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Factors relating to the use of physical restraints in psychogeriatric care: A paradigm for elder abuse

Anwendung von mechanischen Fixierungsmaßnahmen in der stationären Gerontopsychiatrie: ein wichtiger Aspekt des Problemfeldes Gewalt gegen alte Menschen

Summary The purpose of this study was to address one component of the complex topic "elder abuse". A prospective observational study in the psychogeriatric unit of an acute psychiatric hospital demonstrated that 30% (n = 37) of all included patients (n = 122) were physically restrained. The highest incidence (48%) was found in elderly patients with severe cognitive impairments (diagnosis of dementia and/or delirium) (n = 60). The most commonly used devices of physical restraints were bed rails (100%), belts (trunk 93%, limbs 40%) and chair-tables ("gerichair") (41%). Most restraints occurred at the beginning of hospitalization (83%). Physical restraints were continued for many days and on average of many hours a day. Patients with low cognitive status and serious mobility impairments showed a very high risk of being restrained (p = 0.015; OR 32.0 [95% CI:2.0–515.1]). Inability to perform ADL activities increased the frequency of restraint use (p = 0.035; OR27.7 [95%CI: 1.3–604.1]). As possible co-factors repetitive disruptive behaviors were found. There was no significant difference between the frequency of falls in restrained or unrestrained patients during the observational period, but fall-related fractures (n = 2) only occurred in restrained patients. It is possible that restraints increase the use of benzodiazepines and classical neuroleptics.

These results confirm that physical restraints remain a common practice in psychogeriatric care. No evidence-based data support the value of restraints in regard to fall prevention and control of behavioral disturbances in elderly people with serious mental illness. In contrast, these devices can have serious adverse effects and mean one of the most severe interventions in fundamental human rights.

Key words Physical restraints – cognitive impairment – elder abuse – falls – behavioral and psychological symptoms of dementia

Zusammenfassung Die vorliegende prospektive Beobachtungsstudie untersucht die Anwendung von mechanischen Fixierungsmaßnahmen in der stationären Gerontopsychiatrie als einen wichtigen Aspekt des Problemfeldes Gewalt gegen alte Menschen in Institutionen. Circa ein Drittel (n = 37) aller in die Auswertung eingeschlossenen Patienten (n = 122) wurden im Behandlungsverlauf fixiert. Die höchste Fixierungsinzidenz mit 48% (n = 29) wiesen Patienten mit einer höhergradigen kognitiven Einschränkung (Demenz und/oder Delir) (n = 60) auf. Als häufigste Fixierungsmaßnahmen wurden Bettgitter (100%), Gurtfixierungen mittels Bauch- (93%) und Extremitätenmanschetten (40%) und Tischsteckbretter (sog. "Geristuhl) (41%) eingesetzt. Meist wurde gleich zu Beginn des Krankenhausaufenthaltes (83%) fixiert, die Maßnahme dann regelmäßig (über viele Tage), und langdauernd (über viele Stunden

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täglich) aufrechterhalten. Ein besonders hohes Risiko für die Anwendung einer Fixierung hatten demente alte Menschen mit erheblicher Mobilitätseinschränkung ($p = 0{,}015$; OR 32,0 [95% CI:2,0–515,1]). Mit abnehmenden Alltagsfähigkeiten nahm das Risiko für eine Fixierungsmaßnahme zu ($p = 0{,}035$; OR27,7 [95%CI: 1,3–604,1]). Mögliche Co-Faktoren stellen wiederholt auftretendes verbales und körperliches Störverhalten dar. Im Verlauf traten Stürze bei fixierten und nichtfixierten Patienten etwa gleich häufig auf, Frakturen ($n = 2$) allerdings nur bei im Verlauf fixierten Patienten. Fixierungen gingen möglicherweise mit einer erhöhten Verabreichung von typischen Benzodiazepinen und hochpotenten Neuroleptika einher.

