Capacity to Consent for Treatment in Patients with Psychotic Disorder: A Cross-Sectional Study from North Karnataka

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ABSTRACT

Background: Recently, the Mental Healthcare Act (MHCA) 2017 was introduced in India. Being a right-based act, it has made the assessment of the capacity to consent an integral part of clinical work. To the best of our knowledge, there are no Indian studies on this topic. Hence, this study aimed to assess the capacity to consent to mental healthcare and treatment in patients with functional psychosis and the factors affecting the same.

Methods: This cross-sectional study included participants with the ICD-10 DCR diagnosis of a psychotic disorder admitted in the psychiatry ward of a tertiary health care center in Karnataka, India. MacArthur Competence Assessment Tool for Treatment was used to assess the capacity to consent to treatment. Brief Psychiatric Rating Scale (BPRS) and the Beck Cognitive Insight Scale were applied to assess the severity of psychosis and level of insight, respectively.

Results: A hundred participants were recruited. Twenty-four were found to have

an intact capacity to consent to treatment. High BPRS scores (P value = 0.0002) and low insight scores (P value = 0.0002) were associated with an impaired capacity.

Conclusion: About one-fourth of participants had an intact capacity to consent to treatment. Higher severity of psychosis and a poorer insight into the illness were associated with impaired capacity to consent.

Key words: Capacity to consent, MacCAT-T, psychosis, MHCA-2017, India

Key message: Not all patients suffering from a psychotic disorder have an impaired capacity to consent to treatment. Hence, assessment of capacity to consent becomes important before assuming impaired capacity in such patients. Severity of illness and level of insight can serve as predictors towards the status of capacity.

apacity to consent is defined as the mental ability of the patient to understand a given piece of information and make an informed choice. It forms a constituent of informed consent and is considered to be specific to the task at hand and the time at which it is assessed. ¹⁻³ It consists of certain domains, namely: understanding, appreciation, reasoning, and expression of choice. In case of deficiencies in any one of the domains, an impaired capacity is suspected, but the final decision regarding its status is taken by the judge in the court of law. ^{4,5}

The requirement for capacity assessment stems from the need to protect patients from unnecessary harm and protect their rights. It becomes more important for persons with mental illness (PMI) as they are more vulnerable to and at an increased risk for manipulations, coercion, and harm at the hands of caregivers and, at times, the treating physicians.⁶

In India, earlier legislation governing mental health practices did not focus on the rights of PMI, which led to the curtailment of their liberty and denied

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any say in treatment decisions.7 After the ratification of the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) by the Indian parliament, the Mental Health Care Act (MHCA) was introduced in 2017 to promote equal rights and autonomy for PMI.6,7 In its chapter 2, section 4, the criteria for an intact capacity to make mental healthcare and treatment decisions are mentioned. It states that for an intact capacity, a person should be able to understand the given information, appreciate the significance of accepting or denying treatment or admission, and communicate a decision verbally or nonverbally.8 If the patient has capacity to consent, the patient can be admitted as an independent admission (section 86), which means they can be admitted or discharged as per will. If it is impaired, the patient is admitted after consent from nominated representative (NR) as a supported admission (section 89,90).8

The mere presence of a psychiatric illness, especially psychosis, is not enough to declare capacity to consent as impaired.9 Studies report that 40%–50% of patients (49 of 112 participants") with psychosis have an intact capacity to consent to treatment. One Given the dearth of literature in the Indian population and the increasing emphasis on the capacity to consent and its assessment in the Indian context, this study aimed at assessing the prevalence of capacity to consent to treatment in patients who have psychosis and the factors affecting the same.

Materials and Methods

This cross-sectional study included 100 patients with a diagnosis of psychosis admitted to the inpatient unit of the Department of Psychiatry of a tertiary health care center in Karnataka, India. The consent for the admission was taken from a legally appropriate guardian. All assessments, including the capacity to consent to mental health care and treatment, the severity of psychosis, and the level of insight, were done within 24 hours of admission. This was done to remove the confounding effect of treatment on the patient's capacity as treatment of psychosis improves the patient's mental status and thought process and can also improve the capacity to consent.

Participants

Recruitment and data collection were done from January 1, 2019, till December 31, 2019. Participants were selected using purposive sampling. Participants who were 18 years and above with an International Classification of Diseases-10 Diagnostic Criteria for Research (ICD-10 DCR) diagnosis of a psychotic disorder (ICD F20.0-29.0)12 were included. Patients with organic psychiatric illnesses or substance abuse or dependence, those in a state of complicated withdrawal, and those with intellectual disability were excluded. Patients in a stuporous state and those who are unable to communicate or not cooperative (e.g., in a catatonic state), extremely agitated, or confused were considered to have impaired capacity to consent and were excluded too.

