiquette play a major role. The low proportion of severe nomophobia found in the current study may be attributed to parental control over the students' smartphone use because prevalence as high as 73% has been reported by other studies.[19] Many such studies were conducted among medical and health science undergraduates while this study represents Arts and Science undergraduates. This might be due to an increased probability of staying away from home for education, which results in loss of parental control and also contributes to the increased use of social networking and the need to make calls in order to stay connected to friends and family.[8]

Factors associated with nomophobia

We found a significant association between male gender and nomophobia. This is in accordance with studies conducted by Farooqui *et al.*[6] among undergraduate and postgraduate degree students, and by Pooja *et al.*[10] among medical undergraduates. This similarity in the findings may be attributed to the increased freedom males have in their homes and society and females experiencing more parental control in parts of developing countries like India. Significant association was also noted between increasing age and nomophobia scores. This finding is similar to other studies that reported an increased proportion of young adults in the age group of 18–25 being more susceptible to nomophobia.[5,13] This could be attributed to the increased need of young adults to stay connected with friends and family and to access information.

We found that the duration of smartphone usage was significantly related to nomophobia. Chandak *et al.*[13] also found a similar significant association among 35% of the medical postgraduates who used their smartphones for more than 3 hours compared to those who used less than 3 hours. A study conducted in Saudi Arabia among health science undergraduates also found an association between nomophobia and

Table 4: Results of in-depth interviews regarding the perception of smartphone usage

Codes	Statements
Theme 1: Perception About Smartphone Usage	
Necessity	"It is not possible to be without a smartphone."- 18-year-old male with severe nomophobia.
Escape Route	"People use it as an escape route when they are under a lot of pressure, such as during exams."- 19-year-old male with moderate nomophobia.
Sense of belonging	"Friends and family are not spending enough time with them. So, they might be lonely and hence spend more time with their phones."- 18-year-old female with moderate nomophobia.
Staying Updated	"If we don't use the phone, we will be outdated about everything. So, a technology like phone is very important." -20-year-old male with severe nomophobia.
Social Desirability	"When my phone was sent for repairs, I had a button phone. I could never take it to college as my friends would have teased me. It was too embarrassing to be seen with a button phone." -23-year-old male with severe nomophobia.
Independence	"We can google anything by ourselves and get the answer. There is no need to depend on anyone." -18- year-old female with moderate nomophobia.
Routine Habit	"I sleep with my phone next to me. When I wake up, it's the first thing that I see. Even for checking the time, I use only my phone."- 20-year-old male with severe nomophobia.
Theme 2: Facilitating Factors for Smartphone Usage	
Access to Information	"If there is something I don't know about, the first thing I do is to Google it."- 23-year-old male with severe nomophobia.
User-Friendly	"Not just the educated people, even the uneducated can handle it because it is very easy to use." -19-year-old male with moderate nomophobia.
Convenience	"Things which required a lot of paperwork can be done easily over the phone now."- 18-year-old female with moderate nomophobia.
Internet Availability	"When Internet is there, I always would want to watch some videos because I have data left."18-year-old female with moderate nomophobia.
Communication Etiquette	"If I go online and see any messages, I always reply immediately."- 18-year-old female with moderate nomophobia.
Connectedness	"If I want to keep in touch with everyone, I need a phone. I was left out when my phone was under repairs."20-year-old male with severe nomophobia.
Anticipation of Calls/ Texts	"As soon as I finish the work, I'll be very eager to check the phone to see whether I got any calls or messages." -23-year-old male with severe nomophobia.
Replacement for Face-to-Face Interaction	"I think that even though there is no face to face interaction, we are still connected to everyone through the phone. We talk through video calls because it is similar to talking face-to-face"19-year-old male with moderate nomophobia.
Theme 3: Controlling Factors For Smartphone Usage	
Restriction from Family	"My parents scold me saying that I'm always on the phone."-23-year-old male with severe nomophobia.
Security Concerns	"If someone gets my number, it could be used in wrong ways."19-year-old female with severe nomophobia.
Adverse Health Effects	"If I keep staring at the phone for a long time, my eyes start paining and then a headache will start."19-year-old male with moderate nomophobia.
Feeling of Missing Out	I feel like I'm missing something when I'm on the phone. I meant interactions with my family."19-year-old female with severe nomophobia.
Conditional Access by Providers	"We can recharge the phone for specific amounts only. But the users might not even need the amount of data or talk time they get through a plan."20-year-old male with severe nomophobia.
Theme 4: Nomophobia and Addiction	
Loss of Control	"Even if I'm doing some important work, if I hear a message ringtone, I stop the work and check out the messages."19-year-old male with moderate nomophobia.
Sadness	"I feel bad about leaving my phone at home."- 23- year-old male with severe nomophobia.
Anxiety	"I get tensed when my friends have seen my message and don't reply back."-18- year-old female with moderate nomophobia.
Dependency	"If I forget my phone back at home, I get my friend's vehicle and go back to get it."19-year-old female with severe nomophobia.
Frustration	"It is very frustrating whenever I forget my phone at home."19-year-old male with moderate nomophobia.

increase in smartphone usage.[18] The reason for the similarity among the findings of our study, other studies conducted in India, and studies from developed countries might be the facts that the smartphone is a technology having multiple utilities and is considered an essential tool for day-to-day activities all over the world. This may lead to increased hours of usage and nomophobia.

This study found a significant risk for nomophobia in students whose purpose of maximum use was social networking and texting. Studies by Kanmani *et al.* and Pavithra and Suwarna Madhukumar have also found social networking having the highest proportion of users among medical undergraduates, ranging from 56% to 77%.[5,7] Studies from Turkey and Spain also had reported social networking as the most frequent activity among smartphone users.[20,21] Many people consider a smartphone as an essential tool which can link different people, especially family and friends. This becomes more evident when young adults have to stay away from home for higher education or work. Young adults also consider it very important to have a well-established online identity, leading to increased use

of social networking apps.[22] These factors may have contributed to our results.

Checking the smartphone without any reason was found to be significantly contributing to nomophobia on linear regression. More than 65% of the students checked their smartphones without any reason. The proportion of respondents checking their smartphones soon after waking up was 55% in this study, whereas Kanmani *et al.*[5] found this proportion to be 69%. As smartphone usage is becoming necessary, it is also establishing a routine among its users which over time becomes habitual. Hence, users might subconsciously feel the need to browse through their phone or check for notifications, which may explain the high proportion, in both the studies, of participants with nomophobia who checked their phones without any need or as soon as they woke up.

Some participants in our study (38%) also felt that smartphone use hampered their academic performance. A similar result was recorded by Pavithra and Suwarna Madhukumar.[7] where 43% of medical undergraduates expressed concerns regarding their academics due to uncontrolled smartphone usage. Both these findings might mean that some students know the ill effects of overuse but might be in need of help to reduce their smartphone usage.

Around one-fourth of the participants in our study perceived that they have health effects as a result of using a smartphone. A similar proportion of physical symptoms was seen among medical postgraduates by Chandak *et al*.[13] also (37%). Khan's study, conducted among undergraduates in Saudi Arabia, also showed a significant relationship between health problems and the duration of use.[23] The similarity of results obtained in the present study and other studies maybe because of the rampant use of smartphones by participants. A person with nomophobia is anxious about parting from their smartphone, hence considerably increasing the screen time. This, in turn, can lead to health problems, mainly headache and eye strain, which were the highest reported symptoms in the current study. Fatigue may also result due to the constant access to a smartphone.

Perception of nomophobic behavior

The factors derived in the present study, i.e., connectedness, access to information, staying updated, relieving boredom, convenience, etc., also correlate with the themes of a Turkish study by Caglar Yildirim, such as the inability to communicate, inconvenience, and information accessibility.[15] Lidia *et al.*[24] found the personality trait self-esteem having an important impact on nomophobia. In accordance with this, the present study also found that participants felt a smartphone as an essential technology, a status symbol, and a tool for social acceptability. This may indirectly imply a need to have respect among others in the society. Lapointe *et al.*[22] described attributes of addiction such as withdrawal, preoccupation, etc., which were in accordance with the codes dependency and loss of control found in our study. Fullwood *et al.*[25] categorized users based on their perception of use. There were mentions of participants thinking that smartphone is very important for accessing information and for staying in touch with their friends and family, which were similar to the results obtained in the current study. The similarity in these findings shows a constant pattern of nomophobia all over the world.

Because the present study had a comparatively large sample size, the behavior of young adults was explored in detail and with more representative data. The presence of a qualitative component was also one of the strengths of the study. Participants were recruited from different colleges based on the proportion for representativeness of the sample.

However, because the study assessed deviant behavior, there might have been a chance of the social desirability bias. Students might not have wanted to reveal their original smartphone usage pattern to the investigator and could have written what was ideally expected from them. In addition, some missing data in the study could not be addressed properly due to time restrictions from the institutions. Completeness of the forms could not be ensured for all the participants. Telemetric methods for quantifying smartphone usage were not used in the study.

CONCLUSION

The line between normal use and addictive behavior is becoming more blurred among young adults. There is a need for the medical community and educational institutes to coordinate and take necessary measures to ensure that this vulnerable group is given sufficient information and education about nomophobia and to change the prevalent misperceptions. Creating awareness and providing proper counseling methods by trained health professionals can play a crucial role in curbing nomophobia. There is also a need for more studies focusing on the behavior and perception of the population regarding nomophobia.

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Conflicts of interest
There are no conflicts of interest.

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Original Article

Prevalence and Correlates of Excessive Smartphone Use among Medical Students: A Cross-sectional Study

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ABSTRACT

Background: Increasing smartphone use has led to the introduction of smartphone addiction as a behavioral addiction with detrimental effects on health. This phenomenon has not been widely studied in the Indian context. This study assessed the rate of smartphone addiction in a sample of medical students, with a focus on its correlation with sleep quality and stress levels. **Methods:** A cross-sectional study was conducted between November 2016 and January 2017 in 195 medical students. Their smartphone use, level of smartphone addiction, sleep quality, and perceived stress levels were measured using the Smartphone Addiction Scale-Short Version (SAS-SV), the Pittsburgh Sleep Quality Index (PSQI), and the Perceived Stress Scale (PSS-10), respectively. **Results:** Of the 195 students, 90 (46.15%) had smartphone addiction as per the scale. A self-reported feeling of having smartphone addiction, use of the smartphone right before sleeping, PSS scores, and PSQI scores were found to be significantly associated with the SAS-SV scores. Significant positive correlations were observed between the SAS-SV and PSS-10 scores, and the SAS-SV and PSQI scores. **Conclusions:** There is a high magnitude of smartphone addiction in medical students of a college in Western Maharashtra. The significant association of this addiction with poorer sleep quality and higher perceived stress is a cause for concern. The high self-awareness among students about having smartphone addiction is promising. However, further studies are required to determine whether this self-awareness leads to treatment seeking. Further studies are required to explore our finding of the association of smartphone addiction with using the smartphone before sleeping.

Key words: *Addiction, India, medical, smartphone, students*

Key messages:

- A high proportion of the medical students of a college in Western Maharashtra have smartphone addiction.
- Smartphone addiction has significant associations with impaired sleep and high stress.
- Smartphone addiction is significantly associated with a self-reported feeling of having the addiction.

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The 21st century has witnessed a rapid growth in technology and, with the introduction of the Internet, a revolutionization of information access. The legacy of these noteworthy milestones is captured by the innovation and popularization of the "smartphone".[1]

Addiction is a process whereby a behavior that can function both to produce pleasure and to provide an escape from internal discomfort is employed in a pattern characterized by (1) recurrent failure to control the behavior (powerlessness) and (2) continuation of the behavior despite significant negative consequences (unmanageability).[2] The increasing use of and dependence on the Internet brought to the surface a new public health concern near the start of the century "Internet Addiction Disorder," which was eventually included in the Diagnostic and Statistical Manual of diseases (DSM-5) under conditions for further study.[3] On the heels of this, the close association between the internet and the smartphone led to the introduction of "Smartphone Addiction," a behavioral addiction characterized by the presence of symptoms of tolerance, salience, mood changes, and dependence on smartphones.[4] Consequently, the "Smartphone Addiction Scale" was developed for its quantification.[5] This addiction has been associated with depression, anxiety, accidents, poor sleep, poor academic performance, fatigue, and high stress.[6-8] There is some debate among academicians on whether it can be called an "addiction" which is why alternate terms like "Problematic Smartphone Use" and "Smartphone Use Disorder" have been proposed.[9,10]

A 2017 study revealed that over 300 million people in India use a smartphone.[11] A large proportion of the Indian population is thus at potential risk of addiction. However, there is a paucity of studies related to it in the Indian population. Students having birth years between 1990 and 2000 (i.e., the age group of 17--27 years) have been introduced to smartphones in their formative adolescent years. Exploring smartphone addiction in this cohort is, thus, especially crucial.

Recent studies have revealed a high prevalence of smartphone addiction in university students and not only urban but also rural school students.[12-15] Studies in medical students in Jammu and Kashmir, Delhi, and Maharashtra have found a high prevalence of smartphone addiction, ranging from 34% to 40%.[13,14,16,17] However, the studies in Maharashtra have been limited to private medical institutions. The socioeconomic background of students in government-run medical institutions being different from that of private medical institutions makes it important to study the addiction in the former group.

This study aims to assess the prevalence of smartphone addiction in medical students in a government-run medical college in Western Maharashtra. It further aims to explore the sociodemographic and smartphone use related correlates of smartphone addiction, and the association of this addiction with stress levels and quality of sleep. To the best of our knowledge, this is one of the first studies on this topic in a government-run medical college in Western Maharashtra.

MATERIALS AND METHODS

A cross-sectional study was conducted between November 2016 and January 2017 in a Government Medical College in Western Maharashtra. Ethical approval was obtained from the Institutional Ethics Committee.

A questionnaire was prepared using validated scales (described below) and administered as a Google form. Adequate permission was obtained from the authors for the use of the scales. The questionnaire comprised of:

i. Part 1: A semi-structured questionnaire to assess the correlates of smartphone addiction. It recorded the demographic profile (age, sex, residence, and year of MBBS), history of psychiatric/neurological illness, and the pattern of smartphone use (age of commencement of use, most frequent purpose of use, use right before sleeping at night, and the subjective feeling of having smartphone addiction).
ii. Part 2: Validated Scales
    A. Cohen's Perceived Stress Scale (PSS-10):[18,19] It is a self-administered psychological instrument for assessing the perception of stress. It consists of 10 questions on the subjective stress levels of the participant during the previous month. The responses are scored according to a five-point Likert scale. The scale has a minimum score of zero and a maximum score of 40. There is no predetermined cut-off for gauging stress; higher scores indicate a higher stress level. The scale shows good convergent validity and reliability (Cronbach's alpha 0.89).[20] It has been used in the Indian population but has not been validated in the Indian student population.[17,21,22]
    B. Smartphone Addiction Scale-Short Version (SAS-SV):[23] It is a self-administered scale to screen smartphone addiction in the community. It consists of 10 questions scored on a six-point scale that can be self-administered by the participant. It has a minimum score of 10 and a maximum score of 60. The SAS-SV provides a cut-off value for addiction, which is 31 for boys and 33 for girls. It has been previously used for an age group similar to the one chosen for this study.[24] It shows good concurrent validity with the SAS and reliability (Cronbach's alpha 0.91). It has been

widely used in Indian students but has not been validated for this population.[16,17]

C. Pittsburgh Sleep Quality Index (PSQI):[25] The PSQI is a self-administered scale which contains 19 questions related to the previous month's sleep patterns. This questionnaire has seven components that measure the different aspects of sleep (C1-Subjective sleep quality, C2-Sleep latency, C3-Sleep duration, C4-Habitual efficacy, C5-Sleep disturbances, C6-Use of sleep medication, C7-Daytime dysfunction). It has a minimum score of "zero" and a maximum score of "21" with "five" as a cut-off value for impaired sleep. It has acceptable measures of reliability (Cronbach's alpha 0.83) and validity. It has been widely used in the Indian population and has shown good validity in Indian university students.[26,27]

The questionnaire was piloted in 10 students, and clarifications were made based on their recommendations. Based on prior studies that have shown a prevalence of 44% in the Indian population, a minimum required sample size of 112 was calculated to estimate the prevalence of addiction at 95% confidence and 10% precision.[28] The contact numbers of students from each batch were obtained from the class representatives. All the contact numbers that the class representative had saved in his/her phone were included. The researchers then contacted the students via a text message or a phone call and explained the study in detail. Oral informed consent was obtained from those who were willing to participate. For students who had not completed 18 years of age, consent was obtained from their parents over a telephonic conversation. Additionally, there was a consent page at the beginning of the questionnaire, which explained the details of the study and the purpose for which the information provided by the participants would be used. The questionnaire was then sent as a Google form link via text message to the students that were willing to participate. All queries were resolved by the researcher, and a confirmation via text message was requested after the participant had filled the questionnaire. The data collected were transferred from Google Docs to a Microsoft Excel sheet. Incomplete entries were deleted. No identifying information was retained. Students who, in the questionnaire, reported having a history of psychiatric/neurological disorders were excluded. The data was initially split into two groups, "Smartphone Addiction Positive" and "Smartphone Addiction Negative," using predetermined cut-offs of the SAS-SV. The differences in sociodemographic and smartphone use related factors in the two groups were analyzed using the Chi-square, Fisher's exact, and independent samples *t*-test as applicable. This was followed by a multiple regression model with SAS-SV as the dependent variable and the sociodemographic and smartphone use related factors, PSS-10, and PSQI as the independent variables. The correlation of SAS-SV scores with PSS-10 and PSQI scores was assessed by a Pearson's correlation test. A value of $P < 0.05$ was taken to be significant.

RESULTS

Demographics of the study population

We contacted 250 students whose contact numbers were obtained. Two hundred forty students consented to the study. Of these, 215 filled the questionnaire. The response rate was thus 89.6%. Seven students with a self-reported history of psychiatric disorders and 13 whose forms were inadequate were excluded, leaving behind an effective sample size of 195.

The sample consisted of 99 (50.77%) females and 96 (49.23%) males. There were 51 (26.15%) students from the 1st year, 54 (27.70%) from the 2nd year, 47 (24.10%) from the 3rd year (Part 1), and 43 (22.05%) from the 3rd year (Part 2). The age ranged from 17 to 27 years, with a mean (±SD) of 20.23 (±1.63). All students identified themselves as being from the lower middle to upper-middle socioeconomic class.

Smartphone use

The mean age of beginning to use a smartphone was 17.15 (±1.58) years. 66 (33.85%) of 195 students listed Whatsapp as their favorite application, making it the most popular application, followed by Instagram (12.31%) and Facebook (5.13%). Text messaging was the most common purpose of using the smartphone, as stated by 100 (57.14%) of 175 students who responded adequately to this item on the questionnaire. This was followed by internet browsing (10.86%).

Smartphone addiction

Of the195 students, 90 (46.15%) screened positive for smartphone addiction as per the SAS-SV scores. These included 45 (45.45%) of the 99 females and 45 (47.87%) of the 94 males. The SAS-SV scores ranged from 10 to 57, with an average score of 31.59 (±9.89). Of the 90 students who screened positive for addiction, 69 (76.67%) had a self-reported feeling of having smartphone addiction, while of the 105 students who screened negative, 27 (25.71%) felt that they had it. Tables 1 and 2 show the sociodemographic and smartphone use related differences in those with and without smartphone addiction by the Chi-square test, Fisher's exact test, and *t*-test as applicable. A statistically significant proportion of those with a self-reported feeling of having smartphone addiction, and those using the

smartphone right before sleeping were screened positive for smartphone addiction [Table 1]. A multiple regression model was run, which brought forth four significant factors associated with smartphone addiction: (1) a self-reported feeling of having smartphone addiction, (2) use of the smartphone right before sleeping, (3) PSS scores, and (4) PSQI scores [Table 3]. No other sociodemographic or smartphone use related variables were seen to have a significant association with smartphone addiction.

