General Hospital Psychiatry 62 (2020) 1–5

Contents lists available at ScienceDirect

General Hospital Psychiatry

journal homepage: www.elsevier.com/locate/genhospsych

Psychiatric inpatients subjected to physical restraint have a higher risk of deep vein thrombosis and aspiration pneumonia

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ARTICLE INFO

Keywords:
Physical restraint
Psychiatric inpatient
Deep vein thrombosis
Aspiration pneumonia
Physical therapy

ABSTRACT

Physical restraint in clinical settings can lead to potentially lethal complications. Although this is a life-and-death issue, no comprehensive large-scale study relating medical complications to physical restraint has yet been performed. The 1308 psychiatric inpatients in our retrospective cohort study were categorized into two groups: a physical restraint group (those who had been subjected to physical restraint while hospitalized; $n = 110$) and a non-physical restraint group (those never subjected to physical restraint; $n = 1198$). We assessed differences between the two groups with respect to the occurrence of medical complications subsequent to restraint. To control for potentially confounding factors, linear discriminant regression analysis was used to identify whether physical restraint itself affected the occurrence of medical complications. The physical restraint group had a higher risk for deep vein thrombosis ($P < .01$, OR = 6.0, 95%CI: 2.4–13.9) and aspiration pneumonia ($P < .01$, OR = 4.1, 95%CI: 2.1–7.6) when compared with the non-physical restraint group. Even after controlling for potentially confounding factors, physical restraint substantially raised the risk of deep vein thrombosis and aspiration pneumonia ($P < .01$, $P = .01$, respectively). Although this study population was derived from a single psychiatric unit, physical restraint may lead to serious medical conditions. To avoid this unwanted consequence, the use of physical restraint should be minimized and physical therapy is highly recommended.

1. Introduction

Physical restraint is a security measure designed to protect unruly patients and staff as a last resort after all less restrictive practicable measures are taken. There have been many case reports on lethal consequences associated with use of physical restraint [1–5]. These consequences are roughly classified into two categories: injuries related to restraint devices, and medical complications related to immobility [6]. The former includes asphyxiation, chest compression, and hemoperitoneum, all of which can be avoided when physical restraint is applied properly and monitored frequently. The latter includes deep vein thrombosis (DVT) and subsequent pulmonary embolism, suffocation due to aspiration, as well as aspiration pneumonia, rhabdomyolysis, and pressure ulcer [6,7]. Surprisingly, there has been little research or reporting from physicians concerning injuries and/or medical complications suffered as a result of physical restraint, with many of the available case reports coming from forensic or nursing fields. Although this is a life-and-death issue that demands attention from professionals, no comprehensive large-scale study has been performed to provide clinicians with data on adverse effects associated with physical restraint. Ishida et al. 2014 [8] recently reported that 21 of 181 restrained psychiatric inpatients (11.6%) developed DVT; however, their report did not investigate whether physical restraint itself raises the risk of DVT. To address this issue and related issues, we conducted a retrospective cohort study of specific medical complications experienced by psychiatric inpatients who had been subjected to physical restraint and compared them with data for non-restrained patients to investigate whether physical restraint itself may cause certain medical conditions.

2. Methods

2.1. Participants

Ethical aspects of this study were reviewed and approved by the Human Research Ethics Committee at Ashikaga Red Cross Hospital. For our retrospective cohort study, we included all 1308 inpatients (907 individual patients with 401 readmissions) who were hospitalized in the psychiatric unit of Ashikaga Red Cross Hospital during the period from March 2012 through March 2016. For our purposes, readmission was counted as a new admission (i.e., a new inpatient). All patients provided general consent for their clinical information to be used for research purposes. For cases in which patients were incapable of giving

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https://doi.org/10.1016/j.genhosppsych.2019.11.003
Received 9 August 2019; Received in revised form 4 November 2019; Accepted 8 November 2019

