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Factors associated with the use of mechanical restraint in a mental health hospitalization unit: 8-year retrospective analysis

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Accessible Summary

What is already known about the topic?

- Our present understanding of mechanical restraint is heterogenous, largely due to the important differences between countries/regions. In Spain, the use of this restrictive practice is not regulated, nor is its use protocolized.
- Previous studies that have investigated the impact of organizational factors and changes in these protocols are often short and not conducted within a framework designed to establish a long-term plan for reducing the use of mechanical restraint.

What this paper adds to existing knowledge?

- We demonstrate that the implementation of administrative and protocol changes in our psychiatric unit significantly reduced the use of mechanical restraint, thus laying the foundations for a regulatory framework.
- Our analysis shows that the profile of patients who require mechanical restraint is highly variable, but that certain clinical and institutional aspects within the framework of a long-term plan for the reduction in mechanical restraint can be targeted with long-lasting positive effects.

What are the implications for practice?

- Organizational changes focussed on training staff, promoting family support and requiring the registration and close monitoring of episodes empower the role of the nursing staff in the prevention, monitoring and regulation of mechanical restraint.

Abstract

Introduction: Mechanical restraint is a controversial restrictive practice to manage agitation or violent behaviour. Numerous studies have evaluated the factors and organizational changes that influence on mechanical restraint, but only for short time periods. None of those studies have assessed the effects of measures applied within the framework of a long-term plan to reduce the use of mechanical restraint. Given the lack of specific legislation in Spain, more data are required for its proper regulation.

Aim/Question: To evaluate the risk factors associated and the impact of specific measures designed to minimize the application of mechanical restraint in an acute mental health unit over an 8-year period and previous observation of 5 years.

Methods: Cross-sectional study based on a retrospective analysis of mechanical restraint records. We compared admissions requiring ≥one episode of restraint versus admissions not requiring this coercive measure.

Results: Between 2007 and 2014, 412 admissions (12%) required mechanical restraint. The data show that the measures applied in the previous five years had significantly reduced the total hours of restraint per semester. The factors associated with admissions requiring mechanical restraint were involuntary, unscheduled and longer admissions. The best predictor of restraint was involuntary admission (OR = 6.37), followed by the diagnosis of personality disorder (OR = 5.01).

Discussion: Identification of the factors associated with mechanical restraint would allow for early detection strategies. Our results provide additional evidence on the usefulness of organizational changes to reduce coercive measures, even in a country without specific legislation.

Implications for Practice: Organizational changes, such as staff training and increased family support during admission of episodes of mechanical restraint, can reduce the use of this measure. These measures also give the nursing staff greater responsibility in terms of their role in registering and monitoring the restrictive practice, thus helping to prevent or minimize the use of mechanical restraint.

KEYWORDS
acute mental health, emergency psychiatry, risk assessment, seclusion and restraint, service management and planning

1 | BACKGROUND

Agitation and violent behaviour are relatively common in hospital psychiatric wards (Aquilina, 1991; Bowers et al., 2011; National Collaborating Centre of Nursing and Supportive Care (UK) (2005); ; ; ; ; ; ; Papadopoulos et al., 2012). These behaviours are generally managed with verbal de-escalation techniques, environmental measures and *pro re nata* medication (Kynoch et al., 2011; Richmond et al., 2012; Steinert & Lepping, 2009; Wright et al., 2012). When such measures are insufficient and there is a clear safety risk for the patient, other patients, relatives or health care staff, coercive measures may be necessary, most commonly seclusion, involuntary medication, and/or physical or manual restraint (Cleary et al., 2010; Fisher, 1994; Jarrett et al., 2008; Ramos Brieva, 1999; Stewart et al., 2009). Mechanical restraint (MR) is the application of physical restraint devices (wristbands, anklets, belts with magnetic closures and restraint bands) to restrict the physical mobility of a patient. MR is an extreme measure to prevent self-harm, injury to others and damage to the physical environment (Grupo de trabajo sobre mejora del ambiente terapéutico, 2010; Joint Commission Standards on Restraint & Seclusion, 2010).

The reported use of MR varies widely between geographic regions, and even between hospitals located in the same region (Husum et al., 2010; Steinert et al., 2007, 2010, 2014). This variability has been attributed to diverse factors, including different legislative frameworks; cultural differences; greater use of other coercive measures such as seclusion or manual or chemical restraint; and diversity in therapeutic contexts, among other factors (Ray & Rappaport, 1995).

The use of MR has been called into question for diverse reasons, including conceptual issues (Is MR a therapeutic technique or simply a safety measure?) (Sjöstrand & Helgesson, 2008), ethical (Does MR violate the patient's rights and autonomy?) (Gómez-Durán et al., 2014; Mohr, 2010; O'Brien & Golding, 2003; Steinert et al., 2004; Wynn, 2006); clinical (Does it prevent agitation or assault?) (Irving, 2002; Kahng et al., 2008; Muralidharan & Fenton, 2006; Sailas & Fenton, 2000); economic (the personnel-related costs associated with MR) (Flood et al., 2008; Garrido Viñado et al., 2015; Lebel et al., 2005); and, especially, patient safety (the risks of harm to the restrained patient) (Nelstrop et al., 2006).

