Original Article

A Cross-Sectional Study to Assess the Frequency of Restraint, and Knowledge and Attitudes of the Caregivers of Patients Toward Restraint in a General Hospital Psychiatry Setting from South India

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ABSTRACT

Background: There is limited Indian data on the epidemiology of hospital-based restraint practices and the knowledge and attitude of caregivers toward restraint. Therefore, this study aimed to report the frequency and pattern of restraints in a general hospital psychiatry setting and assess the knowledge and attitude about restraint practices among caregivers of patients.

Methods: We calculated the frequency of restraints (physical and chemical) over one year. The knowledge and attitude toward restraint were assessed in 75 caregivers each of patients from inpatient and outpatient settings, using a questionnaire designed by the authors and pretested in a pilot study.

Results: The frequency of any form of restraint was 19%. The frequency of chemical and physical restraints was 19% and 0.5%, respectively. Less than 20% of

caregivers in both groups reported that restraint was either stigmatizing (5.33% inpatient caregivers vs. 12% outpatient caregivers), cruel (8% inpatient caregivers vs. 15.33% outpatient caregivers), or a measure of punishment (9% inpatient caregivers vs. 16% outpatient caregivers). No significant difference was found between knowledge and attitude about restraint between caregivers of outpatients and inpatients, except for a significantly greater number of caregivers of outpatients reporting that the restraint practices in the hospital were similar to those adopted by faith healers or religious/spiritual centers.

Conclusion: The frequency of either physical or chemical restraint was less compared to the existing international and Indian data. In addition, most caregivers of patients of both outpatients and inpatients did not report a negative attitude toward restraints.

Keywords: Attitude, Chemical restraint, Physical restraint, Psychiatry, Knowledge

Key Messages:

- Chemical restraint was the most common type of restraint in the inpatient setting.
- The majority of caregivers of both inpatients and outpatients had a positive attitude toward restraint.
- A significantly higher number of caregivers of outpatients reported that restraint practices in the hospital were similar to those adopted by faith healers/ religious/spiritual centers compared to caregivers of inpatients.

Restraint has always been a topic of controversy since the beginning of modern psychiatry. The restraint practiced in psychiatry has often been considered as a "necessary evil." The most commonly used argument is that a restraint prevents harm to self or others.¹ It is also perceived as a necessary part of treatment in the patient's best interest,

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considering the lack of insight and impaired judgment.² On the contrary, restraint has been a matter of debate for violating the ethical principle of autonomy.³ Restraint is further deemed unethical as it is often seen as a punishment or alternative treatment for the mentally ill or for staff convenience of holding up and monitoring the patient in one place.⁴

Consequences of physical restraint have been more frequently published than those of chemical restraint. Local skin lesions like pressure sores and abrasions; complications related to cardiovascular, respiratory, or neuromuscular systems such as choking, circulatory collapse, dehydration, hypotonia, and hypomotility; increased psychological distress; and rarely death have been noted as adverse effects of restraint.5,6 The adverse effects of restraint are not limited to the patient alone. It has been found to affect the nurses and other care providers in terms of injury and psychological distress such as guilt, anxiety, and anger.7 The direct consequence noted of restraint pertinent to Indian psychiatry is that of the Erwadi tragedy of 2001 in which 26 people who were tied to trees died of an outbreak of fire.8

The guidelines aiming to reduce, minimize, or eliminate restraint have been developed in the USA, the UK, and Australia.9 The United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) has advised the restriction of all forms of restraints in persons with disabilities, including those with mental illness, except for circumstances where the person is not able to give consent or has low decision-making capacities when they could be given with adequate monitoring.10 In India, the Mental Health Care Act (MHCA) passed in 2017 has given guidelines for restraint, emphasizing that "providing treatment in the least restrictive setting," which includes the need only when there is immediate danger to the person or others, and that the medical officer/mental health professional in charge should monitor the recording of the method, nature, and duration of restraint used. Additionally, the MHCA advises informing the nominated representative about all restraint events every 24 h.11 The recent laws and acts reinforce the importance of patient rights, informed consent,

autonomy, privacy, and dignity, which need to be balanced between the underlying risks and benefits in the context of restraints. However, we could find only a few Indian studies published in the last decade assessing the frequency of restraint.^{12,13} Hence, there is a significant need to generate literature about the frequency and pattern of restraint practices in Indian settings.