Smartphone addiction, stress, and sleep

The PSQI scores in the sample ranged from zero to 20, with an average score of 6.37 (±4.47). Of the 195 students, 91 (46.67%) had impaired sleep. The PSS scores ranged from zero to 37, with an average score

Table 1: Sociodemographic and smartphone use related differences in groups with and without smartphone addiction (Chi-Square, Fischer's Exact Test)

Socio-Demographic and Smartphone Use Variables		Addiction Present*	Addiction Absent*	Chi-Square Value (df‡)	*P*§ *(two tailed)*	
					Chi-Square Test	Fisher's Exact Test†
Gender	Male	45 (50.00%)	51 (48.57%)	0.04 (1)	0.84	
	Female	45 (50.00%)	54 (51.43%)			
Year of MBBS	1st year	17 (18.89%)	34 (32.38%)	5.96 (3)	0.11	
	2nd year	24 (26.67%)	30 (28.57%)			
	3rd year	26 (28.89%)	21 (20.00%)			
	4th year	23 (25.56%)	20 (19.05%)			
What do you use your smartphone the most for?	Reading	5 (6.25%)	4 (4.26%)			0.50
	Songs	3 (3.75%)	9 (9.57%)			
	Messaging	47 (58.75%)	53 (56.38%)			
	Internet Browsing	10 (12.50%)	9 (9.57%)			
	Phone calls	1 (1.25%)	6 (6.38%)			
	Social Media	4 (5.00%)	5 (5.32%)			
	Watching videos	3 (3.75%)	3 (3.19%)			
	Gaming	7 (8.75%)	5 (5.32%)			
Do you use your smartphone right before sleeping?	Yes	87 (98.86%)	96 (91.43%)			**0.02**
	No	1 (1.14%)	9 (8.57%)			
Do you think you have smartphone addiction?	Yes	69 (78.41%)	27 (25.71%)	53.18 (1)	**<0.001**	
	No	19 (21.59%)	78 (74.29%)			

*Observed counts of students followed by the column percentage in parenthesis have been reported in each cell. †The Fisher's Exact Test has been used instead of the Chi-Square test when more than 20% of the cells have an expected count of less than five. §The significant p values are in bold letters. ‡df – Degrees of freedom

Table 2: Sociodemographic and smartphone use related differences in groups with and without smartphone addiction (independent samples *t*-test)

Socio-Demographic and Smartphone Use Variables	Addiction Present* (n†)	Addiction Absent* (n†)	*t* (df‡)	*P*§ (two-tailed)
Age (in years)	20.43±1.63, (*n*=86)	20.06±1.61, (*n*=98)	1.54 (182)	0.13
Age of commencing smartphone use (in years)	17.09±1.64, (*n*=89)	17.20±1.54, (*n*=102)	0.46 (189)	0.65
PSS-10 scores	19.73±6.14, (*n*=84)	16.04±5.64, (*n*=102)	4.36 (184)	**<0.001**
PSQI scores	7.60±4.43, (*n*=90)	5.31±4.24, (*n*=105)	3.68 (193)	**<0.001**

*Smartphone Addiction Scale-Short Version (SAS-SV) scores have been reported in the cells as (Mean±Standard Deviation). §The significant p values are in bold letters. †*n* – Total count of participants under each cell; df – Degrees of freedom, PSS-10 – Perceived stress scale, PSQI – Pittsburgh sleep quality index

Table 3: Sociodemographic and smartphone use related correlates of SAS-SV scores (a multiple regression model)

Socio-Demographic and Smartphone Use Variables*,†		β	*P*‡ (two tailed)	95% Confidence Interval	Model Summary
Gender	Male (1) Female (2)	-0.03	0.68	(-2.83, 1.86)	*R*=0.67; R^2=0.45; *F*=19.16; *P*<0.001
Age		0.11	0.11	(-0.16, 1.55)	
Age of onset of smartphone use		0.04	0.62	(-0.66, 1.11)	
Do you use your smartphone right before sleeping?	Yes (1) No (2)	-0.16	**0.01**	(-11.49, -1.65)	
Do you think you have smartphone addiction?	Yes (1) No (2)	-0.48	**<0.001**	(-11.74, -6.93)	
PSQI Scores		0.14	**0.04**	(0.02,0.58)	
PSS Scores		0.18	**0.01**	(0.07,0.51)	

*The variables 'age' and 'year of MBBS' are logically related to each other, causing potential bias in a regression model. Thus, only the 'age' variable has been considered in this model. †The nominal variables have been assigned dummy numbers as enumerated in the cells in parenthesis (E.g., male=1 and female=2). ‡The significant p values are in bold letters. SAS-SV – Smartphone Addiction scale-short version, PSQI – Pittsburgh sleep quality index, PSS-10 – Perceived stress scale

of 17.70 (±6.14). Significantly higher PSS scores and PSQI scores were found in students who screened positive for smartphone addiction than those who did not [Table 2]. A weak positive linear correlation between the SAS-SV and PSQI scores ($r = 0.31$, $P < 0.001$) and a moderate positive linear correlation between the SAS-SV and PSS-10 scores ($r = 0.40$, $P < 0.001$) were found by the Pearson's correlation test [Figures 1 and 2].

DISCUSSION

Smartphones are rapidly evolving, and their use is constantly on the rise. Smartphone addiction has been identified as a behavioral addiction in the recent decade but has not yet been established as a real problem, especially in India. Our results show that within a small population of Indian medical students, almost half (46.15%) screened positive for smartphone addiction. This frequency of smartphone addiction is higher than the range (39% to 44%) found in the Indian population by a meta-analysis of six Indian studies in 2014 and recent studies in medical students.[6,12,13]

This study found no significant gender differences in addiction as opposed to the higher smartphone addiction in female students observed by authors in Korea and the Middle-East.[29-31] Similar to our study, no significant gender difference was observed by Basu *et al*. in medical students in India.[12] Using the smartphone right before sleeping was found to have a significant association with SAS-SV scores in our study. Similar to these results, the night-time usage of smartphones was found to be significantly higher in those having smartphone addiction in a study done in Korea, which used an application to track smartphone usage.[32] We also found a significant association between the PSQI and SAS-SV scores, similar to studies in medical students in Saudi Arabia and China.[24,33] While the former study used the Problematic Mobile Phone Use Questionnaire for gauging addiction, the SAS-SV was used in the latter. It could be hypothesized that higher levels of smartphone addiction cause students to spend more time on their smartphones at night, thus impairing sleep quality. The positive correlation between PSS and SAS-SV scores in our study was higher than the correlation of $r = 0.30$ reported in another study in medical students in Maharashtra.[13] Samaha *et al*. used similar scales and scoring systems and found an association between smartphone addiction and perceived stress, while another Romanian study reiterated these findings, albeit with different scales of measurement.[34,35] Smartphone addiction provides an escape from reality and could be hypothesized to be a mechanism adopted by students to alleviate stress, but further studies are required in this regard.

A positive Pearson's correlation between the smartphone addiction scores with the stress and sleep quality scores depict simultaneous greater values of each than their respective means, which indicates a perfect positive relationship between the two variables and adds weightage to the study. The association of smartphone addiction with higher stress and impaired sleep is concerning, as it has the potential to adversely affect the quality of life.[25]

This study found an association of self-reported feelings of addiction with having smartphone addiction as per the SAS-SV. No other studies reporting this parameter were found. This finding implies that most of those having smartphone addiction are self-aware of their addiction and is important as it suggests an insight into the problem---an important motivator for seeking preventive measures and treatment.

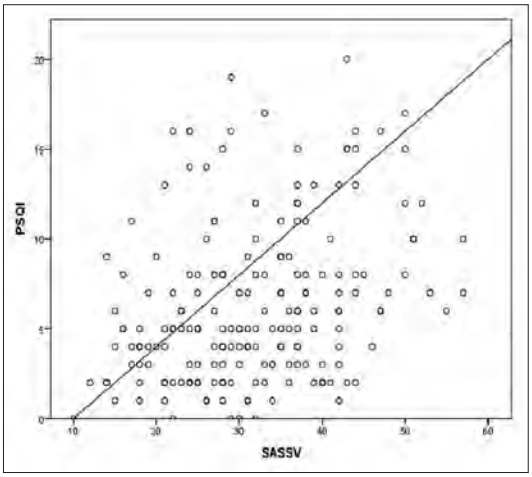

Figure 1: Correlation between SAS-SV and PSQI scores. SAS-SV - Smartphone addiction scale-short version, PSQI - Pittsburgh sleep quality index

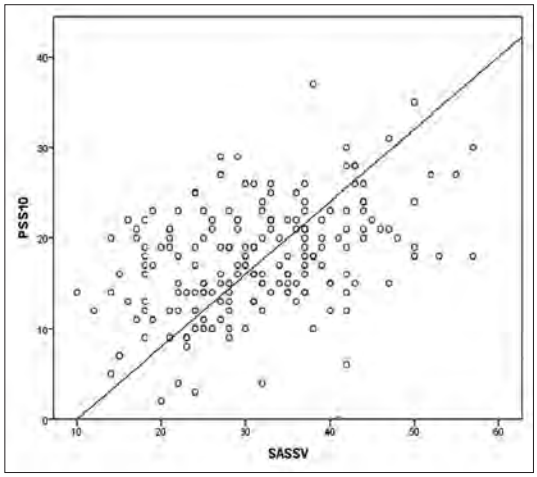

Figure 2: Correlation between SAS-SV and PSS-10 score. SAS-SV - Smartphone addiction scale-short version, PSS-10 - Perceived stress scale

This study is cross-sectional in nature and is limited to a small population of medical students in a college in Western Maharashtra. It is thus limited in terms of generalizability. A sample of convenience was used, leading to a potential bias. The history of psychiatric/neurological illness was obtained by self-reports, which may have led to a limitation in adequately excluding all such cases. The fact that only one self-reported scale was used to assess smartphone addiction is certainly a limitation to the accuracy of the results. However, the study was one of the first of its kind in a government-run medical college in Western Maharashtra. Also, it must be noted that the entrance criteria and curricula of government medical colleges in India are homogeneous, and the findings of this sample may thus be relevant to other medical students.

Smartphone use is not limited to medical students and is ever on the rise. This addiction thus needs to be recognized and made known to the lay public. Further studies of a larger scale across different age groups, professions, and socioeconomic backgrounds are required to adequately define this problem in India. Preventive measures need to be introduced and made popular. Telemetric approaches have been found effective to track smartphone usage and detect excessive smartphone use.[17] High self-awareness of having an addiction was seen in this study, but further studies are required to assess if such self-awareness leads to treatment seeking. Psychosocial treatments like cognitive behavioral therapy, motivational therapy, and mindfulness behavioral cognitive treatment have been recommended to combat excessive smartphone use. However, the efficacy of such interventions remains unsubstantiated due to lack of data, and further studies are required.[36]

Data sharing statement

De-identified individual participant data that underlies the results reported in this article (including data dictionaries) will be made available in addition to the study protocol and statistical analysis plans. The data will be made available upon publication to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Translation and Adaptation into Hindi of Central Religiosity Scale, Brief Religious Coping Scale (Brief RCOPE), and Duke University Religion Index (DUREL)

Sandeep Grover, Devakshi Dua

ABSTRACT

Background: Religion/religiosity plays an important role in the lives of most Indians. However, there are lack of validated instruments in regional languages to assess the various dimensions of religiosity in the Indian population. This limits evaluation of religion/religiosity and comparison of Indian data with western research for health-related issues. **Methods:** The CRS, BRCOPE, and DUREL scales were translated into Hindi by using the standard translation-back-translation methodology as specified by the World Health Organization. Initially, the Hindi version of each scale was completed by 132 participants, and the second time, participants completed either the Hindi or the English version of the scales after 3–7 days. Data were evaluated for cross-language equivalence, test–retest reliability, internal consistency, and split half reliability. **Results:** The Hindi version of CRS, DUREL, and RCOPE had good cross-language equivalence with the English version for all the items and dimensions in all three scales, which was highly significant ($P < 0.001$). The test–retest reliability was also high for all three scales (Cohen's Kappa value >0.67 for various items and subscales $P < 0.001$). Cronbach's alpha for the Hindi version of the scales was 0.95, 0.76, and 0.89 for CRS, DUREL, and BRCOPE, respectively. The Spearman–Brown coefficient was 0.89, 0.70, and 0.43 for CRS, DUREL, and BRCOPE, respectively. **Conclusion:** The Hindi version of CRS, DUREL, and BRCOPE has good cross-language equivalence, internal consistency, split-half reliability, and test–retest reliability. It is expected that availability of these validated versions will provide impetus to research evaluating the association of clinical parameters and religiosity.

Key words: *Adaptation, coping, religion, religiosity, translation*

Key messages: *This study provide information about validity of Hindi versions of Centrality of Religiosity Scale (CRS), Brief Religious Coping Scale (Brief RCOPE), and Duke University Religion Index (DUREL) and shows that Hindi versions of these scales have good test-retest reliability, internal consistency, and split half reliability.*

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Religion has been defined as "*an organized system of beliefs, practices, rituals, and symbols designed to facilitate closeness to the sacred or transcendent*".[1] Religion/religiosity is part and parcel of the daily lives of most Indians. Besides affecting other dimensions of life, religion and religiosity affect various aspects of treatment seeking.[2,3] Various studies which have evaluated the etiological models held by the patients and their caregivers show that many patients with mental illness believe that the illness is caused by black magic or their karma or deeds.[4,5] Similarly, studies from India which have evaluated the pathways to care of patients with various mental disorders suggest that many patients seek help from religious places.[6] It has been seen that in many cases, it forms the first place of contact.[7] Data also suggests that religion/religiosity also affects the manifestation of psychopathology,[7,8] suicidal behaviors,[9] coping of patients, and caregivers,[10] attitude toward psychotropics and other psychiatric treatment modalities,[7] medication compliance,[7] caregiver burden,[11] and quality of life of patients.[10] In a nutshell, it can be said that religion influences various aspects to treatment seeking. Unfortunately, although studies have reported these associations, these studies are often criticized for not evaluating the various dimensions of religion/religiosity, or evaluating these domains only by the use of indigenous instruments which are not comparable with the standard instruments for assessment various aspects of religiosity.

Accordingly, there is a need to evaluate the role of various aspects of religion by using standardised instruments. Further, there is a need to evaluate the similarities and differences in the role of religiosity across different countries so that specific interventions can be planned, taking into consideration the role of religion in the manifestation, help-seeking, compliance to medication and treatment, etc. For cross-national comparisons, there is a need to have instruments which are available in multiple languages and validated across different countries. At present, there are very few such instruments.

Some of these scales include Centrality of Religiosity Scale (CRS), Brief Religious Coping Scale (Brief RCOPE), and Duke University Religion Index (DUREL). CRS is considered a measure of the centrality or importance of religious meaning in a person's life.[12] This scale was used in the global Religion Monitor with samples recruited from 21 countries. Further, this scale has been widely used in multiple studies in sociology and psychology. DUREL is a brief instrument to assess major dimensions of religiosity. It has been widely used across the world and is available in ten languages.[13] Exposure to any stressful situation is associated with the use of coping mechanisms of various types. Brief RCOPE is a measure of religious coping, which has been used in many studies, and use of this scale has enhanced the knowledge with respect to the role of religion in handling crisis and trauma.[14] However, these scales have not been validated in the Indian context and adapted to Indian scenarios. Validating these scales in the Indian context can facilitate the generation of data from India, which can be compared with findings on the same scales from across the globe and can enhance the understanding about the role of religiosity in health care, especially mental health. These can also enhance the cross-cultural understanding about the role of religiosity in the manifestation and management of various mental disorders.

In this background, the aim of this study was to translate, adapt and validate the CRS, DUREL, and Brief RCOPE.

METHODS

This study was approved by the Ethics Committee of the institute. All the participants were recruited after obtaining written informed consent. The study participants included healthy subjects, who completed the different versions of the scales on two occasions at the gap of 3–7 days.

The scales which were translated

Centrality of Religiosity Scale[12]: CRS was designed by Huber and Huber.[12] It is considered as a measure of the centrality, importance or salience of religious meanings in personality. It measures the five theoretically defined core dimensions of religiosity, i.e., public practice, private practice, religious experience, ideology, and intellectual dimensions, which can together be considered as representative of the sum total of religious life. This scale has been used in more than 100 studies in the field of sociology and psychology of religion, and in studies involving assessment of religious issues in over 25 countries, involving participants in excess of 1,00,000. The single largest application of this scale includes its use in the global Religion Monitor with representative samples from 21 countries, including India.

There are three versions of CRS, depending on the number of items, i.e., lengths with 15 (CRS-15), with 10 (CRS-10), and with five items (CRS-5). The CRS-15 includes three items per dimension, and it is considered to have highest ability to

discriminate the various dimensions, which basically means that it has the highest reliability and accuracy in measuring the five core dimensions of religiosity. The reliability of each dimension of CRS-15 ranges from 0.80 to 0.93 and for the whole scale, the reliability statistics range from 0.92 to 0.96. The CRS-10 and CRS-5 are shorter versions of CRS-15, with CRS-10 including two items for each dimension and CRS-5 including one item per dimension of the scale. The CRS-10 has also been reported to have high reliability of each dimension, ranging from 0.89 to 0.94.

The scale is available in about 20 languages and the global religious monitor study, the scale was used in India too, in the Hindi language. However, we could not find the Hindi version. We contacted the authors of the original scale and sought permission to translate the scale to Hindi, to adapt the same to the Indian context, and to validate the same.

Duke Religion Index (DUREL)[13]: It is a five-item scale which measures three main dimensions of religiosity, i.e. organisational religious activity, nonorganizational religious activity, and intrinsic religiosity (or subjective religiosity). The scale has been shown to have high test–retest reliability (intraclass correlation = 0.91), high internal consistency (Cronbach's alpha's = 0.78–0.91), and high convergent validity with other measures of religiosity (correlation coefficient = 0.71–0.86). Studies have also shown the factor structure of DUREL in various study samples. This scale has been used in more than 100 studies conducted throughout the world and is available in ten languages. No Hindi version of the scale is available. Permission was sought from the author of the original scale for translation and adaptation.

Brief Religious Coping Scale[14]: The Religious Coping scale (RCOPE) was designed by Pargament. The initial scale comprised of 105 items and the later versions included 21 and 14 items. The 14-item version is known as Brief RCOPE. The various items of RCOPE were generated through interviews with people experiencing major life stressors. Based on the factor analysis of the full R-COPE, two overarching forms of religious coping, i.e. positive and negative, were conceptualized. Positive religious coping methods reflect a secure relationship with a transcendent force, a sense of spiritual connectedness with others, and a benevolent worldview. Negative religious coping strategies reflect underlying spiritual tensions and struggles within oneself, with others, and with the divine. Reliability estimates were generally high for the full scale, indicating good internal consistency. However, in view of the length of the scale, later versions of RCOPE included 14- and 21-item scales. The 14-item scale is very popular and considered to have reliability statistics comparable to that of the full scale.[15] Studies suggest good internal consistency of the positive and negative subscales of the Brief RCOPE.[14] Available data also suggests that various subscales of Brief RCOPE have good construct validity, predictive validity, and incremental validity.[14] For the translation and adaptation process, we chose the Brief RCOPE because of its brevity. We sought permission from the researchers who developed this scale for the process of translation and adaptation.

The process of translation and adaptation

All the three scales were translated to Hindi by health care professionals with proficiency in both Hindi and English, by following the standard methodology of translation and back translation as per the World Health Organization.[16] To start with, all the scales were translated by three health care professionals into Hindi. The three health care professionals included one psychiatrist, one clinical psychologist, and one social worker. All the three Hindi versions were initially reviewed by a panel of experts who were not part of the initial translation process, for accuracy, semantics, and cultural appropriateness. The three experts included two psychiatrists and one clinical psychologist. Each item from the three scales was evaluated one by one, and out of the available three versions, the translated item which retained the original meaning and conveyed the same in the simplest form was retained. If such was not the case, the expert panel modified the available translated items or designed the same. While choosing the various translated items, importance was laid on the accuracy, semantics, and cultural appropriateness. Wherever it was felt that the item required adaptation keeping the Indian religious practices, the items were modified. Based on all the inputs, an initial translated version was made for each scale. This prefinal version was given to 10 health care professionals and 10 lay people for evaluating the simplicity of the language and cultural appropriateness. Based on their inputs, further modifications were made, and the final translated versions of the scales were prepared. The accepted translated version was back-translated to English by another set of bilingual health care professionals, and the back-translated version was matched with the original version, and if required, suitable modifications were made to retain the same meaning and at the same time, retaining the cultural appropriateness of the scales.

Adaptation of CRS included a further elaboration of certain words to make things more explicit. In the items 3 and 8, the words "religious services" were expanded to going to temple for prayers, participating in group religious activities, or going to certain specific religious conglomerations. In the items 4b and 9b, the word "meditate" was expanded to "meditate, indulge in devotional activities, or remember god". In item 7, description of the resurrection of the dead was excluded as this was considered irrelevant, and it was thought that *"punajanm"* was sufficient to convey the meaning of reincarnation and resurrection.

A few adaptations were included in the Brief RCOPE. The words in item 12, "…church had abandoned me", was elaborated further as "...Church/Temple/GuruDwara/Mosque or my Religious Guru has abandoned me". In item 13, the word devil was replaced by words "Danav/Pichash", as these were considered as colloquial equivalents of the word devil.