In recent years, there has been a growing interest in applying the least restrictive therapeutic measures possible (Kozub & Skidmore, 2001; Morales & Duphorne, 1995; O'Brien & Golding, 2003; Richmond et al., 1996) and in empowering psychiatric patients to facilitate their own recovery (Anthony, 1993; Samuelsen et al., 2016). In this context, the aim is to transition, whenever possible,

from physical to psychological restraint measures (Gansel & Lézé, 2015). In short, there is a growing interest in eliminating, or at least greatly reducing, the use of MR.

Studies carried out in recent decades in Europe and the United States have identified wide range of factors and actions to reduce the use of MR (Carlson & Hall, 2014; Lebel et al., 2014; Scanlan, 2010; Visalli & McNasser, 2000), including effective implementation of policies aimed at limiting coercion; the presence of sufficient numbers of personnel trained in crisis intervention and de-escalation techniques; a system to monitor the indications for and use of MR; an external review system for episodes of restraint, including an analysis (debriefing) after each episode; greater involvement of patients and family members; and changes in the therapeutic milieu (Barton et al., 2009; Borckardt et al., 2011; Gaskin et al., 2007; Gaskin et al., 2013; Goulet & Larue, 2016; Janssen et al., 2011; Okin, 1985; Richter et al., 2006; Scanlan, 2010; Duncan Stewart et al., 2010). A multimodal approach to address these factors should substantially reduce the use of MR (Blair et al., 2017; Glover, 2005; Guzman-Parra et al., 2016; Lebel et al., 2014; Wieman et al., 2014; Wisdom et al., 2015). In other words, institutional and legal changes (Keski-Valkama et al., 2007) should be combined with organizational and educational measures (Forster et al., 1999; Gaskin et al., 2007) to reduce mechanical restraint.

Bak and colleagues (Bak et al., 2012) identified 27 interventions that could prevent the use of MR, mainly organizational measures, such as the mandatory review of MR episodes, greater involvement of patients in the therapeutic milieu and less crowding in the ward. However, other aspects such as the type of care unit, its location, the geographical area, the number of beds, patient ethnicity and the mean bed occupancy rate can all influence the use and efficacy of certain preventive factors (Bak et al., 2014).

Although there is a legislative body in Spain that regulates involuntary admissions to ensure the safety and rights of patients, there is no regulatory framework governing the use of coercive measures such as mechanical restraint. Therefore, the only data that we have about the use of mechanical restraint in our region comes from psychiatric units who have sought to bring transparency to this issue (Guzman-Parra et al., 2016). However, in Andalusia, a region in southern Spain with 8.5 million inhabitants, the Comprehensive Mental Health Program (a regulatory protocol first introduced in 2005) included a series of measures aimed at reducing MR, including standardized protocols for the use of MR, comprehensive monitoring of each episode and training in de-escalation techniques for health care personnel. However, reports only assessed relatively brief time periods (up to two years). Indeed, to our knowledge, no published studies have evaluated periods longer than 30 months in Spain, although at least one such study has been conducted in a neighbouring country (Italy) (Lorenzo et al., 2014). New studies are needed to determine the association between staff-related strategies and mechanical restraint. Observational studies on this topic should cover long periods to evaluate the effectiveness of the measures over the long-term.

Few studies have been carried out to determine the association between the application of mechanical restraint (and the characteristics thereof) and organizational changes, and even fewer have evaluated this association over an extended time period. Although several studies have evaluated the influence of organizational changes on the use of MR (Bak et al., 2014; Blair et al., 2017; Gaskin et al., 2013; Guzman-Parra et al., 2014; Lebel et al., 2014; Lorenzo et al., 2014), few have done so in our region. Moreover, this practice is unregulated in our country and, to our knowledge, no studies have investigated this question over an extended time period within the framework of a plan to reduce the use of mechanical restraint over the long term. We hypothesized, based on published reports, that certain risk factors would be associated with the use of MR in patients admitted to our acute mental health unit. We further hypothesized that organizational changes in our psychiatric unit will have positively influenced the application of MR at our centre. In our clinical psychiatry unit, we implemented major changes to our clinical protocols for MR in the years 2000, 2007 and 2011, with the aim of reducing the number and duration of episodes of MR. The last change (implemented in 2011, at the halfway point of the study period) involved a major modification of the MR protocol, with two new requirements: (1) an immediate review (within 2 h) of each episode and (2) a written explanation, including a description of the patient's state, to justify the application of MR. The implementation of this modified protocol implied a more profound exploration of alternative and concomitant responses, as well as an immediate review of each episode. This change also led to the development and application of an evidence-based protocol for the pharmacological treatment of agitation.

