

Use of Physical Restraints in a General Hospital: a Cross-Sectional Observational Study

Barak Raguan BSc^{1*}, Efrat Wolfovitz MD² and Efrat Gil MD^{1,2,3}

¹Rappaport Faculty of Medicine, Technion-Israel Institute of Technology, Haifa, Israel

²Department of Internal Medicine C and ³Geriatric Service, Bnai Zion Medical Center, Haifa, Israel

ABSTRACT: **Background:** Physical restraints are a common, albeit controversial, tool used in the acute care setting.

Objectives: To determine the prevalence of physical restraint use in an acute care hospital. Secondary objectives were to determine whether physical restraints are used more commonly in night shifts, identify patient risk factors for physical restraint use, and establish if staff-to-patient ratio correlated with physical restraint use.

Methods: An observational cross-sectional study was conducted over 3 months in 2013 in the medical, surgical and intensive care units in a mid-sized general hospital. All the physically restrained patients in each observation were added to the registry. At each observation one department was selected for comparison and all non-restrained patients were added to the registry.

Results: The study population comprised 2163 patients. Seventy-six were restrained and 205 were included as case-controls. The prevalence of physical restraint use was 3.51% (95%CI = 2.79–4.37%). Physical restraint use was more common in night shifts than day shifts: 4.40% vs. 2.56% ($P = 0.03$). Male gender, dependency, invasive ventilation, invasive tubes (nasogastric tube or urine catheter), and bedsores were all significantly correlated with restraint use. Staff-to-patient ratios were not significantly correlated with use of physical restraints.

Conclusions: Physical restraints are relatively common in acute care wards. The use of physical restraints seems to correlate with certain patient characteristics but not with staff-to-patient ratios, and seems more common at night.

IMAJ 2015; 17: 633–638

KEY WORDS: physical restraints, epidemiology, general hospitals, personal autonomy

Physical restraints are broadly defined as any limitation to the freedom of an individual's movement and may include bed-rails, belts, "mittens," wrist restraints and other devices [1]. Physical restraints are an accepted tool in many hospital wards worldwide, albeit not without controversy: physical restraints

*This study met part of the requirements for the MD degree of the first author

are psychologically damaging to the patient by impairing his or her autonomy, and there is mounting evidence that restraints are ineffective in reducing falls and may increase both morbidity and mortality [2–4].

It is estimated that nearly 10,000,000 hospital days in the United States involve physical restraints [5]. Studies examining the point-prevalence of physical restraints in a general hospital (rather than in psychiatric wards, geriatric wards, nursing homes or other settings) are scarce [5–11]. It is difficult to conduct comparisons between studies due to different settings, differing definitions of physical restraints, and different methodologies.

The results of previous studies are summarized in Table 1. Two large studies examining incidence (rather than prevalence) of physical restraint were conducted in the U.S. One, a study of nearly 10,000 hip fracture patients, revealed that 31.5% of patients were restrained at some point in their hospitalization [12]. The second, conducted in 40 acute care hospitals, demonstrated that physical restraints were used on 50 days per 1000 patient-days (on average) [5].

Various risk factors for restraint use have been described, mostly related to patient characteristics. Among these risk factors are age, mobility, dependence in activities of daily living, cognitive decline, incidence of falls, and polypharmacy [1,10]. However, many of these risk factors have proven significant in some studies but not in others.

Risk factors that are patient-independent mostly have to do with health care staff characteristics. One study found increased risk of restraint use when nurse attitudes were supportive of restraint use, but another study failed to confirm this finding [13,14]. While several studies have attempted to demonstrate that a lower ratio of nurses per patient results in a higher frequency of physical restraint use, the data are insufficient to support such a conclusion [10].

In Israel, where our study was performed, only one previous study examined the prevalence of physical restraint use in the hospital setting (medical, surgical and intensive care wards) [15]. In that study, conducted in 1998, the researchers found an average prevalence of 3% of restrained patients (15/504) per day (excluding bed-rails).