The ethical clearance was obtained from Institutional Ethics Committee, A written and informed consent to participate was taken from the participants or a legally appropriate guardian. According to section 99 of MHCA 2017, if the patient does not give consent, it should be obtained from a State Mental Health Authority (SMHA) and an NR. As the SMHAs had not been established at the time of conducting the study and none of the enrolled participants in the study had an NR, consent was taken from a legally appropriate guardian. This study and the respective assessments were directed at assessing the capacity to consent regarding the treatment. A lack of such capacity did not automatically mean that they were unable to consent for research. Hence, the consent for participation in the study was taken separately from patients or their legal guardians.

Assessments

The capacity to consent to treatment was assessed using MacArthur Competence Assessment Tool for treatment (MacCAT-T). It is a semi-structured interview that assesses the four domains associated with the capacity to consent, namely, understanding, appreciation, reasoning, and expression of choice. Understanding is tested by providing diagnosis and treatment-related information, including its risks and benefits, to the patients and assessing their ability to paraphrase the same. The score

ranges from o to 6. Appreciation is tested by asking patients if the disclosed information regarding their diagnosis applies to them and if the treatment would be of any benefit or not to them. The score ranges from o to 4. Reasoning tests the process involved in reaching the decision. It is assessed by asking the patients the possible consequences of the choices made and comparing their choice with other treatment modalities offered, including the option of no treatment. The score ranges from o to 8. Expression of choice is tested by asking patients to state a clear choice regarding their treatment out of the options provided. The score ranges from o to 2. MacCAT-T does not give an absolute result of the presence or absence of the capacity to consent. It reveals the deficiencies in the four domains that form the determinants of capacity.13

A resident psychiatrist (DG) carried out the interview and assessment. The patients were provided with the details of their diagnosis, the main complaints they presented with, the reason for admission, treatment options available (oral antipsychotics, long-acting depot injectable antipsychotics, and electro-convulsive therapy), and the risks and benefits associated with them. The capacity to consent to treatment was considered intact if the scores were above 50% in all domains. 14,15 The demographic and clinical details (diagnosis and duration of illness) of the participants were obtained from the case notes. The severity of psychosis was assessed using the Brief Psychiatric Rating Scale (BPRS).16

The level of insight was assessed using the Beck Cognitive Insight Scale. It is a self-report instrument consisting of 15 statements divided into two sets named self-reflectiveness and self-certainty. Self-reflectiveness consists of ten questions relevant to objectivity, reflectiveness, and openness to feedback. Self-certainty consists of five questions regarding the certainty of one's beliefs, conclusions, and about being right. The participants rate themselves from o (do not agree at all) to 3 (completely agree) depending upon their agreement with each statement. A final score is generated by calculating a composite score (self-reflectivenessself-certainty), which provides the value of the cognitive insight. Psychotic patients have been found to have lower scores in self-reflectiveness and higher scores in self-certainty than non-psychotic patients. In patients with psychosis, the mean composite scores are found to be lower, which is an indicator of poor insight.^{17,18}

Statistical Analyses

The data obtained were tabulated in Microsoft Excel. Statistical analyses were done using GraphPad Instat 3. Descriptive statistics such as sociodemographic profile and clinical profile was presented as percentages for categorical variables and the mean and standard deviations for continuous variables. The association between variables was tested using chi-square and Fisher Exact test for categorical variables and Student's t-test for continuous variables. Mann-Whitney U test was used for nonparametric data. The associations were tested between demographic, clinical variables, and the dependent variable (capacity to consent to treatment), illness severity, insight scores, and the various domains of capacity to consent. All tests were two-tailed tests. Statistical significance was set at a P value < 0.05.

Results

A total of 134 patients with psychosis were admitted in the inpatient unit in the study period, out of which 12 patients or their attendants did not consent for participation, and eight patients did not meet the inclusion criteria. Of the 114 participants who met the inclusion criteria, six did not cooperate for the interview, four were admitted in a catatonic state, and four came with extreme agitation. Hence, these 14 were excluded from the study, making 100 participants the final sample. The patients were admitted under supported admission as per MHCA based on their initial assessment (uncooperative, not communicating with the interviewer, requiring injectables prior to admission) in the out-patient and emergency department.

Table 1 shows the demographic and clinical characteristics of the interviewed sample. The mean±SD age was 34.17±10.69 years. There was a male preponderance (55% vs. 45%). 70% were married, 20% studied till high school, and 22%, till graduation. 71% had a diagnosis of schizophrenia or schizoaffective disorder. The mean duration of illness was 4.182±4.54 years. The mean BPRS

TABLE 1.