Die Ergebnisse belegen, dass Fixierungen häufig, wenn nicht zu häufig angewendet werden. Fixierungen sind weder ein adäquates noch evidenzbasiertes Mittel zur Verhinderung von Stürzen oder Beeinflussung von fordernden Verhaltensweisen bei demenzkranken alten Menschen. Solche Maßnahmen sind allerdings selbst nicht ohne Risiken und stellen einen schweren Eingriff in das Grundrecht des Menschen auf persönliche Freiheit dar.

Schlüsselwörter Mechanische Fixierungen – Demenz – Gewalt gegen alte Menschen – Stürze – fordernde Verhaltensweisen

Introduction

For many years, the use of physical restraints has been a controversially discussed yet frequently employed intervention for the frail, cognitively impaired elderly. The most commonly used restraint devices include bed siderails, belts (waist, wrist, ankle), and chair tables ("gerichair") which prevent a person from rising or moving and cannot be removed independently. The protection and safety of patients, fall prevention and behavior control are still the most frequently cited rationales for restraint use [10, 12]. Unquestionably, this technique means one of the most severe interventions in fundamental human rights and is a key issue of the complex topic "elder abuse". This domain will be a growing concern accompanying the demographic changes and lack of community care resources in the next two decades.

Prevalence of physical restraints in acute care hospitals has been reported to be in the range of 7.4–25% [10, 23]. Patients 70 years of age and older were restrained more frequently (20.3%) than younger patients [13]. In acute geriatric care, the incidence of restraint use is reported with 24% [18] compared to a reported prevalence of 33% of mechanical restraint use in a rehabilitation facility [29]. Concerning psychogeriatric acute care, DeSantis [9] reported an incidence of 27.1%. Only poor data exist about the prevalence of physical restraints in German psychogeriatric acute care: In a long-sectional study, Hirsch RD [16] reported a prevalence of 21.3% in psychogeriatric ward of an acute psychiatric hospital, while a later designed across study of 29 psychogeriatric units of different hospitals showed a prevalence of 24.9% [20]. The use of restraints in residential care is more commonly reported and ranges between 12 and 47% [10, 31]. A comparison of restraint use in nursing homes of different countries highlighted significant differences in practice, with rates from less than 9% of residents in Japan and Denmark to a maximum of almost 40% in Spain [21]. The use of physical restraints in German nursing homes is reported to range from 10–43% [2, 19, 34]. Hamers [14] focussed on the use of physical restraints with cognitively impaired nursing home residents and found a prevalence of 49%.

The purpose of this first German pre-post observational study was to investigate the frequency, duration, patterns and reasons of physical restraints but also to identify the patient characteristics that predict the use of physical restraints in a German psychogeriatric population.

Methods

Patients and setting

A prospective observational study was performed on 129 patients, for four months consecutively admitted into a psychogeriatric unit (three wards with a total capacity of 76 patients) of a large acute psychiatric care facility[1] in Gießen in central Germany. This facility was responsible for a local health care district with urban (*Gießen, Schotten, Hanau*) and rural areas (*Kreis Giessen, Wetteraukreis, Main-Kinzig-Kreis*) with a total population of 641 000 people, of whom about 21% were aged 60 or older at the time of the study.

Data for each patient were collected prospectively for the first three weeks (day 1–18) following admis-

[1] Psychiatrisches Krankenhaus Gießen, Einrichtung des Landeswohlfahrtsverbandes Hessen

sion. Patient consent was not documented as the measuring instruments were either included in the routine admission process or recorded data normally present in the patient's chart. Refusing the functional assessment (or parts of it) was possible and was measured as a result.

Baseline data and assessment of clinical variables

Demographic and clinical data included age, gender, psychiatric primary diagnosis, neurological illness (Parkinson's disease, stroke), severe cardiac arrhythmia, hypotension, dehydratation, underweight, visual deficiency, history of falls and fractures (last three months) and psychotropic medication (last week). Data were obtained from medical charts and by interviewing therapeutical staff (nurses, physicians).