In Israel, physical restraint use is regulated by a Ministry of Health regulation [16] stipulating that physical restraints be

Table 1. Prevalence of physical restraint use in previous studies

Study	Setting	No. of patients	Bed-rails included	Prevalence	Country
Heinze et al. 2011 [10]	Hospital (medical and surgical)	2827	Yes	9.2%	Germany
Kow & Hogan 2000 [9]	Hospital	156	No	7.7%	Canada
Barton-Gooden et al. 2013 [8]	Hospital (medical and surgical)	172	Yes (No)	75% (5%)	Jamaica
De Vries et al. 2004 [6]	Hospital (geriatric wards)		No		
		740		0%	Austria
		652		7–22%	Belgium
		99		3%	Czech Republic
		183		0%	Denmark
		778		7%	France
		1147		0–2%	Germany
		2008		0–3%	Switzerland
		125		2–12%	The Netherlands
Krüger et al. 2013 [11]	Hospital	1276	Yes (No)	11.8% (< 2.5%)	Germany

used only under the following conditions: the restraint is for medical purposes only, the patient might inadvertently harm him- or herself, and all other options at the disposal of the medical staff have been exhausted. The order for restraint must be renewed every 8 hours at most and cannot be extended beyond 24 hours without the approval of the ward chief.

The purpose of our study was to evaluate the prevalence of the use of physical restraints in a general hospital (bed-rails were not included) and to characterize the restrained patients, as a basis for awareness-raising and educational activities. We also wished to test two hypotheses: that physical restraints are used more commonly at night, and that a higher staff-to-patient ratio (i.e., fewer staff per patient) would correlate with a higher prevalence of restraint use.

PATIENTS AND METHODS

This was an observational cross-sectional study. The researchers conducted 10 unannounced visits to the wards, half of them during night shifts. At each participating ward, the researchers recorded the number of patients on the ward the number of restrained patients, and the number of staff in the ward (medical and nursing staff separately). Patient character-

istics were recorded for all restrained patients in every ward, at every observation, but without patient names or other identifying features.

To allow comparison with non-restrained patients, a registry of non-restrained patients was acquired. At each observation, the characteristics of all non-restrained patients were recorded from one ward only, with each ward being chosen once (and only once). Thus, at the end of the study period a registry of non-restrained patients constituted a representative sample of all wards included in the study.

The study was conducted at Bnai Zion Medical Center, Haifa. The study included four medical wards (three of general medicine, one neurology), three surgical wards (general, orthopedics, urology), the general intensive care unit (ICU) and the CICU (cardiac ICU).

DATA COLLECTION

Data on the use of restraints, ventilation, nasogastric (NG) tubes and urine catheters were collected using direct observation. Other data were acquired from the medical records. Due to ethical requirements, all patient data were collected without recording any identifying features.

DEFINITIONS

- *Restraints*: in our institute, wrist restraints are the only kind of physical restraint in use. Restraints used for therapeutic purposes (such as traction in orthopedic use) were not included; neither were handcuffs used on patients in police or prison custody. Bed-rails were not included in our study (see discussion section)
- *Shifts*: morning shifts begin at 7:00 am and end at 3:00 pm; the night shift lasts from 11:00 pm to 7:00 am
- *Ventilation*: classified as either invasive (endotracheal tube, tracheostomy), non-invasive (biphasic or continuous positive airway pressure machines), or none
- *Housing*: the housing status of the patient prior to his or her current hospitalization was classified as either home or nursing home
- *Medical tubing*: the presence of invasive medical tubing (NG tube and/or urine catheter) at observation time was noted. These were recorded as either present or absent, with no distinction as to which or how many tubes were present
- *Charlson Comorbidity Index (CCI)*: calculated as an index of comorbidity, based on the patients' diagnosis list in the medical record [17]
- *Number of medications*: all medications administered on the day of observation were counted
- *Number of psychotropic medications*: defined as drugs whose main locus of action is the central nervous system, and included anticholinergics, anticonvulsants, antidepressants, anti-parkinsonians, antipsychotics, anxiolytics, benzodiazepines, cholinergics, mood stabilizers, and narcotics

- *Antibiotics*: the use of antibiotics, excluding those administered topically.

DATA ANALYSIS

Prevalence rates were computed. Poisson regression analysis was performed to determine whether there was a difference in prevalence between morning and night shifts and between wards. Comparisons of the demographic and clinical data between the restraint group and the control group were done using the Mann-Whitney U test (a non-parametric test) for continuous variables and by chi-square test for categorical data. Logistic regression was used to compute the odds ratio for the continuous variables. In order to model the risk factors for restraint use, the demographic variables were first entered into a stepwise logistic regression model while “forcing” age into the model, regardless of the algorithm for variable selection. The clinical variables were then entered while keeping significant demographic variables and age in the model. Statistical analysis was performed using SPSS (version 19). Significance was set at $P < 0.05$.

ETHICAL CONSIDERATIONS

The study was approved by the Bnai Zion institutional review board. Since data were collected anonymously and patient risk was negligible, informed consent was not required. This article was constructed according to the STROBE criteria [18].

