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The association of biological sex and long-term outcomes in older patients with physical restraint at the emergency department

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Abstract

Background The worldwide population is ageing and self-arm can be prevented with many techniques. Among them coercive measure consisting of physical restraint (PR) is one of the techniques. This study aims to assess the effects of the biological sex on the long-term survival after PR in geriatric patients during the initial emergency department (ED) visit.

Methods This retrospective study included patients between November 2019 to March 2021. All consecutive hospitalized patients after emergency department visit older than 75 years with PR were included. The population was compared according to the biological sex. One-year all-cause mortality was plotted with the Kaplan-Meier curve. Hazard ratios (HRs) for 1-year mortality were calculated using a Cox proportional hazards regression model. Mortality was monitored over a 3-year period.

Results PR was used in 149 patients representing 4.6% of 3210 hospitalized patients older than 75 years after ED visit. Women represented 52% of the study population. Compared to men, women were older [median (IQR) age 89 (85–93) vs. 85 (81–90) years, $P=0.002$]. Women more often presented dementia (93 vs. 80%, $P=0.031$). Both sexes presented the same limited independence. All-cause mortality was significantly lower for women than men after one year (25 vs. 51%, respectively, $P=<0.001$). Likewise, adjusted HR of 1-year all-cause mortality was higher in men [a HR 3.4 (95% confidence interval 1.7–7.1), $P<0.001$].

Conclusion This study suggested that the use of physical restraint in older adults was a more related factor of mortality in men than women. Women were older with lower expectancy life but PR use seemed to be a sign of global health decline in men. Further prospective studies are needed to assess if mortality after PR use is a cause or a consequence of a global health decline.

Keywords Physical restraint, Emergency department, Biological sex, Long-term mortality

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Introduction

The worldwide population is ageing and the same goes for France. In 2023, people aged over 65 represent 21.5% of the French population, with 10.4% aged over 75 years [1]. Despite the fact that people are living longer in better health, 75% of seniors over 65 are living with chronic illnesses such as cancer, cardiovascular diseases, diabetes or dementia [2]. By 2040, it is estimated that 1,200,000 people will be suffering from disability in France, compared to 800,000 today [2]. Due to the frailty and comorbidity, seniors are more susceptible to require emergency department (ED) consultations, with a higher in-hospital mortality and morbidity, especially after overnight waits in the ED for ward admission [3]. Compared to younger adults, older adults are more suceptible to functional decline, complications like immobility, falls or delirium and adverse outcomes such as longer length of stay (LOS), readmission or death [3–5].

Agitation is a common symptom justifying an ED consultation. In the United States, every year agitation occurs in 1.7 million ED visits [6]. In France, agitation is a daily concern in emergency departments, accounting for about 1% of the whole visits [7]. The prevalence of major neurocognitive disorders (also called dementia when having consequences in functional ability) is estimated to be around 5–10% [8]. To prevent self-arm many techniques can be used as de-escalation and agitation reduction methods, as well as coercive measures consisting of physical restraint (PR) and administration of appropriate sedatives [9]. Wong et al. study found that PR use was associated with alcohol or drug use in young male and behavioral disturbance in older population in the ED [10]. A recent systematic reviewreported PR prevalence ranging from 5 to 24.7% in older patients in home care [11]. The exact proportion of individuals undergoing PR in emergency departments is presently unknown, but approximately 33% of restrained patients across all age groups receive a psychiatric diagnosis following their admission [12]. PR is more frequently used in older patients [13]. These patients often suffer from cognitive impairments such as memory loss and difficulty understanding, hospital adaptation challenging [13]. However, the benefit for older patients physically restrained was unclear particularly for falls and fractures preventions [14]. Moreover, the risk of adverse hospital outcomes associated with PR seemed to increase such as functional decline [15, 16], longer LOS [16, 17] and death [16, 18].