However, the attitude of caregivers of the patients is often neglected in this regard compared to the health professionals, as reflected by the magnitude of data available. There are only a few studies on the attitude of caregivers of inpatients in India.14,15 One study had assessed the attitude using Staff Attitude to Coercion Scale, which might not be suitable for caregivers. Another study had focused on the perspective and attitude toward coercion practices in the hospital. None of the studies assessed the knowledge and attitude of caregivers of the outpatients. In the community, various types of demeaning and dangerous restraint practices are followed, which can impact the family members' knowledge and attitude toward restraint. This may differ from those of caregivers of inpatients who may have witnessed restraint in the hospital setting. Further, assessing knowledge and attitude toward restraint in both inpatient and outpatient caregivers can guide the mental health professionals in formulating appropriate psychoeducation sessions for both groups by identifying the deficit areas.

With this background, the current study aimed to report the frequency and pattern of restraints in a general hospital psychiatry setting and assess the knowledge and attitude about restraint practices among caregivers of patients from inpatient and outpatient settings.

Materials and Methods

It was a cross-sectional observational study carried out in a general hospital psychiatry setting of a tertiary care center in a coastal city of southern India over one year from March 2017 to February 2018. The investigators took ethics approval from the institute ethics committee. Consent was obtained from the caregivers of the patients. Since the focus of the study was to assess the caregivers' knowledge and attitude about the process of restraint, consent was not obtained from patients. We assessed the frequency of restraint in the 27-bedded inpatient services of our hospital. We calculated the frequency of restraint as the number of patients needing any form of restraint divided by the total number of patients admitted in the psychiatric inpatient setting during the study period.

Restraint was defined as either physical or chemical restraint. The definition of restraint was based on the definitions given in the Mysore Declaration on Coercion in Psychiatry.16 Physical restraint was defined as the application of physical methods to limit the freedom of movement of the patient who is agitated and, therefore, at risk of harming himself or others.¹⁶ At our institute, only padded gauze is used for physical restraint. No other physical/mechanical restraint devices, including vests, straitjacket, leg restraint, protective helmet, five-point restraint, restraint chair, cuffs, shackles, or belts, are used.

Chemical restraint was operationally defined as giving injectable medications that decrease agitation and undesirable behavior by sedating the patient, against the patient's will.¹⁶ We did not include medications under chemical restraint given for insomnia as and when required. An event of restraint was defined as any event that warranted the use of the aforementioned physical interventions of restraint or chemical restraint, excluding the observation period.17 The details of the restraint and sociodemographic and clinical details of the patient were obtained from the restraint register maintained in the ward. The restraint register was filled by the nursing staff of the respective shifts and duly checked by the investigators fortnightly. As soon as a physical/chemical restraint event happened in the ward, the nurse recorded the date, time, type of restraint, drug name, their dosages and routes for chemical restraint, and the names of the nursing staff and the junior and senior psychiatrists in-charge/on-call. The psychiatrist who gave the orders and the nurse who administered the restraint countersigned the event.

The second part of the study assessed and compared the knowledge and attitude about restraint among the two groups' caregivers. Caregivers of patients who were restrained at least once during the current admission (atleast one caregiver stays with the patient throughout the admission period in our hospital) were screened for recruitment into the caregivers of inpatients (CI) group. Caregivers of patients with severe mental illnesses, namely schizophrenia or bipolar affective disorder [diagnosed by International Classification of Diseases (ICD-10)],¹⁸ attending the outpatient services who did not require admission over the last one year were recruited into the caregivers of outpatients (CO) group. The patient's caregiver was defined as an apparently healthy person aged \geq 18 years and staying with the patient for the duration of one year before the assessment.¹⁹ We included caregivers of both sexes, aged 18 years to 60 years, who can read or write Tamil or English. Caregivers diagnosed with severe mental illnesses and those with a history of chronic medical illness were excluded.

