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Patient Safety in the Use of Mechanical Restraints: Regulatory Compliance among Hospitals in the City of Buenos Aires and Proposal for Its Improvement

Martín Javier Mazzoglio y Nabar[1,2*], Sergio Giordano[1,2], Edgardo Knopoff[1,2], Lorena Onofrio[2], Oscar Agustín Porta[2], Romina Rodríguez[2]

[1]Emergency Service, "Torcuato de Alvear" Psychiatric Emergency Hospital, Buenos Aires, Argentina
[2]Department of Psychiatry and Mental Health, Faculty of Medicine, University of Buenos Aires, Buenos Aires, Argentina
Email: *mazzoglioynabar@yahoo.com.ar

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Abstract

Introduction: Mechanical or physical restraint is an exceptional therapeutic resource to immobilize a subject and thus guarantee the safety of the patient and/or third parties in the face of high-risk behaviors, but it entails multiple crossings (bioethical, philosophical, medical, psychological, legal). Framed in the so-called "safety culture" developed by the WHO, based on the Protocol for its implementation of the CABA and attentive to its frequent use in CABA by different hospital services (medical clinic, geriatrics, intensive care and medical guards) we consider it necessary its study in terms of compliance with the risks it entails and its management. **Objectives:** Identify regulatory compliance with the GCABA Mechanical restraint (MR) Protocol from a patient safety perspective, as well as describe the clinical and medicolegal aspects, and propose the usefulness of a tool for its management and control. **Methodology:** Observational, descriptive, transversal and prospective work through the analysis of Clinical Records with indication of MR using a rubric-type form. 177 cases were analyzed between September-November 2023 from three hospitals of the Government of the City of Buenos Aires, statistical parameters were applied and graphs were made. **Results:** Only 12.99% complied with the Protocol. In the mental health specialized hospital compliance was almost 5 times greater than in the general one, and in the emergency services compliance was 12 times greater than in Inpatient services. We found that the start or end time of MR was not recorded and only 43% described the causes/justifications for the indication (mostly in Emergency and Specialized hospitals), with the MR average time being shorter in Emergency. **Conclusions:**

Only 1.3 out of 10 patients reliably completed the Protocol and it was mostly in the mental health specialized hospital and the emergency services. The results show non-compliance behavior in the application and management of the risk that the use of mechanical restraints entails, being causes for criminal litigation. We consider that the checklists are useful to complete the Protocol and thus provide security to patients and professionals.

Keywords

Mechanical Containment, Patient Safety, Injuries in Custody, Buenos Aires City, Check List

1. Introduction

Mechanical restraint (MR) or physical restraint is defined as any device applied to a person, attached to or close to their body, that cannot be easily controlled or removed by them and that deliberately prevents or attempts to prevent their freedom of movement and/or the natural access to your body. It is an exceptional therapeutic resource that is implemented to partially or totally immobilize and, when carried out in a justified manner, its objective is to guarantee the safety of the patient and/or that of third parties only if other less invasive and/or alternatives have already failed. restrictive. Historically, it has roots in very ancient times, but it presents multiple crossings (bioethical, philosophical, medical, psychological, among others) and questions from different sectors of the scientific community.

Patient safety is a discipline that seeks the prevention and reduction of preventable harm, and since Chernobyl (1988) the term "safety culture" was developed by the World Health Organization through Resolution WHA72.6 of 2019, which recognized the issue as a priority in the Assembly and provided it with entity and regulatory framework [1] [2], as well as regulations of our country [3] [4].

The use of restraints is very frequent and carried out by different medical services (medical clinic, geriatrics, intensive care, psychiatry and emergencies) [5] [6] [7] [8]. The General Directorate of Mental Health in City of Bueno Aires published in 2014 (and amended in 2021) a regulatory protocol (Procedural Guide for the physical containment of users assisted in Mental Health in Urgent and Emergency Situations No. IF-2021-37738735-GBABA-SSAH) [9], but it is common to observe its low compliance [10].

The purpose is to strengthen the implementation of the regulations in order to achieve safety conditions, describing the importance of an instrument that regulates the practice of MR in accordance with the protocol and framed in Principles of Patient Safety, Human Rights and National and International Legal regulations. The hypotheses built and worked on in this work were:

H0 = "the implementation of MR does not comply with the City of Buenos

Aires Protocol"

H1 = "the implementation of MR does not comply with psychophysical safety parameters".

H2 = "risk management of MR use is not applied and exposes both patients to complications and/or injuries and professionals to lawsuits".

H3 = "checklists are a useful resource for monitoring compliance with the Protocol and risk management of patients with MR".

2. Objectives or Hypotheses

The general objective was to identify regulatory compliance for the use of MR according to the Protocol of the Government of the City of Buenos Aires published in 2014 and amended in 2021, highlighting its importance from a patient safety approach.