This study hypothesis was that the use of PR in geriatric (≥75 years) patients leads to specific outcomes based on patient profiles, especially the biological sex. Biological sex is first and foremost a genetic modifier of disease pathophysiology, clinical presentation, and response to treatment [19]. In 2021, life expectancy in France was 79.1 years for men and 85.1 years for women, but life expectancy in good health was 64.4 years for men and 65.9 years for women [20]. Older and severely ill patients were primarily affected by the use of restraints [21]. Muscle atrophy due to disuse, is a condition resulting from prolonged bed rest or joint immobilization, leading to the loss of skeletal muscle mass. Women were more prone to disuse muscle atrophy than men and exhibited different functional changes under atrophic conditions. Additionally, age-related sarcopenia was particularly pronounced in elderly women compared to men [22]. This could result in different outcomes based on biological sex.

The aim of the study was to assess the effects of the biological sex on the long-term survival after PR in geriatric patients during the initial ED visit.

Methods

Data collection

This was a retrospective cohort observational study in the ED of the Beaujon University Hospital. All consecutive older patients ≥75-year-old hospitalized to the observation unit or to the ward from the ED were included from November 2019 to March 2021 if PR were mentioned in their medical records. Patients younger than 75 years old, without PR or not hospitalized were excluded. If a patient was admitted more than once, only the first episode was taken as index admission.

Demographic data, comorbidities of which dementia, history of fall, chief complaint were collected directly in medical record by 2 to of the co-authors (LM and MC) and checked by a third one (PVA). There were very few missing data because of the inclusion criteria were only patients older than 75 years with PR and needed information were collected in the medical record. Independence for daily life activities was collected by systematic review of previous medical record or nursing home record using the GIR (Groupe Iso-Ressource) scale [23]. This classification system outlines the level of care needed by older and disabled individuals, ranging from 1 (fully dependent) to 6 (fully independent). Patients categorized as GIR 5 or 6 are those who do not face issues with independence in their daily activities. Also, the reasons of PR, the type of PR (wrist restraint, belts and leg restraint, bed rails) and the use of sedatives were listed. The biological sex referred to physical attributes designated at birth and categorized as male and female (or men and women).

Outcomes

We defined "ED length of stay" the delay between ED presentation and admission to the ward. The outcome of "in-hospital length of stay" was calculated from ED entry, and therefore includes the time spent in the ED. Mortality was obtained through electronic health records, or hospital administrative data if needed with a follow-up of 3 years.

Ethics

The work conformed to the Declaration of Helsinki. This study was retrospective and non-interventional. Patient data has been anonymized. This single-center study complies with the use of the tool "Cohort360" implemented by the Clinical Data Warehouse (CDW) from the Assistance Publique des Hôpitaux de Paris (AP-HP) Health Data Space (AHDS). The informed consent was waived by the institutional review board called AP-HP CDW Scientific and Ethics Committee (Conseil Scientifique et Ethique; IRB number : 00011591) [24]. The study was registered at ClinicalTrials.gov (NCT06491706).

Sample size calculation

Using an unstratified log-rank test at the two-sided 5% significance level, a total of 66 events would allow 80% power to demonstrate a 50% risk increase of mortality [hazard ratio (HR) of 2] for men [25].

Statistical analysis

Continuous variables are expressed as median (interquartile range, IQR). Categorical variables are presented as number (percentage). All variables were tested for normality using the Shapiro–Wilk test. Group characteristics were compared with the t-test for normally distributed continuous variables or Mann–Whitney test for non-normally distributed continuous variables and chi² test for categorical variables. One-year all-cause mortality was plotted with the Kaplan-Meier curve. Hazard ratios (HRs) for 1-year mortality were calculated using a Cox proportional hazards regression model. HRs for 1-year mortality were calculated using a Cox proportional hazards regression model with and without adjustment. Variables with a $p < 0.10$ on univariate analysis were entered into the Cox regression model to describe how the factors jointly impact survival. We also kept comorbidity as key confounders. The optimal model selection involved finding the best compromise between the number of factors to keep and the accuracy of the Cox regression analysis. The model was adjusted with age, dementia, poly-medication $n > 5$, nursing home resident, hypertension, atrial fibrillation, diabetes mellitus, coronary artery disease, dyslipidemia, active malignancy, asthma or chronic obstructive pulmonary disease, prior stroke, chronic kidney disease. The proportional hazards assumption was checked using statistical tests based on the scaled Schoenfeld residuals [26].