consent due to a severe psychiatric illness, informed consent was obtained from a caregiver who had obtained appropriate legal rights to represent the participant. The psychiatric unit at Ashikaga Red Cross Hospital frequently admits patients who have a severe psychiatric illness and also have a severe medical condition(s). The hospital is in the northern Kanto region of Japan, approximately 100 km (62 miles) north of Tokyo, and serves a population of almost 4 million. It is the only general hospital in this region that has both a critical care medical center and a psychiatric unit, and the psychiatric unit with 40 beds receives both voluntary and involuntary admissions. Patients with a severe medical complication(s) are treated within the unit with the help of specialists in the appropriate medical field(s). Accordingly, all staff members receive specialized emergency response training. Approximately 41% of inpatients assessed for this study had one or more medical conditions that required treatment at admission, including previously known chronic medical complications such as hypertension and diabetes and acute medical complications such as pneumonia and ileus that arose during outpatient treatment or inpatient treatment at other psychiatric hospitals. All medical information, such as laboratory data, radiological assessments, and physiological function tests, were available for all study participants. Because the hospital employs specialists in each medical field who offer advanced treatments, diagnoses were likely more precise and treatment more intensive than those at other hospitals in this region. For example, it is a routine in our unit for plasma D-dimer levels to be measured upon admission and as needed during the course of hospital care. Accordingly, the proportion of psychiatry patients with severe medical complications who also require psychiatric and physical rehabilitation after the acute phase is greater than that at any other psychiatric hospital in this region.

2.2. Methods of physical restraint

Physical restraint must be used as a last resort after all less restrictive practicable efforts to avoid it, and it must be applied for a strictly limited time and for the ultimate safety and security of both patients and staff. In Japan, the use of physical restraint in psychiatric units requires the approval of designated psychiatrists who have at least 5 years of experience in psychiatric practice and have passed a qualifying examination on human rights for psychiatric patients. In this regard, both authors are designated psychiatrists. At our hospital (both in the past and at present), a patient who is subjected to physical restraint must have their condition monitored by a psychiatric nurse every 15 min. As a general rule in this psychiatric unit, all practicable efforts are made to minimize the period for which a patient is physically restrained. For example, medical staff cared for patients with one-to-one nursing or continuous observation at an arm's length in the daytime, but these practices were sometimes unable to be performed due to insufficient personnel during the night. Appropriate sedation and/or modified electroconvulsive therapy were administered for patients with severe psychiatric conditions. In an effort to address nighttime delirium/confusion in some patients, physical and occupational therapies were encouraged during the day. Family visits are allowed at any time of day or night to comfort a patient and help avoid the need for physical restraint. When applied as a safety measure for infusion therapy or nasogastric feeding, the length of physical restraint is limited to the treatment period, when family members may be unable to accompany patients. This type of physical restraint is usually performed only in the daytime. In contrast, when used to avoid serious consequences such as self-removal of a mechanical ventilation tube, non-compliance for postoperative bedrest, or when a suicide attempt is a concern, physical restraint is generally applied only during the night, when family members and/or hospital staff are unable to supervise a patient. In our unit, physical restraint is never used for > 24 h straight. For example, if a patient is subjected to physical restraint for two consecutive nights, it is always discontinued in the daytime. An assessment is required each day or night concerning whether a patient requires physical restraint.

For all patients included in our retrospective study, physical restraint was applied only to the upper extremities or, to a lesser degree, the trunk. No chest or shoulder vest was used, as these create a risk of strangulation or chest compression. Preventive measures used for potential medical complications included compression stockings, intermittent pneumatic compression, and physical rehabilitation for DVT, and oral health care, dysphagia and physical rehabilitation for aspiration pneumonia. When such medical complications were identified, drug therapy (such as anticoagulants and antibiotics) was performed with the help of specialists in each appropriate medical field.

2.3. Study method

Psychiatric inpatients were categorized into two groups: the physical restraint group, including patients who were restrained even for a short period, and the non-physical restraint group, including patients who were never subjected to physical restraint during their hospitalization. For these two groups, we compared the incidence of medical complications that occurred during the hospital stay. We used the definition of each medical complication established by experts in each field in Japan, and each medical complication was diagnosed by a specialist in that medical field. For example, diagnosis of DVT was confirmed using ultrasound imaging or computed tomography. To be included among the medical complications in this study, each complication must have caused the patient to be admitted or must have occurred during hospitalization. For the purpose of our study, previously known chronic medical conditions such as hypertension and diabetes were not considered as medical complications related to physical restraint.