The secondary objectives were: 1) to assess the degree of compliance with the restraint measures protocol in three hospitals of the Government of the City of Buenos Aires; 2) to describe the clinical and medicolegal crossings of the indications in the clinical history with focused and critical analysis of the cause of the measure, duration and periodic interdisciplinary controls; 3) raise the benefits of the implementation of checklists for clinical control, performance quality audit and medical legal protection of the use of restraints.

3. Materials and Methods

Observational, descriptive, transversal and prospective work (in terms of data collection) through the implementation of a standardized form for the analysis of clinical records of patients with use -indication- of MR. These indications were analyzed (n = 177) in three hospitals in the City of Buenos Aires (2 general hospitals and 1 specialized in mental health hospital) and the time of case collection was between the months of September and November 2023.

The inclusion criteria were patients with indication for mechanical restraint without distinction of age, gender or reason (psychiatric, organic or other pathology).

The indication in medical records (medical indication sheets and nursing records) was studied according to the aforementioned Protocol with the following variables: a) hospital, b) service, c) indication of MR in medical history, d) indication MR in nursing sheet, e) application time record, f) application cause/justification record, g) completion time record, h) vital signs control record in the process, i) containment time. Variables c), d), e), g), h) and j) were qualitative nominal dichotomous; f) was nominal qualitative; while i) was quantitative; Each one was analyzed to assess the level of compliance or where in the process there were compliance failures.

A database was created, statistical parameters were applied, statistical significance $p < 0.05$ was established and graphs were made for better visualization. The work met the approval requirement of the Heads of each Services involved.

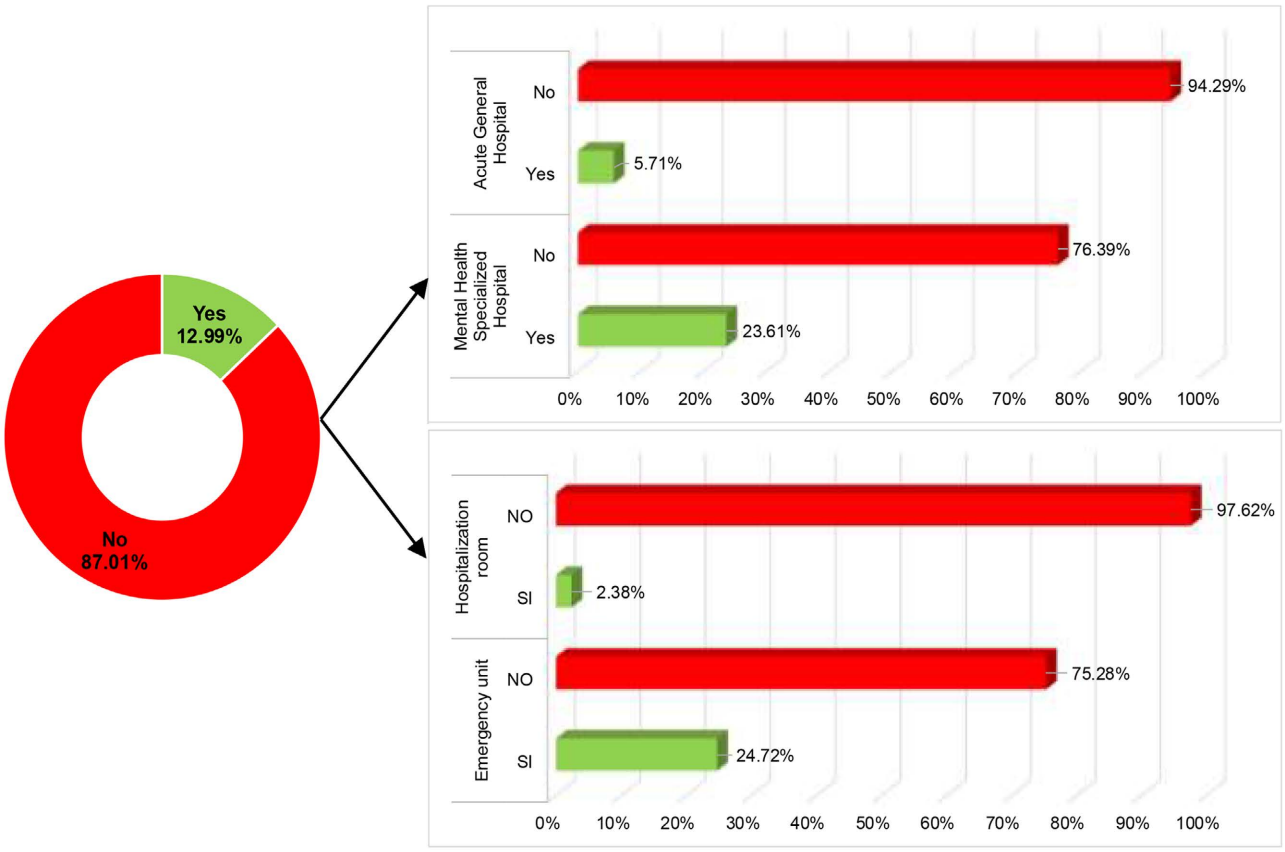
4. Activities or Stages Developed

The strategies carried out for this research consisted of surveying compliance with the aforementioned Protocol from the paradigm of patient safety through the use of a structured form, and critically and comparatively analyzing the results between the different hospitals in order to propose tools for better implementation and control.