The analyses were performed with R software (R Development Core Team, R Foundation for Statistical Computing, Vienna, Austria). A two-sided *P*-value of < 0.05 was considered statistically significant.

Results

Biological sex-specific clinical, physical restrain characteristics and outcomes

Among 5093 patients aged 75 years and older consulting the ED over the study period (3038 women (60%) vs. 2055 men (40%) *P*-value = 0.007), 3210 were hospitalized (1766 women (57%) vs. 1354 men (43%) *P*-value = 0.24). The study flow chart (Fig. 1) showed that physical restrains was used in 149 older patients with 48 % of men, representing 4.6% (4.4% in women vs. 5.3% in men) of hospitalized patients.

Table 1 compared older patient's characteristics, comorbidities and restrains characteristics according to the biological sex. Compared to men, women were older [median (IQR) age 89 (85–93) vs. 85 (81–90) years, $P = 0.002$]. Women more often presented dementia (93 vs. 80%, $P = 0.031$) and were nursing home residents (47 vs. 24%, $P = 0.005$). The BMI was the same in both groups (24 (20–26) vs. 23 (21–27), $P = 0.61$). Both groups presented the same independence, and it was limited (GIR ≤ 3) for 111 patients (76%). Causes of PR were the same in both groups mainly due to agitation. Interestingly, refusal of care was a major cause of PR among women only (36 vs. 1%, $P < 0.001$). The introduction of PR was notified in the medical record in 71% by nurses and in 63% by doctors.

Table 2 Compared older patients' admission, length of stay, mortality after PR. After the ED visit, 82% of patients were admitted and mainly in geriatric or internal medicine unit. ED median hospital length of stay was shorter for women than men [23 (19–29) vs. 24 (19–45) hours, respectively, $P = 0.046$]. Median hospital length of stay was equal for men and women [6 (1–12) vs. 5 (2–17) days, respectively, $P = 0.64$]. The in-hospital mortality was 16% and it was lower for women than men, respectively 10 vs. 22%, $P = 0.049$.

Long-term outcomes

After one year of follow- up, 38% ($n = 56$) of patients died. All-cause mortality was significantly lower for women compared to men after one year (25 vs. 51%, respectively, $P = 0.0008$),after two years (32 vs. 54%, $P = 0.003$) and not significant after three years (40 vs. 56%, respectively, $p = 0.06$) (Table 2). Likewise, HR of 1-year all-cause mortality was higher in men compared to women [HR 2.4 (95% confidence interval (CI) 1.4–4.2), $P < 0.001$]. Adjusted HR for mortality confirmed the more pejorative outcome for men with an aHR at 3.4 (CI 1.7–7.1). The Schoenfeld test was not statistically significant for each of the covariates, and the global test is also not statistically significant (p-value = 0.33). Therefore, the proportional hazards were assumed with this model. The Fig. 2 compared one year Kaplan-Meier survival curves between older (> 75 years) men and women. After two years HR was higher in men [respectively HR 1.6 (95%