The adaptations for DUREL item 1 included a further elaboration of words "church or other religious meetings" into "church/temple/mosque/gurudwara or any other place related to religious activities". The adaptation of item 2 included an elaboration of "religious activities, such as prayer, meditation or Bible study" into "indulge in prayers, meditation, and reading religious books like Ramayana, Quran, Guru Granth Sahib, Bible, etc".

The process of evaluation of psychometric properties

For the purpose of validation, initially, the Hindi versions of all the three scales were given to 132 healthy subjects selected by purposive sampling. They were asked to complete the scales by themselves. They were explained about the purpose of the study and only those who provided written informed consent were recruited. The same group of subjects were approached again after a gap of 3–7 days and asked to either complete the Hindi version again (N = 61) or the English version of the scale (N = 71).

Statistical analysis

The data was analyzed by using the SPSS 14 (SPSS, Chicago [IL], US). Categorical data were extracted in the form of frequencies and percentages, whereas the continuous data were extracted in the form of mean and standard deviations. Intraclass correlation coefficient (ICC) and Pearson's correlation coefficient were used to evaluate the agreement between the Hindi–Hindi version and Hindi–English version. Cohen's kappa value was used to evaluate the test–retest reliability of each scale. Internal consistency of various scales was evaluated in terms of Cronbach's alpha, and split-half reliability of Hindi versions of the scales were evaluated in terms of the Spearman–Brown coefficient.

RESULTS

Table 1 shows the sociodemographic profile of the participants.

Psychometric properties

Concurrence between Hindi and English versions

Agreement between the Hindi (provided as an online-only supplementary file) and the English versions was evaluated by using ICC and Pearson's correlation coefficients. As is evident from Tables S1-S3, for all the items of CRS, DUREL, and Brief RCOPE, the Pearson correlation coefficients and ICC were above 0.85 and significant at the level of <0.001. ICC values and Pearson correlation coefficients values were above 0.9 and significant at the level of <0.001 for various dimensions of CRS, total CRS score, intrinsic religiosity domain of DUREL, positive RCOPE, and negative RCOPE.

Test–retest reliability

In terms of test–retest validity of Hindi-version of all the three scales, the kappa values and ICC values were above ≥0.74 and significant at the level of <0.001, suggesting high test–retest reliability.

Internal consistency and split-half reliability

Cronbach's alpha (as a measure of internal consistency) for Hindi version of all the three scales and various domains of CRS, DUREL, and brief RCOPE were also found to be high [Table 2]. The Spearman–Brown coefficient and Guttmann split half value (for assessing split-half reliability) for all the three scales, and their

Table 1: Sociodemographic profile of the study participants

Variable	Mean (SD) [range] or *n* (%) [*n*=132]
Age	32.5 (8.3) [20-57]
Education in years	15.22 (2.73) [10-20]
Gender	
Male	68 (51.5%)
Female	64 (48.5%)
Marital status	
Single	56 (42.4)
Married	76 (57.6)
Family type	
Nuclear	74 (56.1%)
Extended/joint	58 (43.9%)
Religion	
Hindu	79 (59.8)
Muslim	5 (3.8)
Sikh	44 (33.3)
Christian	4 (3.0)
Locality	
Urban	121 (91.7)
Rural	11 (8.3)

Table 2: Split-half reliability of the three scales

	Cronbach's Alpha for the scale/domains	Cronbach's alpha		Spearman-Brown coefficient	Guttmann Split half
		Part-1	Part-2		
CRS					
Intellect	0.66***	0.79***	1.00***	0.44***	0.37***
Ideology	0.75***	0.56***	1.00***	0.79***	0.73***
Public practice	0.84***	0.76***	1.00***	0.85***	0.80***
Private practice	0.86***	0.79***	0.76***	0.83***	0.83***
Experience	0.77***	0.65***	0.72***	0.93***	0.90***
Total CRS	0.95***	0.93***	0.91***	0.89***	0.89***
DUREL					
DUREL Total	0.76***	0.71***	0.59***	0.71***	0.66***
Brief RCOPE					
Total Brief RCOPE	0.89***	0.89***	0.93***	0.43***	0.43***
Positive Brief RCOPE	0.89***	0.84***	0.71***	0.92***	0.88***
Negative Brief RCOPE	0.92***	0.87***	0.89***	0.89***	0.88***

*** $P<0.001$. CRS: Centrality of religiosity scale; DUREL: Duke religion index; RCOPE: Religious coping scale

Table 3: Correlations of CRS with DUREL and Brief RCOPE

	CRS total	DUREL Total
Total CRS	X	X
DUREL Total	0.52***	X
Brief RCOPE		
Positive Brief RCOPE	0.45***	0.39***
Negative Brief RCOPE	-0.23**	0.07
Total Brief RCOPE	0.11	0.27***

* $P<0.05$; ** $P<0.01$; *** $P<0.001$. CRS: Centrality of religiosity scale; DUREL: Duke religion index; RCOPE: Religious coping scale

various dimensions/domains, were also high (≥0.73) except for the intellect dimension of CRS and Brief RCOPE total score. The Cronbach's alpha value for each half of the CRS and each dimension of CRS, DUREL, and positive and negative subscales of RCOPE was also found to be in the acceptable ranges [Table 2].

Correlations between different scales

As shown in Table 3, when the associations of CRS, DUREL, and RCOPE with each other were evaluated, CRS total score correlated positively with DUREL total score and positive RCOPE score, and negatively with negative RCOPE score. When the association of DUREL and RCOPE was evaluated, positive RCOPE and total RCOPE scores correlated positively, whereas negative RCOPE score correlated negatively.

DISCUSSION

The present study demonstrated high agreement for all the items of Hindi and the English version of CRS, DUREL, and Brief RCOPE. The Pearson correlation coefficients and ICC values were above 0.85, suggesting a high level of agreement between the scales of both the languages. The ICC and Pearson correlation coefficient values for the Hindi and English versions were also above 0.9 for the various dimensions of CRS, total CRS score, intrinsic religiosity domain of DUREL, positive RCOPE, and negative RCOPE suggesting an excellent agreement between the Hindi and English versions of the scale.

The test–retest reliability of all the items of Hindi version of all the three scales was above 0.8 for most of the items, indicating test–retest reliability to be good to excellent. Similarly, the kappa values for various dimensions of CRS, domains of DUREL, and subscales of brief RCOPE were also above 0.7 for most of these variables, indicating acceptable test–retest reliability. The Cronbach's alpha for CRS and brief RCOPE were around 0.9 or above, indicating excellent internal consistency for the full scales. The Cronbach's alpha for DUREL was 0.76, indicating acceptable internal consistency. The split-half reliability of all the scales was also in the good to excellent range. Accordingly, overall, it can be said that the Hindi versions of CRS, DUREL, and brief RCOPE have good to excellent psychometric properties and have good cross-language equivalence with the English version. Hence, it can be said that the findings of the Hindi version would be comparable with those of the English language version and that the Hindi version would yield scores which can be compared with those reported from other countries using different language versions.

The total DUREL score also had an acceptable correlation coefficient with the total CRS score, indicating good concordance between the two scales.

Religious coping methods are understood as "sacred" strategies, which are often used to handle the stressors of day to day life. The word "sacred" is used to denote not only the "traditional notions of God, divine or higher powers, but also to denote other aspects of life that are thought to be influenced or associated with

the divine or are associated with a feeling of divine-like qualities".[17,18] Considering this, it can be said that high religiosity may be associated with higher use of religious coping. Keeping this in mind, we evaluated the correlation of brief RCOPE with CRS and DUREL. We found that positive RCOPE had a significant correlation with total CRS score, and total DUREL score. However, most of the correlation coefficients were in the range of 0.3–0.5. Negative RCOPE subscale had a significant negative correlation with total CRS. However, these correlation coefficients were less robust. These low correlation coefficients suggest that religiosity may not be a true reflection of the use of either positive or negative religious coping. Overall, it can be said that convergent validity between these scales is average to low. This could possibly be due to the differences in the various aspects of religiosity across these three different scales.

To conclude, the present study suggests that the Hindi version of CRS, DUREL, and brief RCOPE has good cross-language equivalence with the English version. The test–retest reliability, internal consistency and split half reliability of CRS, DUREL, and brief RCOPE are good to excellent. It is hoped that the availability of Hindi versions of these scales will improve our understanding of the contribution of religiosity in various dimensions of health care. Various components of religiosity are closely associated with mental health. It is not uncommon for patients with various mental illnesses to present with symptoms having religious content. Further, religiosity and religious practices influence the type of help-seeking, medication compliance, adherence to treatment, acceptance of illness, etiological models of illnesses, etc., It is hoped that the availability of these instruments will help the researchers in studying the association of these variables with religiosity.

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Conflicts of interest
There are no conflicts of interest.

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Original Article

Development of Comprehensive Satisfaction Index (ComSI) and Its Association with WHOQOL-BREF

Bhupendra Singh, Nisha Mani Pandey, Betsy Mehrotra, Anamika Srivastava, Alok Kumar Chowdhury, S. C. Tiwari

ABSTRACT

Background: Comprehensive satisfaction in life may be considered as a significant contributor to health for everyone, including the aging population (individuals aged 45 years and above). For understanding the comprehensive satisfaction, an assessment measure with various psychometric properties may be useful. During a longitudinal study of aging and geriatric mental health, a 26-item tool was developed in Hindi for the assessment of satisfaction. This article aimed to analyze the items of Comprehensive Satisfaction Index (ComSI) applying Varimax rotation and to find out its association with World Health Organization Quality of Life Brief (WHOQOL-BREF). **Methods:** Data of 260 subjects were extracted from the longitudinal study to analyze the psychometric properties of the tool named as Comprehensive Satisfaction Index and its association with various domains of WHOQOL-BREF. Varimax rotation was applied after computing Kaiser–Meyer–Olkin and Bartlett's test of sphericity. Furthermore, the association between various components of ComSI and various domains of WHOQOL-BREF was explored. **Results:** Of the total 26 items of the tool, item no. 17 was excluded due to its –ve/ <0.31 value. A total of three components were generated with >1 eigenvalues; maximum items were loaded in component 1 (19) followed by components 2 (4) and 3 (2). Each of these factors has been significantly correlated with each other. Furthermore, these components also were compared with various domains of WHOQOL-BREF, and positive correlation was obtained for most of them. **Conclusion:** There is a positive association between ComSI and WHOQOL-BREF. This tool will help in identifying the satisfaction level of the aging subjects promptly and efficiently, which would further help in making strategies for interventions.

Key words: *Aging, association, comprehensive satisfaction, World Health Organization Quality of Life Brief*

Key messages: *Satisfaction is the ultimate achievement which develops contentment and makes a person happy. However, it is an imperceptible and intangible concept having many levels i.e. from physical infrastructure to recreational and spiritual facets. In view of the importance of the subject the author thought to develop an index for measuring the level of satisfaction within the lives of elderly; keeping in mind the cultural intricacies and social roles along with contextual existing notions of ageing in India.*

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Santoshah Paramam Sukham (satisfaction with one's situation is the ultimate bliss) is one of the oldest sayings in Indian scriptures. Neugarten *et al*. call life satisfaction as "an operational definition of 'successful aging'." It is universally observed that an individual usually performs any activity which is directed to satiate his or her level of satisfaction to restore any kind of imbalance, which often causes unhappiness or discomfort.[1] Life satisfaction is characterized, in agreement with the cognitive theory, as "individual's cognitive judgment about comparisons based on the compatibility of their own living conditions with the standards."[2] If we further analyze the notion for an aging population, comprehensive satisfaction is generally associated with the fulfillment of basic necessities of life as, if that remains unfulfilled, negative emotions come out. In addition, if that remains the case for a longer time, it may impair one's well-being, generate health-related problems, and delay recovery from poor health. Hence, an index of comprehensive satisfaction is needed to assess its level in the individual. Among the aging population, for assessment of satisfaction, one's subjective well-being is frequently used.[3-6] As an irreversible degenerative process, aging is associated with changes in a variety of external and internal factors, including health, socioeconomic status, living arrangements, care, and the existence of social support groups.[7] Subjective expression of the quality of life (QoL) may be assessed by level of satisfaction, which is a forecaster of longevity, morbidity, disease, and injury as well as successful aging.[2,8,9] It is also reported that life satisfaction is a comprehensive indicator of successful aging, and proper social support, active participation in activities, and economic satisfaction are positively correlated with better self-rated health and greater satisfaction with life.[10] It may be said that comprehensive satisfaction is a positive phenomenon for assessing or managing problems of old age and improving health and well-being.

The aging population is more concerned for their satisfaction and health conditions and that is often influenced by their socioeconomic status and limited work performance.[11,12] It will be worth mentioning that changes in demographic pattern along with ever-changing psychosocial milieu and disintegration of joint families often make the elderly dissatisfied with the surroundings. This disintegration has profoundly affected the incipient aging population. In rural areas, the health of older persons is mostly predominated by poverty, lack of education (especially for women), poor nutrition, and increased risk of accidents.[13,14] An article reveals that one's subjective QoL may be defined in terms of the level of life satisfaction and subjective well-being, happiness, and morale.[15] To assess one's level of well-being, happiness, and life satisfaction, the Comprehensive Satisfaction Index (ComSI) may be helpful.

Taking it into cognizance, during a large-scale cross-sectional study of aging titled "Lucknow Elderly Study (LES) in aging and geriatric mental health," a 26-item tool was developed for assessing level of overall satisfaction of the participants. This was further named as Comprehensive Satisfaction Index. This tool was developed in Hindi and assesses satisfaction of aging individuals on various significant aspects of life by taking their own viewpoint on a 5-point scale [Table 1]. These aspects are explained in simple statements and related to one's physical environment/infrastructure, availability of food, and its quality, psychosocial milieu, economic, spiritual, and well-being-related securities, and so on. This article aims to examine the psychometric properties of this tool and its association with World Health Organization Quality of Life Brief (WHOQOL-BREF) to ascertain its reliability.

Objectives

1. To analyze and explore items of ComSI administered on a rural aging population
2. To assess and find out the association of ComSI with various domains of WHOQOL-BREF.

METHODOLOGY

A longitudinal study was planned, developed, and proposed for studying various dimensions of aging and is being carried out on individuals age 45 years and above. In this study, data pertaining to a wide range of variables are being obtained related to subjects' demographic – socioeconomic status, physical and mental health status, lifestyle, habits, healthcare preferences, comprehensive satisfaction, routine, and QoL. For assessing these variables, some of the available tools are being applied, and for some, we have developed questionnaires in Hindi. One of these was ComSI. In developing ComSI, initially, we have identified various domains of ComSI (initially named as life satisfaction), for which the steps of tool development were followed.[16] A brief description of steps applied for tool development is as following:

To develop the tool, we had a discussion among the team to come on a consensus for identifying domains of satisfaction. After discussions with the LES team of experts (three psychiatrists and three psychologists) and with consensus, we identified six domains (namely, physical environment, psychological environment, social environment, health facilities, economic independence, and recreation). It will be worth mentioning that an individual generally feels contented and happy if his physical-psycho-social-financial-recreational needs

Table 1: Varimax rotated factor matrix for items of ComSI applied on rural participants of LES age ≥45 years (*n*=260)

Item no.	Item details	Satisfaction with		
		Living environment and IPR	Economic and self-freedom	Leisure
Item 1	Satisfaction with the environment of the place of residence where (you) live	**0.76**	0.27	-0.07
Item 2	Satisfaction with the arrangements related to light, air, water inside the household	**0.85**	0.15	0.02
Item 3	Satisfaction with the structure and construction (rooms, kitchen, washrooms, stairs, terrace, courtyard, lawn) of the house	**0.73**	0.27	-0.09
Item 4	Satisfaction with the quality and nutritional value of the food cooked in the household	**0.88**	0.09	0.06
Item 5	Satisfaction with the food that is cooked in the house, keeping your likes in mind	**0.90**	0.08	0.08
Item 6	Satisfaction with the mediums of entertainment (radio, television, internet, mobile phones) available in the household	0.03	0.15	**0.78**
Item 7	Satisfaction with the availability of mediums of daily information (newspapers, magazines etc.)	0.25	0.00	**0.67**
Item 8	Satisfaction with the traditions and practices followed during festivals at the home	**0.87**	0.18	0.12
Item 9	Satisfaction with the security measures in the house	**0.90**	0.06	0.15
Item 10	Satisfaction with the available transportation facilities near the house	**0.82**	0.02	0.13
Item 11	Satisfaction with the availability of medicines near the house	**0.86**	-0.03	0.20
Item 12	Satisfaction with the financial support and aid/care given by family members during any illness	**0.83**	0.18	0.03
Item 13	Satisfaction with the process of regular/ irregular exercises done	-0.18	**0.57**	0.29
Item 14	Satisfaction with the religious activities (puja, namaz, kirtan, meditation etc.) performed in the house	0.24	**0.48**	0.22
Item 15	Satisfaction with the rules in the house	**0.84**	0.09	0.11
Item 16	Satisfaction with the performance of activities according to self interest	**0.71**	0.17	0.16
Item 17	Satisfaction with the availability of employment opportunities (stitching, weaving, farming, cooking etc.) near the house	-0.55	0.30	0.14
Item 18	Satisfaction with the level of financial dependence on the family members	0.39	**0.65**	-0.10
Item 19	Satisfaction with financial independence of self	0.31	**0.79**	-0.08
Item 20	Satisfaction with family members and social relationships	**0.80**	0.32	0.05
Item 21	Satisfaction with the level of help/ support extended by family members	**0.83**	0.30	0.04
Item 22	Satisfaction with the duration and quality of time spent with family members	**0.83**	0.26	0.06
Item 23	Satisfaction with the opportunities to express likes and dislikes of self within the family	**0.83**	0.27	0.10
Item 24	Satisfaction with the role accorded to self with regard to decision making within the family	**0.81**	0.17	0.18
Item 25	Satisfaction with the quality of life	**0.84**	0.20	0.11
Item 26	Satisfaction with the opportunities available to express feelings/ emotions	**0.85**	0.20	0.12

Items with higher values included in the particular component are highlighted. ComSI – Comprehensive Satisfaction Index; LES – Lucknow Elderly Study; IPR – Interpersonal relationship

are fulfilled, and this makes him or her satisfied too. Keeping this in mind, on these six domains, items were generated by three independent psychologists. All items were then given to five independent experts to check the validity of contents of the items and rate the items on a 5-point scale, ranging from *not relevant at all* to *very relevant*. After the validation exercise, a 26-item tool was developed. These items were related to family infrastructure, psychosocial milieu, interpersonal relationship (IPR), available facilities, and so on, which are rated on a 5-point scale ranging from *completely satisfied* to *completely dissatisfied*. The content of the ComSI was validated by the group of experts, and the tool was pretested on a small group (30 subjects) to ascertain its feasibility. After pretesting, the items have further been modified and shaped in its present version. The tool gives an inclusive index of satisfaction, including individuals' personal, social, and recreational activities as well as available facilities in the milieu and satisfaction with self. With consensus, we have modified the name of this questionnaire from Life Satisfaction to ComSI.

After the entire exercise, the present version is being administered on the LES population. As we have a considerable number of surveyed proforma, we set

to analyze the items of ComSI. Data of 260 rural subjects were extracted and analyzed, applying principal component analysis (PCA) and Varimax rotation. To get various statistical values, that is, Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy, Bartlett's test of sphericity, PCA, eigenvalues, and Varimax with Kaiser normalization, the software of Statistical Package for the Social Sciences (SPSS-20) was used.

Ethical approval for the main study was obtained from the Institutional Ethical Committee. Eligible respondents of the study were briefed about the purpose of the study. Prior to data collection, we have obtained written informed consent from all participants.

RESULTS

Data of 260 subjects were analyzed. It was a representative proportion of the study population, namely, sex (male = 42.3%; female = 57.7%), age (45–59 years = 42.3%; 60–69 years = 28.1%; 70 years and above = 13.1%), and socioeconomic status (upper = 7.3%; middle = 63.1%; lower = 29.6%) [Figure 1]. KMO and Bartlett's test were applied to see sampling adequacy, which reveals appropriateness of sample size. KMO measure of sampling adequacy was found to be very good, that is, 0.957, and Bartlett's test of sphericity (app. χ^2 = 6684.6, Df = 325, P = 0.001) shows that norms for factor analysis are met. Thus, PCA and Varimax rotation were applied. The percentages of >1 initial eigenvalues, variance, and extracted sum of square loadings were found to be 56.43, 6.68, and 4.79 respectively, and thus, a total of three components were extracted. Through PCA, three components were identified. The items of these are related with (1) living environment and IPR; (2) freedom for economic and self-activities; and (3) satisfaction with leisure activities. On the rotated component matrix, the minimum value was 0.478, which was obtained for item no. 24 (component 2). Only one item had to be excluded, as it projected a negative value/<0.31 (item 17). The details of the analysis are provided in Table 1. Furthermore, Pearson's *r* was applied to assess the strength and magnitude of the association of factor scores with each other and with WHOQOL-BREF.