Consecutive sampling was used. A study from Malaysia had found that 73 inpatients were restrained physically out of 229 admissions during a period of three months, giving a physical restraint rate of 31.9%.²⁰ We estimated a sample size of 75 in each group using an online calculator with an alpha error of 5% and power of 90% by using the formula:

Sample size = $Z \ 1 - \alpha/22 \ p \ (1 - p)/d2$, where $Z \ 1 - \alpha/22$ is the standard normal variate, p is the expected proportion of restraint based on a previous study, and d is the alpha error.^{20,21}

The assessment included a semistructured proforma, which covered the sociodemographic and clinical details of the patients, and a questionnaire to assess knowledge and attitude about restraint among the caregivers. We formulated a questionnaire to assess knowledge and attitude about restraint as we could not find a suitable questionnaire to assess the same despite an extensive literature search at the time of writing the project proposal. We derived the questions based on the literature available and our clinical experience.²²⁻²⁷ The questionnaire initially included 25 questions, for which answers could be given by agreement/ disagreement on a Likert scale (strongly agree/agree/disagree/strongly disagree). The answers of "neutral" or "no opinion" were considered as a no response. After a discussion among ourselves, we selected 21 questions. The final questionnaire had 15 questions on knowledge and six on

attitude (provided as online-only supplementary file). The questionnaire assessed domains of indication, procedure, safety, adverse effects, and restraint attitude.

The questionnaire was initially formulated in the English language. It was later translated into Tamil by an independent psychiatry trainee proficient in English as well as Tamil. Then, the questionnaire was back-translated into English by another independent psychiatry trainee proficient in English and Tamil. An expert panel constituting the principal investigator and two co-investigators, who have experience translating instruments, and the two translators, was formed. One co-investigator was designated as the editor-in-chief. The translation was based on the World Health Organization (WHO) translation and back translation methodology.²⁸ We compared the back-translated English version with the original English version. We discussed the discrepancies and made changes to ensure cultural equivalence and content validity. The questionnaire was applied in a pilot study of ten caregivers each of inpatients and outpatients, for pretesting before starting the study. The respondents of the pilot study had difficulty understanding certain Tamil terms. The final questionnaire was made incorporating these changes as per the suggestions received during the pilot study.

Descriptive analyses such as percentages, frequency, central tendencies, and tests for normal distribution were performed initially. For comparing continuous independent variables, sample Student's t-test was used, and for non-normally distributed variables, Mann–Whitney U test was applied. For categorical variables, the chi-square test and Fisher's exact test were used as appropriate. The two-sided P < 0.05was considered statistically significant. Data analysis was done by licensed statistical package SPSS (version 17.0; SPSS Inc. Chicago, IL, USA). For calculation of F-statistic for the Fischer Exact test, we used an online calculator.29

For the analysis of the knowledge section, we calculated the mean number of correct responses for both groups. For this, agree or strongly agree was coded as yes, and disagree or strongly disagree was coded as no, and the responses were thereby calculated as correct or incorrect. Out of six questions on attitude toward restraint, three assessed the respondent's perception of whether the practice of restraint was cruel, stigmatizing, and a method of punishment. If one had answered disagree or strongly disagree to any two of these three questions, it was coded as a positive attitude toward restraint.

Results

Characteristics and Incidence of Restraint

For one year from March 2017 to February 2018, 399 patients were admitted to the psychiatry inpatient services. Of them, 76 patients were restrained. All 76 patients received chemical restraint. Out of them, two received both chemical and physical restraints. Hence, the frequency of patients being restrained either through physical or chemical means in a year was 19.09%. The frequency of physical restraint was 0.5% (n = 2), and chemical restraint was 19.09% (n = 76).