The functional psychogeriatric assessment based upon Nikolaus [25] was performed within 72 hours of admission (T1), within a 48-hour period in case of being physically restrained for the first time ("facultative" T2) and three weeks (day 18–21) after admission (T3).

The Barthel Index (BI) was used to determine ADL dependency (activities of daily living). Mobility was assessed by a data set including general mobility status (e.g., devices), static balance using the modified Rombergtest (feet parallel open/closed, semitandem position, tandem position) [3], one-leg balance based on Vellas et al., "Stops walking when talking" (Lundin-Olsson et al.), Timed "Up&Go" (Podsialdo & Richardson) and Performance-Oriented Mobility Assessment, version I (POMA I) based on Tinetti.

Cognitive function was measured using Folstein's Mini-Mental State Examination (MMSE) and the Global Deterioration Scale (GDS) based on Reisberg.

Behavioral and psychological symptoms were determined by a translated and modified version based on a) the Cohen Mansfield's Agitation Inventory (CMAI) for disruptive and agitative behaviors in the elderly and b) the Behavior Mapping Inventory (BMI) used by the research group led by R. Neufeld of The Jewish Home and Hospital for Aged (JHHA) in New York [7]. The German Weyerer's assessment for behavior disturbances was also used [35].

Mechanical restraint use

Data on type, location, frequency of and reasons for mechanical restraints use were obtained from daily protocols including visual checks. In accordance to the results of the pilot study, the valid restraint forms of the *Landeswohlfahrtsverband Hessen* had been modified in the sense of multiple choice for types of and reasons for restraints to facilitate statistical analysis. Mechanical restraints in this study were defined as belts (waist, wrist, ankle) used in beds and/or chairs and wheelchairs, bed siderails, chair-tables ("gerichair") and other devices (e.g. overalls, mittens, tapes) which prevent persons from rising or moving and which cannot be removed independently. Bed siderails were excluded in case of total inability to move independently (maximal immobility). Frequency of restraint use was defined using both the number of days and the average hours a day of being restrained during the follow-up of three weeks after admission. Data were collected from restraint documentation forms but also monitored by daily site visits of the investigator. The "day of first restraint" and daytime (day/night) of restraint were also registered.

Statistical analysis

Baseline data were described for the entire group of psychogeriatric patients (n = 122). Univariate associations were analyzed for the identified high-risk subgroup of patients (*see Restraint use*) with cognitive impairments using contingency table (clinical variable – restraint use), Fisher's Exact-Test (2-tailed; p) and relative risk. In a second step, relevant correlations were identified and dependent clinical variables eliminated using contingency tables. For multivariate analysis Categorical Data Modelling (CATMOD) procedure in SAS software was used for forward stepwise variable selection. Multiple logistic regression was performed to determine the independent association between restraint use and primary endpoint variables (ROC curve, p, Odds ratio). An additional multivariate analysis was performed after using a classification tree (preselection of the high-risk subgroup of patients with severe cognitive *and* mobility impairments). Risk factors instead of predictors were described due to the small number of patients and the vulnerability of the mathematical model (Hosmer and lemeshow Goodness-of-Fit Test $p < 1$). The identified risk factors tended to show a higher sensitivity but a lower specifity.
Further analyses were done to describe the follow-up of relevant clinical variables (T3).

Results

Patients characteristics

Statistical analysis was performed on a total of 122 psychogeriatric patients (seven drop-outs as early

dismission or death). The median age (33.9%) of all patients was 70–74 years (evaluation was performed in five-year groups from 60–64 to 90–94). A total of 91 patients (74.6%) were women. 60 (49.2%) of all patients had severe cognitive impairments (psychiatric primary diagnosis of dementia and/or delirium). In this subgroup, the median age was 85–89 years (35.0%) and 39 patients (65.0%) were female.