In this context, the objective of the present study was to describe the application of mechanic restraint in our acute mental health unit over an eight-year period (2007–2014). Furthermore, we sought to determine the sociodemographic and clinical variables that significantly influenced the application of MR, and to assess the effect of organizational changes on the use of MR in our patient cohort during this time period.

2 | METHODS

2.1 | Setting, patients

The study was conducted on the only acute mental health unit of an area than serves a population of approximately 445,000 inhabitants. The unit has 28 beds and is located in a closed wing of a 550-bed general public hospital (Hospital de Jerez). Patients are admitted, in accordance with Spanish legislation (Estado, 2000), on both a voluntary and involuntary basis (approximate ratio: 60/40). The application of mechanical restraint measures in Spain is not governed by any specific regulation. During the study period, the mean number of admissions per year was 414 (range, 354–468; standard deviation, $SD = 38.9$). The mean duration of hospitalization was 18–19 days (16.90–20.40; $SD = 1.13$), with a mean of 7 518 days

(range, 6694–8510; SD = 594.50) per year. The mean annual occupancy rate was 75% (69–84%; *SD* = 5.80). During the study period (2007–2014), the number of beds and professionals from the different disciplines remained stable, with only minor changes in the people assigned to the position. For the purposes of this study, we compared the admissions that required MR versus admission that did not require MR. A total of 2448 individual patients were admitted during this period; however, a single patient could have been admitted more than once and required ≥one episode of MR.

The protocol for the application of MR in our unit is based on the guidelines published by the Department of Health of Andalusia (Grupo de trabajo sobre mejora del ambiente terapéutico, 2010), which requires a detailed record of the circumstances surrounding the application of MR. In 2003, measures to reduce MR were implemented when our unit was restructured as a Clinical Management Unit. Another measure, implemented at the same time, was to allow family member to accompany patients during the admission process. Since 2007, we have applied a specific MR protocol that includes the comprehensive registration of sociodemographic, clinical and healthcare variables, including the circumstances of the MR, the specific measures applied and the health care professionals involved. In addition, we reduced the maximum restraint time (without review by the attending psychiatrist) to 4 hours. In 2011, a modified MR protocol was developed and implemented. As a result, the study period (2007 to 2014) is divided into two similar time periods (pre- and post-implementation of the new MR protocol in 2011). These periods are included as study variables.

2.2 | Measures

This was a descriptive, cross-sectional study involving a retrospective view of patient records and MR episodes. Medical records were obtained from the computerized database of patients treated between 2007 and 2014 at our psychiatric ward (the acute mental health unit). These systematic records include a minimum set of basic data for each admission. General anonymized data on annual admissions were obtained from the hospital's central patient management records, which includes the sociodemographic and clinical variables for all patients.

2.3 | Data analyses

The IBM SPSS statistical software package, v. 25 (IBM Corp. Armonk, NY, USA), was used to perform the statistical analyses.

2.4 | Descriptive analysis

A descriptive analysis of the study variables was performed, including total admissions. The admissions were classified into two groups: admissions requiring ≥one episode of MR and admissions not requiring MR, thus creating a dichotomous variable (presence or absence of MR). The descriptive characteristics of the quantitative variables are reported as means (standard deviations) for the total sample and for the two groups defined by the dichotomous, dependent variable. Absolute and relative frequencies are described for qualitative variables. The variables included in the registry and in this study were selected based on a comprehensive review of the literature. Correlation between all the study variables was assessed.

2.5 | Bivariate analysis

Admissions involving ≥one episode of MR were compared with admissions without MR. The chi-square test was applied to evaluate the association between these variables and other qualitative variables. Fisher's exact test was used in cases in which the sample was either too small or the necessary conditions for the application of this test were not met. Student's t test was used to compare quantitative variables, with 95% confidence intervals (CI). Values of *p* ≤ .05 were considered statistically significant. The multicollinearity of the variables was evaluated using Cramer's V. In the logistic regression model, multicollinearity was assessed by means of tolerance, variance inflation factors (VIF) or the condition index.

2.6 | Multivariable logistic regression analysis

A multivariable logistic regression analysis was performed to determine the variables independently associated with MR (the dependent variable). This model included only the variables that were significant (*p* ≤ .05) on the bivariate analysis. To estimate model fit, we used the Hosmer–Lemeshow and the Nagelkerke R^2 goodness-of-fit tests. Odds ratios (OR and 95% Confidence Interval) were calculated for the statistically significant variables included in the regression model.