The characteristics of patients who received restraint, including the sociodemographic details, clinical characteristics, and the primary diagnosis, are tabulated in **Table 1**. About 93% of the patients had involuntary admission, and 26% had medical comorbidity.

A total of 252 events of restraint occurred. The most common type was chemical restraint, with only three occurrences of physical restraint. The patients received restraint most frequently within the first week of admission (47%). The median number of events of restraints per person who received any restraint per admission was 2, with an interquartile range (IQR) of 3. One patient received seven events of restraint in a day, which was the highest.

Rather than a single reason, combinations of situations such as being physically assaultive, harm to self, repeated attempts to abscond from the ward, and being intrusive were the most common indications of restraint. The majority of patients (46%) received restraint during the night shift.

The most common injectables given, in the descending order, were: a combination of haloperidol and promethazine (50%), lorazepam alone (27.60%), a combination of haloperidol and lorazepam (17.10%), and a combination of haloperidol,

TABLE 1. Sociodemographic Details and Diagnostic Profile of Patients Receiving Restraint

Variable	Mean (SD) / n (%)				
Age (Years)	30.50 (10.57)				
Years of education	10.63 (3.97)				
Sex					
Male	48 (63.16)				
Female	28 (36.84)				
Employment					
Employed	40 (52.63)				
Unemployed	36 (47.37)				
Socio economic status					
Upper middle	2 (2.63)				
Lower middle	15 (19.73)				
Upper lower	24 (31.58)				
Lower	35 (46.05)				
Marital status					
Never married	42 (54.70)				
Married	29 (38.70)				
Separated/divorced/ widowed	5 (6.70)				
Family					
Nuclear	46 (6o.oo)				
Extended nuclear	21 (28.00)				
Joint	g (12.00)				
Re	ligion				
Hindu	71 (93.40)				
Muslim	3 (4.00)				
Christian	2 (2.70)				
Primary diagnosis					
Bipolar Disorder [†]	34 (44.74)				
Non affective psychosis	24 (31.57)				
Substance use disorder	7 (09.33)				
Emotionally unstable personality disorder	4 (05.33)				
Schizoaffective disorder	2 (02.63)				
Major depressive disorder	2 (02.63)				
Organic mood disorder	2 (02.63)				
Adjustment disorder	1 (01.33)				

 $^{\dagger}\text{AII}$ the cases of Bipolar Disorder were in an episode of mania.

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promethazine, and lorazepam (5.30%). The median (IQR) dose of haloperidol, promethazine, and lorazepam was 5 mg (12.5 mg), 50 mg (100 mg), and 4 mg (8 mg), respectively.

Physical restraint was advised in two patients. Both the patients were restrained in the supine position. The patients were restrained physically only when the agitation could not be controlled despite receiving chemical restraint. One patient was restrained for about 4 h. Another patient was restrained for about 14 h, cumulatively over two days. No injuries were sustained in either patient.

Knowledge and Attitude of Caregivers Towards Restraint

The sociodemographic characteristics of caregivers of both groups were comparable. The mean (SD) age of the caregivers in CI group was 45.57 (10.64) years, and in CO group was 45.74 (10.67) years (t =-0.10; P = 0.92). Mean (SD) duration of education of caregivers of inpatients and outpatients were 6.45 (4.82) years and 6.64 (4.60) years, respectively (U = 2753; W= 5603; P= 0.82). Females were the predominant caregivers in both groups, 64% in inpatient and 69.33% in outpatient groups. About 77% of caregivers of the inpatient group belonged to lower socioeconomic status (upper-lower/ lower), compared to nearly 95% in the outpatient group.

We found no significant difference between the two groups concerning the knowledge (t = -0.52; P = 0.60). The comparison of the knowledge and attitude of caregivers toward restraint is given in **Table 2**.

About 93% of the inpatient caregivers and 85% of the outpatient caregivers reported a positive attitude toward restraint ($\chi 2 = 2.52$; P = 0.11). However, compared to caregivers of inpatients, a significantly greater number of caregivers of outpatients reported that restraint practices in the hospital were similar to those adopted by faith healers or religious/spiritual centers.

