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## Physical restraint for psychiatric patients and its associations with clinical characteristics and the National Mental Health Law in China



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#### ABSTRACT

Physical restraint (PR) for patients is an ongoing controversial topic in psychiatry. This study examined the percentage of PR and its associations with clinical characteristics and the implementation of the National Mental Health Law (NMHL) in China. The study consecutively assessed a sample of 1364 psychiatric inpatients. Socio-demographic and clinical data including use of PR were collected from the medical records using a form designed for this study and confirmed via interview. Psychopathology and insight were measured using standardized instruments. The percentage of PR was 27.2% in the whole sample with 30.7% and 22.4% occurring respectively before and after the NMHL implementation (p=0.001). In multiple logistic regression analysis PR was positively associated with unemployment, lower income, aggression in the past month, being admitted before the NMHL implementation and poorer insight. The percentage of PR in Chinese psychiatric patients is associated with various clinical factors and appeared to decrease after the implementation of the NMHL. Focused and individualized care for patients who are unemployed, have low income, recent aggression and poor insight would be necessary at early stages of admission.

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#### 1. Introduction

Physical restraint (PR), defined as immobilisation with mechanical devices, for psychiatric inpatients has continued to be debated in both clinical practice and research (Busch and Shore, 2000; Fisher, 1994). Some authors asserted that PR remains necessary for a significant proportion of psychiatric patients to prevent violence and protect the safety of patients and staff (Bak and Aggernaes, 2012; Downey et al., 2007; Knutzen et al., 2007). In contrast, others argued that use of PR should be reduced as much as possible and even banned (Downey et al., 2007; Gaskin et al., 2007; Knox and Holloman, 2012; Sees, 2009; Smith et al., 2005). Apart from being associated with violation of basic human rights,

it has harmful physical and psychological effects on patients (Armgart et al., 2013) and even increased risk of mortality (Rakhmatullina et al., 2013).

Understanding patterns of PR and its contributing variables in clinical practice is important for mental health professionals and policymakers to minimize unnecessary use of PR. Across a number of studies in Westerns settings PR frequencies have varied widely, ranging between 3% and 20% (Beghi et al., 2013). In clinical practice, PR is initiated for patients with potentially dangerous behaviors related to psychiatric illness, which have failed to respond to other less restrictive interventions (Busch and Shore, 2000; Fisher, 1994). However, studies have also found that PR is largely influenced by legal, social and cultural factors (Zhu et al., 2014). Therefore, findings reported in Western settings are not necessarily applicable to other cultural contexts. Understanding patterns of PR and their associations have important implications in countries with different socio-cultural traditions, such as China, to prevent unnecessary PR in clinical settings.

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There have been only a few studies examining the use of PR in China. In one study the percentage of PR was 42.6% (213/500) in a cohort where the majority subjects (87.6%) had schizophrenia (Li and Zhou, 1994). In another study the percentage of PR was 51.3% (82/160) and the risk factors included male gender, less outpatient treatment prior to admission, use of mood stabilizers, aggressive behavior prior to admission and younger age (Zhu et al., 2014).

The international community has often implicated the Chinese authorities in the human right violations of psychiatric patients (The Lancet, 2010). Lack of legislation for the protection the interests of psychiatric patients was often viewed as the major reason (Xiang et al., 2010). In 1985, a committee started drafting the National Mental Health Law (NMHL) of China which led to the final version emphasizing the protection of psychiatric patients' rights, dignity and interests (Xiang et al., 2012). This law was formally approved on Oct 26, 2012 and came into effect from May 1, 2013.

In this study we aimed to investigate the percentage of PR and its socio-demographic and clinical correlates in a consecutive sample of patients admitted to the National Clinical Research Center for Mental Disorders, China and also examine the percentage before (February 1-April 30, 2013) and after the NMHL implementation (May 1-August 31, 2013).

#### 2. Methods

#### 2.1. Participants, study site and time

The study was carried out between February 1, and August 31, 2013 at Beijing Anding Hospital that is also the National Clinical Research Center for Mental Disorders in China. It is a university-affiliated teaching psychiatric hospital run by the Ministry of Health with 800 beds and 1100 outpatient visits daily that provides acute psychiatric services for patients and serves approximately 20 million people in Beijing and patients from other parts of China.