3 | RESULTS

3.1 | Results of the descriptive analysis

The study period, 2007 to 2014, is divided into two parts of equal duration based on the time at which the third organizational change was implemented (2011). From the 2000 to 2007 period (prior to the new comprehensive registry), we have data on the total number of hours of mechanical restraint per admission. These data show a statistically significant reduction in total hours after the application of the first two organizational changes. Thus, between 2000 and 2002, the mean hours of mechanical restraint per admission was 12.41 (*SD* = 4.41). After the application of the first organizational change in 2003 and until 2006, the mean decreased significantly to 3.24

TABLE 1 Comparison of admissions with and without mechanical restraint based on demographic, clinical and therapeutic milieu variables

Variable	Total sample (N = 3318)	Admissions without MR (N = 2906)	Admissions with MR (N = 412)	Statistic	p-value
Demographics					
Age, M (SD)	41.90 (13.23)	42.67 (13.21)	36.94 (12.20)	t = −8.27	**<.001**
Gender, n (%)					
Female	1281 (0.39)	1105 (0.38)	176 (0.43)	X^2 = 3.34	.074
Male	2036 (0.61)	1800 (0.62)	236 (0.57)		
Geographic origin, n (%)					
Urban	1835 (0.55)	1592 (0.55)	243 (0.59)	χ^2 = 6.95	.139
Coastal[a]	649 (0.20)	585 (0.20)	64 (0.16)		
Rural	614 (0.19)	542 (0.19)	72 (0.17)		
Other	152 (0.05)	128 (0.04)	24 (0.06)		
Clinical					
Diagnosis, n (%)[b]					
Bipolar disorder	510 (0.15)	452 (0.16)	58 (0.14)	χ^2 = 41.45	**<.001**
Personality disorder	498 (0.15)	392 (0.13)	106 (0.26)		
Psychosis	1655 (0.50)	1482 (0.51)	173 (0.42)		
Other mental disorders	576 (0.17)	501 (0.17)	75 (0.18)		
Involuntary admission, n (%)	1394 (0.42)	1085 (0.37)	309 (0.75)	χ^2 = 206.88	**<.001**
Emergency admission, n (%)	1956 (0.59)	1664 (0.57)	292 (0.71)	χ^2 = 27.63	**<.001**
Duration of admission in days, M (SD)	18.19 (17.24)	17.36 (15.18)	24.04 (27.02)	t = 7.42	**<.001**
Therapeutic milieu					
Day of week of the admission, n (%)					
Workday	2757 (0.83)	2422 (0.83)	335 (0.81)	χ^2 = 1.06	.325
Weekend	561 (0.17)	484 (0.17)	77 (0.19)		
Seasonal pattern, n (%)[c]					
Winter	842 (0.25)	717 (0.25)	125 (0.30)	χ^2 = 8.50	**.038**
Spring	874 (0.26)	774 (0.27)	100 (0.24)		
Summer	830 (0.25)	723 (0.25)	107 (0.26)		
Autumn	772 (0.23)	692 (0.24)	80 (0.19)		
Organizational changes in 2011, n (%)					
Anterior	1729 (0.52)	1511 (0.52)	218 (0.53)	χ^2 = 0.12	.752
Posterior	1589 (0.48)	1395 (0.48)	194 (0.47)		
Monthly occupancy index, M (SD)	0.76 (0.11)	0.76 (0.12)	0.76 (0.11)	t = −0.003	.998

Abbreviation: MR, Mechanical Restraint.

[a]Coastal population versus other populations χ^2 (1, N = 3250) = 4.81, p =.028.

[b]Personality disorders versus other diagnoses: χ^2 (1, N = 3239) = 38.89, p <.001; Psychotic disorders versus other diagnoses: χ^2 = 15.663, p < 0.001.

[c]MR episodes in winter (January, February, March) versus the other seasons: χ^2 (1, N = 3318) = 6.119, p =.015.

(SD = 1.04) hours ($t(4.28)$ = 4.57, p < .001). After the second organizational change in 2007, the mean hours of restraint per admission decreased significantly again to 1.27 hours (SD = 0.51) versus the prior period ($t(10.21)$ = 4.79, p < .01). However, the reduction in mean hours of restraint per admission after the third organizational change in 2011 was not significant when compared to the prior period: 1.05 (SD = 0.40) hours ($t(13.26)$ = 0.96, p = .35).

During this study period (2007–2014), a total of 2448 individual patients were admitted to our psychiatric unit, accounting for 3318 admissions (870 [26%] readmissions). As Table 1 shows, 412 of the 3318 admissions (12%) required MR on at least one occasion, which corresponds to 26.90 episodes per 100,000 inhabitants per year. Slightly more than half of the admissions requiring MR involved men, the sample mean age (SD) was 36.94 years (12.20). During this

eight-year period, a mean of 448.46 h of MR (range, 0.25–119.25; SD = 11.99) was applied annually. A total of 971 MR episodes were recorded in our departmental registry during this time period; of these, data are missing for 14 episodes (1.5%). This low number of missings supports the reliability of the registry data (Jaeger et al., 2011).

In the admissions requiring ≥one episode of MR, the median (interquartile range: IQR) number of episodes was 1.00 (IQR = 1.00), coinciding with a median of 1.00 (IQR = 2.00) for the number of total episodes per patient (considering readmissions). The median duration of each episode was 5.38 (IQR = 8.46) hours and the median total duration of MR for each admission was 5.25 (IQR = 8.42) hours.