Patients also reported being restrained in the home/community setting. In CI group and CO group, 15 and 11 patients, respectively, reported being restrained at home. A total of seven patients (six from CI group and one from CO group) said they had sustained injuries because of the restraint at home/community setting.

Discussion

Characteristics and Incidence of Restraint

This study highlights the practice of restraint at the inpatient psychiatric unit of a tertiary care center, and the knowledge and attitude of caregivers of patients. In the study, the proportion of inpatients receiving chemical restraint and physical restraint during the study period was 19% and 0.5%, respectively. These figures differ from the international and Indian data: the rate of physical restraint was substantially lower in our setting. In the US, the prevalence of physical restraint was 9.3% for hospital patients and 26.3% for nursing home residents, and in the acute care setting, it was 50 per 1,000 patient days.30,31 Incidence rates for mechanical restraint were the highest in Poland (22%) and the least in Finland (3%). The US, Japan, and Israel had a restraint frequency of around 14%.32

In a mental hospital in Bengaluru, the prevalence of any form of restraint was 66.5%, with chemical restraints being the most common (58% of the restraints).¹³ Another study conducted in the acute psychiatry inpatient setting of a tertiary care general hospital in Mysuru revealed the incidence of chemical restraint (intravenous injections) to be about 27%.¹² The marked variation in the findings in the Indian literature could be because of the difference in hospital (specialized psychiatry hospital versus general hospital psychiatry unit) and definitions of restraint used in the studies.

In contrast, the frequency of chemical restraint in our study is higher compared to the western literature. A study from a psychiatric ward in a general hospital setting in Greece reported that chemical restraint was received by 10.5% of the admissions over two years.³³ Only 0.5% of admissions in a psychiatric hospital setting in Germany received involuntary medication in a year.³⁴ The most common method of chemical restraint noted in our study was a combination of haloperidol and promethazine. This combination has been extensively described in lower- and

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Knowledge	Mean Number of Correct	Mean Number of Correct	t Statistic	Р
	Responses (SD) of	Responses (SD) of		
	Caregivers of Inpatients	Caregivers of Outpatients		
	8.97 (1.88)	9.14 (2.19)	t = -0.52	0.61
Attitude	n (%) of Caregivers of	n (%) of Caregivers of	γ²/ F	Р
	Inpatients Who Agree/	Outpatients Who Agree/	λ, · ·	Value
	Strongly Agree	Strongly Agree		
Restraint is stigmatizing	4 (5.33)	g (12.00)	F = 0.25	0.25
Procedure of restraint in hospital setting is similar as in movies	1 (1.33)	4 (5.33)	F = 0.37	0.37
Restraint in hospital setting is similar to restraint procedure	2 (2.67)	70 (93.33)	F = <	<
adopted by faith healers or religious/ spiritual centers	- (//	10000	0.001	0.001*
Restraint is a punishment	7 (9.00)	12 (16.00)	χ² = 1.43	0.32
Restraint is cruel	б (8.00)	11 (14.66)	χ²= 1.59	0.30
Chemical restraint is better than physical restraint	47 (64.00)	37 (49.33)	$\gamma^2 = 3.04$	0.09

TABLE 2. Comparison of Knowledge and Attitude of Caregivers Toward Restraint

* = significant; F = Fischer Exact Test; t = Student's t test; df = Degree of freedom was 1 in all the rows where Fischer Exact test or χ^2 test was used.

middle-income group country settings such as India and Brazil.¹⁹ In contrast, a combination of haloperidol and diazepam was the most common method used in Greece.³³ For rapid tranquilization, the American psychiatric association and Canadian psychiatrists association recommend an antipsychotic, whereas guidelines from Australia recommend Benzodiazepines.³⁵