RESULTS

A total of 2163 patients were observed in the study. The study comprised 10 observations over a 3 month period: average 216.3 per observation, 95% confidence interval (CI) = 204.5–228.1%. Among the 2163 patients, 76 patients were restrained, and 205 were included in the comparison group (see study design, above). Demographic and clinical data of these 281 patients are presented in Table 2.

The prevalence of restrained patients was calculated by dividing the number of restrained patients in each ward by the total number of patients in that ward. The average prevalence was 3.51% (95%CI = 2.79–4.37%). The highest overall prevalence observed was 7.5%, and the lowest 2.0%.

The majority of restrained patients were in the medical wards: 67 in the medical wards (5.19%), 3 in the surgical wards (0.41%) and 6 in the ICU (4.22%).

Restraint prevalence in the morning shifts was 2.56% which was statistically significantly lower than in night shifts (4.40%) ($P = 0.03$). Since the rate of restraint use in the non-medical wards was so low, the analysis was repeated using the data for the medical wards only. In this analysis the difference was of borderline statistical significance (4.10% vs. 6.33%, $P < 0.08$).

Poisson regression analysis revealed a statistically significant difference in restraint use between the morning and night shift with the odds of restraint use on the night shift 1.6 times

Table 2. Selected demographic and clinical characteristics of patients

Characteristic	Mean (1st, median, 3rd quartile)
Age (years)	68.5 (57.7, 75, 83)
Length of stay (days)	10.8 (2, 4, 10)
CCI	2.2 (0, 2, 3)
No. of medications	9.3 (6, 9, 12)
No. of psychotropics	1.5 (0, 1, 2)

	% (No.)
Shift	
Morning	44.64 (125)
Night	53.36 (155)
Gender	
Men	48.57 (136)
Women	51.43 (144)
Family status	
Single	11.79 (33)
Married	57.86 (162)
Divorced	11.43 (32)
Widowed	18.93 (53)
Housing	
Home	80.71 (226)
Nursing Home	16.7 (45)
N/A	3.21 (9)
Independent	
Yes	59.64 (167)
No	37.14 (104)
N/A	3.21 (9)
NG tube	
Yes	20 (56)
No	80 (224)
Urine catheter	13.21 (37)
No catheter	66.79 (187)
Ward	
Medical	64.29 (180)
Internal A	18.57 (52)
Internal B	22.14 (62)
Internal C	16.43 (46)
Neurology	7.14 (20)
Surgery	27.50 (77)
General surgery	11.79 (33)
Orthopedics	9.64 (27)
Urology	6.07 (17)
ICU	
General ICU	8.21 (23)
CICU	3.93 (11)
	4.28 (12)
Ventilation	
Invasive	12.86 (36)
Non-invasive	1.07 (3)
None	86.07 (241)
Bedsore	
Yes	12.14 (34)
No	86.43 (242)
N/A	1.43 (4)
Antibiotics	
Yes	60.71 (170)
No	38.21 (107)
N/A	1.07 (3)

CCI = Charlson Comorbidity Index, N/A = not available

Table 3. Risk factors and odds ratios for use of restraints

	Control (N=205)	Restrained (N=76)	χ^2	P value	OR	95%CI
Mean age (SD)	66.4 (19.3)	74.4 (19.6)	8.76*	0.003	1.02	1.01–1.04
Men	44.88%	57.89%	3.76	0.05	1.69	1.00–2.88
Nursing home	8.04%	39.73%	38.84	< 0.001	7.54	3.77–15.08
Family status			10.14	0.02	ref	–
Married	61.95%	46.05%		0.97	1.00	–
Divorced	12.20%	9.21%		0.15	1.02	0.41–2.54
Single	10.73%	14.47%		0.003	1.81	0.80–4.10
Widowed	15.12%	30.26%		< 0.001	2.69	1.40–5.19
Dependent	26.00%	73.61%	50.63	< 0.001	7.94	4.31–14.70
CCI	1.9 (1.9)	2.9 (2.2)	12.03	0.001	1.25	1.10–1.42
Invasive ventilation	4.41%	36.84%	51.07	< 0.001	12.70	5.62–28.69
Bedsore	5.42%	32.39%	35.00	< 0.001	8.32	3.80–18.24
NG tube or urine catheter	15.61%	80.26%	104.67	< 0.001	21.98	11.15–43.36
Antibiotics	54.45%	80.00%	15.05	< 0.001	3.34	1.78–6.28
Mean no. of medications (SD)	8.5 (4.3)	11.3 (4.7)	18.72*	< 0.001	1.14	1.08–1.22
Mean no. of psychotropics (SD)	1.2 (1.3)	2.1 (2.7)	10.47*	0.001	1.26	1.10–1.45
Mean length of stay (SD)	7.0 (14.7)	21.2 (27.7)	16.17*	< 0.001	1.05	1.03–1.07