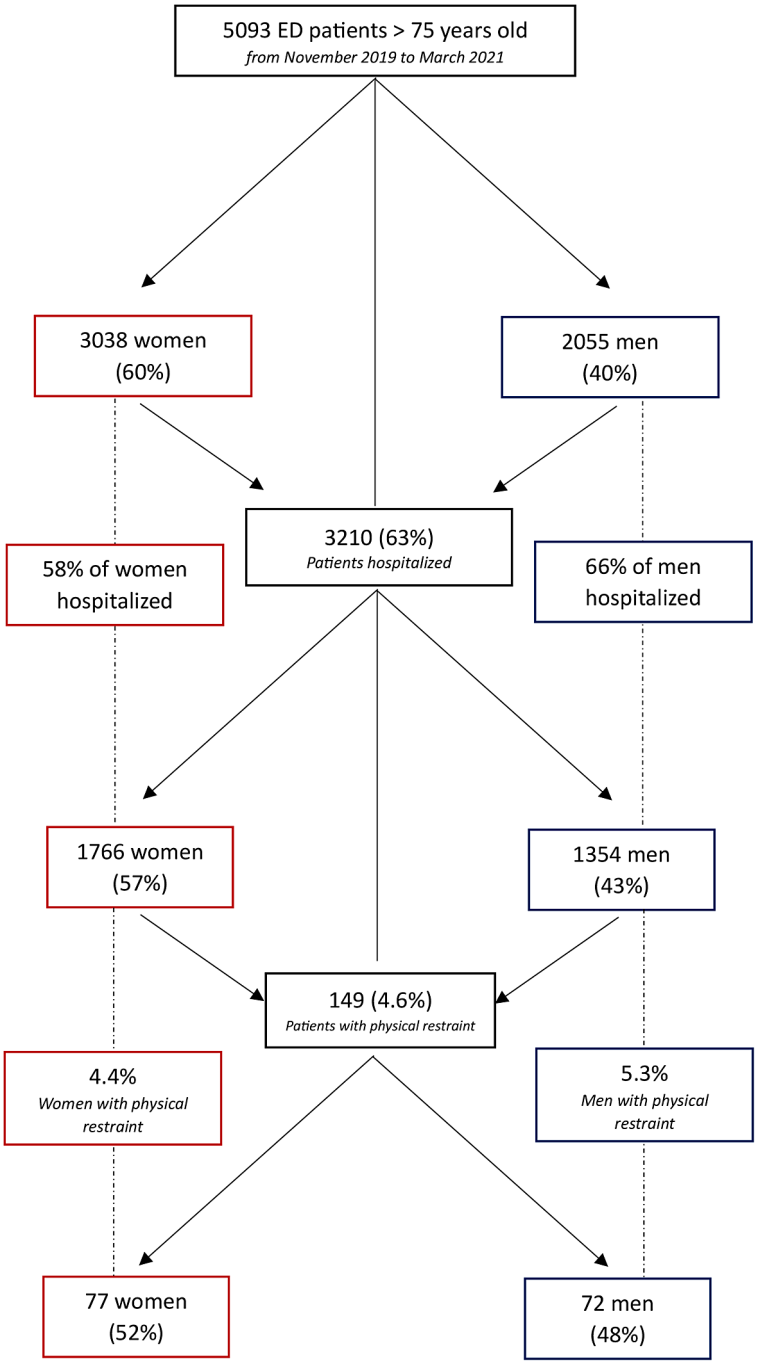

Fig. 1 Flow chart of study older patients with physical restrains in the emergency department

CI 0.9–2.6), $P = 0.09$ and aHR was 1.5 (95% CI 0.7–3.3), $P = 0.3$]. Finally, after three years, HR was also higher in men [respectively HR 2.02 (95% CI 1.2–3.3), $P = 0.005$ and aHR was 2.9 (95% CI 1.4-6.0), $P = 0.004$].

Discussion

This study describes the long-term outcomes after ED visits involving PR among geriatric patients. Notably, highlights more unfavorable long-term outcomes for men compared to women in older patients. To our knowledge, no other study assess the long-term mortality after PR use in ED.