Restraint use

A total of 37 (30.3%) patients were found to be restrained at least once during the follow-up period; 29 (78.4%) of the physically restrained patients had severe cognitive impairments. The correlation between psychiatric primary diagnosis and restraint use is shown in Fig. 1. Accordingly, patients with the diagnosis of dementia and/or delirium were more likely to be restrained (48.3%) than patients with other diagnoses. To further evaluate the association between physical restraint use and clinical variables, this patient subgroup with severe cognitive impairments (n = 60) was identified as a high-risk group for the use of physical restraints.

Focusing on restrained patients (n = 29) of the cognitively impaired patients, initiation of restraint use was distributed on day one and two (82.8%), day four, five and seven (10.3%) and day 14 and 16 (6.9%) after admission. 15 (51.7%) of the patients were continually restrained for 14 to 18 days, 7 (24.1%) for 7 to 13 days and 4 (13.8%) for 1 to 2 days (in the 18 days of follow-up after admission). The median duration of the average restraint use a day was 8–12 h (34%), 12–16 h (24.1%), 16–20 h (17.2%) 4–8 h (17.2%) and for one patient (3.4%) 20–24 h. No patient met criteria for short intermittent restraint use (2–4 hours a day). Types of physical restraint use and reasons for restraint ascertained from the responsible physician are shown in Figs. 2 and 3 (single analysis). Of the patients, 25% were exclusively restrained by means of bed rails and trunk belts. Another commonly used physical restraint combination included bed rails and trunk belt and at least one limb (33.3%). This variant

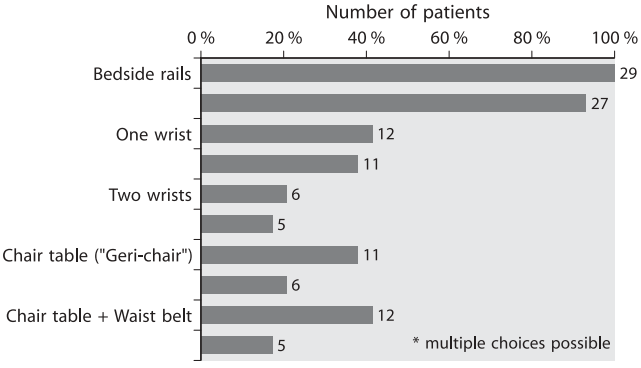

Fig. 2 Type of restraints used in physically restrained patients with cognitive impairments (n = 29)

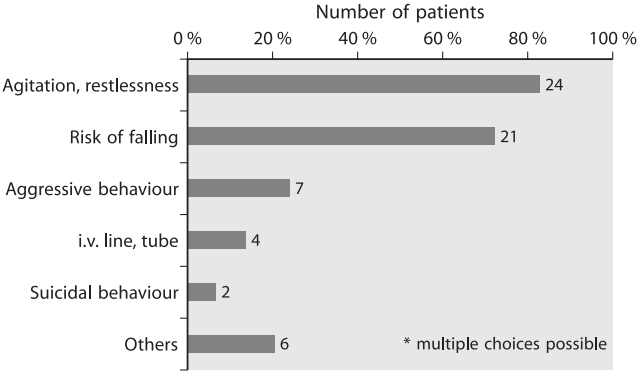

Fig. 3 Reasons for restraints in physically restrained patients with cognitive impairments (= 29)