Data in percent unless otherwise noted

* Wald statistic

CCI = Charlson Comorbidity Index

that of the day shift: odds ratio (OR) = 1.65, 95%CI 1.04–2.63, $P < 0.03$. In addition, there was a statistically significant difference in restraint use between the wards: the medical and ICU wards had a statistically significantly higher use than the surgical ward (OR = 22.82, 95%CI 7.18–72.60, $P < 0.001$; OR = 12.81, 95%CI 3.21–51.37, $P < 0.001$, respectively).

Plotting the rate of restraint use against staff-to-patient ratios revealed no significant correlation ($r^2 = 0.01$).

Gender and dependency were statistically significant demographic predictors of restraint use. The unadjusted odds ratios (bivariate analysis) [Table 3] indicated that nearly all the investigated factors were statistically significant. However, once logistic regression was performed (multivariate analysis) [Table 4], several risk factors were no longer statistically significant.

There was a significant age difference between restrained patients and the control group (66.4 vs. 74.4, $P = 0.003$). However, once other factors were included in the multivariate analysis, age was no longer statistically significant.

The clinical variables (Charlson Comorbidity Index), invasive ventilation, NG tube or urine catheter, bedsore, length of stay, number of medications, number of psychotropics, antibiotics) were added as potential predictors to age and the significant demographic variables (gender, housing and dependency) via backward stepwise logistic regression [Table 4]. Invasive ventilation, NG tube or urine catheter and bedsore were all significant predictors of restraint use.

DISCUSSION

Our study indicates that in a mid-sized general hospital the prevalence of physical restraint use is approximately 3.59%. This is similar to a previous study conducted in Israel in 1998, where the prevalence over the 5 day observation period was 6%, with an average of 3% per day [15]. Though it is impossible to deduce a trend from two data points, this would imply that the prevalence of physical restraint use remained stable in the 15 years between the two studies. When compared internationally, our study may suggest that restraint use in Israel is less prevalent than in most, but not all, countries [6,8–10].

COMPARING DAY AND NIGHT SHIFTS

Our study has shown that restraint use is more common in night shifts than day shifts, unlike previous studies (which found no significant difference) [5]. However, many studies on the subject did not examine this factor. Several factors may explain why restraint use is more common at night. Delirium is more common at night [19]. Furthermore, staff are less likely to use physical restraints when patients are accompanied by family members [7], who are less likely to be present at night. This might be due to the calming effect of having a family member nearby, to the influence that family members have on the decision making of nurses and physicians, or simply to the presence of a dedicated chaperone. This finding carries some importance. From a research perspective, this suggests that

future research on interventions to reduce the rate of physical restraint use should focus on night shifts.

STAFF-TO-PATIENT RATIO

Our study failed to show a correlation between staff-to-patient ratio and physical restraint use. This finding seems to counter the assumption some may hold that physical restraints are sometimes used as a compromise for understaffing.

RISK FACTORS ASSOCIATED WITH RESTRAINT USE

Care dependence and the presence of bedsores proved statistically significant in the multivariate analysis. Care dependence has been shown previously to correlate with a higher rate of restraint use [10]. Bedsores were not studied as a risk factor in previous studies (one study observed that 20% of restrained patients had bedsores, without comparison to non-restrained patients) [15]. Our study has shown bedsores to be an independent risk factor for the use of physical restraints.

Pre-hospital housing in a nursing home and higher CCI only proved statistically significant in the bivariate analysis. This agrees with other studies in which comorbidity was a risk factor for physical restraint use [5,10].

Older age was previously considered a risk factor for the use of restraints [10], although this effect may be ameliorated in the very old [20]. Our results, however, suggest that older age is not a significant independent risk factor.

Mechanical ventilation and use of invasive tubes are often cited as a reason for the use of restraints, in an attempt to prevent inadvertent removal by the patient [3]. Our results concur with previous studies indicating that these are major risk factors for physical restraint use [5].

Gender has been examined as a risk factor but the data are conflicting: in the German study cited here, women were found to be at higher risk, whereas in the U.S. study, men were at increased risk of physical restraint use [5,10]. Our study has also shown men to be at higher risk for restraint use, but the inconsistency of results in various studies precludes drawing any conclusions on this question.