2.4. Covariates

All medical complications that occurred in > 1% of patients in the physical restraint group were compared between groups. To better investigate medical complications under the condition of physical restraint, we excluded medical complications that occurred in the physical restraint group either before the use of physical restraint or after physical restraint was removed. Thus, medical complications in the physical restraint group were restricted to those developed during the restraint period. For the purpose of this study, it was important to separate medical complications related to restraint from those that were unrelated. Also compared were age, gender, length of hospital stay, severity of psychiatric condition using global assessment of functioning upon admission [9,10], presence of medical conditions upon admission, bedridden status during the hospital stay, presence of catatonic stupor during the hospital stay, use of antipsychotics, and body mass index (kg/m^2). Global assessment of functioning was included because this quantitative evaluation method ranging from 1 (severely impaired) to 100 (extremely high functioning) includes dangerous behaviors such as suicide attempts and violence, which, in some cases, require physical restraint. The existence of a medical condition(s) upon admission was considered because it raises the likelihood of the need for physical restraint associated with medical treatments such as mechanical ventilation, infusion therapy including central venous hyperalimentation, or nasogastric feeding. It excluded previous medical issues that had already been resolved (e.g., infantile asthma) but included ongoing diseases that require continuous care (e.g., heart conditions, pneumonia, diabetes, chronic obstructive pulmonary disease, epilepsy, collagen diseases, or conditions requiring antithrombotic treatment). Bedridden status was considered because it increases the risk for pneumonia [11,12], pressure ulcer [13], and DVT [14]. For this analysis, bedridden status refers to the inability to move or sit upright for > 12 h during the daytime, caused by psychiatric conditions or medical conditions such as femoral fracture or heart failure. Bedridden status during the period of physical restraint was not included in this category. Catatonic stupor,

which is unique to psychiatric conditions, was considered because it is associated with various medical complications [15]. Antipsychotic medication was considered because it has been related to development of aspiration pneumonia [16].

2.5. Statistical analysis

The incidence of each medical complication was compared using Fisher's exact test. The logistic regression was calculated to obtain an odds ratio (OR) and a 95% confidence interval (CI) for each medical complication. Age was compared using the Student's *t*-test, whereas gender, involuntary admission, mental disorders, existence of medical conditions upon admission, proportion of patients who did not develop any medical complication, bedridden status, catatonic stupor, and use of antipsychotics were compared using the χ^2 test. The length of hospital stay upon admission was compared using the Mann-Whitney *U* test. Global assessment of functioning upon admission and body mass index were compared using the Student's *t*-test.

To account for potential confounding factors, linear discriminant regression analysis was performed for medical complications that differed significantly between groups. Potential confounding factors included demographics (age, gender, length of hospital stay), medical conditions (presence of specific medical conditions upon admission that raise the risk for the individual medical complication, bedridden status during hospital stay, body mass index), and psychiatric conditions (global assessment of functioning upon admission, catatonic stupor, and use of antipsychotics). The existence of a medical condition(s) upon admission in case control study was reclassified as a specific medical condition(s) that raises the risk of encountering that medical complication(s) to better cover the specific medical risk factors. For example, risk factors for DVT include cancer, major trauma, recent surgery, heart failure, stroke, noninfectious inflammatory conditions, prior venous thromboembolism, use of birth control pills or hormone replacement therapy, pregnancy and postpartum status, dehydration, thrombophilias, and long-distance travel. With respect to aspiration pneumonia, we considered specific medical conditions such as gastroesophageal reflux disease, achalasia, esophageal disorders, throat cancer, stroke, degenerative disorders, myasthenia gravis, lung diseases, as well as impaired consciousness [17] (eye opening subscale of 2 or less in Glasgow Coma Scale, i.e., eye opening to pain or no eye opening at all) and malnutrition (using serum albumin level) [18].

Excel 2010 with the add-in software Mulcel (OMS Ltd., Tokyo, Japan) and statistical software R were used for all statistical analyses. Two-tailed *p* values are reported, with $p < 0.05$ considered statistically significant.