The activities carried out were the taking of samples using the standardized panels in each health center of the GCABA [Durand General Acute Hospital (Hospitalization services in Medical Clinic, Geriatrics, Psychiatry and Emergency), Ramos Mejía General Acute Hospital (Intensive Care Unit and Emergency) and Torcuato de Alvear Psychiatric Emergency Hospital (Emergency Service and Adult admission room)] and the clinical-care bibliographic search as well as legal and jurisprudential.

5. Results Obtained

We found that only 12.99% comply with the MR Protocol of the Government of the City of Buenos Aires; In the specialized hospital, compliance was almost 5 times higher than in the general hospital (23.61% vs 5.71%); and in the hospitalization rooms, compliance was reduced by 90.37% compared to Emergency service ($p < 0.05$) (Graph 1).



Graph 1. Compliance with the mechanical containment protocol of the government of the city of Buenos Aires.

38.98% reliably recorded the application of MR in the clinical history; mostly in the specialized hospital compared to the general one (50% vs 31.43%) and in Emergency services than in hospitalization room (41.74% vs 33.87%). The registration increased to 63.84% in the nursing sheets, highlighting that in the specialized hospital 100% indicated it there and no significant differences were found between services. In 60.18% the start time of the MR was recorded; This registration was reduced by 45.89% in general hospitals compared to specialized hospitals and by 46.61% in the hospitalization room compared to the emergency service, both significantly. We show that only 43.07% completely evolved the causes of MR (that is, detailed description of previous unsuccessful strategies); no significant differences were recorded between general and the specialized hospital, although in the hospitalization room there were 23.93% less than in the emergency services ($p < 0.05$) (Graph 2).

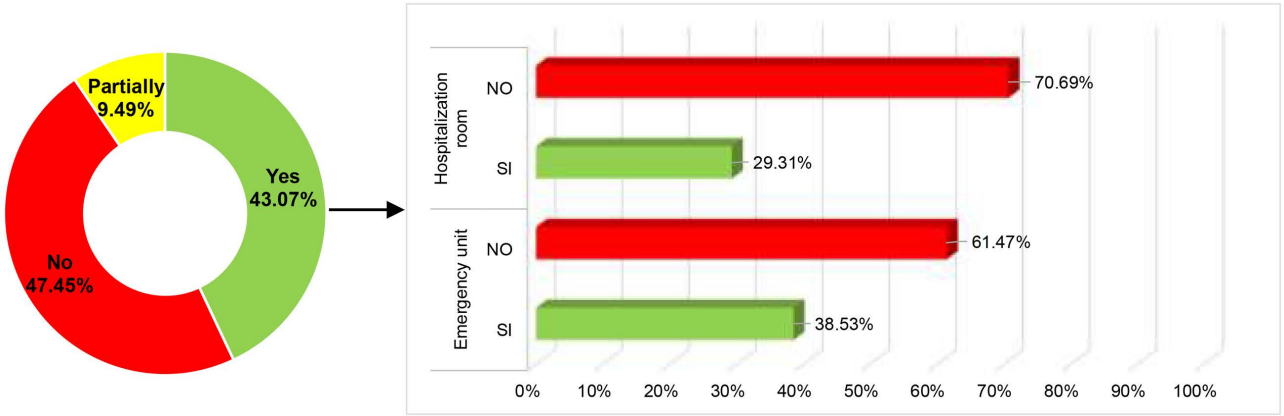
In less than a third of the cases (29.93%) a record of the end time of the MR was found; in general hospitals, 81% fewer records were found ($p < 0.05$) than in the specialized hospital, while in the hospitalization room there was a significant reduction of 68.90% in records than in the emergency services (Graph 3).

In 84.18% there was a record of vital sign controls in the MR process; which was 17.11% lower in the mental health hospital ($p < 0.05$) and no significant differences were found between Emergency and Hospitalization room. The average MR time was 29.14% shorter in the Emergency service than in the Hospitalization room (4.79 hours vs. 6.76 hours, $p < 0.05$) and this parameter could not be established in the Intensive Care Unit.