The items incorporated in various factors have been categorized as follows:

- Component 1: Family environment and IPR (19 items, i.e., item nos. 1, 2, 3, 4, 5, 8, 9, 10, 11, 12, 15, 16, 20, 21, 22, 23, 24, 25, and 26): An Indian aging adult often quotes "Care and respect in family gives strength" or "it doesn't matter if we get less food, but we need due respect." Responses on ComSI also give more weight to items related to care, respect, and opportunities to emotional expression; this all can be expressed with one word, that is, IPR/bonded relationship. These items significantly correlated with domains of WHOQOL-BREF except social relation [Table 2]
- Component 2: Satisfaction with financial and self-activities-related independence (4 items, i.e., item nos. 13, 14, 18, and 19): The items related to the second factor of the ComSI are related to subjects' satisfaction with available freedom for

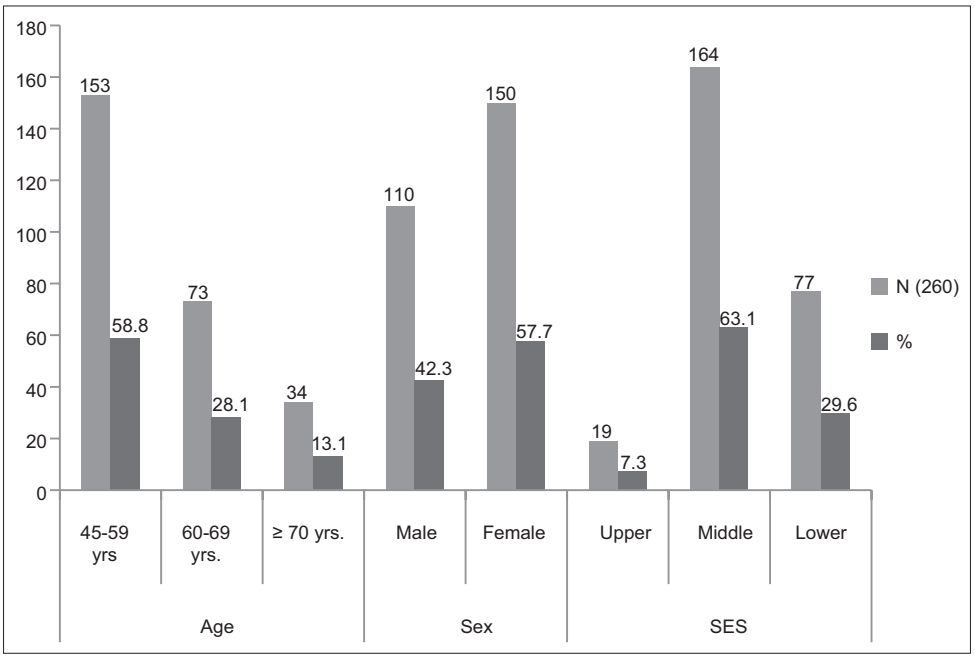

Figure 1: Socio- demographic details of the Study Participants. SES - Socioeconomic status

financial matters and self-activities. This was found to significantly correlate with social and environment domains of WHOQOL-BREF [Table 2]

- Component 3: Satisfaction with available leisure activities (2 items, i.e., item nos. 6 and 7): There are two items in this factor which are related to satisfaction with available recreational activities. Factor 3 was also found to significantly correlate with all domains of WHOQOL-BREF, excluding social relations [Table 2].

Table 3 provides the association of various factor scores with each other, applying Pearson's correlation coefficient.

Table 3 reveals that all these items are positively and significantly correlated with each other. Furthermore, the association between various domains of WHOQOL-BREF scores with various factor scores of ComSI was also computed, applying Pearson' *r* [Table 2].

Most of the factors of ComSI are positively and significantly correlated with various domains of WHOQOL-BREF.

DISCUSSION

Most tools for assessing various aspects related to life satisfaction among the aging population were developed either in western countries or were developed targeting a particular community of the society, that is, hospital-based/urban or rural. Hardly any tools have been developed in our country for assessing the satisfaction index of any population. The present tool was aimed to assess comprehensive satisfaction in both rural and urban areas and was initially administered on the rural population. In India, a larger proportion of the aging population lives in villages; the proportion of the population age 45 years and above is 2:1 (rural = 171.4; urban = 82.3 million).[17]

PCA and Varimax rotation were applied and three components emerged. One of the items (no. 17) of ComSI was excluded due to its negative value on component 1 and lesser value on second and third components. Therefore, a total of 25 items has been finalized. Furthermore, the intercorrelation between each component of the tool was computed using Pearson's correlation. All factors of the tool were found to be positively and significantly correlated with each other. This tool provides key features regarding one's satisfaction, and therefore, with consensus of the team members, it was named as ComSI. The items loaded with different factors were further subgrouped and named as satisfaction with the family environment and IPR, satisfaction with financial and self-activities-related independence, and satisfaction with available leisure activities.

Various empirical studies provide favorable results on these themes, which strengthen ComSI. Studies report that one's level of satisfaction with family support is a significant factor for the better psychological well-being of the aging individuals;[18] social support was found to be most influential factor for overall satisfaction;[19] family solidarity improves overall satisfaction and poor family solidarity reduces the

Table 2: Correlation coefficient (Pearson's *r*) between various components of ComSI vis a vis domains of WHOQOL-BREF (*n*=260)

Description	Physical health	Psychological	Social relation	Environment
Physical health	-	0.76**	0.53**	0.40**
Psychological	-	-	0.59**	0.51**
Social relation	-	-	-	0.59**
Satisfaction with living environment and IPR	0.15**	0.14*	0.08	0.18**
Satisfaction with economic and self-freedom	0.11*	0.11*	0.27**	0.19**
Satisfaction with leisure	0.15**	0.14*	0.08	0.18**
ComSI total	0.13*	0.14*	0.12*	0.14*

ComSI – Comprehensive Satisfaction Index; WHOQOL-BREF – World Health Organization Quality of Life Brief; IPR – Interpersonal relationship; ns nonsignificant. **Correlation is significant at the 0.01 level; *Correlation is significant at the 0.05 level

Table 3: Correlation coefficient (Pearson's *r*) between various components of ComSI (*n*=260)

Description	ComSI items			ComSI total
	Living environment and IPR	Economic and self-freedom	Leisure	
Satisfaction with living environment and IPR	1.00	0.24**	1.00**	**0.42****
Satisfaction with economic and self-freedom	0.24**	1.00	0.24**	**0.55****
Satisfaction with leisure	1.00**	0.24**	1.00	**0.42****

ComSI – Comprehensive Satisfaction Index; As the correlation coefficient has been checked with ComSI total therefore, highlighted. IPR – Interpersonal relationship, **Correlation is significant at the 0.01 level

overall satisfaction.[20] Social engagements and activities were also reported as a positive indicators of satisfaction.[21] Family relations were also reported as an important indicator of satisfaction.[19] With few exceptions, economic security, functional ability, and social integration were all conditions that in the same way significantly contribute to the satisfaction of older adults.[22] In view of the analysis of ComSI items and its association with WHOQOL-BREF, it may be said that ComSI may provide an index for identifying the level of comprehensive satisfaction of an aging population, which further may help in developing better management strategies for health and well-being of this segment of the population. A recent study revealed that lower levels and steeper declines of life satisfaction were each uniquely predictive of higher mortality risks, independent of sociodemographic variables, physical health, perceived control, and social orientation.[23] The study further reveals that high level of life satisfaction improves QoL, whereas low satisfaction marks serious shortcomings.

Although satisfaction plays a major factor in one's health and well-being, with an advancement in age, comprehensive satisfaction may be treated as a key component. ComSI not only identifies, addresses, and assesses the comprehensive satisfaction of the aging population but also gives clues for intervening components. It identifies three components of comprehensive satisfaction, which were found to be positively associated with each other and WHOQOL-BREF domains.

The tool has been administered on rural subjects, and therefore, it cannot be generalized until urban data have been analyzed. Second, because of the cross-sectional design, this study has limited extrapolative value. Third, again, because it is a cross-sectional study, the results may change over time.

CONCLUSION

This tool emerged with three components, that is, satisfaction with the family environment and IPR, satisfaction with financial and self-activities-related independence, and satisfaction with available leisure activities. There is a positive relationship between the scores of various aspects of ComSI. With proper care and support, a cordial relationship may be developed, and with pleasant IPR, a majority of elderly may remain satisfied, which will further help in enhancing their health and well-being. The present tool will enable us to determine the satisfaction index of the aging subjects, which may give clues for proper intervention and management.

Future plan

After completion of reliability exercise on urban data, this tool will be translated and circulated to obtain data from various study centers as a process of further validation of the tool.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Development of a Scale of Positive Temperament in Indian Context

Jyotika Bedi, Tarun Verma[1]

ABSTRACT

Background: Available tests of temperament measure the traits of different categories (like reward dependence, emotionality) with a large number of items. These tests do not deal specifically with traits of positive temperament (emotionality), and most scales measure negative emotionality as a counterpart of positive emotionality. The current study reports the development of a new scale of positive temperament, with fewer items and applicable in the Indian context. **Methods:** Items were developed with help from available scales of positive temperament, which led to the selection of 36 items from six different constructs. The data were collected in two stages for exploratory and confirmatory factor analysis of the scale. Stage one and two consisted of 278 and 338 participants, respectively, in the age group of 18–80 years, from both the genders and different professions. Data was collected online through the Qualtrics survey website. The participants responded on a 5-point Likert scale from 0–4 indicating how often they behave in a particular way as asked by the item. The test was reconducted on a subsample of 98 participants after 4 weeks to measure test-retest reliability. Convergent validity was also established using strengths and difficulties questionnaire and neuroticism scale, and divergent validity was found with age. **Results:** Exploratory factor analysis revealed four factors: optimism, perseverance, self-contentment, and adaptability. Confirmatory factor analysis later revealed that the 4-factor model fits best with the data, having comparative fit index (CFI) of 0.96 and root mean square error of approximation (RMSEA) of 0.063. The internal consistency estimates of the four factors ranged from 0.72 to 0.91, indicating a stable structure of scales. The final scale is of 28 items, with seven items in each factor. The test-retest reliability coefficients ranged from 0.79–0.96. Two second-order factors were also identified. **Conclusions:** The positive temperament inventory is a four-factor, 28-item validated inventory with a stable set of items, having specific applicability in measuring positive temperament and fewer items for ease of use in different situations. This is the first scale of its kind in the Indian context and holds a promising future in the area of personality and clinical research.

Key words: *Development, emotionality, factor analysis, India, positive temperament, scale*

Key messages: *Positive temperament inventory is a new scale believed to have wide applications in the English-speaking Indian population. It is short and has four important facets of positive temperament, with two second-order factors. Unlike previously available scales in India which are meant only for children, this scale can be used with adults (18–80 years).*

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Temperament is defined as individual differences in reactivity and self-regulation, which are constitutionally based and are influenced by genes, maturation, and experience across development.[1] "Constitutional" implies a biological basis to temperament. "Reactivity" implies dispositions toward emotional activity and attentional reactions. "Self-regulation" implies motivational tendencies to utilize our attentional mechanisms in order to control our thoughts and emotions by either approaching or withdrawing from a stimulus. The temperament, as the definition indicates, begins to develop from the conception at the prenatal stage, through genetic influences, and continues throughout the lifespan because it is altered by biological maturation and psychosocial experiences.[2]

The construct of temperament is a part of a broader construct of personality, which is a dynamic organization of the systems determining an individual's unique adjustment to the environment.[3] Temperament traits, as a subset of personality traits, refer to emotional (affect), motor (activity), and attentional (three As) reactive tendencies seen early in development. These are predominant in an infant's reactions to adjustments in the environment. However, during adulthood, these may overlap significantly with a broader variety of traits as measured by personality inventories like Big Five.[4] Because temperamental traits persist somehow independently of personality traits and are conceptualized as certain persistent reactive tendencies within an individual throughout the lifespan, it becomes important to study these traits as separate structures of behavioral dispositions and how they are related to life's various outcomes.[5]

Most theories of child and adult temperament describe these traits as constituting approach or withdrawal tendencies. The early models were based on two methods: top-down (deriving trait factors through behaviors and finding their biological basis) and bottom-up (developing biological-oriented theories from human or animal studies and conceptualizing behaviors as their dispositions). Top-down methods include models like Big Three,[6] Big Five,[7] and the Alternative Five.[8] In the bottom-up category, Gray's[9] model of behavioral inhibition and activation systems is the most commonly cited. However, these models describe traits that overlap with each other to a great extent, as revealed by factor analyses.[2] Tellegen[10] developed a three-factor model of temperament based on the affectivity component of biological systems. His three trait domains are positive emotionality, negative emotionality, and constraint. These three factors have 11 facets. Cloninger *et al*.[11] initially devised a three-factor model of temperament (novelty seeking, harm avoidance, and reward dependence). But later, through factor analyses results, he added four new factors (persistence, self-directiveness, cooperativeness, and self-transcendence—the last three being character traits).

A common trend across the most popular and widely accepted temperament models is the neglect of positive emotionality (PE). The trait of PE has been dealt with as an opposite aspect of negative emotionality (NE), and the absence or lower intensity of negative affect is generally considered a higher side of positive affect. Thomas and Chess[12] made the first attempts to classify mood as a significant aspect of temperament. However, their three facets of temperament largely referred to tendencies toward adaptability, rather than active displays in behaviors, as markers of positive affect. Buss and Plomin[13] conceptualized behaviors like crying as part of emotionality dimension, but not experiences of pleasure-displeasure. The focus on positive emotions as distinct traits of the pleasantness of experiences is generally restricted to explorations of NE.

Tellegen[10] have strongly influenced the investigations into positive temperamental trait by their structural model of two dimensions: pleasantness-unpleasantness and engagement-disengagement. Through later analyses, they labeled the first dimension as Positive Affect (enthusiasm, excited), which involves traits of positive engagement, and Negative Affect (fearful, distressed). The affective experiences in a situation, pleasant or unpleasant, either motivate toward or away from the activity, resulting in engagement or disengagement. Tellegen[10] suggested that these mood dimensions underlie the most common structural models of personality traits. Costa and McCrae[14] asserted that tendencies to experience positive emotions form the core feature of the trait of Extraversion.[15]

Similarly, positive emotions are sometimes experienced in the absence of any approachable circumstances or goals. Caspi and Roberts[16] indicated that traits of positive affectivity in childhood predict extraversion and agreeableness in adulthood and also correlate with high persistence and low activity levels. Prosocial behaviors involving the need to get along with others, with strong affiliative and agreeable needs, underlie positive experiences in mood and overall emotionality.

Common temperament scales for adults that exist in western literature are adult temperament questionnaire (ATQ),[4] emotionality, activity, and sociability temperament survey for adults (EAS[17]), temperament and character inventory (TCI,[11]), behavioral inhibition and activation scales (BIS/BAS[18]), and positive and negative affect schedule (PANAS).[19] A review of the literature suggests a lack of an Indian version of an adult temperament scale. To the authors' knowledge, these

scales in English have not been translated or adapted to Hindi or any other regional/official languages of India. Therefore, the need arises for the availability of such a scale in India that can be used for the assessment of temperament traits in adults.

As described above, a scale of temperament is required in the Indian context to accelerate the research in the personality field, as well as for clinical purposes. However, recent trends indicate that excessive focus of the scales on the negative dimensions of temperament would limit their applicability to clinical contexts. A scale of temperament should cover aspects of interpersonal as well as intrapersonal life, whose application would benefit in healthy growth of the individuals. Currently, the existing temperament scales are used to identify those traits in personality which are impacting the individual's growth in negative manners. Counselors and psychologists adopt such tests to counsel against the dangers of negative temperament. However, motivation toward life's goals requires actualization of positive attributes. These positive traits are inherent in personality but if the professionals ignore them, it would only devoid individuals from finding an appropriate direction in their life. The purpose of counseling is to increase the positive well-being of people, which is possible through the discovery of positive traits that would guide them in finding the right solutions. With this aim, we intend to develop a new scale of positive temperament that can serve the needs of counselors and psychologists as well as fill the gap in the literature.

SUBJECTS AND METHODS

Item construction and selection: Based on the available scales of temperament, several traits of positive temperament were identified. The items of these trait-scales were reviewed by a team of two experts from the Indian community, who have extensive experience in the field of test construction. These experts carefully noted those items that reflected the most common behaviors that are relevant in the Indian context. Selection of items revealed that out of 15 factors identified initially, six factors constituted the most prevalent positive traits. These six factors had high correlations with outcomes of positive well-being and predicted happiness. These factors were optimism, assertiveness, internal locus of control, adaptability, self-contentment, and perseverance. These six factors could not be excluded compared to others and retained the maximum number of items. Rest of the other nine factors had either 2 or 3 items left, while these six factors had at least six items, which was considered appropriate.

Alternatives to these items were prepared, which retained the essential meaning [Table 1] of the original items and would be suitable for application in Indian communities. To keep the theoretical basis of the new scale intact and in line with previous conceptions of PE, it was considered convenient that the present scale should be based on items that are existing in the literature. Since we are not aiming at any conceptual revision of PE, and only desire to create an Indian version of the PE scale, existing constructs can provide appropriate directions in the development of this scale. None of the items were copied from the previous scales, all of them were modified or originally generated. Some of the sample items are given in Table 1.

Through selection and construction of new items, six factors as outlined above with six items each were considered to constitute the newly developed scale having 36 items, and the scale was ready for item analysis through data collection. The scale is named positive temperament inventory (PTI). All items were positively worded. The items are responded on a 5-point Likert scale ranging from 0–4 indicating how often one behaves in the particular way as inquired by the item.

Participants

Stage 1: The data on the initial scale were taken from 278 participants for exploratory analysis. These participants were in the age group of 18–80 years, with 160 females (58%) and 118 males (42%). Age mean was 48.72 years (SD = 16.30). The participants had a formal English education and could fluently read and understand English. They were from diverse educational and professional backgrounds and were selected irrespective of their religion or ethnicity.

Stage 2: The data were taken from 338 individuals for confirmatory analysis. The participants were in the age group of 18–78 years, with 212 females (63%) and 126 males (37%). Age mean was 47.87 years (SD = 16.48). The characteristics of these participants were similar to those of those taken for exploratory analysis. After the initial analyses of factorization, second-order factors were identified on this sample.

Tools for convergent and discriminant validity

Convergent validity was assessed through the use of two questionnaires:

Strengths and difficulties questionnaire–adults (SDQ)[20]: This scale measures strengths and difficulties in context of mental health problems. It is a 25-item scale and consists of 5 subscales with 5 items in each which are rated on a 3-point Likert scale (from 0 to 2). The subscales are emotional problems, conduct problems, peer relationship problems,

Table 1: Factor loadings of four components through principal component analysis with varimax rotation (*n*=278)

Item Number	Optimism	Perseverance	Self-Contentment	Adaptability
36. learn from experiences "I tend to learn from new experiences rather than getting stressed by them."	0.646			
19. imagine the best outcomes	0.643			
7. feel confident	0.622			
6. try new ways	0.606			
31. see others positive	0.535			
12. don't get anxious	0.534			
1. hopeful about future	0.502			
11. take hardships		0.781		
25. best future conditions		0.705		
17. don't give up "I don't give up on something despite repeated disappointments."		0.653		
27. repeat efforts to achieve		0.571		
5. work enthusiasm		0.488		
23. don't get discouraged		0.467		
35. firm focus		0.454		
15. hard work			0.742	
26. stand for myself "When required I am able to stand up for myself"			0.638	
28. realistic expectations			0.534	
16. accept myself			0.481	
32. take initiatives			0.466	
4. feel happy satisfied			0.465	
14. emphasize views			0.443	
24. accept help				0.764
18. accept others' suggestions				0.741
29. pursue goal				0.728
20. take criticism				0.633
34. do not grudge "I do not grudge about things that I do not have and others have."				0.497
10. no comparison				0.434
2. speak clearly calmly				0.417
Eigenvalue	4.557	3.613	2.273	1.435
% of Variance	19.624	16.462	12.077	10.729

hyperactivity/inattention, and prosocial behaviors. Three derived scores are obtained: (a) Total difficulties score by summing the scores of all subscales except prosocial behaviors, (b) Externalization score by summing the scores from conduct and hyperactivity problems, and (c) Internalization score by summing the scores form emotional and peer relationship problems. The scale has acceptable reliabilities and is valid across different populations.[21]

Neuroticism subscale (20-item version) of international personality item pool (IPIP)[22]: This scale measures the trait of emotional stability and is based on big-five traits. The scale is reliable and valid and is freely available for use in researches (www.ipip.org). It has been widely used in various studies since its development.[23] It is rated on a 5-point Likert scale.