3. Results

Among all 1308 psychiatric inpatients, the following disorders (and percentage frequencies) were noted: 40.4% had schizophrenia disorders; 28.4%, mood disorders; 14.3%, organic mental disorders; 4.6%, neurotic disorders; 4.1%, eating disorders; 3.9%, intellectual disabilities and developmental disorders; 3.5%, substance abuse; and 0.8%, personality disorders. Table 1 compares demographic characteristics and medical and psychiatric conditions between the restraint and non-restraint groups. Proportions of organic mental disorders and developmental disorders were higher for the physical restraint group compared with the non-physical restraint group ($p = .03$, $p < .01$, respectively), whereas the proportion of mood disorders was higher for the non-physical restraint group ($p = .02$). No differences were found for the other disorders examined. Physical restraint was used for 110 (101 individual patients with 9 readmissions) of 1308 inpatients (8.4%), a rate that was much lower than in de Hert's report [19] but is similar to that reported in Hilger's study [20]. Although no patient was subjected to physical restraint for 24 h continuously, the total number of physical restraint days for the 110 inpatients was 16.0 ± 31.0 (range: 1 to 267 days, median: 7 days). One patient with schizophrenia was subjected to physical restraint for 267 days because he suffered from repeated fractures as a result of suicide attempts even during hospitalization, which was itself initiated as a result of multiple fractures due to suicide attempt. Another patient with schizophrenia was subjected to physical restraint for 153 days because she continued to eat inedible substances, which on one occasion led to intestinal perforation and emergency surgery. The reasons for physical restraints included violence or agitation (26.3%), suicide attempt (13.6%), and self-removal of medical devices or need to keep bed rest (60.0%). Age, bedridden status, and use of antipsychotics did not differ between the two groups. Male patients were subjected to physical restraint more than female patients, mostly owing to aggressive behavior. The rate of involuntary admission, the presence of medical complications upon admission, and the presence of catatonia were higher for the physical restraint group than the non-physical restraint group, which required a longer hospital stay for patients of the physical restraint group. The proportion of patients who did not develop any medical complication during the hospital stay was higher for patients of the non-physical restraint group.(See Table 1).

Table 2 compares the incidence of each medical complication between the two groups. Pneumonia and DVT were more frequently apparent for the physical restraint group than the non-physical restraint group ($p = 0.001$, $p = 7.3 \times 10^{-5}$, respectively). No patient with DVT in the physical restraint group developed pulmonary embolism, most likely due to preventive measures and anticoagulant therapy following diagnosis of DVT. Among medical complications with a frequency of < 1%, one patient had bleeding from burns when he struggled to get free from the physical restraint and subsequent rubbing of his burns on the hospital bed. His burns did not require medical treatment. This was the only injury related to physical restraint in the physical restraint group. All their medical complications related to physical restraint were fully treated and had no after-effects. In the physical restraint group, medical complications occurred mostly during the restraint period. For example, the incidence of DVT that occurred either before the use of physical restraint or after its removal was low at 1.6% when compared with the rate of 9.3% which was assigned to the restraint period. Likewise, the incidence of aspiration pneumonia either before the use of physical restraint or after its removal was lower than that during the restraint period (7.4% and 15.4%, respectively).

The two medical complications that were associated with physical restraint, i.e., pneumonia and DVT, were further evaluated using linear discriminant regression analysis. No variable was correlated with other variables with a correlation coefficient of > 0.4. This analysis indicated that physical restraint was positively correlated with DVT and aspiration pneumonia; the difference between groups was significant after controlling for all other variables ($p = 1.2 \times 10^{-5}$, $p = 0.01$, respectively) (Figs. 1, 2). Physical restraint had the greatest impact on the incidence of DVT among the variables, and the fourth greatest impact on aspiration pneumonia. Several other variables were also correlated with DVT and aspiration pneumonia. Bedridden status was positively correlated with DVT and aspiration pneumonia ($p = 9.1 \times 10^{-5}$, $p = 1.5 \times 10^{-9}$, respectively). Poor scores on the global assessment of psychiatric functioning and length of hospital stay were also positively correlated with DVT and aspiration pneumonia ($p = 0.01$, $p = 8.0 \times 10^{-6}$, respectively, for poor global assessment scores; $p = 0.02$, p = 0.01, respectively, for length of hospital stay). Older age and female gender were positively correlated with DVT (p = 0.01, $p = 0.03$, respectively), whereas lower body mass index and impaired consciousness were positively correlated with aspiration pneumonia (p = 0.03, $p = 0.04$, respectively). The other variables did not correlate with either of these medical complications.

In summary, physical restraint significantly affected the incidence of DVT and aspiration pneumonia, as did bedridden status and poor psychiatric functioning. All results for linear discriminant regression analysis for DVT and aspiration pneumonia produced *p* values

Table 1
Demographics and medical and psychiatric conditions of physical restraint and non-physical restraint groups.