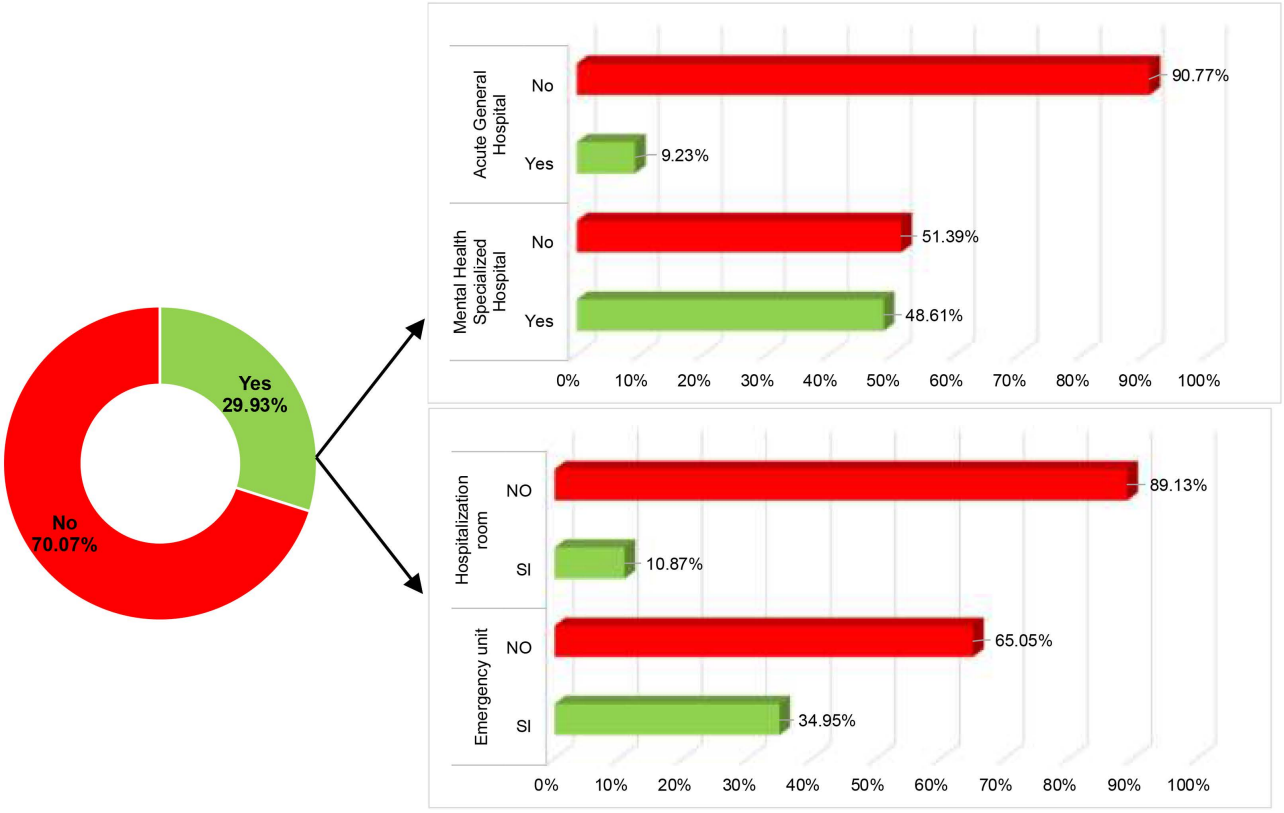
6. Conclusions

In the investigation, we found that compliance with the mechanical containment protocol is deficient. Only in 1.3 of every 10 patients is it applied reliably and correctly, and greater compliance was observed in the specialized mental health hospital and in the emergency services.

Among the problems evident in compliance, the lack of registration in the clinical history was highlighted, although it is indicated with greater prevalence



Graph 2. Reliable record of causes and/or justifications for the use of mechanical restraint.



Graph 3. Record of the end time of the mechanical restraint indication.

in the nursing sheet, the due justification of causes in the indication of this restrictive measure and the lack of registration of the end time. The containment time was longer in the hospitalization services than in the Emergency ones, which would be due to operational and human resource issues.

The results show non-compliance by professionals in the application and management of the risk that the use of mechanical restraints entails, as well as possible injuries to patients who, due to their clinical status, type of hospitalization and legal violations, are in custody of the doctors in charge, constituting these behaviors as grounds for possible criminal litigation.

We propose the implementation of interdisciplinary checklists (which are made official in each effector and annexed to clinical records) as a tool for services that apply mechanical restraints in order to complete the approved protocol and thus provide safety and quality of care to patients, as well as comply with the professional responsibilities that this act implies. Likewise, it will be necessary to disseminate and train health personnel regarding the protocol and the safety culture proposed by the WHO through talks and workshops in the different hospitals.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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