The discriminant validity of temperament factors was found with age, as it was assumed that positive temperament may not show any association with age since temperament is biologically linked.

Procedure

The participants were approached online for data collection through a demographic sheet and the newly developed 36-item PTI. Consent form included the details about objectives of the study, the researchers conducting the study and their contact details, the ethical review board (http://www.kpeindia.com/) that approved the study (EC approval no. KPE/R/PTI.01-04), and the surety of confidentiality of data. Agreeing to provide data was considered as their consent through online mode. They were screened for current or previous psychiatric illness. They were provided an incentive of getting their results after the development of the valid scale. The average time taken on the questionnaires was 15 min. Links to the questionnaire were distributed through professional contacts of the first author, and the data was collected from several professional organizations throughout India. The study had got ethical approval. Similar procedures were followed for both exploratory and confirmatory analyses.

RESULTS

Exploratory factor analysis

To analyze the factor structure of 36 items in the scale, we ran the principal component analysis with varimax rotation using SPSS (version 25). The sample size of 278 individuals was around eight times the number of items on the scale (36), which made it adequate (must be 5–10 times) to qualify for factor analysis (Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.81). The results of the factor analysis yielded four principal factors that included seven items each, making a total of 28 items instead of the original 36 items. These factors had eigenvalues of greater than 1, with the factor loadings on the items ranging from. 417 to. 781. Factors with eigenvalues lower than 1 and items with factor loadings of less than. 4 were excluded. Scree plot also showed a four-factor solution [Figure 1]. These four components were optimism (19.62% variance), perseverance (16.46% variance), self-contentment (12.08% variance), and adaptability (10.73% variance). The four components included items from all six scales that were initially identified during item selection. However, only four of these happened to have maximum loadings with items that did not overlap with others. The results of the exploratory factor analysis (EFA) are presented in Table 1.

Confirmatory factor analysis

To confirm the factor structure obtained through exploratory analysis, the data was analyzed for confirmatory analysis on a sample of 338 individuals (KMO measure was 0.84). Four models were tested to obtain the best fit statistics. For 1-factor and 2-factor models, χ^2 value was <0.05, indicating a poor fit. Rest of the values of CFI and RMSEA and adjusted goodness of fit index (AGFI) also followed similar patterns. For the 3-factor model, χ^2 was >0.05, which indicated a good fit. AGFI for the 3-factor model was <0.90, whereas for the 4-factor model AGFI was > 0.90 (.932), which indicated a good fit for the 4-factor model. RMSEA for the 3-factor model was 0.091 (>0.08), whereas for the 4-factor model was 0.063 (<0.08), which indicates a good fit for the 4-factor solution. CFI for the 3-factor solution was 0.81, whereas for the 4-factor model was 0.96, indicating a good fit for the 4-factor model. The coefficient of internal consistency for all factors ranged from 0.72 to 0.91. Factor loadings for all 36 items ranged from 0.428 to 0.753, indicating high values. The results of the confirmatory factor analysis (CFA) are presented in Table 2. Correlations among the factors were computed. Optimism and perseverance had significant moderate relationships ($r = 0.54, P < 0.01$) while adaptability and self-contentment had moderate associations with each other ($r = 0.48, P < 0.05$). Other correlations were lower than 0.3 and not significant.

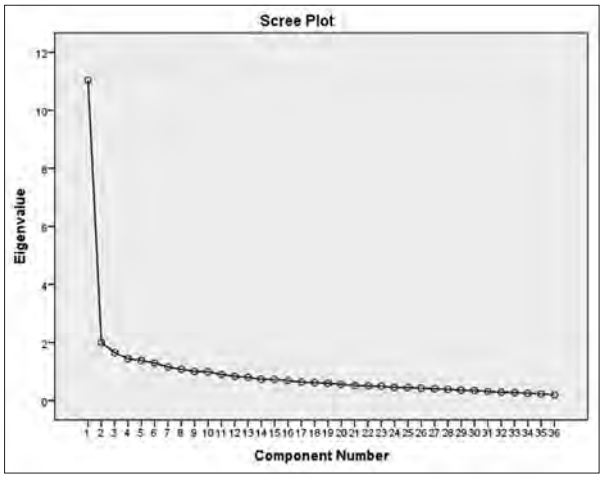

Figure 1: Scree plot of principal factors

Second-order factors

Since the correlations between optimism and perseverance, and between adaptability and self-contentment were moderately significant, it was considered appropriate to conduct a second-order factor analysis using the correlation matrix of first-order factors. Higher-order factors were extracted using principal components analysis and promax rotation with Kaiser normalization (KMO measure for sampling adequacy was 0.83). The analysis [Table 3] revealed two uncorrelated factors ($r = 0.13, P > 0.05$), where items from optimism and perseverance factored into one component (factor 1) while items from adaptability and self-contentment grouped into the other component (factor 2). These factors were named Temporal positivity (factor 1: due to the future orientation of item contents and long-term goal-persistence with a positive attitude) and Dynamic positivity (factor 2: due to item contents focusing on adaptive skills and continuous evaluation of goal-attainments to maintain feelings of satisfaction).

Table 2: CFA statistics for the four-factor solution (*n*=338)

Factor	Cronbach's α	Eigen values	% of variance	Test-retest Reliability, *r* (*n*=98)
Optimism	0.84	4.35	21.46	0.89
Perseverance	0.86	3.26	16.22	0.86
Self-contentment	0.91	2.64	13.12	0.96
Adaptability	0.72	1.05	10.54	0.79

CFA - Confirmatory factor analysis

Table 3: Factor loadings of second-order factors

First-order factor	Temporal	Dynamic
Optimism	0.824	
Perseveration	0.711	
Self-Contentment		0.876
Adaptability		0.751
Eigenvalue	2.662	1.536
% of Variance	20.74	14.29

Reliability analysis

Test-retest reliability was assessed on a subsample of 98 participants from Stage 2 (CFA sample) after a period of 4 weeks. The test-retest reliabilities of the four factors ranged from 0.79–0.96 indicating consistency in factor scores [Table 2].

Validity analysis

The results of validity analysis are given in Table 4 (n = 98). The convergent validity was established by correlating PTI factor scores with domains of SDQ and neuroticism subscale of IPIP. The factors of PTI had significant negative relationships with emotional problems, peer relationship problems, total difficulties, and internalization scores (r = −0.34 to −0.63) while associations with externalization scores were not significant. Positive relationships were found with prosocial behaviors scale (r = 0.42 to 0.56). Associations of factor scores of PTI were significantly negative with neuroticism subscale of IPIP (r = −0.57 to −0.71). The values of r for relationships of PTI factors with age ranged from 0.08 to 0.22, and none of the coefficients were significant, thereby establishing the divergent validity of the PTI. The discriminant validity is also established in the current study for conduct problems, hyperactivity/inattention, and externalization behaviors.

DISCUSSION

The current study aimed to develop a scale of positive temperament. To the authors' knowledge, the construction of such a scale is attempted in the Indian context for the first time. The scale was constructed from previously available scales in the English language, and after the initial extraction of 15 factors, the process of item selection helped to finalize six factors which had a higher potential for contributing to happiness and satisfaction from life. The results of EFA of 36 items revealed that the scale contains four factors having 28 items, with seven items in each, where the items from six initial factors distributed to form only four. These factors were optimism, perseverance, self-contentment, and adaptability. The results from CFA confirmed the structure of four factors. Hence, the final Positive Temperament Inventory (PTI) contains four factors with 28 items. Second-order factors were identified which grouped optimism and perseverance into one component called temporal positivity, while the other two factors of adaptability and self-contentment were grouped into dynamic positivity. The scale is short as compared to most available temperament scales. This makes its application convenient in counseling as well as research areas.

The six factors chosen for this study were based on theories of Cloninger *et al*.,[11] Tellegen,[10] Buss and Plomin,[13] Evans and Rothbart,[4] and Gray[9] where the authors had used TCI, EAS, ATQ, and PANAS for the measurement of temperament. The factors constitute positive dimensions of temperamental traits, and those factors with NE content were excluded during the initial selection process. As our review revealed, most of the factors (78%) in existing scales were not measuring PE, and rest others were having mild-to-moderate correlations with PE.[24] Although in many cases they had acceptable correlations with PE traits (like extraversion), conceptually speaking, PE is only one of the several aspects of such temperamental traits, and that too distantly related.[25] The construction of this scale has added value to the literature by offering an alternative to the current temperament scales. Previous scales have several factors across different dimensions of temperament, while PTI has only positive temperament as its core construct.

However, despite this being a full scale of positive temperament, we did not find any single-factor pervading all the items. Hence, a total score cannot be calculated to give a composite score. These factors can best be treated as individual traits of positive temperament, which possibly contribute to distinct areas of positive functioning. For example, optimism may imply positive future orientation, but only through perseverance, one can achieve high results. According to Putnam,[26] there are two different types of constructs of PE that can be classified on the basis of the prominence of approach behaviors associated with emotions: approach based (like extraversion, surgency, sensation seeking) and nonapproach based (like agreeableness, affiliation). It is expected that these traits would lead to different outcomes in one's life, and overall satisfaction (well-being) is not possible through any one of them.[27] Although any one of them is enough to make someone

Table 4: Validity statistics for PTI (n=98)

Variable	Emotional problems	Conduct problems	Hyperactivity	Peer relationships	Prosocial behaviors	Total difficulties	Externalization	Internalization	Neuroticism	Age
Optimism	-0.37*	0.03	0.08	−0.34*	0.47*	-0.48*	0.11	-0.59*	−0.59*	0.11
Perseverance	−0.49*	0.14	0.17	−0.45*	0.42*	−0.52*	0.15	−0.63*	−0.71**	0.21
Adaptability	−0.36*	0.21	0.13	−0.58*	0.53*	−0.58*	0.18	−0.52*	−0.57**	0.08
Self-contentment	−0.41*	0.26	0.10	−0.46*	0.56*	−0.54*	0.19	−0.57*	−0.62**	0.22

*P<0.05, **P<0.01. PTI – Positive Temperament Inventory

positive, the presence of other positive traits is equally needed. Approach-based traits involve an orientation toward high stimulus intensity, while the others involve a subjective state of well-being irrespective of stimuli intensity.[28] Hence, PTI can be said to have perseverance and adaptability as approach-based constructs, which require active efforts toward increased well-being, while optimism and self-contentment are more subjective in nature and do not need any force of motivation. However, the analysis for second-order factors found that temporal positivity constitutes those domains that require future orientation, and not approach-based behaviors, while the dynamic positivity implies temperamental traits that are focused on present-state positivity. This conception is different from the ones realized by previous authors[12,26] who emphasized more on the motivational aspects of temperament, rather than the time-related ones. It can be mentioned that time-perspective is an important component of our personalities and people differ in their time-orientation toward life, which is related to their emotionality.[14]

Each factor deserves a separate mention. Optimism describes a positive outlook in the future. It implies that things would eventually turn out to be good and favorable, despite odds in current circumstances.[29] Optimism is related to better subjective health outcomes. A chronic or severe health condition brings a threat to one's life and existence. Optimism has been found linked with better coping during unhealthy states.[30] Although objective outcomes may vary, optimism helps to improve functionality in life and contributes to happiness during crisis conditions.[31] Such a trait helps to welcome the positive possibility in the future, in the face of uncertain circumstances. This lessens the distress associated with crisis situations. In PTI, optimism has the maximum variance of 21.5% in scores of positive temperament. This trait seems to be the most significant of all, somehow contributing to larger variations in happiness. It does look obvious from a theoretical point of view also because higher optimism is a subjective evaluation of a better future. It is more abstract and there is no limit to what extent one can be optimistic. Whatever be the distress, optimism always gives hope and a positive feeling of a better future. In fact, optimism can be a cognitive aspect to the feelings of happiness because a happy and positive outlook is characteristic of well-being.[32]

Perseverance is the second most important factor in PTI. It leads to 16.2% variance in positive temperament. It also constitutes one of the important factors in Cloninger's model of temperament. Persistence in tasks makes one expect the best results. Perseverance, like optimism, depends on positive subjective evaluations of best possible outcomes. One has to persist on any difficult task to achieve a desirable outcome in the future, near or distant. Persistence leads to better success and higher rates of achievement through goal-directed behaviors.[33] It has been found to correlate to success in sports, business, and even gambling. People who believe in their abilities would not leave the results of their efforts to luck or chance and prefer to make constant attempts in fulfilling the goal. Perseverance has been correlated with self-efficacy and internal locus of control as well as higher impulsivity and low frustration tolerance.[34] In fact, this factor has two items from the locus of control trait that constituted six initial factors. Unlike optimism, perseverance predicts better outcomes in career and relationships, rather than health conditions. In conditions of high perseverance and low optimism, levels of depression are high, accompanied by feelings of increased arousal and anxiety.[35] Therefore, both are equally important for mental health.

The third important factor of PTI that causes 13.1% of the variance in scores is self-contentment. This trait is important because we all make evaluations of past accomplishments, and positive self-evaluations are an important marker of a healthy mindset. Unlike the other two traits discussed above, which were primarily concerned with future outcomes, self-contentment is associated with positive evaluations of the past, whether success or failures. This makes PTI significant as it assesses positive subjective past interpretations, in addition to healthy futuristic expectations. Self-contentment measures overall perceptions about past experiences and outcomes that are currently part of our life's script and are unchangeable. This trait signifies the extent to which one accepts past life as a consequence of favorable as well as unfavorable circumstances. This helps one to accept life as it is, with little to no resistance as how it should have been. Studies show that people with a high number of traits that lead to self-contentment have fewer experiences of negative mood and lower rates of depression.[36] It is negatively related to neuroticism and other clinical variables which otherwise suggest higher ruminative tendencies.[37] It also encourages self-compassionate thinking by lowering the effects of intrusions and negative thoughts.

The fourth trait of adaptability, or loosely described as flexibility, contributes to 10.5% of the variance in positive temperament scores. Adaptability implies changing oneself to changing circumstances of daily life (accommodation-assimilation). It fits quite accurately, in theoretical ways, with the other three traits of PE in PTI. Adaptability helps to shift from past to future, brings balance in expectations, and yields contentment and optimism.[38] With increased flexibility, one can be positive in life because negative

events and poor relationships effect less in such cases. Adaptability helps in adjusting to difficult conditions which can't be controlled or changed, hence, leading to higher acceptance. This helps in reducing distress and developing coping strategies to deal with stresses. Adaptability has significance over the developmental course where one has to pass through changing circumstances.[39] It signifies an immediate reaction tendency, unlike the other three traits, because it is under constant updation due to varying stressful conditions. It is necessary not only in competitive environments but also in interpersonal contexts which demand a constant change of expectations and perceptions.

Applications of PTI

PTI can be utilized for various purposes like counseling, career assessment, clinical decision making, as well as in work-related environments. In counseling, it can help to inform about positive prospects of growth and future happiness. Positive traits are generally less explored in everyday life; hence, during times of stress, they may not be available as a source of inspiration. However, as theory suggests, we all have several positive traits in varying degrees that are biological and cultivated through experience.[40] Positive guidance for positive outcomes is one of the main goals of counseling and may aid the individual to choose the right course of action based on one's predispositional positive traits.

Career counseling requires an evaluation of one's strengths and weaknesses in order to select the right career. Positive temperament provides a source of encouragement and helps in developing a positive attitude toward goals for future success. Career decisions are complicated sometimes and may require belief in favorable outcomes under uncertain circumstances. Optimism and perseverance are related to successful career growth and achievements.[41]

Clinical interventions focus on reducing negative outcomes of illnesses that have resulted in reduced capacities to perform in daily life. It is equally necessary that positive attributes of personality be reinforced in order to help in overcoming distress. Building coping skills and learning conflict-resolution strategies require a positive mindset toward successful treatment. Lower levels of adaptability are generally implicated in depression and anxiety disorders.[42] Therefore, increasing one's adaptability may aid in relieving the distress caused by illness.

A workplace is a stressful situation and offers several challenges to deliver optimal performance. Such a performance is detrimental to one's success in life and career. Lack of success is generally related to lower levels of positive traits and a higher number of stressors.[43] In the face of stressors, positive temperamental traits provide the necessary sustainability and persistence. Career sometimes gives results after a long-term effort. Traits like perseverance and adaptability are some of the most necessary constituents of future success.[44]

CONCLUSIONS

Positive temperament inventory is a new scale that caters to the growing need for assessing positive traits in personality. The scale is reliable and valid, as shown in this study. The dearth of literature and fewer scales measuring positive temperament inspired the authors to create this scale. The prime intention was to develop such a scale for measuring positive temperament in the Indian context. The dataset used to create this scale was taken from adult individuals in a wide age range across various professions. The shorter nature of the scale would make it applicable across wider contexts owing to possibility of fast administration and easy scoring. Authors assert that the four factors of the scale make it brief and provide a concise measurement of some major dimensions of PE. Future studies would enlighten about other properties and correlates of the scale, like validation with scales of happiness and positive affect. The development of this scale would enable researchers to study predictors of positive outcomes. In the future, clinicians can also benefit by making predictions of positive health outcomes.

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Conflicts of interest

There are no conflicts of interest.

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Dialectical Behavior Therapy in Emotion Dysregulation - Report of Two Cases

ABSTRACT

Emotion dysregulation is the inability to control and modulate one's affective state, and it might be associated with mental disorders. The development of secure attachment with significant others, in early childhood, has been theorized to be essential to the development of emotional regulation. Disruption of the formation of secure internal representations may, therefore, substantially compromise the acquisition of emotional-regulation capacities in childhood and lead to social maladjustment in later life. It is a pre-post case study design of two adolescents who presented with acts of self-harm and history indicating a provisional diagnosis of personality disorder. However, an in-depth assessment revealed emotional dysregulation. The model of Dialectical Behavior therapy (DBT) recommended for non-clinical populations was delivered in 12-16 sessions, resulting in a positive outcome that sustained for 12-24 months follow-up, improving interpersonal effectiveness. The role of DBT as an early intervention in emotional dysregulation is highlighted, as it enhances social adjustment by altering the attribution style.

Key words: *Dialectical behavior therapy, emotional dysregulation, personality disorders*
Key messages: *Intervention for emotional dysregulation in early years of life might be a preventive measure against mental health issues of adulthood.*

Emotion dysregulation is the inability to control and modulate one's affective state, and it might be associated with mental disorders.[1] The development of a secure attachment with significant others in early childhood has been theorized to be essential to the development of emotional regulation. Disruption in the formation of secure internal representations may therefore substantially compromise the acquisition of emotional-regulation capacities in childhood and lead to social maladjustment in later life.[2] Dialectical Behavior Therapy (DBT) focuses on reducing self-harm and behaviors that interfere with quality of life by keeping an individual engaged in treatment.[3]

CASE #1

S, a 23-year-old unmarried female, pursuing post-graduation and hailing from an urban nuclear family of middle socio-economic status, presented with difficulties in interpersonal relations and feeling unwanted for years. These symptoms were causing significant distress, and for the last two months, she was unable to focus in studies as she felt ignored and rejected. She came for the consultation after reading an article on mental health in a newspaper, which made her think about the unhappiness in her interpersonal relationships.

The assessment revealed that at the age of 9 or 10 years, during family conversations, she discovered she was born out of an unplanned and unwanted pregnancy. Since then, she started thinking that she was unwanted and the family did not love her. This changed her perception towards the actions of others around her. She had friends, but her friendships did not last long. She thought that her friends made plans and usually ignored her or that they wished she did not accompany them in their plan of action. While she was studying in high school, her family members found out about her relationship with a boy from another religion. She got into an altercation with her brother due to this, and consequently, he slapped her in the face. She felt that no one understood her and made multiple superficial cuts on her wrist with a blade, out of anger, the scars being visible during the sessions. She reported that her two romantic relationships were out of boredom and to enjoy the attention, but she felt no emotional connect with either of them. While the therapy was ongoing, the third boy whom she had been dating for the last two months broke up with her, as he found her clingy. She was disturbed because of this, and the cognitions of being unwanted and rejected were reactivated.

The psychiatrist gave no medication, and DBT was planned. Stage one (sessions 1-3) aimed to decrease destabilizing behaviors such as putting cuts on the

forearm with blade and sending multiple messages on social media, by discussing the consequences of such behaviors and other adaptive ways to channelize the impulses such as using cue cards, scribbling on paper, and tearing or cutting paper with scissors. The contact number of suicide prevention helpline was provided for use in emergency. Activity scheduling was assigned to regulate studies and to prevent stalking the ex-boyfriend on social media.