STUDY STRENGTHS AND LIMITATIONS

Our study has several strengths. Data were collected by direct observation of patients as well as review of patient records. Since this was a prospective study, data on patient characteristics and clinical condition were collected at the time of restraint, thereby avoiding the bias of a retrospective review of patient records. The methodology of using trained observers, supplemented by nursing and medical records, has been studied and found to be effective and to produce consistent results [21]. Our study population was limited enough to allow an extensive review of risk factors, but also wide enough to reflect the day-to-day reality of a mid-sized hospital.

Table 4. Multivariate analysis

	β	SE	Wald	df	Sig	Exp(β)	95%CI for EXP(β)	
							Lower	Upper
Step 1*								
Age	0.015	0.015	0.900	1	0.343	1.015	0.985	1.046
Male	1.049	0.454	5.334	1	0.021	2.855	1.172	6.956
Nursing home	0.682	0.541	1.589	1	0.207	1.978	0.685	5.712
Dependent	1.185	0.525	5.090	1	0.024	3.271	1.168	9.159
CCI	0.135	0.114	1.404	1	0.236	1.145	0.915	1.432
Invasive ventilation	1.542	0.570	7.322	1	0.007	4.676	1.530	14.290
Invasive tubing	2.043	0.446	20.966	1	0.000	7.716	3.218	18.503
Bedsores	-1.112	0.584	3.624	1	0.057	0.329	0.105	1.033
Length of stay	0.006	0.012	0.279	1	0.597	1.006	0.983	1.030
No. of medications	0.000	0.057	0.000	1	0.997	1.000	0.894	1.118
No. of psychotropics	0.110	0.150	0.542	1	0.462	1.116	0.833	1.497
Antibiotics	-0.667	0.489	1.862	1	0.172	0.513	0.197	1.338
Constant	-4.129	1.443	8.191	1	0.004	0.016		
Step 6*								
Age	0.010	0.012	0.726	1	0.394	1.010	0.987	1.034
Male	1.231	0.440	7.835	1	0.005	3.423	1.446	8.104
Nursing home	0.935	0.523	3.196	1	0.074	2.548	0.914	7.103
Dependent	1.304	0.506	6.648	1	0.010	3.685	1.367	9.933
Invasive ventilation	1.648	0.523	9.915	1	0.002	5.195	1.863	14.488
Invasive tubing	2.236	0.428	27.333	1	0.000	9.353	4.045	21.625
Bedsores	1.200	0.541	4.924	1	0.026	3.319	1.150	9.577
Constant	-3.646	1.057	11.891	1	0.001	0.026		

*Variable(s) entered on step 1: CCI (Charlson Comorbidity Index), invasive ventilation, invasive tubing, bed sores, length of stay, no. of medications, no. of psychotropics, antibiotics
CI = confidence interval

Our study does have some limitations. The methodology bears some inherent drawbacks. As a descriptive study it makes causality difficult to infer. The fact that the study was performed in a single center may limit its generalizability. We did not record the length of restraint, only the point-prevalence.

The group of restrained patients comprises a cumulative list of 10 different observations. Since ethical requirements necessitated that data be collected anonymously, we had no way of identifying restrained patients who had been included in the registry at an earlier observation (having been restrained on multiple observations). Hence, our group of 76 restrained patients might actually contain fewer patients, with several of them counted more than once. Spreading the observations over a time frame of 3 months helped keep the risk of repeat observation low.

We chose to investigate certain risk factors and not others. One glaring omission is that of the diagnoses of dementia and/or delirium. However, data on the diagnoses of patients were obtained from medical records, and both dementia and delirium are grossly under-reported in patient records [22,23]. We preferred to exclude these important risk factors from our study rather than risk producing misleading results regarding them. Several other factors, such as independence or housing situation, are part of the structured medical form in certain wards but not in others, which may result in observation bias.

GENERALIZABILITY

Our study offers observational data on the use of physical restraints in a particular setting – an acute care hospital. Since our study included only one center, more research is required before findings can be generalized to other acute care centers.

In Israel, physical restraint is legally regulated by the aforementioned Ministry of Health directive [16]. Bed-rails are not considered physical restraints by this directive, nor treated as such by medical staffs. These features differ from other countries.

Correspondence

Dr. E. Gil

40 HaTishbi St., Haifa 3452501, Israel

Fax: (972-4) 835-9419

email: Efrat.gil@b-zion.org.il

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