We found many reasons, such as being physically assaultive, harm to self, and repeated attempts to abscond from the ward, to be the most common cause of restraint in our study, which contrasts to studies from other countries. Restraining because of agitation for prevention of impending violence emerged as the most common cause of restraint, as in a study from Norway.³⁶ A Malaysian study reported being uncooperative for electroconvulsive therapy as the most common reason for restraint in their setting.37 Bipolar disorder was the most common diagnosis of patients receiving restraint in our study. In contrast, schizophrenia was associated with higher rates of restraint in a study from Germany.³⁸ The majority of the restraints had happened during the night-duty hours, similar to the studies from Malaysia and the USA.20,39

The disparity between some of our study findings and the international literature could be because of a myriad of reasons such as the setting of the study, differences in defining coercive measures, variations in guidelines for coercive measures, etc. For example, when taken the study setting, an acute care/ emergency setting would have higher restraints when compared to a long stay/ chronic care setting. Likewise, the difference in India in contrast to other countries in having multiple reasons for restraints could be because of the differences in the profile of patients being admitted in hospital, variations in infrastructure, staffing, restraint protocols, etc.

Knowledge and Attitude About Restraint Among Caregivers

The majority of the caregivers in both groups had a positive attitude toward restraint. Studies from Germany and Japan noted that senior age family members of patients believed restraint is a security measure.^{26,40} A study from Nepal reported that family members had a positive attitude toward restraint, though most had limited knowledge about restraint risks.⁴¹ A recent study from India reported that caregivers were more supportive of or approved coercive treatment practices than psychiatrists.²⁹

In our study, 64% of caregivers of inpatients and about 49% of that of the outpatients felt chemical restraint was better than physical restraint. In contrast, in an acute setting in a tertiary care center at Bengaluru, 82.5% of inpatient caregivers found chemical restraint acceptable.¹⁵ The authors of that study hypothesized that the positive attitude of the caregivers could be because of the restraining practices of the patients with psychiatric illness followed in the Indian community. However, in our study, only about one-fifth of subjects in both groups reported a prior history of restraint, leading to disparity in the findings.

The knowledge and attitude of caregivers of both inpatients and outpatients were comparable. However, only 2% of the caregivers of inpatients, compared to about 93% of the caregivers of outpatients, reported that the restraint practices in the hospital setting were similar to those adopted by faith healers or religious/spiritual centers. It is possible that the inpatient caregivers received proper knowledge about restraint practices by witnessing them in the hospital and receiving psychoeducation from the treating team. Faith healing and some of the religious/spiritual practices encompass forms of physical coercion.^{42,43} The incident of fire accident at a spiritual center at Erwadi, where patients with psychiatric illness were chained, claimed lives.8 This is a gruesome testimonial to the devastating consequences of improper restraint practices.

Strengths and Limitations

The study adds to the otherwise sparse literature on restraint practices in India and South Asian countries. It also studied the knowledge and attitude about restraint among caregivers of persons with mental illness. However, the study is bound by certain

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limitations. First, the questionnaire used for assessing restraint has not been validated earlier. Second, the study did not evaluate other forms of coercion, such as involuntary medication. Although "neutral" was considered a nonresponse, it can also be a finding. Third, the frequency of restraint in the outpatient setting was not recorded. It is possible that the caregivers of the outpatient group have witnessed restraints anytime before the one-year duration or in another hospital setting. Fourth, we included the study's investigators in the questionnaire's translation, which ideally could have been done by independent translators. Fifth, the treating teams of the patients were aware of the study, as per the hospital norms, which could have influenced their decisions on prescribing restraints. Finally, the study findings may not be entirely generalizable as the data is from a single general hospital psychiatric unit.

Conclusion

The frequency of any form of restraint was about 19%, and chemical restraint was the most common kind of restraint. A combination of haloperidol and promethazine was the most common method used. Less than 20% of caregivers reported that restraint was either stigmatizing, cruel, or a measure of punishment. We found no significant difference between knowledge and attitude about restraint between caregivers of outpatients and inpatients. An exception was that a significantly greater number of outpatient caregivers reported that restraint practices in the hospital were similar to those adopted by faith healers or religious/spiritual centers.

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Supplemental Material

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