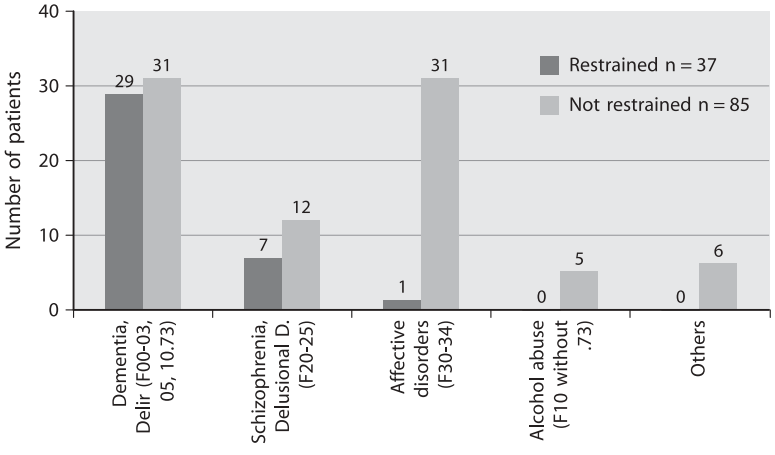

Fig. 1 Correlation between primary psychiatric diagnosis and physical restraint use in all psychogeriatric patients (n = 122)

mostly means the so called "cross-over" practice restraining trunk, one arm and the contra-lateral leg, but also the maximum "five-point" restraining practice concerning trunk and all limbs.

Correlations between baseline data and restraint use

For all psychogeriatric patients, a possible correlation ($p = 0.046$) could be found between old age and physical restraint use but not for the subgroup of cognitively impaired patients. Men were more likely to be restrained than women ($p = 0.117$): 13 (41.9%) of 31 male and 24 (26.4%) of 91 female patients were restrained during the three-week follow-up. All physically restrained men (100.0%) suffered from severe cognitive impairment.

Correlations between clinical variables and restraint use in cognitively impaired patients (univariate level)

Focusing on the high-risk group for the use of physical restraints ($n = 60$), patients with most severe cognitive impairment ("Reisberg VII") (8 from 10) were more likely to be restrained (80.0%) than less cognitively impaired patients ("Reisberg IV–V") (2 of 13; 15.4%) ($p < 0.01$). Possible correlations could be found between stroke history ($p = 0.037$) and physical restraint use, also for dehydration ($p = 0.011$) at time of admission. Frequency of restraint use increased according to increase of ADL dependency ($p = 0.001$). 16 (88.9%) of 18 patients with a Barthel-Index (BI) ≤ 20 were physically restrained but no patient with a BI ≥ 85.

Restraint use was significantly associated with mobility impairments. Patients with independent mobility ($n = 27$) were less likely to be restrained (33.3%) than patients with dependent mobility (devices or person's help or immobility) (60.6%) ($p = 0.042$; RR = 0.53 [0.30–0.96]). Univariate analysis of relevant mobility assessment results are shown in table 1. To preselect dependent variables for multivariate analysis, a significant association could be identified between results of POMA I and the Semitandem Position ($p < 0.0001$), also for ADL dependency (BI) and the Semitandem Position (p<0,0001). No significant association was found between history of falls and fractures and physical restraint use.

Relevant associations ($p \leq 0.05$) between behavioral disorders assessed with modified CMAI/BMI and the use of physical restraints are listed in Table 2. Subclassification of behavioral items is based upon the published data of Miller (1995) on CMAI. Data analysis (p, RR) was limited on items occurring with a frequency of $\geq 10\%$. Behavioral disturbances as measured by Weyerer's inventory were not significantly related to restraint use. No significant association could be identified between history of subclassified psychotropic medication (last week for admission) and physical restraint use.

Table 1 Association between restraint use and mobility impairment in cognitively impaired patients ($n = 60$) at univariate level. The mobility (sub-)tests listed are those relevant for further data analysis

Mobility Test	Restrained/ Not Restrained	P	Relative Risk (RR) (95% CI)
Semitandem Position			
possible	2/12		
not possible	27/19	0.005	0.24 (0.09–0.64)
POMA I <20 Points	27/20		
≥20 Points	2/11	0.011	3.73 (1.42–9.85)

Table 2 Relevant associations ($p \leq 0.05$) between behavioral disturbances and physical restraint use at the univariate level. Only items with a frequency of occurrence of $\leq 10\%$ were analyzed