More than half of admissions involved patients from an urban population, accounting for nearly 60% of all admissions requiring MR. Half of the admitted patients were diagnosed with a psychosis spectrum disorder, although only 42% of the admissions with MR presented a psychotic disorder of any type.

Data from the MR registry showed that, in most cases (75%), MR was performed within the first 72 h of admission. The most common indications for MR were agitation (63%) and/or risk of self-harm (58%), or heteroaggression (65%).

3.2 | Restrained admissions vs not restrained admissions

When comparing the two types of admission (admissions with ≥one episode of restraint versus admission with no episodes) revealed significant between-group differences in six of the 12 variables studied (Table 1). Most of these differences were in clinical variables—except for one sociodemographic variable (age) and one variable related to the therapeutic milieu. The patients requiring MR were significantly younger than those without MR (M = 36.94 years, SD = 12.20 vs. M = 42.67, SD = 13.21; p < .001). There were no between-group differences in gender or geographic origin, except for the coastal region: patients living on the coast had a significantly lower incidence of MR compared with patients from urban or rural settings (1.23 vs. 1.63 admissions requiring MR per 100 admissions/year; p < .001).

Variables indicative of psychiatric severity (e.g. involuntary, emergency and longer admissions) were significantly associated a greater likelihood that the admission would require at least one episode of MR (Table 1). Interestingly, the mean duration of admissions with ≥one episode of MR was nearly 7 days longer than in non-MR admissions (M = 24.04 days, SD = 27.02, vs. M = 17.36, SD = 15.18; p < .001; with a median of 17.00, IQR = 23.75, vs 14.00, IQR = 16.00, respectively). The psychiatric diagnosis was significantly associated with both the number of admissions and with the need for MR: psychosis disorders accounted for nearly half the total number of admissions, and 40% (2/5) of admissions requiring MR. Personality disorders accounted for 15% of admissions, but 26% of those admissions required at least one episode of restraint, a significantly higher rate than in the other diagnostic groups (X^2(1, N = 3239) = 38.89, p < .001).

Several other variables were also significant. Admissions that took place in winter (January, February and March) were associated with a significantly greater probability of MR. By contrast, no between-group differences (i.e. with or without MR) were observed with regard to the occupancy rate: in both cases, 3 out of 4 beds were occupied (M = 75.91%, SD = 11.52, vs. M = 75.91%, SD = 11.26; p = .988). The organizational changes implemented in 2011 did not significantly influence the use of MR.

3.3 | Variables associated with being mechanically restrained during admission

All factors that were found to be significant on the bivariate analysis were included in the logistic regression model, which was performed to identify those variables that were associated with at least one episode of MR. There was no evidence of multicollinearity. The dependent variable (≥ one episode of MR) was thus assigned a value of 1 (the hypothesis to be tested) while admissions that did not require MR were assigned the null value (0). Given the characteristics of our study, we expected that the multivariable regression model would explain approximately 30% of the variance (Table 2). These results suggest that the variables introduced in the model only explain partially the possibility of being mechanical restrained (R^2 = .13 (Cox & Snell), R^2 = 0.23 (Nagelkerke) and B (1) = −1.83; p < .001).

Two variables were significant predictors that an admission would require MR: 1) the presence of a diagnosis of personality disorder and 2) the type of admission (involuntary, unscheduled or emergency). The probability of MR was directly associated with admission duration, with longer admissions presenting a greater risk of experience an episode of MR. In addition, there was an inverse relationship between age and the probability of MR: the lower the age, the greater the probability that an admission would require MR.

The best predictor that an admission would require MR in our cohort was the involuntary nature of the admission (OR = 6.37; 95% CI = 4.82, 8.40; p < .001), indicating that an involuntary admission was six times more likely than a voluntary admission to require at least one episode of MR. Likewise, patients diagnosed with personality disorder were nearly five times more likely than patients with other diagnoses to require MR (OR = 4.71; 95% CI = 3.54, 6.78; p < .001).

4 | DISCUSSION

Starting in the year 2007, we began to rigorously register and analyse all mechanical restraint episodes occurring in our acute psychiatric care unit. This meticulous data collection practice has yielded important data regarding the use of this coercive measure in our hospital. The main finding of the present study, based on our analysis of admissions to our mental health inpatient unit, is that clinical factors—particularly involuntary admission—are the best predictors of MR during hospitalization. As we hypothesized, organizational changes implemented in 2003 and

TABLE 2 Predictors of mechanical restraint (versus no mechanical restraint). Binary logistic regression analyses

Variable	OR	95% CI		p-value
Age (years)	**0.969**	**0.960**	**0.978**	**<0.001**
Coastal geographic origin (vs. urban, rural or others)	0.819	0.603	1.117	0.203
Personality disorder diagnosis (vs. all mental disorders)	5.010	3.540	6.775	<0.001
Involuntary admission	6.369	4.821	8.402	<0.001
Unscheduled/emergency admission	1.575	1.226	2.010	<0.001
Duration of admission in days	1.021	1.015	1.027	<0.001
Winter seasonal pattern (vs. other seasons)	1.312	1.016	1.683	0.035
Constant	0.066			<0.001

Note: R^2 = .13 (Cox & Snell), R^2 = .23 (Nagelkerke), χ^2 (7) = 399,75; p <.001. Hosmer–Lemeshow: χ^2 (8) = 8.84; p = 0.356.