In this acute setting, , patients undergoing PR represent less than 5% of the population, a lower rate than the 5%-25% reported in other studies [11, 16]. The low proportion of this study could be explained by the difference of the settings. Previous research predominantly focused on residential or home care rather than ED

Table 1 Comparison of older patient's characteristics, comorbidities and restrains characteristics according the biological sex

	N	All Patients (*N* = 149)	Women *N* = 77 (52%)	Men *N* = 72 (48%)	*P*-value
Patients' characteristics					
Age	149	87 (82–92)	89 (85–93)	85 (81–90)	0.002
Dementia	136	117 (86%)	62 (93%)	55 (80%)	0.031
BMI	80	24 (21–27)	24 (20–26)	23 (21–27)	NS
Weight (kg)	94	60 (52–68)	56 (48–64)	65 (58–75)	< 0.001
Fall history	149	61 (41%)	34 (44%)	27 (38%)	NS
Information of patient and family	149	15 (10%)	5 (6%)	10 (14%)	NS
Nursing home	147	53 (36%)	36 (47%)	17 (24%)	0.005
Poly-medication ($n > 5$)	141	42 (30%)	17 (23%)	25 (37%)	NS
Comorbidity					
Hypertension	149	68 (46%)	34 (44%)	34 (47%)	NS
Atrial fibrillation/flutter	149	35 (23%)	13 (17%)	22 (31%)	0.049
Diabetes mellitus	149	34 (23%)	13 (17%)	21 (29%)	NS
Coronary artery disease	149	14 (9%)	4 (5%)	10 (14%)	NS
Dyslipidemia	149	13 (9%)	3 (4%)	10 (14%)	0.031
Active malignancy	149	13 (9%)	5 (6%)	8 (11%)	NS
Asthma COPD	149	10 (7%)	6 (8%)	4 (6%)	NS
Priorstroke	149	16 (11%)	8 (10%)	8 (11%)	NS
Chronic kidney disease	149	12 (8%)	4 (5%)	8 (11%)	NS
Heart failure	149	13 (9%)	9 (12%)	4 (6%)	NS
Smoking	149	3 (2%)	0 (0%)	3 (4%)	NS
Alcohol abuse	149	3 (2%)	1 (1%)	2 (3%)	NS
Depression	149	15 (10%)	9 (12%)	6 (8%)	NS
Independence					
GIR1 (completely dependent)	145	11 (8%)	5 (7%)	6 (9%)	NS
GIR2	145	50 (34%)	29 (39%)	21 (30%)	NS
GIR3	145	50 (34%)	28 (37%)	22 (31%)	NS
GIR4	145	14 (10%)	5 (7%)	9 (13%)	NS
GIR5	145	9 (6%)	4 (5%)	5 (7%)	NS
GIR6 (completely independent)	145	11 (8%)	4 (5%)	7 (10%)	NS
Main complaint					
Fall	149	35 (23%)	21 (27%)	14 (19%)	NS
Confusion	149	29 (19%)	15 (19%)	14 (19%)	NS
Dyspnea	149	25 (17%)	13 (17%)	12 (17%)	NS
Asthenia	149	22 (15%)	10 (13%)	12 (17%)	NS
Abdominal pain	149	11 (7%)	7 (9%)	4 (6%)	NS
Impossibility to stay at home	149	9 (6%)	4 (5%)	5 (7%)	NS
Sepsis	149	9 (6%)	1 (1%)	8 (11%)	0.03
Faint	149	6 (4%)	3 (4%)	3 (4%)	NS
Intoxication	149	3 (2%)	3 (4%)	0 (0%)	NS
Causes of PR					
Agitation	149	79 (53%)	43 (56%)	36 (50%)	NS
Fall prevention	149	41 (28%)	21 (27%)	20 (28%)	NS
Unknown	149	25 (17%)	9 (12%)	16 (22%)	NS
Behavioral disturbances or aggressivity	149	16 (11%)	6 (8%)	10 (14%)	NS
Refusal of care	149	29 (19%)	28 (36%)	1 (1%)	< 0.001
Restraints noted in medical record					
By Doctors	149	94 (63%)	52 (68%)	42 (58%)	NS
By nurses	149	106 (71%)	52 (68%)	54 (75%)	NS
Sedatives	149	93 (62%)	49 (64%)	44 (61%)	NS
Monitoring	148	24 (16%)	12 (16%)	12 (17%)	NS
Type of restraints					