Behavioral Item (modified CMAI)	Restrained/ Not Restrained	P	Relative Risk (RR) (95% CI)
1. Aggressive behavior			
Grabbing onto people	7/1	0.024	2.07 (1.13–3.78)
Throwing things	6/1	0.049	1.98 (1.04–3.74)
2. Physically nonaggressive behavior			
Performing repetitious mannerisms	7/1	0.024	2.07 (1.13–3.78)
(General) Restlessness	26/21	0.060	2.40 (1.04–5.55)
3. Verbally agitated behavior			
Screaming, calling, crying	12/4	0.019	1.94 (1.15–3.29)
Constant unwarranted requests for attention or help	14/16	0.028	1.87 (1.11–3.14)
Repetitive sentences or questions	8/2	0.039	1.90 (1.07–3.40

Risk factors for physical restraint use

In multivariate analysis, impaired mobility (Semitandem Position not possible) was identified as an independent risk factor ($p = 0.015$; Odds ratio (OR)

Table 3 Predictive values of independent variables (T1) for physical restraint use in multivariate analysis (logistic regression) before using classification tree

Independent risk factor	P	Odds ratio (95% CI)
Semitandem Position	0.015	31.96 (1.98–515.15)
Throwing things	0.035	27.66 (1.27–604.12)
Performing repetitious mannerisms	0.039	10.71 (1.13–101.71)
Repetitive sentences or questions	0.013	23.12 (1.93– 277.01)

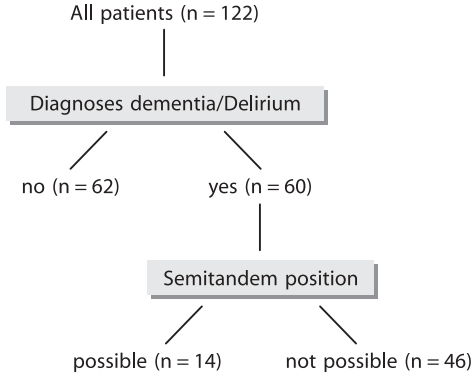

Fig. 4 Preselection of the high-risk group of patients with severe cognitive impairments and impaired mobility for the CATMOD procedure and logistic regression (classification tree)

Table 4 Predictive values of independent variables (T1) for physical restraint use in multivariate analysis (logistic regression) after preselection using the classification tree (Fig. 4)

Independent risk factor	P	Odds ratio (95% CI)
(General) Restlessness	0.055	4.74 (0.97–23.22)
Constant unwarranted requests for attention or help	0.078	3.54 (0.87–14.43)

[95% CI] 31.96 [1.98–515.15]) for the use of physical restraints in cognitively impaired patients (preselected high-risk group). Disruptive behaviors as throwing things ($p = 0.035$; OR 27.66 [1.27–604.12]), performing repetitious repetitive mannerisms ($p = 0.039$; OR 10.71 [1.13–101.71]) and repetitive sentences or questions ($p = 0.013$; OR 23.12 [1.93–277.01]) were co-factors for restraint use. Results are shown in Table 3. By preselecting the subgroup of cognitively impaired patients with mobility impairments by means of a classification tree (Fig. 4) multivariate analysis identified different disruptive behaviors as possible co-factors: (general) restlessness ($p = 0.055$; OR 4.74 [0.97–23.22]) and constant unwarranted requests for attention or help ($p = 0.078$ OR 3.54 [0.87–14.4]) (Table 4).

Comparison between clinical variables of restrained and unrestrained cognitively impaired patients after three weeks of follow-up

A total of 25 (41.7%) patients with cognitive impairment fell at least once during the observational period (day 1–18 after admission). Fall risk and the frequency of serious and less serious injuries did not differ significantly between restrained and unrestrained patients. However, the two registered hip fractures occurred in the group of restrained patients. No fracture happened in unrestrained patients.

A possible correlation could be found between restraint use and application of neuroleptics with high potency ($p < 0.14$) and typical benzodiazepines ($p = 0.154$).

For mobility impairment, ADL dependency and behavioral disturbances, no significant changes could be identified within the observational period (scatter plot).