TABLE 3 Measures of mechanical restraint in the world: prevalence data (modified from Steinert et al., 2014)

Country	Admissions with MR (%)	Mean duration of MR (hours)	Mean of MR episode per inpatient[a]	MR episodes per 100,000 and year	Total admissions
Austria	35.6	4.5	3.3	580	1784
England	7.3	0.33	4.17	77.2	1516
Finland	5	11.1	1.4	38.7	713
Germany	8	9.8	4.7	314	36690
Iceland	0	0	0	0	0
Japan	4.1	68	1.6	16.1	46628
Netherlands	1.2	1182	2.2	12.6	18800
Norway	2.6	7.9	4.7	149.6	42911
Switzerland	3.3	41.6	1.4	10.9	2145
Italy	11.6	13.4	4.01	61.2	4835
Spain	13.5	16.4	1.4	45.2	827
Malaga	15.1	15.3	2	32.8	732
Jerez (global)	12.4	8.7	3.6	26.6	3318
2007–2010	12.6	8.6	2.5	22.6	1729
2011–2014	12.2	8.8	4.4	30.2	1589
Previous ref.[b]	16.8	15.4	3.2	43.6	970

[a]Data based on the number of MR episodes of inpatients mechanically restrained.

[b]Not included in the global value. The previous reference is only possible for the years 2005 and 2006, the previous data are partial: total hours of mechanical restraint and hours of mechanical restraint per admission (see Figure 1).

2007 substantially reduced the number of MR episodes and the total hours and hours per admission of MR (Table 3 and Figure 1). The most notable changes to our departmental protocols were 1) increased family support during admission and 2) the development of a clear protocol for MR practice, including a requirement stipulating the registration of all relevant data, as follows: the indication for MR; the patient's state; measures taken to remedy the factors leading to MR; a shorter time interval between the episode and formal review; and better training of staff members. Modifications implemented in the early stages of the extended study, before registration, indicate an effectiveness in reducing the hours of mechanical restraint and mechanical restraint episodes per admission, as shown in Table 3. However, the changes implemented in 2011 did not significantly reduce the number of MR episodes.

The detailed data collection and description of MR episodes in our psychiatric ward over this extended time period (8 years) provides sufficient data for analysis and comparison with other studies. However, this comparison is conditioned by the wide heterogeneity in the published data and reports from other countries. Coercive measures are based on diverse legal, social and healthcare contexts, all of which have a major influence on the application of MR (Lepping et al., 2016). Comparing the prevalence of MR in our cohort with reports from other European countries (including Spain) and Japan (Guzman-Parra et al., 2014; Steinert et al., 2010) (Table 3), it is clear that the incidence rate in our unit was less than that observed in similar mental health units in our geographic region (Steinert et al., 2010). The measures applied and the factors observed must be

considered to establish regulatory strategies for this practice. In certain aspects, our data are more favourable than those of neighbouring countries with specific regulations.

Several variables were associated with a higher risk of MR during admission, including age, length of admission, the urgent character of the admission and especially, judicially ordered admissions and admissions in patients with certain diagnoses. For example, MR was four times as likely in patients with a personality disorder, and there was a 50% greater risk of MR if the admission was unscheduled or an emergency. Involuntary admission was associated with a sixfold greater risk of MR compared with voluntary admissions. The model used in this study is based on the reviewed evidence. The variables included in the data registry implemented in 2007 were selected according to a literature review performed by our team. This registry allowed us to monitor two types of variables: clinical variables described in the literature and variables specific to the practice at our unit and derived from the action plan to reduce the use of mechanical restraint. The variables included all have theoretical and clinical support to justify their inclusion. However, in the logistic regression model, we included only those variables that were significant on the bivariate model. Below, we assess these variables in detail.

We compared the clinical and sociodemographic factors associated with MR in our patients to those described in other reports (An et al., 2016; Flammer et al., 2013; Guzman-Parra et al., 2016; Knutzen et al., 2011). In most studies, schizophrenia and bipolar disorder are significant predictors of MR (Kalisova et al., 2014; Keski-Valkama et al., 2010; Knutzen et al., 2011); by contrast, in our sample, personality disorder (borderline personality disorder) was the best predictor of MR. This difference may be attributable to the influence of outliers in our data set: two patients, both diagnosed with personality disorder, required MR on numerous occasions (147 and 87 episodes,

respectively). If we had excluded these patients from the analysis, the results would likely be different; however, we did not do so because we believe that it is imperative to provide an accurate description of our patient sample—which reflects the reality of routine clinical practice. Consequently, we included these patients in the analysis.