Table 1 (continued)

	N	All Patients (*N* = 149)	Women *N* = 77 (52%)	Men *N* = 72 (48%)	*P*-value
Wrist restraints	145	142 (98%)	73 (99%)	69 (97%)	NS
Bed rails	149	23 (15%)	13 (17%)	10 (14%)	NS
Leg restraints	149	7 (5%)	6 (8%)	1 (1%)	NS
Others	149	5 (3%)	3 (4%)	2 (3%)	NS

Data are presented as median (interquartile range) for continuous data and as percentage (n=) for categorical data. The *P*-value to the right represent the test for trend determined by either Wilcoxon rank-sum (continuous data) or chi-square [categorical data]

PR: physical restraint; GIR : Groupe Iso-Ressource; BMI : body mass index ; COPD : chronic obstructive pulmonary disease

Table 2 Comparison of older patients' admission, length of stay, mortality after physical restrains

Outcomes	*N*	All Patients (*N* = 149)	Women *N* = 77 (52%)	Men *N* = 72 (48%)	*P*-value
Admission	149	122 (82%)	61 (79%)	61 (85%)	0.38
Return Home	149	26 (17%)	17 (22%)	9 (12%)	0.12
Geriatric or internal unit	149	89 (60%)	46 (60%)	43 (60%)	1.00
Surgery unit	149	7 (5%)	4 (5%)	3 (4%)	1.00
Covid unit	149	10 (7%)	1 (1%)	9 (12%)	0.008
Restraints after admission in ward	82	11 (13%)	4 (11%)	7 (15%)	0.75
ED length of stay (hours)	149	24 (19–42)	23 (19–29)	24 (19–45)	0.046
Length of stay (days)	120	6 (1–13)	6 (1–12)	5 (2–17)	0.64
In-Hospital mortality	149	24 (16%)	8 (10%)	16 (22%)	0.049
1-year mortality	149	56 (38%)	19 (25%)	37 (51%)	< 0.001
2-years mortality	149	64 (43%)	25 (32%)	39 (54%)	0.007
3-year mortality	149	71 (48%)	31 (40%)	40 (56%)	0.06

Data are presented as median (interquartile range) for continuous data and as percentage (n=) for categorical data. The *P*-value to the right represent the test for trend determined by either Wilcoxon rank-sum (continuous data) or chi-square [categorical data]

ED: emergency department

environments. The variability in reported prevalence can be attributed to differences in conceptualization and the definition of the PR. Notably, there is significant variation in the reported prevalence of PR use in long-term residential care, which tends to be higher compared to home care settings [11]. In 2016, a consensus by Bleijlevens et al. attempted to standardize the definition of PR to fulfill the lack of a clear definition and the variety of PR used in different settings [27].

This low PR proportion in our study may also be attributed to the collaboration between emergency physician and the geriatric team supported by a mobile geriatric unit available during weekdays.. Additionally, French emergency physicians undergo geriatric training during their residency, likely influencing their approach to managing geriatric patients.

Symptoms of delirium (agitation, behavioral disturbances, aggressivity), rather than fall prevention, were the primary reasons for PR use in the present study. Witlox et al. demonstrated the relationship between delirium in older patients and post discharge mortality, institutionalization and dementia [4]. The lower in-hospital mortality rate compared to Chou et al.'s study [16] may reflect the inclusion of all patients hospitalized or not in our analysis. . Many studies showed that PR were used on frailer patients. They were older [10, 16], with poorer autonomy or health [10, 16, 28].These factors likely contribute to longer hospital stays, functional decline, and higher mortality rates following PR use [15–17] . However, ED visits themselves are indicatos of excess of mortality and readmission for older people [29]. The ED visit was a sign of global health decline and according this study PR could be a confounding factor in this deterioration.