Stage two (sessions 4-8) focused on the resolution of perceived discrimination in the family and feelings of abandonment in childhood that had led to unstable interpersonal relationships. Daily thought record (DTR) identified her inability to say 'no' to others. Out of this fear, so as to avoid rejection, she used to please everyone around. Dysfunctional statements in the DTR were rephrased by externalizing the attribution style. Her erroneous cognitions were challenged and more functional cognitions were generated using devils' court and generating evidence. Also, exposure-based procedures were used to target her negative emotions such as anger and sadness. Her natural action tendencies of withdrawing due to such emotions were replaced by encouraging her to communicate her emotions effectively. Now she understood how, culturally, a male child is given more preference, and regardless of this, she was ultimately taken care of as a child and adequate opportunities were given by her parents. By the 9th session, she developed insight into her cognitions that she lacked the ability to see others' perspective.

The dilemmas related to higher education and jobs were addressed in stage three (Sessions 9-11) by working through decision making. Now, she was not getting offended with remarks/comments of friends. She had developed insight how her core belief of feeling unwanted had impaired her interpersonal relationships. Consequently, her communication skills improved, resulting in enhanced interpersonal effectiveness.

Stage four (session 12-16) aimed to generate capacity for joy and meaning in life by strengthening the skills acquired so far and by assisting her in the generalization of these skills to real-life situations. The exposure based activities had increased her social participation which she earlier avoided due to shame and fear of rejection. Regular practice of mindfulness and of strategies to alter thoughts and emotions were reviewed and evaluated in mutual discussions. Emphasis was made on preventing relapse, stabilizing the emotional reactivity, and regular monitoring of the cognitive patterns through DTR.

On a telephonic follow-up after two years from the date of termination of the therapy, she reported to be teaching in a private school and simultaneously preparing for a scholarship exam to enroll for a doctoral program. She reported the ability to deal with situations (triggers) rationally without acting impulsively, and has been enjoying fulfilling relationships.

CASE # 2

A, an 18-year-old unmarried female, student, belonging to an urban family of middle socio-economic status, presented with sadness of mood, anger outbursts, self-harm behavior, and a chronic feeling of emptiness for the last one year. The assessment revealed significant interpersonal conflicts between the parents, due to alcohol consumption of father, depression in mother, and financial stressors. Her spinster paternal aunt, who lived in another city, working in a government organization offered to take the patient to her home to support the family. She got admitted in class eighth. She adapted well to studies and the school environment. But the aunt noticed that the patient would easily get irritable on small things, like if food is not of her choice or cold, having any clash with a friend in school, etc. But the aunt kept ignoring these issues until she once noticed some marks on the forearm of the patient. On inquiry, the aunt found out that the patient had been indulging in self-harm as she felt rejected or ignored by the peers in school. Hence she was brought for consultation.

Cognitive behavioral formulation identified childhood experiences leading to schema – *I am unwanted*, causing faulty assumptions and negative thoughts about self, and impairing social and interpersonal functioning. DBT was planned, aiming at erroneous cognition and poor emotional regulation. Sessions 3-10 emphasized on psycho-educating about the formulation, maintaining DTR, and practicing mindfulness. DTR revealed negative cognitions and ruminations that induced negative emotions and to deal with this, she would cut the skin of her forearm with a blade. This thought was cognitively restructured using techniques such as examining the evidence, guided discovery, and Socratic questioning.

She reported improvement in interpersonal relationships and the ability to understand others' perspective without being emotionally overwhelmed by their actions. Her ruminations now lasted for a day, which earlier used to last for two to three days. In order to minimize self-harm behavior, the blade was replaced by marker or pens and she was suggested to write or draw on the forearm. She was able to alter her emotional state and thoughts by the tenth session of therapy. For effectiveness in interpersonal communication, role plays were used in the sessions. Theoretical concept of theory of mind was used while discussing the perspective

Table 1: Pre and post assessment scores on clinical outcome measures

Measures	Case #1		Case # 2	
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention
DERS				
Awareness	8	7	10	11
Clarity	13	5	8	7
Goals	13	4	12	3
Impulse	11	3	9	3
Nonacceptance	10	3	8	3
Strategies	11	3	11	3
Total	66	25	58	30
GHQ-28				
Somatic symptoms	5	0	5	1
Anxiety/insomnia	8	3	10	4
Social dysfunction	16	2	13	4
Severe depression	13	0	9	2
Total	42	5	41	11

DERS – Difficulties in Emotional Regulation Scale; GHQ – General Health Questionnaire

taking and its role in interpersonal communication. The termination proceeded with monthly booster sessions (11th to 14th). The family members reported significant improvement at home as well as in the behavior with the peers. On visual analog scale (VAS), she and the aunt reported 90-95% improvement at the termination. She had started engaging herself in pleasurable activities such as listening to music, going to walk, and playing table tennis daily than getting affected by negative experiences or negative emotions. Improvement was sustained up to one year of the last therapy session, and she felt adequate pleasure in social relations.

DISCUSSION

Due to the anger outbursts, mood fluctuations and self-harm behaviors, both the cases had initially received a provisional diagnosis of disorders of adult personality and behavior.[4] But later, detailed clinical interview revealed the cases to be non-clinical. This highlights how emotional dysregulation might appear as a personality-related disorder. Both the cases had negative self-schema, which led to erroneous thinking arising from negative emotions, and impaired interpersonal functioning. The common features were interpersonal conflict and the use of self-harm behaviors as a coping mechanism. The intervention helped change the underlying perception of being rejected or unwanted, which resulted in improved interpersonal functioning. In both the cases, the feelings of rejection first experienced within their respective families had been generalized, leading to emotional dysregulation. The same reflected in objective measures; namely, Difficulties in Emotion Regulation Scale (DERS)[5] and General Health Questionnaire (GHQ-28).[6] With the progress in therapy, scores on DERS revealed increased acceptance and clarity to distress, decreased difficulties in concentration on goals and decreased impulse, indicating increased control of one's behavior. There was a decrease in difficulties in using planning strategies in distress, which indicated the use of alternatives and reflected in enhanced social functioning. There was an alleviation of psychological symptoms and social dysfunction on GHQ-28 [Table 1].

Multiple interdependent processes, spanning the biological, psychological, and interpersonal domains, are involved in emotional regulation. A fundamental interplay exists between emotional and cognitive operations where, in both the cases, any event inducing a feeling of rejection activated the memories of the past emotionally-loaded event, the attention being centered around such negative-emotion-inducing events.[7] This further strengthened the patterns of avoidance in interpersonal dealing. These processes operate in such a way that self-harm behaviors are seen to be rewarding, distracting, and minimizing the experience of negative emotions. Bowlby highlighted how the deficits in responsiveness by the significant others in the early years of life might compromise the development of interpersonal communication and interpretation of social cues.[8]

In both the cases, the outcome gains had been maintained even after 24 and 14 months, respectively, of the termination of therapy, as enquired via a telephone call. On reflecting back, it appears that DBT in a non-clinical population might be used to prevent the onset of psychiatric or personality disorders. Also, it was the early intervention that helped in both the cases to modify cognitive and

emotional reaction patterns – in later years, these would have probably caused psychopathology. Besides, with maturing age, these would have become stronger and harder to modify. Whereas, unlike personality issues, a persistent change in adaptive functioning might be achieved from 10-12 sessions and 2-4 booster sessions.

CONCLUSION

DBT might be a good option for a non-clinical population of adolescents and youth having emotional issues as it enhances social adjustment by altering the attribution style. The schemas and attribution might have been internalized from social interaction with primary relations. Intervention improves not only emotion regulation but also interpersonal relationships with significant others, resulting in an increased sense of well-being. It can be the primary intervention preventing the onset of psychopathology in the adulthood.

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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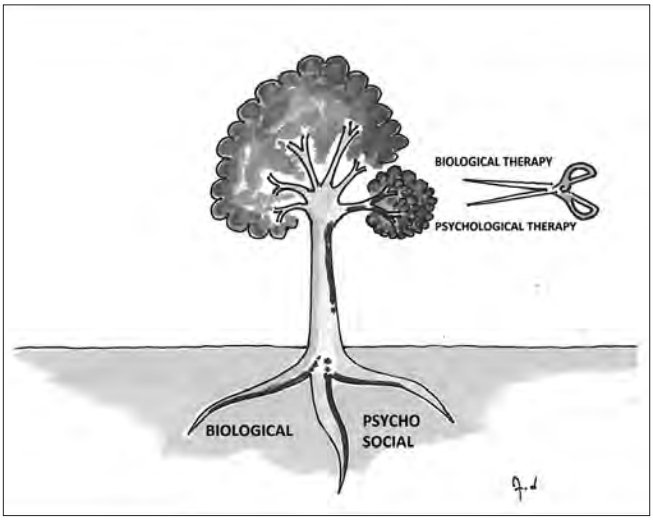
Biopsychosocial Model in Contemporary Psychiatry: Current Validity and Future Prospects

The biopsychosocial model (BPS) was proposed by George L. Engel in 1977 as a needed medical model to explain psychiatric disorders.[1] Since then, this model had gained wide acceptability across the globe. It systematically explained the complex interplay of three major dimensions (biological, psychological, and social) in the development of psychiatric disorders. It explained that a person does not suffer as isolated organs but rather as a whole. This provided a holistic approach to psychiatric illnesses. The emotional tone of a person, his/her personality, the surrounding environment, and other social parameters do influence the manifestation of illness. The model established a holistic and empathetic approach in psychiatric practice[2] Over the past four decades, many changes happened in our understanding of psychiatric disorders, and hence, there is reluctance in accepting the biopsychosocial model in reality.[3,4]



WHY THERE IS A DOUBT ON THE VALIDITY OF THE MODEL?

Various biological breakthroughs such as exponential progress in neuroimaging, neurophysiology, neurochemistry, neuro-immunology, neuroendocrinology, and genomics and the advancements in psychopharmacology have changed the very face of psychiatry in the last few decades. Newer neurobiological discoveries along with advances in science and technologies have paved the way for a more evidence-based, objectively verifiable and biologically grounded medical discipline of psychiatry.[5] This progress has started giving hope of improving the understanding of mental processes during health and disease as well as the etio-pathological basis of psychiatric illnesses. This biological framework promises new and improved management strategies. In this enthusiasm for the latest growth, psychosocial aspects of psychiatric illnesses are being relegated to the backside and are considered outdated. It has been seen that there is a deficient theoretical background regarding the content of the biopsychosocial model and also it's functioning. There is also a lack of consensus on how these separate factors interact and result in the expression of the disease. Thus, this model is being questioned, and the biomedical model is promoted as a marker of progressive thinking.

Unprecedented developments in biological psychiatry have amassed a wealth of knowledge and demystified some of the aspects of brain and mind. It has started influencing the understanding of causation, diagnostic, and assessment strategies as well as management to certain extents. While working with this new framework, it is easy to get disillusioned with speculative and theoretical psychosocial schools of understanding psychiatry persisting for long. On the other hand, supporters of psychosocial schools often criticize the growth of biological psychiatry by ridiculing the consistently changing terrain of the research; nonreplicability of earlier celebrated neurochemical and genetic findings in larger samples; nonspecificity of neurochemical, neurophysiological, neuroimaging, and genetic findings and almost negligible effect of biological progress on outcome of the psychiatric illnesses till date. The provocative sloganeering and ostracizing by a rhetorical attack of followers of both the camps had made the supporters seem to be in conflict.

THE GROWTH IN BIOLOGICAL PSYCHIATRY

Developments in neurobiology heralded in an expansion of the biological framework for psychiatry

and provided a scientific and rational outlook to psychiatry. Etio-pathological understandings have greatly improved, and it had an effect on understanding and, to some extent, the classification of psychiatric disorders. Psychopharmacological research has led to the development of more specific medications with increasingly benign side effects. These changes have overarching benefits to psychiatry. The medical model has a major influence on the inclusion of psychiatry in mainstream medicine. Professionals in other disciplines could relate to it easily, and psychiatric disorders and its management looked less esoteric to them. It helped in the reduction of stigma, resulting in a larger number of clients seeking treatment. Those patients of common mental disorders who till now feared psychiatry have started seeking help with less hesitation. With a greater emphasis on biology, there is an increase in the chances of talented students taking up psychiatry. The discipline becomes a more technologically sophisticated and more medicine-allied branch.[6]

PITFALLS OF BIOLOGICAL PSYCHIATRY

Despite the growth of biological psychiatry, the outcome of the patients with psychiatric illness has only marginally improved in the past decades.[7,8] Exciting research and better etio-pathological understanding had minimal translational results. Application in clinical practice remained elusive than expected. Although advances in biological psychiatry are imminently useful, nothing very assuring is apparent even today that can transform management and outcome. The biomedical model, which described mental disorders as defects in brain structure or dysregulations in a neurotransmitter system or any genetic defect, could not lead to the identification of any reliable biomarker for specific psychiatric disorders. The prevalent chemical imbalance theory could not provide any diagnostic test involving estimation of neurotransmitter levels that could be utilized in clinical practice. Neither of the primary nosological systems of psychiatric disorders such as the DSM or ICD has incorporated biological tests to identify, diagnose, or classify psychiatric disorders nor are there any valid and reliable biological tests available to diagnose any psychiatric illnesses.[9] It is also blamed for the dehumanization of medicine and focusing only on the disease, at the expense of ignoring the uniqueness and individuality of each client. The reductionist approach of the biomedical model, which conceptualized all behavioral manifestations as derangements in physicochemical principles, could not suffice to explain all facets of a disorder. Similarly, the exclusionist principle of excluding everything from the category of disease if not explainable was also not able to holistically conceptualize psychiatric disorders. The "one care suits all" approach of the biomedical model also undermines the "client-centered" approach, and thus, the individual variations are not taken into account.

THE INTEGRATION OF BIOLOGICAL AND PSYCHOSOCIAL COMPONENTS

Advances in our understanding of genomics and neurobiology have provided irrefutable evidence that psychological and social influence impact the flexible and adaptive biological system powerfully. For example, genetics contribute to the causation of schizophrenia, and the likelihood of development of illness is dependent on the closeness of the relationship, i.e., monozygotic twins' concordance is 50% and four to five times that of dizygotic twins. Nevertheless, it clearly demonstrates that the psychosocial environment plays an important role. Gene expression is influenced by environmental exposure. The role of epigenetics and thus, the importance of the environment in the causation of psychiatric disorders are well established now. Psychiatric disorders are not the result of a linear cause and effect medical model but are the result of a complex circular model of multiple causes and effects. In addition, these causes and effects are not hierarchical and can influence each other. As the inherited changes in psychiatric disorders are generally polygenic, a single gene cannot be pointed out for the causation of a disorder. Genes are a basic unit of inheritance and provide structural and functional information for the development and functioning of the human body and brain. Ideally, they help or serve a function. Genetic defects or dysfunctions contribute to most of the psychiatric disorders. Research on epigenetics has provided evidence about the interactions of genes and the environment. The environment, which determines the psychosocial milieu of an individual, has a definite impact on the manifestations in behavior. The role of epigenetics is already evident for psychiatric disorders such as major psychosis, Alzheimer's disease, and autism spectrum disorders. The activating or silencing of genes and their regulation are majorly via environmental contributions, and thus, the role of psychosocial determinants is overwhelming.[10]

The etiological complexity of psychiatric disorders has made it impossible to explain their causation through a single explanation. Simple Mendelian disorders or infectious diseases can be explained easily through the biomedical model; but for psychiatric disorders, there is a need to incorporate several factors. Thus, both biological and psychosocial models are unable to explain psychiatric disorders adequately. For example, if we take one of the most prevalent psychiatric disorders, depression, on one side, improvement through pharmacological mechanisms targeting the

neurotransmitter imbalance can be observed, and on the other side, despite adequate and rational treatments, there might not be noticeable improvement with them in individuals experiencing ongoing psychosocial stressors. Psychiatric disorders cannot be fully explained with only behavioral or psychodynamic perspective. It is also accepted that psychological experiences are also dependent on the functioning of the brain. Thus, the causal bridge about how biological factors can result in psychological manifestations are to be studied in detail. However, there is still scarcity in the identification of any psychological manifestation which can be adequately explained through biology only. Various facets such as neurochemistry, cognition, personality, environment, and so on should be analyzed while formulating a psychiatric disorder. Substance use disorder can be explained well with this formulation. It is known that there are cognitive predispositions in this group of individuals, which act vulnerable to them. The presence of environmental cues in the form of peer pressure also forms an important part. Family history also has a social and a biological component. The personality of the patient also acts as an important predisposing and perpetuating factor. Thus, the biopsychosocial approach provides us with the most integrative causality for such a complex interplay of factors.

In psychiatry, each patient is different. The beliefs, wishes, and drives of a patient encompass many facets and also impact his/her treatment process. Other psychosocial aspects such as social support, family, and the role of culture in psychiatric disorders also point to the fact that the individual differences are not solely due to neurobiological dysfunctions or any biological models.[5] The system of human beings comprises of a subpersonal component comprising of the nervous system, made of neural networks and cells, which are made of molecules and atoms. The other part is supra-personal, which comprises of the psychosocial context of the individual, which is made of the family, culture, community, and the society of the individual.[11] Even for psychiatric disorders like schizophrenia, where biological explanations prevail, there remains a role of the suprapersonal aspect. It has been seen that stressful events indeed precipitate or cause fluctuations in the disease. The role of social support is also well established for such disorders. Interventions, however, can be based on a factor that has the maximum impact with the least harm or is the most responsive to interventions within the least possible time and the least amount of resources, etc. The Global Mental Health (GMH) initiatives undertaken by WHO also endorse the biopsychosocial approach.[12] The multisectoral interventions for tackling mental health problems such as involving the public sector can also prove helpful in psychiatric disorders. Psychotherapy research in depression, anxiety disorders, obsessive-compulsive disorders, and personality disorders have proven that effective therapy normalizes basal brain metabolism and basal cerebral blood flow, and they resemble neurobiological changes after successful psychopharmacological treatments.[13-15] This provides evidence for the bridge between the two models: biopsychosocial and biomedical.

Psychiatry cannot afford to ignore social determinants of health such as poverty, illiteracy, migration, unplanned urbanization, and inequitable distribution of resources as well as personal attributes such as lifestyle choices, personality, motivation, desires, and fantasies in the understanding of illnesses. These social factors indeed powerfully influence the course and outcome of psychiatric disorders. Inequitable social availability of resources in childhood can pave the pathway for future psychiatric disorders.[16,17] Disruption in social support or social network predisposes psychiatric disorders. The social facet, which also involves culture, has shown that there are specific ramifications of psychiatric disorders due to cultural context.

CONCLUSION

The biopsychosocial model will continue to remain valid in medicine and more so in psychiatry. Mutual disrespect or contempt of biological or psychosocial schools of psychiatry are not based on science.[2] Presently, a collaborative approach involving both the psychosocial and biomedical model is needed to enhance the horizon of psychiatric knowledge. The reality that mental disorders are caused by multi-level mechanisms makes the biopsychosocial approach valid. What remains is to stitch the different factors to make a reliable network of factors that can provide a reliable framework to explain psychiatric disorders. Questions could be raised, such as "Can we ever think about dealing with a patient of dissociative disorder with an understanding of neurobiology alone?" or "Can we effectively manage a patient with schizophrenia only with psychological treatments?" Both approaches have "kernels of truth" for an understanding of complex phenomena arising from the brain. Persistent evolution of biological science and its integration with psychology for understanding complex diseases is necessary for holistic understanding and management of disorders. The medical curriculum should be regularly upgraded to incorporate the latest biological framework, and an understanding of psychosocial theories in light of the latest knowledge and discoveries should be done. The need of the hour is about resetting relative positions of biological and psychosocial models in context with each other, for better development and progress of the psychiatry.

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Letters to Editor

Opioid Substitution Treatment Using Buprenorphine for Management of Dependence on Natural Opioids: Case Series

Dear Sir,

Opioids are a group of psychoactive substances that are similar in action to that of opium poppy and include natural, semi-synthetic, and synthetic opioids. Buprenorphine maintenance as a treatment option for opioid-dependent subjects is well established.[1,2] However, the evidence is largely from studies on heroin or prescription opioid users. In India, even though a substantial proportion of opioid-dependent individuals use raw opium (*afeem*) or poppy husk (*doda*), evidence regarding treatment options for them is scanty. Opium users have longer durations of use and lesser severity of dependence than opioid-dependent individuals.[3] A recent Cochrane review found inconclusive evidence for opioid substitution treatment (OST) among opium-dependent patients.[4] Indian Psychiatric Society's treatment guidelines, however, do not distinguish between treatment agents with respect to the type of opioid the patient is dependent upon.[5] We present a series of three cases of natural opioid dependence that were managed with buprenorphine maintenance.