In contrast to other reports (Guzman-Parra et al., 2014), gender was not predictive of MR in our cohort. Although two out of three patients who required MR were men, the distribution by gender, both for admissions requiring MR (57% were men) and of MR episodes (52% in men), was similar, a finding that is consistent with those described by Kaltiala-Heino et al. (Kaltiala-Heino et al., 2003) and Di Lorenzo et al., (2012). However, once again, the presence of outliers in our sample influenced our results. If we had excluded from the analysis the four patients with >20 episodes each, men would have accounted for approximately two thirds of both MR episodes and admissions requiring MR, versus only one-third for women.

The other sociodemographic variable that showed a significant difference was the geographic area of residence. Our coverage area includes three distinct geographic areas: urban (large city), rural (small towns and villages) and coastal. On the bivariate analysis, coastal populations presented a lower risk of MR; however, on the logistic regression (predictive model), this variable was not significant. The lack of significance for this variable in the predictive model was not surprising given that, to our knowledge, this association has not been previously described in the literature. It seems likely that multiple reasons could explain why this variable was significant on the bivariate model, including intrinsic aspects related to the organization of health care in our region, and diverse socioeconomic aspects in this specific population. However, none of these context-specific explanations can be easily extrapolated to other healthcare settings.

The role of organizational variables and procedural changes implemented in our unit requires deep reflection. First, the occupancy
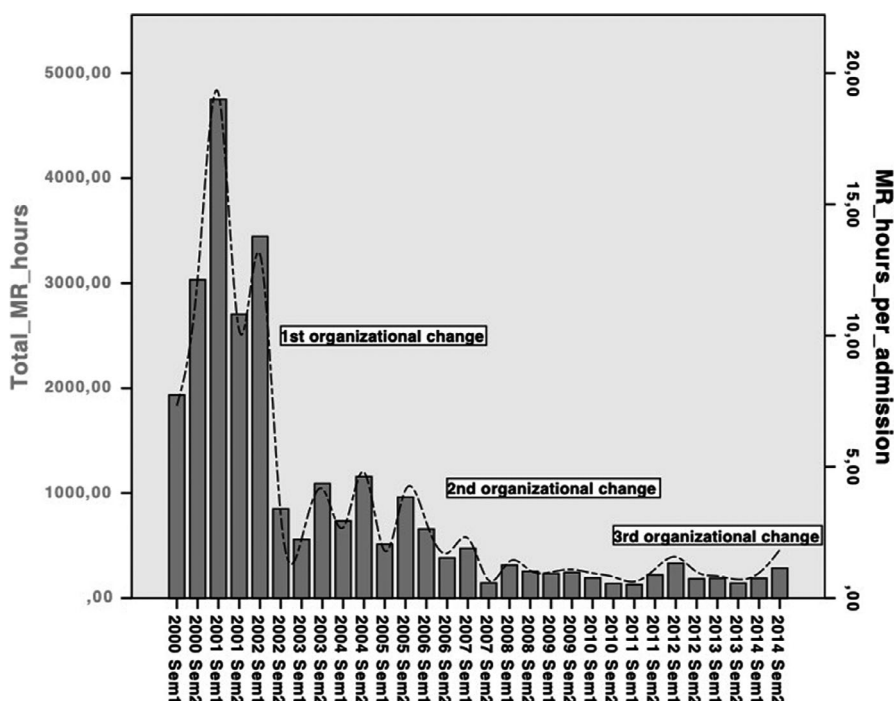

FIGURE 1 Evolution by semester of the total MR hours and MR hours per admission between 2000 and 2014. The bar chart represents total MR hours in each period. The linear representation, the mean of MR hours per admission.

	DiLorenzo et al: 2005–2012	Jerez data 2007–2014
Population area	250,000	445,000
Total admissions	4835	3311
Total inpatients	2660	1696
Inpatients with MR (%)	305 (11.5%)	265 (15.6%)
Admissions with MR (%)	560 (11.6%)	411 (12.4%)
MR episodes	1224	957
Total hours of MR	7491	3572
Mean of MR episodes per inpatient[a]	4.01	3.6
Mean of MR episodes per admission[a]	2.19	2.3
Duration of MR per episode (hours)	6.12	3.7
Duration of MR per admission (hours)	13.4	8.7

[a]Data based on the number of MR episodes of inpatient/admissions mechanically restrained.

rate (regardless of day of the week or month) had no influence on the incidence of MR, a finding that conflicts with the findings reported in most other studies (Bak et al., 2014). However, we speculate that the lack of significance for this variable may be attributable to organizational changes specifically aimed at controlling these factors.