Biological sex has been consistently recognized as a confounding factor in long-term outcomes across various diseases [19, 30, 31]. Use of PR is more associated in men [32, 33] in ED, as seen in the present study where a slightly higher proportion of men underwent PR. In practice, PR seemed useful for men first to try to contain their behavior, where women were restrained to continue their treatment. Compared to men, women were less likely to receive emergency treatment [34]. In this study, more than half of the men had died after one year, compared to one quarter of the women. In France, in 2021, according the public health data base and the age of this study population, life expectancy is 5.6 years for women after the age of 89 years. After 85 years, for men, it was 6.2 years old [1]. According to this fact, in this study women were older, had more dementia but had a better survival after three years of follow up with a similar independence level. This findings supports the influence of biological sex on survival even if women were older than men. The use of PR in men was more associated with mortality with the highest mortality ratio three years after the ED visit. The PR use in men could indicate a more significant health decline.

This study had several limitations. First, due to the retrospective nature of data the incidence of PR and the mortality could be underestimated. The patients included in the study were only those whose passive physical restraint was recorded or prescribed in the medical record. There are restrained patients who could not be

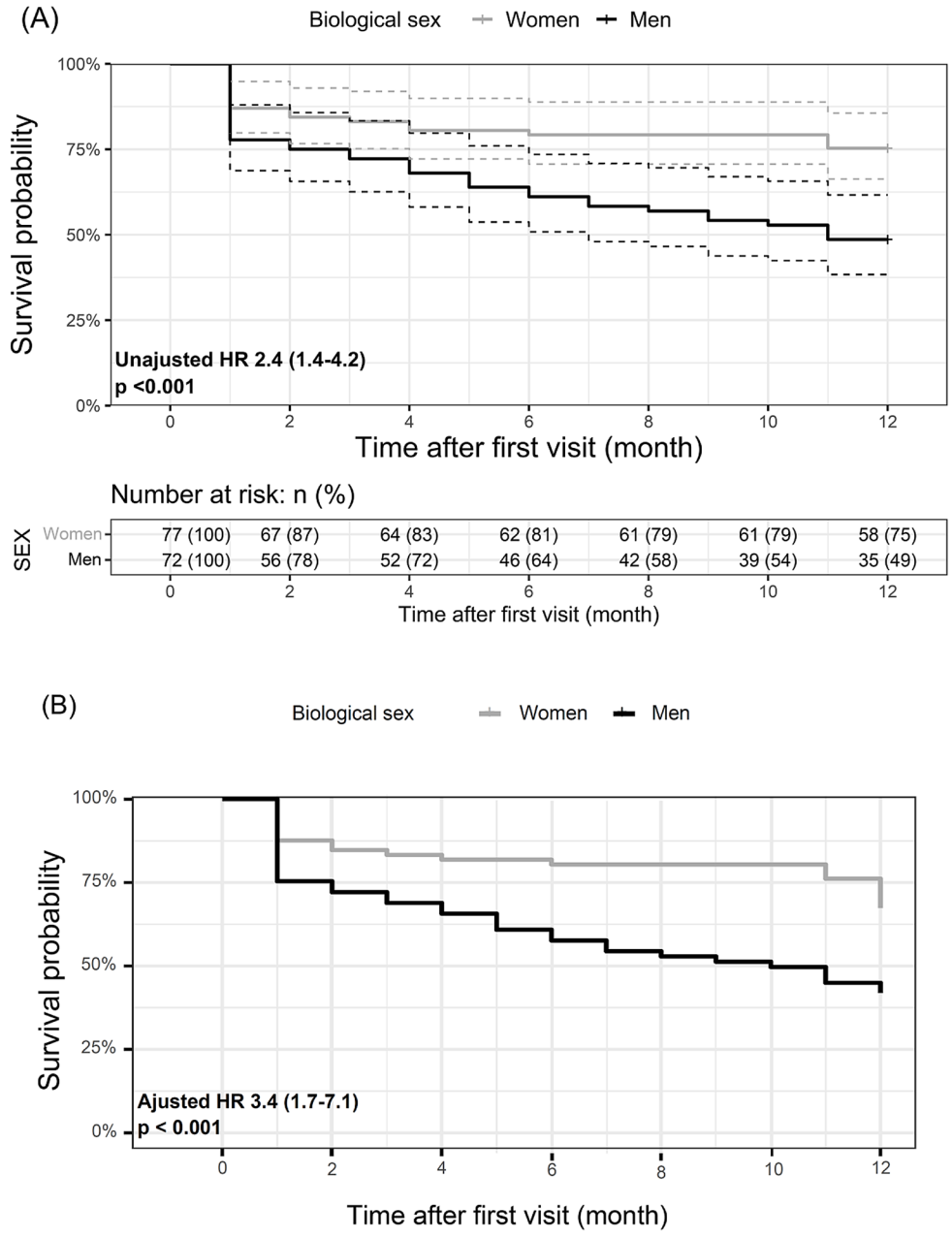

Fig. 2 One year Kaplan-Meier survival curves: comparison of mortality between older (> 75 years) men and women. (**A**) Graphical display of hazard ratio (HR) for long-term mortality according to the biological sex after patients PR. Unadjusted HRs and 95% confidence intervals for the association between sex and long-term all-cause mortality. (**B**) Graphical display of hazard ratio (HR) for long-term mortality according to the biological sex after patients PR. Adjusted HRs and 95% confidence intervals for the association between sex and long-term all-cause mortality

included in the study due to a lack of traceability. This constitutes a significant selection bias. Also, the duration of PR use was unknown, this was an important factor which could influence the association between PR use and mortality. As already said in introduction the muscle atrophy could had more consequence according the biological sex [21, 22].Second, the absence of a control group (patients without PR) in this study represents a weakness. But it was not really the purpose of this study and this issue, had already been investigated in few studies [16, 35]. Third, the effect of sedatives was not taken in account because of their disparity . In the literature, chemical restraint showed few effects on outcomes compared to PR [15, 36]. But the absence in the medical clinical monitoring as heart rate, blood pressure, or respiratory rate when sedatives were administered could give more information about the tolerance or not of these medication and may had consequences on mortality. Lastly, it's