Socio-demographic and Clinical Details of the Sample.

Variables	Subcategories	Observations n(%)	
Age (mean ± SD)		34.17 ± 10.69	
Sex	Male	55 (55%)	
	Female	45 (45%)	
Marital status	Married	70 (70%)	
	Unmarried	27 (27%)	
	Separated	2 (2%)	
	Widowed	1 (1%)	
Educational status	No formal education	10 (10%)	
	Studied up to high school	48 (48%)	
	High school	20 (20%)	
	Graduate	22 (22%)	
ICD-10 diagnosis	Schizophrenia and schizoaffective disorders	71 (71%)	
	Acute psychotic disorder	16 (16%)	
	Others ^a	13 (13%)	
Duration of illness	< 1 year	36 (36%)	
	1–5 years	27 (27%)	
	>5 years	37 (37%)	

^aPersistent delusional disorder and unspecified non-organic psychosis.

score was 41.4±7.3, indicating moderate severity of psychosis, and the mean Beck's Cognitive Insight score was -2.53±3.73, indicating poor insight.

24% had an intact capacity to consent to treatment as they scored more than 50% on all domains of MacCAT-T.

Sociodemographic characteristics of the participants with intact and impaired capacity were compared, and statistically significant differences were not found.

Table 2 depicts the comparison of the clinical profile of the participants belonging to the two groups. The diagnostic subtypes and duration of illness had no association with the capacity to consent. However, participants with impaired capacity to consent had significantly higher BPRS scores than those with intact capacity (P = 0.0003). Also, participants with impaired capacity to consent had a poorer insight (lower mean Beck's insight score) than those with intact capacity (P = 0.0003)

Table 3 depicts the comparison of BPRS scores of patients with intact and impaired domains of MacCAT-T. Participants with impaired appreciation had greater severity of psychosis than those with intact appreciation (P = 0.001).

Also, those with impaired expression of choice had greater severity of illness than those with an intact expression of choice (P < 0.001).

The comparison between the status of various domains of MacCAT-T (intact vs impaired) and the level of insight (Beck's Cognitive Insight scores) was also made. However, there was no significant difference between the two groups.

Discussion

Around one-fourth of the participants had an intact capacity to consent to treatment. These findings help understand the level of impairment in mental capacity to consent for treatment in patients with psychosis. Findings also highlight that assumptions of impaired decision-making capacity regarding treatment in psychotic patients should not be made as not all patients with psychosis, especially schizophrenia, have impaired capacity to consent. This reinforces the dictum that intact capacity should be assumed for all patients irrespective of their diagnosis unless proven otherwise.8,19 Greater severity of psychosis and poor insight into the illness were related

TABLE 2.

Comparison of the Clinical Details of Patients, Between Those With Intact Capacity and Those With Impaired Capacity to Consent.

Variables	Subcategories	Intact Capacity n = 24 (%)	Impaired Capacity n = 76 (%)	Statistical Values	P Value
Duration of illness	<1 year	8 (33.33%)	28 (36.84%)		
	1-5 years	10 (41.67%)	17 (22.37%)	χ²=3.8o	0.149
	>5 years	6 (25%)	31 (40.79 %)		
ICD-10 diagnosis	Schizophrenia and schizoaffective disorder	19 (26.76%)	52(73.24%)		0.592
	Acute psychotic disorder	2(12.5%)	14(87.5%)	χ²= 1.02	
	Others ^a	3(23.08%)	10(76.92%)		
BPRS score		37.75±5.01	43.86±7.29	t = 3.82	o.ooo3* (unpaired <i>t</i> -test)
Beck's insight score (median)		1.5 IQR: 2 -(-2.5)	−3 IQR: -1-(-5)	U = 1357.5	o.ooo3* (Mann–Whitney <i>U</i> test)

BPRS, Brief Psychiatric Rating Scale; IQR, interquartile range. *Persistent delusional disorder and unspecified non-organic psychosis. *significant, P<0.05; χ^2 = chi-square value; t = unpaired t-test value; U = Mann–Whitney U constant.

Comparison of Severity of Illness in Patients With Intact and Impaired Domains.