Discussion

This study has shown that physical restraints are used very commonly (possibly overused?) in psychogeriatric acute care in Germany. Nearly one third (30.3%) of patients cared for in a psychogeriatric unit of an acute psychiatric facility had been restrained physically on some occasion during the prospective observational period of three weeks after admission. The highest incidence (48.3%) was found in the high-risk group of patients with severe cognitive impairments (dementia and/or delirium). These findings are generally consistent with the prementioned limited previous research existing on restraint use in psychogeriatric facilities [9, 16, 20]. The somewhat higher incidence of restraint use in this study is possibly due to the applied prospective pre-post-observational design. Restraint data collection was not only limited to retrospective evaluation of documentation, but also controlled and monitored by daily site visits in order to diminish the number of unknown cases (e.g., chair-tables, tapes, bed rails).

Since this research was conducted in only one psychogeriatric unit, the findings are limited and may not generalize to other settings. The wide disparity between law and guideline practices in different German states and facilities has also to be considered. In addition, the staff was aware of the study, and this may have influenced the use of restraints as found in a previous study [16]. However, a retrospective data analysis of documented physical re-

straint use in the same psychogeriatric unit half a year before this study a prevalence of about 25%.

The most frequent use of physical restraints was found in patients with severe cognitive impairments (78% of the restrained psychogeriatric patients). Cognitive impairment has been described as a strong predictor of the use of physical restraint [18, 29, 32].

Based upon our corresponding findings, further evaluation was focused on the high-risk group of patients with psychiatric diagnosis of dementia and/or delirium.

The decision to use physical restraints was mainly done (82.8%) already at the time of admission (day 1–2). Physical restraints were very often used continuously throughout the observational period (51.7% over 14–18 days) with an average of many hours a day (79.3% > 8 h). These findings support the clinical psychiatric experience "once restrained, always restrained" but also results from previous research [29]. Corresponding with the findings of Hirsch and Kranzhoff [15], the most commonly used devices of physical restraints were bed rails (100%) and trunk belts (93%). The common use of combinations of restraint devices in this study as bed rails and "over-cross" technique restraining one arm and the contra-lateral leg with belts or maximum "five-point" restraint practice (trunk and all limbs) might be based upon valid restraint guidelines of the facility and automatic routines to secure patient's safety.

In accordance with previous comparable research [15, 19], fall risk (including imbalance of transfers and gait) (72%) and agitated behavior (general restlessness) (83%) were the most common reasons cited by staff for the use of physical restraints. Aggressive behavior as a common reason for physical restraint use in younger psychiatric patients was less relevant (24%). Suicidal behavior or medical reasons as tubes and i.v. lines were also of minor importance (7–14%). It is possible that the responsible physicians chose to report a reason which they thought might morally justify their acting rather than other reasons experienced as more doubtful. For example, disruptive behavior is not generally accepted as a legitimate reason for restraint use, while risk of falling is a generally well accepted legitimation.

As documented in previous studies we also found that lower cognitive status, inability to perfom ADL acitivities, mobility impairments and disruptive behaviors closely relate to physical restraints [14, 17, 30]. Although cognitive impairment proved to be a very important factor for the use of physical restraints, the study could show significant differences between the restrained and the unrestrained cognitively impaired patients. The restrained cognitively impaired patients were more dependent on ADLs and mobility and had the lowest cognitive status (Reisberg VI–VII). Risk of falling (Semitandem Position not possible) and disruptive behaviors as possible cofactors were associated independently with physical restraint use. Particularly verbally (repetitive sentences) or physically agitated behavior (repetitious mannerisms, general restlessness, constant unwarranted requests for help or attention), rather than aggressive behavior were found as independent risk factors for the use of physical restraints. These findings correspond with results of earlier investigations [9, 18, 30].