worth noting that this study was conducted at a single center, but the hospital is situated in an area with a high density of nursing homes for older people. It's probable that the physicians involved in the study had established best practices for caring these patients and with less use of PR. These findings couldn't be generalized.

Conclusions

This retrospective study suggested that the use in ED of physical restrain for restless old patients was more associated with mortality in men than women, indicating a potential sign of greater health decline in men. In this study, women had a lower long-term mortality even though they were older with the same independency level, higher dementia and lower average life expectancy. The use of PR has consequences on long-term outcomes and need to be use with caution. Further prospective studies are necessary to accurately assess PR rates in older patients and determine whether PR is a cause or consequence of global health decline.

Abbreviations

ED	Emergency Department
HR	Hazard Ratio
IQR	Interquartile Range
LOS	Length of Stay
PR	Physical Restraint

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Author contributions

LM contributed to data acquisition, data interpretation and drafting and revision of the paper for important intellectual content.MP contributed to design, data interpretation and revision of the paper for important intellectual content.Pradeebane VA contributed to statistical analysis, data interpretation and revision of the paper for important intellectual content.MG contributed to data acquisition and revision of the paper for important intellectual content.MC contributed to conception, data acquisition, data interpretation and revision of the paper for important intellectual content.Prabakar VA contributed to conception, design, data acquisition, statistical analysis, data interpretation and drafting and revision of the paper for important intellectual content.All authors read and approved the final version of the manuscript.

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Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The work conformed to the Declaration of Helsinki. The informed consent was waived by the institutional review board called Assistance Publique des Hôpitaux de Paris Clinical Data Warehouse (AP-HP CDW) Scientific and Ethics Committee (Conseil Scientifique et Ethique; IRB number : 00011591).

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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