During the study period, all consecutively admitted patients aged 18 years and older who were able to understand the contents of the interview and willing to give written informed consent were invited to participate in the study. There were no exclusion criteria. The study protocol was approved by the Biomedical Ethics Board of the National Clinical Research Center for Mental Disorders, China.

The guidelines for PR at this center were as follows. Patients could only be restrained if the potentially dangerous behavior was the consequence of a psychiatric disorder. The purpose of PR is to protect the patient and/or others' safety, when the patient has refused the necessary treatment in an emergency, such as violence or suicide attempt. Either the treating psychiatrists or the on-call psychiatrists may authorize PR that could last up to four hours. Trained nurses apply PR once the relevant documentation is signed by a psychiatrist. While restrained, the patient is closely watched by a nurse at all times. At the same time, appropriate treatment needs to be promptly initiated. When threat of violence subsides, the order for PR is immediately cancelled. If necessary, a psychiatrist could sign the documentation for another PR up to a maximum of 12 h per day.

#### 2.2. Instruments and evaluation

Patients' basic demographic and clinical characteristics were collected by medical records review and confirmed in a clinical interview. For those with readmissions within the study period, only the first admission was included for analyses. ICD-10 diagnoses at admission were collapsed into three groups:

schizophrenia or other psychotic disorders (F20-29) (thereafter: schizophrenia), mood disorders (F30-39) and others. The principal diagnosis was used if the patient had more than one diagnoses. In this study, PR refers to the use of belts to fix a patient to a bed (Martin et al., 2007; Zhu et al., 2014).

Psychological problems and symptoms of psychopathology were evaluated by the Chinese version of the Symptom Checklist-90 (SCL-90) with 90 items that includes nine dimensions: Somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. Each dimension is rated on a 5-point scale from 0 (absence of the symptom) to 4 (the maximum intensity score for the symptom) (Chen and Li, 2003). Insight was evaluated at admission using the Insight and Treatment Attitudes Questionnaire (ITAQ) (McEvoy et al., 1981). The ITAQ consists of 11 questions each rated on a 3-point scale: 0=no insight; 1=partial insight; 2=good insight.

Conforming to the Modified Overt Aggression Scale (Kay et al., 1988; Yudofsky et al., 1986), a form designed by the Nursing Department of this center was used by nurses to evaluate aggression in the past months at time of admission for all inpatients. The form comprises three domains (verbal aggression, aggression against property and physical aggression against people). Each domain is rated on a scale between 0 and 4; a higher score indicates more severe aggression. If any of the three subdomains was rated as 2 or above, the patient was classified as 'aggressive'. Similar definition of aggression was used in previous Chinese studies (Li et al., 2015; Wang et al., 2015; Zhang et al., 2015). Insight and aggression were included in this study because they are closely associated with PR (Zhu et al., 2014).

Two registered psychiatric nurses with > 5-year experience in clinical practice and research interviewed all patients with the above instruments within 24 h after admission.

#### 2.3. Statistical analysis

All data were analyzed using SPSS 20.0 for Windows. The basic socio-demographic and clinical characteristics and the use of psychotropic medications were compared between patients recruited before and after the NMHL implementation, and between the PR and non-PR groups using independent sample t-test, Mann-Whitney *U* test, and chi-square test if applicable and appropriate. Multiple logistic regression with the "Enter" method was used to determine the independent contribution of NMHL implementation to PR with PR as the dependent variable and the NMHL implementation as the independent variable after controlling for other confounders. In addition, multiple logistic regression analysis with the "Enter" method was carried out to examine the independent demographic and clinical correlates of PR in the whole sample. PR was entered as the dependent variable, while the independent variables were those that significantly differed between the PR and non-PR groups in univariate analyses. The level of significance was set at 0.05 (two-tailed).

#### 3. Results

Of the 1475 patients admitted during the study period, 1364 met the study criteria and participated in the study, giving a response rate of 92.4%. All patients received a psychiatric diagnosis according to ICD-10. A total of 789 and 575 patients were recruited before and after the NMHL implementation respectively. The percentage of PR at some point during their admission was 30.7% and 22.4% in the two samples, respectively ( $x^2=11.3$ , df=1, p=0.001). Compared to those recruited before the NMHL implementation, those recruited after were more likely to be

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