		Physical restraint group (n = 110)	Non-physical restraint group (n = 1198)	P value
Demographics	Age (years)	51.5 ± 18.6	51.1 ± 17.7	P = .81
	Gender (female, %)	46.3%	60.1%	P < .01
	Proportion of involuntary admission	46.4%	21.0%	P < .01
	Length of hospital stay (days)	64.1 ± 111.8	34.9 ± 35.7	P < .01
Proportion of mental disorders	Schizophrenic disorders	40.0%	40.5%	P = .98
	Mood disorders	18.2%	29.3%	P < .05
	Organic disorders	21.8%	13.6%	P < .05
Medical conditions	Medical complications upon admission	57.3%	39.3%	P < .01
	Patients who did not develop any medical complication	27.3%	57.3%	P < .01
	Bedridden status due to medical complications during hospitalization, but not due to physical restraint	39.2%	34.6%	P = .41
	Body mass index	21.1 ± 4.4	21.5 ± 4.8	P = .39
Psychiatric conditions	Severity of psychiatric illness (GAF: 0, worst; 100, best)	23.1 ± 6.9	27.8 ± 8.0	P < .01
	Catatonia	10.9%	3.2%	P < .01
	Use of antipsychotics	63.6%	57.8%	P = .28

GAF: Global Assessment of Functioning.

of < 0.01, i.e., $p = 1.1 \times 10^{-7}$ and $p = 5.4 \times 10^{-37}$, respectively, with Mahalanobis distances of 2.8 (error rate, 0.20) and 2.4 (0.22).

4. Discussion

Our findings indicate that physical restraint during hospitalization raises the risk of developing DVT and/or aspiration pneumonia for psychiatric patients. These medical complications were successfully treated with medication along with oxygen administration and rehabilitation; however, they involve a risk of serious consequences, such as pulmonary embolism or lethal aspiration pneumonia. To our knowledge, this is the first large-scale comprehensive study on medical complications associated with physical restraint. Our study also found that bedridden status was closely related to the incidence of DVT and aspiration pneumonia. This common observation may not be surprising, given that physical restraint can be considered an externally forced bedridden status, whereas medical conditions that lead to bedridden status can be considered an internally induced bedridden status. Therefore, the inability to walk may have a more significant effect on development of DVT and aspiration pneumonia than other established medical risk factors.

Our findings are compatible with published results [4,6,8]. The frequency of DVT under the condition of physical restraint was estimated to be as high as 10% in our study and 11.6% in Ishida's study [8]. According to De Hert et al. (2010) [19] and Hilger et al. (2016) [20], prophylactic administration of anticoagulants reduces the incidence of DVT. In contrast, Ishida et al. [21] found that prophylactic use of anticoagulants was not associated with any reduction in the incidence of DVT in restrained psychiatric patients. Rather, they found that sedation, physical comorbidities, and a longer duration of restraint were associated with an increased incidence of DVT. The association between bedridden status and the incidence of DVT has been reported previously [14]. Given these published results and our findings, prevention

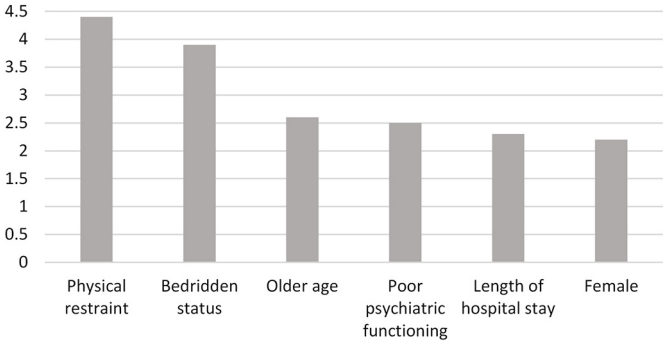

Fig. 1. Impact represented by absolute T value on the incidence of deep vein thrombosis.

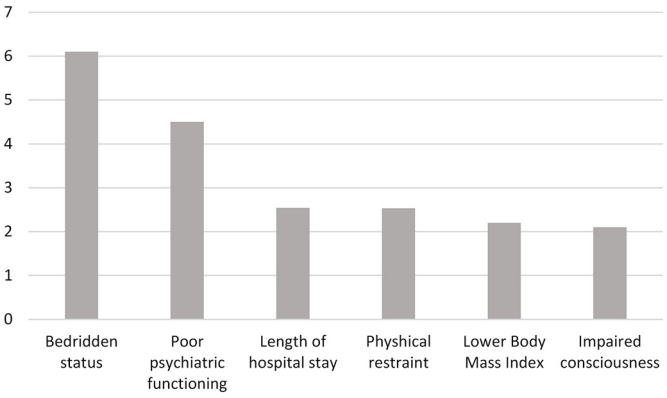

Fig. 2. Impact represented by absolute T value on the incidence of aspiration pneumonia.