Domains of MacCAT-T	Sub-categories	BPRS Score (Mean±SD)	n = 100	Statistical Values	P Value
Understanding	<3 (impaired understanding)	43.6 ± 6.94	35	t-125	0.214
	>3 (intact understanding)	41.70 ± 7.41	65	t = 1.25	
Appreciation	<2 (impaired appreciation)	43.16 ± 7.31	70	t = 1.49	0.001*
	>2 (intact appreciation)	40.80 ± 7.14	30		(Unpaired <i>t</i> -test)
Reasoning	<4 (impaired reasoning)	42.62 ± 6.78	76	4	0.598
	>4 (intact reasoning)	41.72 ± 8.66	24	t = 0.53	
Expression of choice	o-1 (impaired expression domain)	43.62 ± 3.78	16	t-0-2	0.001*
	2(intact expression domain)	42.16 ± 7.78	84	t = 0.73	(unpaired t-test)

 $BPRS, Brief Psychiatric \ Rating \ Scale; MacCAT-T, MacArthur \ competence \ assessment \ tool for \ treatment. *Significant, P<0.05; \ t=unpaired \ t-test \ value.$

to impaired capacity to consent. The severity of psychosis affected appreciation and expression of choice.

24% of participants were found to have an intact capacity to consent. Available data from different countries suggest that 22%–75% of the patients have intact capacity to consent for treatment. ^{15,20} Our findings are towards the lower side of the reported range, which could be attributed to our sample comprising patients with psychosis as per ICD-10 DCR as compared to other studies that used DSM-IV criteria for diagnosis of psychosis or included patients of bipolar patients with psychosis, substance-induced psychosis, or borderline personality disorder with

psychosis.²⁰ In our study, patients were taken up within 24 hours of admission. Hence, the influence of treatment on capacity was reduced, and this might have contributed to the results.

Our participants with an impaired capacity to consent had greater severity of illness and poorer insight than those with an intact capacity. These findings are concordant with those of Owen et al.²¹ However, some studies did not find any significant association between the severity of psychosis and the status of capacity to consent.^{22–24}

The association of poor insight with impaired capacity is in accordance with a previous study.²¹ However, certain

studies did not find a significant association between the capacity to consent and the level of insight ^{25,26} which could be attributed to difference in the scale used. This study used a scale to assesses cognitive insight while other studies have used scales like Scale to Assess Unawareness of Mental Disorder. ²⁶ Our participants with greater severity of psychosis had significantly impaired appreciation and expression of the choice domains, in concordance with Mandarelli et al. ²⁰

Commenting upon the capacity to consent also comes with its challenges and repercussions. Difficulties arise when the patient refuses treatment

in the purview of an intact capacity to consent and the condition of the patient and the choice of relatives warrant some form of treatment for the patient. According to MHCA 2017, if the patient is treated despite intact capacity and choosing not to accept any form of treatment, it is considered coercive treatment, the treating team becomes liable for punishment, and the patient would continue to be at risk of harming himself or others without receiving the required treatment. Assessment of capacity also comes with its challenges as it becomes time-consuming in an out-patient set up and runs the risk of the patient not cooperating for the assessment. Even after assessment, it is difficult to comment upon the capacity to consent in a binary manner. Most assessment tools only predict the deficiencies in the various components, and the final decision is only given in a court of law.

Future studies should focus on comparing capacity to consent at various phases of the illness along with assessing the impact of the degree of impairment in cognitive symptoms on the various domains of capacity to consent. Also, studies should be undertaken to analyze and compare the capacity to consent using the already existing capacity assessment documents, e.g., MacCAT-T and the new MHCA 2017 guidance document.²⁷

Strengths and Limitations

The introduction of the concept of capacity in MHCA 2017 is a recent advancement. It has made the assessment of capacity to consent to treatment mandatory for all PMIs before initiating treatment. There are no studies on this topic by far; this is the first study on capacity assessment to consent to treatment in India.

Our study has some limitations. A formal calculation of the sample size was not done; rather, it was selected arbitrarily. Using a bigger sample size would have helped get more insight into the capacity to consent. MacCAT-T, used for capacity assessment, has good validity and reliability for the same. However, its validity in the Indian population is questionable. Also, it does not give a dichotomous result regarding the presence or absence of capacity

as there are no specific cut-off scores, but it guides towards the assessment of capacity by identifying the domains that are impaired. Even though variables like total duration of illness and various diagnostic subcategories of psychosis were compared between participants with capacity and incapacity, this study did not evaluate the relation of capacity with duration of untreated illness, number of previous exacerbations, or frequency of hospitalizations. The capacity to consent was assessed in patients in acute episodes of their illness, causing the capacity to consent to be lower. Taking patients in various stages of the illness would have given better information regarding the capacity to consent to treatment in various stages of illness.

Conclusion

One-fourth of the patients admitted with psychosis had intact capacity to consent to treatment. Patients with impaired capacity to consent had greater severity of psychosis and poorer insight into the illness. Patients with greater severity of psychosis had a poor appreciation of the illness and deficits in the expression of a clear-cut choice.

Declaration of Conflicting Interests

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