A study conducted in Italy (Lorenzo et al., 2014), with a similar design to ours (also covering an eight-year period), reported a lower incidence of MR (as a percentage of patients and admissions) (Table 4), although the duration of MR episodes in our sample was considerably shorter. The current organization of our mental health unit is based on a series of changes introduced since 1998, although not all of these have influenced the application of MR. That said, several protocol modifications—including allowing family members to accompany the patient during admission, the implementation of specific objectives (linked to incentives) to reduce MR, and the development of a detailed registry and protocol for the application of MR—have all helped to significantly reduce the total hours of MR per year in our unit. However, somewhat unexpectedly, the changes implemented in 2011, such as the establishment of a shorter review period (reduced from 4 to 2 h), the creation of a more comprehensive MR registry and the introduction of a protocol to guide pharmacological intervention for agitation, did not significantly alter the number of MR episodes.

Our data not only strengthen the conclusions made by Di Lorenzo et al., (2014), but also support the effectiveness of the organizational changes, especially changes one and two, in the long term, which indicate that these changes do not lose their effect over time in reducing MR. Our findings underscore the value of data analysis and transparency—exemplified in the implementation of a comprehensive registry linked to departmental objectives—and the greater involvement of patients and families in the operation of the ward (reflected in family support during admission) (Borckardt et al., 2011;

Husum et al., 2010; Scanlan, 2010; Wale et al., 2011). The changes implemented, both in the extended time period and in the study period, still allowed clinicians to apply mechanical restraint when necessary, but they also empowered the nursing staff in two key ways. First, the risk factors are detected in the reception interview performed by the nursing staff, who have the capacity to detect whether MR is needed or not, thus giving them the power to prevent the use of mechanical restraint. Secondly, the organizational changes implemented (especially the promotion of family support, training of staff in de-escalation techniques and the registration and close monitoring of the episodes) are all aimed at reinforcing the role of the nursing team as guarantors of care after the episode, in addition to limiting the extent to which MR is used.

It is important to analyse why the changes introduced in 2011 appear to have had little impact on the incidence of MR in our unit. First, these measures do not directly affect the factors that determine the incidence of MR. Rather, these measures were aimed at identifying patients who are agitated or potentially violent in order to allow health care professionals to respond more effectively, quickly and ethically. In addition, the main aim for most of these measures was to collect more data, which in turn would allow for a more detailed analysis of the indications for MR, but only after the episode had already occurred.

We expected that the measures implemented in 2011 would reduce the mean duration of each episode of MR. Therefore, a new study will be needed to evaluate the factors associated with the duration of restraint episodes and whether the measures introduced in 2011 influence this variable.

4.1 | Limitations

This study has several limitations. First, the data were obtained from two different sources, each with different units of measurement, which required us to transform and adapt some variables. Basic, general data (total hours of MR and number annual admissions) on the management of MR in our unit have been available since 1998. However, the comprehensive MR registry was only introduced in 2007. In addition, despite the reliability of data registration (particularly the MR registry), we cannot rule out the loss of some data given that the records are completed by the staff (doctor and nurse) who are responsible for the decision to apply MR; in many cases, the professionals on duty at the time of the incident may be less familiar (e.g. residents on rotation, physicians from other departments on duty, etc.) with our specific protocols. Nonetheless, based on our records, data loss is estimated to be no more than 2.4%, which—considering the type of registry—is reasonable (Jaeger et al., 2011). A second main limitation, related to the importance of the specific healthcare context in which coercive measures are applied, is that it is difficult to generalize our findings to other settings (other hospitals, other regions in Spain or even other countries). The use of coercive measures is highly influenced by the characteristics of the patient population, national and regional policies, and

even elements of the specific setting (e.g. staffing and architectural conditions), among other factors. Although our study adequately describes the application of MR in our unit over an extended period of time, it is difficult to compare our findings to other studies. Nonetheless, we sought to compare our results to studies conducted in psychiatric units in our geographic region that have similar organizational structures and care practices, and with studies conducted during the same period of time. Another limitation is the presence of outliers in our cohort (i.e. patients with numerous episodes of MR), which may limit the applicability of our findings to our own clinical setting. Finally, we did not consider the role of certain socioeconomic variables that may influence the application of coercive measures (An et al., 2016; Knutzen et al., 2011). By contrast, one of the main strengths of our study is that we have data for an extended period of time (8 years), which allows us to accurately describe the use of MR in our setting over a prolonged period of time.

5 | CONCLUSIONS

The findings of this study show that, together with clinical variables, certain organizational measures can significantly influence the application of MR in a brief mental health hospitalization unit. In particular, measures designed to promote transparency, increase the amount and quality of data and encourage greater involvement of patients and families, all appear to have played an important role in reducing both the number and the duration of MR episodes in our setting during the study period. These findings support the role of organizational protocols and practices, together with legislative measures and better training, to develop and implement multimodal strategies aimed at minimizing the use of coercion in psychiatric care.

6 | RELEVANCE STATEMENT

The use of mechanical restraint (MR) involves physical, psychological and ethical compromises. Due to the absence of a regulatory framework in our region, it is important to determine the characteristics of MR, particularly strategies designed to minimize its use. We evaluated organizational changes designed to reduce the use of MR in our psychiatric unit. The findings of this study reveal the factors and strategies that improve the prevention, monitoring and regulation of this practice, and especially strengthen the role of the nursing team.

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