Table 2
Frequency of medical complications in physical restraint and non-physical restraint groups.

Medical complications	Physical restraint group (n = 110)	Non-physical restraint group (n = 1198)	P value and odds ratio
Aspiration pneumonia	15.4%	4.3%	P < .01, OR = 4.1 (95%CI: 2.1–7.6)
Deep vein thrombosis	9.3%	1.7%	P < .01, OR = 6.0 (95%CI: 2.4–13.9)
Rhabdomyolysis	4.6%	2.7%	P = .20, OR = 1.9 (95%CI: 0.6–5.0)
Pressure ulcer	4.6%	2.4%	P = .19, OR = 2.0 (95%CI: 0.6–5.3)
Urinary tract infection	2.8%	1.8%	P = .15, OR = 2.1 (95% CI: 0.5–2.1)
Sepsis	1.9%	1.6%	P = .69, OR = 1.2 (95% CI: 0.1–5.1)
Urinary retention	1.9%	1.3%	P = .65, OR = 1.4 (95%CI: 0.2–6.2)
Gastrointestinal bleeding	1.9%	0.9%	P = .29, OR = 2.1(95%CI: 0.2–9.6)

measures to avoid bedridden status (in particular, provision of physical therapy) are warranted when patients have been subjected to physical restraint. Physical therapy might be an option for patients who have aspiration pneumonia with little or no respiratory failure. Although physical rehabilitation might be difficult when patients are extremely aggressive, appropriate sedation and rehabilitation by several staff members may help patients walk to prevent thrombus formation.

Although our staff in this psychiatric unit used physical restraint as a last resort, there may have been room for improvement. A comprehensive staff training on the management of assaultive behavior [22–24] might reduce the use of physical restraint further. Switching from infusion therapy or nasogastric feeding to oral intake through intensive dysphagia rehabilitation might diminish the need for physical restraints as well for safety measure. The physical restraint group had a higher rate of involuntary admission in our study, suggesting that patients who were unable to consent to treatment were more likely to be subjected to physical restraint. In this regard, in some cases, greater efforts at building a collaborative relationship between psychiatrists and patients might lead to more frequent voluntary admissions and possibly reduce the need of physical restraint. The medical complications in this study might have never occurred at this rate if these management methods had properly administered.

Our study has several limitations that should be considered. First, the incidence of medical complications under the condition of physical restraint might be underestimated because medical complications that occurred in the physical restraint group before the use of physical restraint or after its removal were excluded. In particular, DVT can become manifest after the period of physical restraint. Second, although plasma D-dimer levels are routinely measured in our unit upon admission and as needed during the course of hospital care, asymptomatic DVT might still have been missed. Third, although bedridden status affected the occurrence of aspiration pneumonia in most cases, there might have been a few patients in which aspiration pneumonia itself led to bedridden status. This issue might have been solved if we separated medical complications related to bedridden status from those that were unrelated. However, it was difficult to determine whether bedridden status preceded aspiration pneumonia in cases that already had aspiration pneumonia upon admission. Fourth, the generalizability of our results is limited because our study population was derived from a single psychiatric unit, where psychiatric inpatients with severe medical conditions were admitted. Generally speaking, our study setting might have covered not only the medical complexity found in an inpatient psychiatry unit but that on medical floors. In addition, methods and duration of physical restraint vary considerably by hospitals and patient characteristics. Finally, because this study was a retrospective analysis, prospective studies are needed to confirm the findings.

Despite the aforementioned limitations, our study demonstrates that physical restraint can lead to serious medical conditions. To avoid such conditions, the use of physical restraint should be minimized, and physical therapy is recommended even under the condition of physical restraint.

Ethics committee approval

Ethical aspects of this study were reviewed and approved by the Ashikaga Red Cross Hospital Human Research Ethics Committee (20198).

Author contribution

MF initiated and coordinated the study. MF and TT collected the data. MF wrote the first draft of the manuscript. MF and TT interpreted the data and prepared the final manuscript.

Role of funding

The authors report that there were no sources of funding.

Data availability statement

The datasets generated and/or analyzed during the current study are available from the corresponding author (MF) upon request.

Declaration of competing interest

The authors report that there were no conflicts of interest.

Acknowledgements

We thank Dr. Tsuyoshi Akiyama for supervising this study.

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