The first case is a 54-year-old married male, educated up to 12th standard, with history of tobacco use since 15 years of age, characterized by craving, tolerance, and withdrawal. He had consumed alcohol since 21 years of age, characterized by craving, tolerance, and withdrawal, but has been abstaining from alcohol after 1 year of its daily use at 22 years of age. He has been using *doda* since 23 years of age. At 23 years, he had tried one tablespoon of *doda* for abdominal pain, liked its euphoric effects, and started daily use. He developed craving and tolerance to *doda* within 2 years and increased the dose to 250 g daily within 5 years. On days when *doda* was unavailable, he could not work due to withdrawals, leading to lesser contribution to family expenses. Following familial conflicts, he tried multiple times to quit *doda* but failed. He also restarted his daily alcohol use (180 mL whisky). At 42 years, he presented to our center (in 2005), with a desire to quit *doda* predominantly. He had not taken any treatment previously. He was diagnosed to have opioid dependence, tobacco dependence, and alcohol dependence. Mental status examination revealed good motivation. He was prescribed cap. dextropropoxyphene 650 mg, with a plan to taper and stop it in view of first treatment seeking attempt and good psychosocial support, and tab. diazepam 20 mg in tapering doses to manage alcohol withdrawal. The patient had quit alcohol for 8 months, after which he started monthly use of alcohol, which continues till date. He also abstained from *doda*, but any attempt to taper dextropropoxyphene resulted in withdrawals and relapse to use of *doda*. Inpatient detoxification was attempted in 2007 when his abdominal pain increased and he was diagnosed with intestinal tuberculosis. Antitubercular treatment (ATT) was initiated and the treatment plan changed to buprenorphine maintenance in view of medical comorbidity, increase in pain on detoxification, and patient's preference. He was stabilized on daily observed sublingual buprenorphine 10 mg and shifted to buprenorphine–naloxone in 2009 (as weekly "take-home"). The patient completed ATT and is also compliant to OST till date, with repeated urine screens negative for illicit opioids. He also reports no craving for illicit opioids after the start of OST. His quality of life also improved, with a regular job, financial stability, and improved familial relations. He believes that to maintain these gains, the agonist treatment must continue.

The second case is a 45-year-old married male, educated up to 12th standard, an electrician by occupation, who presented to our center in 2008 at 35 years of age with chief complaints of *doda* use for 10 years characterized by tolerance, craving, and withdrawals. Despite social derision, familial conflicts and financial drain, he could not abstain, even when he tried to, on his own. He had good motivation to quit at the time of presentation. He was diagnosed to have opioid dependence. In view of his unstable job at the time of presentation, long duration of opioid use, and poor psychosocial support, plan for agonist maintenance was made. He was initiated on daily supervised sublingual buprenorphine in 2008, stabilized on 14 mg, and shifted to buprenorphine–naloxone (weekly take home) within a few months, which continues till date. After stabilization of

buprenorphine dose, he reports no craving for *doda* and is abstinent from *doda* till date, corroborated by repeated negative urine screen. He is working regularly, and his familial relations have also improved.

The third case is a 53-year-old married male, educated up to 8th standard, who presented to our center in 2007 when he was 42 years of age, with history of nicotine use in the form of beedi since 12 years of age, characterized by craving, tolerance, and withdrawal. He had history of opioid use since 16 years of age. He had initiated oral *afeem* use with 1 g daily for enjoyment, which progressed gradually to 25 g daily within 7 years due to tolerance. He also experienced a craving to take *afeem*. However, due to cost constraints, he shifted to *doda*. His job suffered on days when he could not take *afeem* or *doda* due to withdrawals. To sustain his *afeem/doda* use, he started to sell household things, leading to familial conflicts. He was diagnosed to have opioid dependence syndrome and nicotine dependence syndrome and was prescribed cap. dextropropoxyphene 390 mg/day with a plan to taper and stop it in view of logistic reasons and patient's preference. The patient abstained from *doda* but could not taper dextropropoxyphene because of withdrawal symptoms. After discussion with the patient, the treatment plan was changed to agonist maintenance and he was started on tab. buprenorphine–naloxone (2 mg/0.5 mg combination). The dose of agonist was stabilized to 10 mg of tab. buprenorphine (combined with a total of 2.5 mg naloxone in the combination tablets). After the start of agonist maintenance, he reported no craving for *doda* or *afeem* and is abstinent for illicit opioids. The patient is still on regular follow-up, with repeated urine screens negative for illicit opioids. He also started working as a security guard regularly, is stable financially, and enjoys good relations with his family.

Two broad approaches of opioid dependence management are (a) withdrawal management or detoxification (followed by "drug-free" or antagonist maintenance) and (b) agonist maintenance. In our patients, attempts at detoxification were unsuccessful. Also, they had a long history of opioid dependence, high habit size, and socio-occupational complications. Once put on OST with buprenorphine, all displayed psychosocial improvement, treatment retention, and maintained abstinence. This suggests that OST with buprenorphine is an effective approach for patients(a) with dependence on low-potency, natural opioids (raw opium or poppy husk) and (b) for whom detoxification has not worked for some reason.

The most interesting part of our cases is the long duration of follow-up, retention, and abstinence. Most prospective studies of OST have a follow-up of 1–6 years, with very few studies on methadone having a follow-up of 11–13 years.[6] In our patients, buprenorphine maintenance has been continued (and still ongoing) for longer durations (about 10 years in two cases and 5 years in one case).

In general, because natural opioid use is rarer in the developed world (from where most research is published), there is limited literature on treatment of dependence to natural opium. However, the available literature, largely from Asia, points toward effectiveness of OST – buprenorphine[7] and methadone[8,9] – with better retention for higher doses.[7,10]

Indian guidelines and recommendations should be based on Indian realities, experiences, and evidence, and not based only on western literature. As of now, there are no well-designed Indian studies testing OST's efficacy among natural opium users. However, as can be seen from this case series, all our patients had an improvement in various aspects of their life with OST.

This case series, thus, suggests that buprenorphine maintenance may be a viable treatment option for opium-dependent patients. Those with long-term opium use and unsuccessful detoxification attempts may be more suitable candidates for OST. Optimum medication doses can stave off illicit opium use and help in a better outcome. For more conclusive evidence, we recommend methodologically robust, prospective studies in this population.

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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There are no conflicts of interest.

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Dystonia after Shooting Street Heroin: An Underreported Matter of Concern

Recent World Drug Report mentions opioids as the most harmful drugs in terms of health effects.[1] Neurological sequelae have been reported in a few cases of inhalational heroin use ('chasing the dragon'). It is conjectured that vapours (pyrolysate) produced after heating black market heroin on aluminium foil, rather than pure pharmaceutical diamorphine, are responsible for the brain damage, although the incriminated adulterant has not been isolated till now.[2] The brain pathology associated with such use is spongiform leukoencephalopathy which can lead to long-term consequences or can even be fatal.[3] Structural brain imaging of these spongiform leukoencephalopathy cases showed the involvement of the posterior fossa, pallidum, corpus callosum and supratentorial white matter tract.[4] In this case series, we shall discuss six patients with acute onset transient dystonia following injection heroin use. To the best of our knowledge, no such cases have been described until date in the literature.

CASE SERIES

Case identification was retrospective and based on the patient self-report and informant description. The patients reported to us in a short span of time, i.e., between July to October 2017 and belonged to the same locality or adjacent districts. Here, we include six cases, of which five were inpatients and one outpatient. All the cases were dependent on injection heroin. We assessed the cases with a thorough general physical examination, including neurological examination, relevant investigations and brain magnetic resonance imaging (MRI).

All patients reported experiencing dystonic symptoms within minutes of injecting heroin which developed

to full in a few hours. All patients reported that the heroin they used had a little effect and instead they developed opioid withdrawals in addition to the dystonic symptoms. All the patients approached medical emergency settings for treatment. Two of the patients reported to our emergency department and were examined thoroughly by the internal medicine team, and consultations were taken from the neurology and psychiatry teams also. Routine emergency tests including serum electrolytes were within normal limits. They were administered injection promethazine 50 mg intravenous which gave complete relief in 10–15 min. The remaining four patients received treatment in the emergency departments of other hospitals. One patient reported being given intravenous calcium without any relief, but later, in another hospital, some intravenous drug was given which gave complete relief. For the rest, treatment details were not available, but they received some intravenous drugs that produced complete relief of dystonia within a few minutes. There was no confusion at the time of dystonia, and patients had sufficient awareness of the symptoms. There was no report of tonic-clonic movement or tremors. All patients developed cervical dystonia with variable involvement of the tongue, face and upper limb. The details of demographics, case description and investigations are provided in Table 1.

None of the patients could produce a sample of the heroin used by them before developing dystonia. As per the patients, they had either finished their dose or discarded it after recovering from dystonia. Despite reassurance of confidentiality and anonymity, inability to provide the sample could also be due to fear of being prosecuted. Three of the patients recalled that the texture and colour of the heroin sample were different from usual. Laboratory investigations included complete blood count (CBC), renal function tests (RFT), liver function tests (LFT), fasting blood sugar (FBS) and lipid profile. Except for the reports mentioned in the table, rest of the values were normal in all subjects. Ultrasonography (USG) whole abdomen, chest X-ray and electrocardiography (ECG) were normal in all patients. 3T MRI brain was also normal in all the patients. All the patients received treatment for opioid dependence in our opioid substitution therapy (OST) clinic. They received individualised doses of Tab buprenorphine/naloxone 2.5 mg combination sublingually.

At the time of writing this case series in October 2017, we have not received any new patients with a dystonic reaction after injection heroin use. All patients are in follow-up at our OST clinic without any recurrence of dystonia, and four of them were drug-free at last follow-up.

DISCUSSION

In this cases series, we described acute dystonia in dependent heroin users. There was a clear temporal relationship with the use of injection heroin and the appearance of predominantly localised cervical dystonias. The absence of any other neurological

Table 1: Clinical profile, laboratory investigations and clinical features of dystonia of cases

Clinical profile and laboratory investigations of cases				
Initials, Age (years)	**Other substance dependence**	**Physical illness**	**Psychiatric illness**	**Significant reports**
M 24	Tobacco dependence (ST)	HCV+	None	HCV RNA-TND, LDL-167 IU/L, TG-186 IU/L
H 27	Cannabis and tobacco dependence (ST)	None	None	None
I 26	Tobacco dependence (SLT), alcohol and cannabis dependence currently abstinent	None	None	AST/ALT-86/42 IU/L
A 30	Cannabis, alcohol and tobacco dependence (ST)	Seizure disorder	Bipolar affective disorder	TG-204 IU/L
S 20	Tobacco dependence (ST), cannabis dependence currently abstinent	None	None	None
L 20	Tobacco dependence syndrome (SLT)	None	None	None

Clinical features of dystonia as described by patients and informants							
Initials Age (years)	**Heroin amount used (g)**	**Time to onset of dystonia (minutes)**	**Duration of symptom (hours)**	**Distribution of muscular involvement**			
				Retrocollis/torticollis (side)	**Tongue protrusion**	**Grimacing and trismus**	**Ipsilateral upper limb involvement**
M 24	½	30	3	Y/Y Right	Y	N	Y, wrist flexion
H 27	1	120	2	Y/Y Right	Y	Y	Y, wrist flexion and locked elbow
I 26	½	20	6	Y/Y Left	Y	N	N
A 30	3	30	2	Y/Y Right	Y	N	N
S 20	½	180	1	Y/N Midline	N	N	N
L 20	½	30	3	Y/Y Right	Y	N	Y, wrist flexion and locked elbow

Y=Yes, N=No, ST/SLT=Smoked tobacco/smokeless tobacco, HCV=Hepatitis C virus, LDL=Low Density Cholesterol, TND=Target not detected, ALT=Alanine aminotransferase, AST=Aspartate aminotransferase, TG=Triglycerides

abnormalities in the past, at the time of presentation or in subsequent follow-ups rule out the possibility of any underlying neurological disorder. There was no discernible electrolyte abnormality. None of the patients had received any other drug (over the counter or prescription medication) prior to the onset of dystonia. Hence, temporal connection, specificity of presentation and lack of any other apparent cause strongly suggest the role of injection heroin in producing acute dystonias. Next question is whether dystonias in these patients occurred as a result of direct effect of heroin or due to the adulterants (or cutting agents) mixed with it.

As already mentioned, incidents of acute dystonia following heroin use has never been reported. The reports published so far have described long-lasting features of residual central nervous system (CNS) damage, almost always following inhalational heroin use (rather than injection).[3] Hence, the atypical presentation prompted us to look into the possibility of dystonia induced by adulterants. Reporting of cases in a short span of time, from the same locality, and a similar subjective experience following heroin use too support the adulterant hypothesis. Moreover, being a transit area for South-West Asian heroin, the northern part of India (from where the cases were reported) is no doubt vulnerable to be exposed to the adulterated street heroin as the small-time local drug dealers try to compound their profit.[5] If the adulterant hypothesis is convincing, the nature of the adulterant needs to be speculated.

On the basis of a review of the literature, we speculate the involvement of a couple of offending agents, namely strychnine and chloroquine. A 2005 report by the United Nations Office on Drugs and Crime (UNODC) listed a range of alkaloidal impurities and adulterants isolated from street heroin samples. A thorough check of the list revealed that a probable candidate could be strychnine, which is a non-opiate cutting agent with pharmacological effects. Strychnine blocks the inhibitory action of glycine at interneuron-motor axon synapses and causes exaggerated motor activity.[6] In 1974, analyses of street heroin samples from Amsterdam were reported to be containing strychnine. Though the samples contained less than the lethal dose, low dose strychnine can produce dystonic reactions.[7,8] In another UNODC report (2009), chloroquine was identified as one of the cutting agents present in heroin manufactured in Afghanistan.[9] Though chloroquine is considered a non-toxic drug, there are five reported cases of chloroquine-induced extrapyramidal symptoms, including cervical dystonias from India. The exact mechanism of chloroquine-induced dystonia has not been identified, but chloroquine is believed to cause an imbalance in the neurochemical control of psychomotor activity in the basal ganglia.[10] So, chloroquine could be the second candidate which can produce dystonia.

A major limitation is not being able to gather any sample of the used street heroin. Hence, it is impossible to assert about the chemical nature of the adulterant. There are several learning points. In addition to obvious dangers of heroin, the adulterants or cutting agents too are a matter of real concern. We also reiterate the need for improved forensic capacities to identify specific adulterants and periodic monitoring for the level and nature of impurities. Like the United States had a Drug Abuse Warning Network (DAWN) been present in India, a detailed account of the source, nature, cause and extent of these events would have been generated, which in a way would have helped in shaping a public health response.

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Acute Dystonia Following Opioid Withdrawal: An Uncommon Presentation

Sir,

Opioids have been abused by humans since ages to obtain pleasure. Repeated use of this group of substances leads to a loss of control and a compulsive pattern of use, which ultimately leads to the development of dependence. The reduction in the usual dose or abstinence from opioids can result in a varying range of withdrawal symptoms, including rhinorrhoea, lacrimation, salivation, body aches, anhedonia, tremors, restlessness, mydriasis, diarrhoea, etc.[1] Dystonia is a movement disorder characterized by sustained or intermittent muscular contraction resulting in either abnormal posturing, movements, or both. They are mainly known to occur as a side-effect to a certain group of medications (antipsychotics, antiemetics, etc.) and are also seen in some neurological conditions.[2] Very few reports of opioid withdrawal-related dystonia are available in the existing literature. We report a case of opioid dependence who presented with acute dystonia during the acute opioid withdrawal phase and discuss the possible neurobiological mechanism to explain the presentation.

A 24-year-old educated, employed, unmarried male was brought to the emergency unit by his mother, with complaints of an involuntary movement of his neck to the right side, along with head tilting, which was associated with a pain in the nape of the neck for the last half an hour. A call was given to the psychiatry department because the history revealed a recent use of brown sugar. The patient could well sense the motor symptom and also reported difficulty in swallowing. A diagnosis of acute dystonia was made, and he was given intramuscular injection of promethazine 1 ampoule (50 mg) that resulted in a dramatic recovery of the motor problem.

A detailed interview revealed daily intake of brown sugar (street heroin or diamorphine), an opioid, for the last 3 years. He was introduced to it by one of his close friends, and he started to chase it as a means to experiment with the substance. He used to buy around 1 g of brown sugar from a drug peddler and would consume it in 2 days. He developed tolerance to its effects, and although he tried to stop chasing, he failed because of withdrawal symptoms like lacrimation, runny nose, low back pain, tremulousness of the whole body, insomnia, anhedonia, and diarrhoea. He last consumed brown sugar 15 h before experiencing the current motor symptom. There was no history of taking any antipsychotic, antiemetic, or any over-the-counter medications prior to this motor problem. He had neither history of any past neurological condition nor any family history of such problems and also no history of taking other substances of abuse. Such symptom never occurred to him in the past. He responded well to promethazine.

On physical examination, he showed signs and symptoms of opioid withdrawal and no focal neurological deficits. Clinical Opiate Withdrawal Scale (COWS)[3] revealed a score of 22, suggestive of

moderate opioid withdrawal. He was admitted to the psychiatry department with plans for acute withdrawal management and maintenance therapy. His routine blood investigations (complete hemogram; liver, renal, and thyroid function tests; serum sodium, potassium, calcium, and phosphate) were all found to be within normal ranges. A computed tomography (CT) scan of the brain revealed no abnormality.

The patient was taking brown sugar for a long period of time in a dependence pattern. The temporal relation between sudden discontinuation of brown sugar and the emergence of acute dystonia possibly suggests this movement disorder to be a withdrawal effect. The absence of intake of any antipsychotic or other dopamine blockers/depleters and a negative history of any neurological disorder, both in the patient and his family, rules out other possible causes for the presentation. He also experienced other symptoms of opioid withdrawal, as objectively revealed by COWS.

A literature search revealed a single report that depicted dystonia which occurred as a withdrawal effect to injection pentazocine, morphine, and pethidine (also opioids), which the patient was taking in a dependence pattern for 3 years.[4] While the patient in our case presented with acute dystonia that responded well to anticholinergic medication, the previously reported case had persistent dystonia for 2 years, which was nearly refractory to available treatment modalities.[4]

Dystonia is an extrapyramidal symptom that occurs due to dopamine depletion in the basal ganglia. It can be caused by both inherited and acquired conditions of the nervous system. In psychiatry, it is mostly seen as a side-effect of antipsychotics, though a host of other pharmacological agents can also lead to this symptom.[2] What caused acute dystonia in opioid withdrawal is not clear. However, a plausible causative mechanism between the two can be postulated in light of underlying neurobiological underpinnings of these two conditions.

Opioid receptors have been found on the GABAergic interneurons in the ventral tegmental area (VTA). Here, they facilitate dopaminergic transmission to the nucleus accumbens (NA) by inhibiting the inhibitory gamma-amino butyric acid-A (GABA-A) interneurons, which mechanism explains the addictive potentiality of opioids.[5] This inhibition of GABAergic interneurons is thought to be because of activation of potassium conductance.[6] Hence, during an opioid abstinent state, opioid receptors will not be activated, resulting in a lack of inhibition of the inhibitory GABAergic interneurons in the VTA, ultimately leading to decreased dopamine neurotransmission to the NA, creating a dopamine depletion state, which in turn causes dystonia.

There are evidences to this proposed mechanism. Morphine withdrawal has been shown to dramatically alter medium spiny neurone density of the shell portion of NA, thereby impoverishing dopamine transmission.[7] In addition, kappa receptor activation by agonists have been found to have antidystonic property.[8] These might be the postulated biological mechanisms that can explain dystonia in opioid withdrawal state.

However, there are some limitations of the current report. First, temporal relation between discontinuation of the opioid and the occurrence of dystonia has been considered to be the possible proof for causality here, though this cannot be taken as a full proof for such causality. Second, street heroin may contain many chemical impurities whose discontinuation can possibly cause dystonia.[9] We did not conduct a test to unravel the chemical nature of these impurities, which stays a limitation of our report.

Nevertheless, in conclusion, it may be pointed out that clinicians should be observant about the occurrence of motor symptoms like dystonia in opioid withdrawal state to guide early recognition of the problem, thus facilitating a targeted management protocol.

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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Tramadol-Related Adverse Drug Reactions at an Addiction Psychiatry Setting: A Cross-Sectional Analysis

Sir,

Continued reporting of adverse drug reactions (ADRs) is important for the promotion of safe use of medications and to encourage well-informed prescribing practices among health care providers.[1,2] Understanding the ADR profile in the billion plus population of India may prevent ADR-related hospital admissions and mortality.[3] The Pharmacovigilance Programme of India (PvPI) has been launched to collect, synthesize, classify, and disseminate information about ADRs on a national scale and contributes to global data generation and synthesis.[4] The PvPI has set up ADR Monitoring Centers (AMCs) across the country to fulfil its objective, and the National Drug Dependence Treatment Centre (NDDTC), Ghaziabad has been serving as an AMC and providing key insights into ADRs related to medications used for the treatment of substance use disorders. Tramadol is a synthetic opioid and serotonin reuptake inhibitor drug utilized in opioid detoxification. Sometimes, the detoxification may be prolonged, reaching almost the status of maintenance treatment.[5] However, several adverse events with tramadol have been reported. We present the ADRs encountered with tramadol in a specialized treatment facility for substance use disorders.