However, some methodological limitations should, be considered when these results are interpreted. It is obvious that the small number of patients influenced the stability of the mathematical model used. A possible alternative could have been to refer further data evaluation to the total number of physical restraints or hours of restraint [15]. We rejected this possibility for reasons of better clinical transparency and relevance of the results as well as comparability to other international findings. For reasons of practicability (a single investigator) and statistical analysis, behavioral disturbances (modified CMAI/BMI) were only registered dichotomously (yes/no) with the consequence of lacking information about frequency and daytime of occurrence. Further data analysis was performed without considering whether a behavioral item occurred only once or more, a very important meaning for the stress load of staff. We cannot eliminate the possibility that other relevant factors than those assessed in this study may have contributed to the decision regarding restraint use.

It has been reported that the use of physical restraints is also influenced by factors of staff and facility. Sullivan-Marx [30] found staff mix as an independent predictor for restraint use. The use of physical restraints has been reported to pose an ethical dilemma on caregivers: whether to promote the safety of the frail elderly and prevent him from direct harm or to allow him the autonomy of making choices, taking a risk and remaining ambulatory [8]. In addition, caregivers experience a wide range of negative emotions and inner conflicts using restraints. As a result, these emotions can lead to the well-known and widespread "Burnout Syndrome" in caregiver professions. Accordingly, the decision-making of the use of physical restraints can be influenced of conscious and unconscious motivations and emotions by staff. Unfortunately, it was not possible to realize a prepared staff questionnaire in the present study.

The use of physical restraints in the cognitively impaired elderly also reflects the conflict of autono-

my and dependency of the concerned person. The restrained patients' inability to perform ADL activities and unimpaired mobility shows that these patients need a lot of help from their caregivers and depend on them to manage their everyday lives. The severity of cognitive impairment commonly associated with impaired speech means that it is difficult or even impossible for these patients to influence decisions regarding the use of restraints. On the other hand, this also means that these patients are often unable to understand or remind the reason of being restrained or to say what it is like to be physically restrained, but makes them agitated and restless. Although we could not confirm a general increase of behavioral disturbances in restrained patients throughout the follow-up with our findings, a previous review reported that the use of physical restraints has a negative psychological impact [6]. As a possible indirect marker, an increase of the application of neuroleptics with high potency and typical benzodiazepines could be found in the restrained patients throughout the follow-up. Physical restraints are known to produce intense psychological stress on people and animals [33]. A recent experimental investigation with Wistar rats reported the negative effect of chronic restraint stress on spatial learning and memory by stress induced lipid peroxidation in the hippocampus and frontal cortex [1].

No controlled studies that evaluate the value of restraints of those with serious mental illness exist [28, Cochrane Review]. In contrast there are reports of serious adverse effects such as decline in social behavior, cognition and mobility, development of pressure sores, internal complications (e.g., thrombosis, pneumonia), lacerations, strangulations, psychological stress and death [4, 11, 26, 27]. On the other hand – as an effect of legislative attempts to initiate a major restraint reduction movement in the U.S. (Omnibus Budget Reconciliation Act, OBRA of 1987) – recent international trials reported that physical restraints are inadequate to prevent falls. Efforts of reducing restraint use do not seem to lead to increased fall-related injuries [5, 24].

Thus, controlled studies cannot support the continued use of physical restraints and evidence-based data do not exist about effective alternative methods or interventions.

The findings of this study confirm that the frequent use of physical restraints in the cognitively impaired frail elderly might be rather based upon routines and personal values and beliefs than on evidence-based informed consent decisions.

Reducing the use of physical restraints must consider clinical, ethical and legal concerns. Factors that influence health care providers' decisions regarding whether to use physical restraints, include organizational characteristics, systems of care, environmental characteristics, specific clinical guidelines or protocols as well as individual patient characteristics [17, 19, 30]. Further studies should be designed with the aim of restraint reduction, considering staff education about risks, adequate alternatives and interventions (e.g., strategies of fall prevention, management of disruptive behavior) of physical restraints, based upon previous research and the findings of this study.

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