This cross-sectional, descriptive analysis of data was done at the NDDTC, Ghaziabad. The Center is a specialized treatment facility which caters to patients with substance use disorders. The center has both inpatient and outpatient facilities, and patients with opioid and alcohol use disorders primarily comprise the clientele. Tramadol is commonly used for detoxification in patients with opioid dependence. All spontaneously reported ADRs with tramadol over a period of 12 months from March 2017 to February 2018 were analyzed. Both inpatient- and outpatient-based reports were included. The nature and type of ADRs due to tramadol were analyzed along with patient-related factors. The World Health Organization Uppsala Monitoring Center's terminology was used to report

the tramadol-related ADRs. Patient demographics, reaction characteristics like system organ classification, and outcome were recorded as per the information provided by the health-care providers and medical records. Descriptive statistics were used to represent the data.

During the study period, 103 tramadol-related ADRs were recorded. The mean age of the sample was 36.69 ± 13.70 years, and all the patients were males. Various ADRs reported with tramadol are shown in Table 1.

The most common ADR reported was constipation, followed by decrease in appetite. Nearly, one-third of the ADRs (n = 32, 31.1%) were not labelled, suggesting that these were either hitherto unreported or so rare that they did not find mention in the package insert. Remaining (n = 71, 68.9%) were labelled ADRs.

According to the system organ classification, gastrointestinal (n = 43, 41.7%), skin and appendage (n = 22, 21.4%) and central nervous system (CNS) (n = 19, 18.4%), were the most common systems implicated, followed by psychiatric (n = 6, 5.8%), urinary (n = 5, 4.9%), metabolic (n = 4, 3.9%), musculoskeletal (n = 2, 1.9%), respiratory and ophthalmic (n = 1, 1% each) systems.

As per causality assessment, the ADRs were largely classified as 'possible' (n = 95, 92.2%). Six reports (5.8%) were considered causally 'probable.' One report (1.0%) was considered 'certain' in terms of causality, while another one was 'unlikely.' Four reports (3.9%) were considered serious (generalized seizures suggestive of tonic–clonic type and atonic type which required hospitalization), while the remaining were considered as nonserious.

The present report advances the knowledge about the ADRs related to tramadol. Constipation was the most frequent ADR reported. Though constipation is a natural effect of any opiate or opioid and is dose dependent in nature, it has the potential to impact on quality of life. Though a minor proportion of the ADRs was serious in nature, they merit attention as they escalate the health-care costs and pose a significant threat to the physical health of the individual. A fair proportion of the ADRs was unlabelled, indicating that new ADRs were discerned and hence continued surveillance is helpful.

The findings need to be interpreted in view of some constraints. It is likely that some ADRs were missed as the reporting was voluntary or they were transient or too mild in severity to be taken note of. Also, limited information can be gleaned from ADR reports. Yet, the present findings provide perspective with regards to the ADRS reported with tramadol. This would help practitioners in safer and more rational use of tramadol in the field of addiction psychiatry.

Table 1: Types of ADRs with tramadol

Variable	*n* (%)
Constipation	21 (20.4)
Appetite decreased	13 (12.6)
Seizures	8 (7.8)
Fullness of head	5 (4.9)
Itching	5 (4.9)
Pruritus and rash	5 (4.9)
Rash pruritic	5 (4.9)
Gastric irritation	3 (2.9)
Skin eruption	2 (1.9)
Skin exfoliation localized	2 (1.9)
Urinary hesitation	2 (1.9)
Weight decreased	2 (1.9)
Headache	2 (1.9)
Others*	28 (27.2)

*Others included 1 each of abdominal pain, acute gastritis, anxiety, bowel obstruction, breathing difficulty, bullous lesions, body aches, chills, eating disorder, insomnia, lacrimation increased, micturition pain, mouth dry, muscle spasticity, localized numbness, pica, polyuria, rash, rigors, sleep difficulty, tingling skin, tongue discoloration, oliguria, vertigo, vision difficulty, vomiting, and weight increase

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Substance Use Related Emergencies in a Tertiary Care General Hospital Setting: Observations and Discussion

Sir,

Those with a substance use are less likely to seek routine medical care. Emergency services may serve as their primary, and often, the sole, contact with healthcare services.[1,2] Some are still active users, whereas others contact after their substance use is interrupted or stopped.

Specific data pertaining to substance use related emergencies in the Indian context are sparse and dated.[3-5] A few studies available on the general psychiatric emergencies have no/minimal representation of substance use patients. There are several gaps in the available knowledge about the pattern and profile of substance use related visits in the Indian context.

This letter aims to discuss a few observations gathered from a retrospective, descriptive analysis of consecutive drug-related emergency psychiatric referrals made from a general hospital emergency department and attended by psychiatry on-call/emergency team over a 13-month period. The records of all the mental and behavioral emergencies are maintained routinely, from which the relevant data pertaining to substance-related emergencies attended between Jan 2015 and Jan 2016 were extracted using a semi-structured proforma.

Substance use related emergency referrals constituted 12.6% (84/666) of the total mental and behavioral emergencies attended in the period. The visits were distributed equally throughout the year, with no significant difference observed over the year quarters. The socio-demographic and substance use profile of the sample is shown in Table 1. Compared to the non-drug related emergencies (n = 582) attended during the same study period, substance use group (n = 84) had a significantly older age ($P < 0.01$) and a higher likelihood to be male ($P < 0.01$).

The proportion of substance use referrals within the total psychiatric referrals (12.6%) is comparable to that seen in prior studies from India (12-14%),[3,5] and is much less than the rates found by similar western studies [29-43%].[6,7] The under-representation of substance-related referrals in general hospital Indian settings in comparison to most western studies[1,2] might be because of under-utilization, under-detection, under-reporting, or low rates of referrals. Administration of brief screening tools or having a psychiatry resident stationed within psychiatry emergency has been reported to enhance referrals by several fold.[8]

The prevalence of comorbid psychiatric illness and comorbid medical illness was much lower than that reported for the general population and emergency visits.[9,10] The low prevalence of comorbid illness may be because the evaluation is often more focused on the primary cause of the visit. In addition, many patients were brought by police or non-related attendants, leading to a lack of information regarding comorbidity. In addition, there might be a selection bias in the sample, as patients with more severe medical comorbidities are less likely to be referred for psychiatric evaluation.

A comparison with an earlier study from three decades ago from the same center[3] reveals certain useful *insights* that be summed up as (i) about three-quarters of the earlier study sample was brought by the police after disruptive behaviors (as opposed to only one-fourths in the current sample). It appears that a higher proportion of referrals are now driven by clinical rather than legal reasons; (ii) co-occurring psychiatric illness was detected in 16% of the previous sample, compared to 10.7% in present sample; and (iii) over 85% of the patients in the earlier study explicitly refused any advice or need for further follow-up, in contrast to none in present study. This change might be reflective of a higher acceptance of the medical model of substance use. Another Indian study[11] from the same decade did not have their presentation of a single case of substance-related emergency among psychiatric emergencies seen in a general hospital. There is an upward trend for substance-related referrals in general hospitals over the past three decades in India, even if such figures are less than those from the western settings.

Female under-representation in treatment-seeking samples of substance users is a well-known finding. It could be because of stigma and socio-cultural factors. Alcohol was the most common substance (73.4%) to precipitate emergency visit in the present study, in consonance to a previous study from India.[4] Alcohol withdrawal management often needs a multi-disciplinary setting of a general hospital, in view of the comorbidities and anticipated complications.

It appears that opioid users are not availing emergency services adequately, in contrast to the findings of some western studies.[1,12] This could be because of a fear of medico-legal repercussions, poor resources, or a preference for alternate community-level health services from other governmental and non-government organizations. Community-based secondary prevention is needed to prevent emergencies in such users, including management of opioid overdose, basic supportive care, and first aid for substance intoxication.

Table 1: Socio demographic and clinical profile of substance use related psychiatric emergency referrals (*n*=84)

Variable	*n* (%)
Age (in years)	36.3±14.8
Gender	
Male	77 (91.7%)
Female	7 (8.3%)
Religion#	
Hindu	75 (89.3%)
Muslim	4 (4.8%)
Sikh	2 (2.4%)
Christian	2 (2.4%)
Medico Legal Case#	
MLC	21 (25.0%)
Non-MLC	61 (72.6%)
Known substance use disorder+	24 (28.6%)
Known medical illness+	9 (10.7%)
Primary drug of use	
Alcohol	62 (73.8%)
Opioids	10 (11.9%)
Cannabis	7 (8.3%)
Sedatives/hypnotics	2 (2.4%)
Multiple substance use	3 (3.6%)
Pattern of substance use	
Dependent use	71 (84.5%)
Harmful use	13 (15.5%)
Comorbid psychiatric disorder (ICD 10)	9 (10.7%)
Common reasons for presentation$	
Alcohol withdrawals	49 (58.3%)
Complicated alcohol withdrawals (seizures)	12 (14.3%)
Complicated alcohol withdrawals (delirium tremens)	19 (22.6)
Sedative-hypnotic withdrawal	1 (1.1%)
Any substance intoxication	20 (23.8%)
Opioid overdose	8 (9.5%)

MLC – Medico-legal case. #data on religion not available for 1 patient and MLC data not available for 2 patients; ≤ previously, diagnosed illness as reported by patient/attendants/treatment records $categories provided are overlapping and not mutually exclusive

Interpretations are limited by a reliance on records for data extraction and an exclusive focus on referred population. Further, a proportion of cases, such as those shifted to intensive care or medical wards, may not have been referred immediately.

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Comments on "Correlation of Cognitive Resilience, Cognitive Flexibility and Impulsivity in Attempted Suicide"

Sir,

A correlational study[1] recently reported that impulsivity, cognitive flexibility (CF), and cognitive resilience (CR) were linked in a sample of 270 people who attempted suicide. The authors, however, have erroneously mentioned regression analysis as correlation. Nowhere in the text does one find correlation coefficients (r); on the contrary, regression coefficients (β), calculated through multiple regression analysis, have been described as equivalent to correlation coefficients, even when there are several independent variables (IVs) in the regression model. This flaw is reflected all over the text, which does not give an accurate interpretation of the analysis results. Moreover, the results in Tables 2-4[1] consist of many biased and questionable values, which puts the validity of the research under serious doubt.

In a simple linear regression with only one IV, the value of β is equal to the value of r between the two variables. Table 4 has β = 1.00, which implies that CF and CR are perfectly correlated. Even the standard error is also shown to be 0, which is only theoretically possible, this is impossible on practical grounds because errors in measurements are likely to be there due to known or unknown sources. However, the authors have defended these results in their text, which seems unreasonable. On the contrary, the authors should have looked into this error more carefully as the two variables of CF and CR do not seem to share an absolute relationship theoretically or empirically. These two variables are reported with contradictory relationships based on unstandardized coefficient (B) (10% variance in CR by CF) and β values, along with the unlikely value of R^2 = 1.00, which can range between 0 and 1.0 only. Standardized coefficient (β) is interpreted to account for the variance in the dependent variable (DV) by the IV, which as the study indicates is 100%, but that is impossible because there is only one IV. It is possible to get significant β values greater than 1, but such values are comprehensible when there are multiple IVs.

The most surprising findings are perceived in Tables 2 and 3. The values of all parameters are the same, except in the column of unstandardized values, which in Table 3 are 10 times the values in Table 2. Even the values of R^2 and F are similar for both regression models with different DVs. Do the authors mean to imply that in their study CR and CF are the same variables? And if they have the same values by chance, as indicated by their perfect association in Table 4, how come it is even remotely possible that these two distinct variables came out to be exactly the same? The mean values of the two scales measuring CR and CF are 4.49 and 44.93, respectively, which again represent a 10-fold difference between the two scores. The same pattern is observed for standard deviations of the two variables. These results require further exploration. How come the distributions of CR and CF appear to be so similar in this study that is unlikely to occur in any research? The variance and other statistical values for these two variables should be different enough such that the actual variation in the data is reflected in the table values.

It is also not clear why the authors have put CR and CF as DVs. Regression analysis is meant to predict the variation in DV by an IV or a set of IVs, not to measure correlation. β weights determine relative variances (amount of explained variation) in the DV by different IVs, and are not limited to any range, unlike r, which can range between −1.0 and 1.0 only. Correlation, on the other hand, measures covariation or the extent of dependency between only two variables. R^2 is the variation in DV explained by the model which includes some set of IVs, where some variation in DV is left unexplained by this model making the value of R^2 less than 1. The whole rationale behind the application of statistical tests seems unreasonable and unclear in this study. Why didn't the authors simply use Pearson's product-moment correlation method? If the study is correlational then using the Pearson method is sufficient to find the underlying relationships among variables. Regression analysis could have been used if they had to statistically control some variable(s) in order to understand the hierarchical relationships among variables.

Research quality is greatly affected by the inaccurate interpretation of statistical analyses and results. Wrong

or unclear findings in studies mislead the readers and future researchers.[2] Researchers may take the help of statisticians to give them guidance for proper analysis and interpretation of data.[3] Expert statisticians can also be consulted to verify the inferences drawn from the results.[4] Insufficient analysis reduces its validity and the readers may not show any interest in the aforementioned implications of the study.[5] In this study,[1] the results look spurious and extremely theoretical, with no practical validity. The authors should have used appropriate tests to make conclusions from their data because various errors have been overlooked, which reduces the utility of this study.

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Need for and Practical Interpretations of the Person-Year Construct in Neuropsychiatric Research

Chittaranjan Andrade

ABSTRACT

In observational studies, groups of interest may be carved out of predictors of interest. Thus, for example, if cardiovascular (CVS) health at age 50 years is the predictor of interest for dementia as the long-term outcome, groups of interest could comprise persons with poor, intermediate, and optimal CVS health at age 50. These groups would almost certainly be unbalanced in terms of sample size and duration of follow-up when incident dementia is assessed. The present article is a companion to the previous article in this column; it explains why the duration of follow-up needs to be factored into the sample size in each group, making person-years rather than persons as the unit for risk assessment. Next, this article explains how to reverse calculate an estimate of the number needed to treat (NNT) statistic in such situations. Finally, this article explains why the NNT so estimated is an approximation and not a true estimate of the NNT in the population.

Key words: *Cardiovascular health, confounding, dementia risk, measures of effect size, number needed to treat, person-years unit*

Sabia *et al*.[1] described a prospective cohort study of 7899 subjects whose cardiovascular (CVS) health was assessed as poor, intermediate, or optimal at a baseline age of 50 years. These subjects were followed up for a median duration of 24.7 years, by when dementia had developed in 347 (4.4%) subjects. The incidence rate of dementia was 3.2, 1.7, and 1.3 per 1000 person-years, respectively, in subjects with poor, intermediate, and optimal baseline CVS health. In analyses adjusted for confounding variables, poor baseline CVS health was found to be a significant predictor of long-term dementia risk.

Looking at these results, the reader may ask (a) why the findings were expressed using a person-year unit and not as a percentage and (b) whether it's worth taking care of one's CVS health at age 50 in order to reduce one's dementia risk; that is, are the statistically significant findings clinically significant? Each of these questions is answered in turn.

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Why was the person-year unit used?

Dementia is a disease of old age. People in poor CVS health may die early, before those vulnerable to dementia have a chance to develop the disease. Therefore, if dementia incidence is expressed as a percentage of the sample size, the risk of dementia in the poor CVS health group may falsely be assessed as low. In contrast, the risk of dementia will be assessed as high(er) in people with good CVS health because they lived long enough for dementia-related changes (in vulnerable individuals) to manifest. So, if the median duration of follow-up was systematically dissimilar in the poor, intermediate, and optimal CVS health groups, it could be fallacious to report dementia incidence as a percentage of the sample size.

In such situations, instead of using persons as a unit of sample size, person-years may be used. Person-years refer to the number of years for which persons contribute data. Thus, somebody who was followed up for 5 years would be a five person-year subject. Person-years are totalled in each group to yield the sample size in that group, as expressed in person-years. The risk of dementia in each group is then calculated based on person-years of follow-up. Because the incidence values would be very small for one person-year of follow-up, it is easier to express the values based on the uniform unit of, say, 1000 person-years of follow-up. Now, dissimilarities in follow-up across groups are no longer as important as they were.

As a side note, person-years of follow-up is not a perfect unit when dementia is an outcome. This is because 500 poor CVS health subjects may each be followed from age 50 to age 52 years, totaling to 1000 patient-years of follow-up, and 50 optimal CVS health subjects may each be followed from age 50 to 70 years, also totaling to 1000 patient-years of follow-up. The risk in the optimal health group will be higher (even with a person-year unit) because the poor health group was not followed up long enough for dementia to have a reasonable chance to manifest in individuals at risk.

Are the findings clinically significant?

The risk of dementia in the optimal CVS health group was reduced by 1.9 (i.e., 3.2-1.3) per 1000 person-years, relative to the poor CVS health group. An advantage of 1.9 per 1000 person-years is the same as an advantage of 1.9 per 100 × 10 years, and this is the same as an advantage of 1.9% across 10 years, and this is the same as an advantage of 3.8% across 20 years, and this is the same as an advantage of 4.75% across 25 years. Thus, in persons who are in optimal CVS health at age 50, the absolute incidence of dementia will be nearly 5% lower than that in persons who are in poor CVS health at age 50.

Note that 4.75% is 4.75/100, or 1 in 21. This means that 21 people would have to move from low to optimal CVS health groups for one extra person to be protected against dementia between age 50 and age 75 years. That is, the number needed to treat (NNT) is 21.[2] Given that the NNT in statin primary prevention trials in CVS disease studies are in the 1 in 50 to 1 in 200 range,[3] and given that dementia is serious and irreversible and of as much concern as CVS disease, an NNT value of 1 in 21 should be considered clinically significant.

As a side note, this was not a randomized controlled trial (RCT); So, inadequately measured, unmeasured, and unknown risk factors for dementia may not have been balanced across the three groups and would not have been adjusted for in the analyses. These confounds, therefore, could have augmented the benefits attributed to membership in the optimal CVS health group. So the estimated NNT is not a true NNT. The actual NNT value could be higher; that is, the actual benefit could be smaller. Furthermore, because cohort studies are observational studies and because observational studies can only identify an association, not cause (as RCTs might do), there is even a possibility that optimal CVS health is only a marker for lower dementia risk and not a cause of lower dementia risk.

The take-home message is that whereas it is desirable to maintain optimal CVS health for CVS reasons, the lower risk of dementia could be an added bonus.

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- Login as an author
- Click on 'Submit new article' under 'Submissions'
- Follow the steps (guidelines provided while submitting the article)
- On successful submission you will receive an acknowledgement quoting the manuscript ID

3 Tracking the progress

- Login as an author
- The report on the main page gives status of the articles and its due date to move to next phase
- More details can be obtained by clicking on the ManuscriptID
- Comments sent by the editor and reviewer will be available from these pages

4 Submitting a revised article

- Login as an author
- On the main page click on 'Articles for Revision'
- Click on the link "Click here to revise your article" against the required manuscript ID
- Follow the steps (guidelines provided while revising the article)
- Include the reviewers' comments along with the point to point clarifications at the beginning of the revised article file.
- Do not include authors' name in the article file.
- Upload the revised article file against New Article File - Browse, choose your file and then click "Upload" OR Click "Finish"
- On completion of revision process you will be able to check the latest file uploaded from Article Cycle (In Review Articles-> Click on manuscript id -> Latest file will have a number with 'R', for example XXXX_100_15R3.docx)

Facilities

- Submission of new articles with images
- Submission of revised articles
- Checking of proofs
- Track the progress of article until published

Advantages

- Any-time, any-where access
- Faster review
- Cost saving on postage
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- Ability to track the progress
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Requirements for usage

- Computer and internet connection
- Web-browser (Latest versions - IE, Chrome, Safari, FireFox, Opera)
- Cookies and javascript to be enabled in web-browser

Online submission checklist

- First Page File (rtf/doc/docx file) with title page, covering letter, acknowledgement, etc.
- Article File (rtf/doc/docx file) - text of the article, beginning from Title, Abstract till References (including tables). File size limit 4 MB. Do not include images in this file.
- Images (jpg/jpeg/png/gif/tif/tiff): Submit good quality colour images. Each image should be less than 10 MB) in size
- Upload copyright form in .doc / .docx / .pdf / .jpg / .png / .gif format, duly signed by all authors, during the time mentioned in the instructions.

Help

- Check Frequently Asked Questions (FAQs) on the site
- In case of any difficulty contact the editor

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