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# Restraint use in the acute-care hospital setting: A cross-sectional multi-centre study



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# ABSTRACT

*Background:* Restraints are likely to negatively affect patients' health and therefore a reduction in their usage is recommended for all health-care settings. To date, research on restrictive practices has concentrated on mental health and long-term care settings. In the acute-care hospital setting few studies have been published and these studies mainly focus on physical/mechanical restraints in specific subpopulations and/or on intensive care units. However, to ensure restraints are used as little as possible in the acute-care hospital setting, it seems important to investigate more comprehensively the use of restraints, to include all types of restraints irrespective of ward type or subpopulations and to identify factors associated with restraint use.

*Objective:* The aim of this study was to investigate restraint use regardless of ward type in the acutecare hospital setting, including restraint type, reasons for restraint use, process indicators when using restraints and restraint use-associated patient characteristics.

*Methods:* Using a cross-sectional multi-centre design, data were collected by means of an annual international prevalence measurement in acute-care hospitals in Switzerland and Austria. All hospitalised patients aged 18+ who gave informed consent were included. Data were collected at three measurement points between 2016 and 2018. Descriptive and multivariate logistic regression analyses were performed. *Results:* A total of 29,477 patients hospitalised in 140 hospitals were included in this study. The prevalence rate for the use of at least one restraint over a 30-day period was 8.7% (n = 2577), with mechanical restraints representing the highest proportion of restraint type used (55.0%, n = 1417). The main reason for restraint use was fall prevention (43.8%, n = 1129), followed by confusion or delirious behaviour (20.4%, n = 525). In 64.3% of the cases (n = 1657), restraint use was documented in the patient file. Regular evaluation occurred in 42.9% of the cases (n = 1105). Care dependency had the strongest association with restraint use (odds ratio [OR] 25.00, 95% confidence interval [CI] 21.01–29.78 for completely dependant patients in comparison to completely independent patients), followed by mental and behavioural disorders (OR 2.36, 95% CI 2.15–2.59).

*Conclusions:* Restraints are often utilised in hospitals in complex care situations such as with patients at risk of falling or with delirium. When using restraints the consideration of processes like documentation and evaluation shows great potential for improvement. Standardisation of these processes and education of the interprofessional team could be beneficial for raising awareness and for the sustainable reduction of restraint use.

**Tweetable abstract:** In hospitals restraints are often used in complex care situations. However, their use seems to be insufficiently documented and evaluated.

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# What is already known about the topic?

- A reduction in restraint use is recommended for all health-care settings due to their negative effects on patients.
- With regard to the acute-care hospital setting, little is known internationally as few studies have been published, and these studies mainly focus on physical/mechanical restraints in specific subpopulations and/or on intensive care units.
- To reduce restraint use in the acute-care hospital setting as much as possible, it seems important to investigate more comprehensively the use of restraints.

# What this paper adds

- The 30-day prevalence of patients with at least one restraint was 8.7%, including different restraint types such as bed rails and electronic or pharmacological measures.
- The main reasons for restraint use were the prevention of falls and the management of confusion or delirious behaviour.
- Documentation was part of restraint use in 64.3% of the cases and evaluation in 42.9%.

# 1. Background

Restraints can have negative effects on patients' physical and mental health, therefore a reduction in their use is recommended for all health-care settings (Registered Nurses' Association of Ontario, 2012). To date, research and regulations on restraint use have focused on mental health and long-term care settings (Cusack et al., 2018; Möhler et al., 2011; Scheepmans et al., 2020). However, in the somatic acute-care hospital setting (henceforth referred to as "hospital") little is known internationally about the use of restraints and clear regulations are lacking (Xyrichis et al., 2018). Nevertheless, restraints may be used for various reasons in hospitals. To ensure that restraints are used as little as possible in this setting as well it is important to describe the restrictive practices. Thus, more information will be available to identify and develop quality improvement approaches.

Restraints are defined as "interventions that may infringe [on] a person's human rights and freedom of movement, including observation, seclusion, manual restraint, mechanical restraint and rapid tranquillisation" (National Institute for Health and Care Excellence [NICE], 2015, p. 17). Previous studies on the prevalence of restraint use in hospitals showed that rates range between 0% and 100% (Benbenbishty et al., 2010; Krüger et al., 2013). These large differences in the prevalence rates may be influenced by varying conditions, such as the restraint definition used, the legal situation in the country of origin or the availability of equipment (for example, for body fixation) (De Bellis et al., 2013; Goethals et al., 2013; Hignett et al., 2013; Lach et al., 2016). In general, the few published studies in the hospital setting have mainly focused on physical/mechanical restraints in specific subpopulations and/or in intensive care units (ICUs). Comprehensive research on restraints, including various interventions limiting a person's human rights and irrespective of specific ward types and subpopulations, is lacking (Xyrichis et al., 2018).

The reasons for using restraints have been studied in various settings, and within the long-term care and hospital setting similar reasons for their usage were found in the research. The most frequently stated reasons were patient safety (especially fall prevention), cognitive impairment, and particularly in the hospital setting the prevention of therapy interruption (for example, preventing self-extubation) (Farina-Lopez et al., 2014; Freeman et al., 2016; Gu et al., 2019; Hofmann and Hahn, 2014; Perez et al., 2019; Scheepmans et al., 2020). However, various studies reveal that restraints have no impact or even a negative impact on patient safety, fall prevention and self-extubation (Ai et al., 2018; Chuang et al., 2015; Cosper et al., 2015; Enns et al., 2014; Kiekkas et al., 2013; LeLaurin and Shorr, 2019; Perez et al., 2019; Rose et al., 2016; Sze et al., 2012). Thus, one of the basic ethical principles governing restraint use (that the expected benefit must exceed the damage) appears to be violated.

To reduce restraint use in the hospital setting as much as possible it seems important to investigate more comprehensively the use of restraints, including all types of restraints regardless of ward type (Xyrichis et al., 2018), and to determine predictors for their usage (Farina-Lopez et al., 2018; Freeman et al., 2016; Luk et al., 2014). This would support the identification of at-risk patients, raise awareness amongst health professionals regarding restrictive practices and reveal possible alternatives to their usage.

Therefore, the aim of this study was to investigate the use of restraints in the somatic acute-care hospital setting, including restraint type, reasons for restraint use and process indicators when using restraints. Additionally, the patient characteristics associated with restraint use will be examined.

# 2. Methods

# 2.1. Study design

Utilising a cross-sectional multi-centre design, data on the use of restraints were collected from hospitals in Switzerland and Austria. These countries are participants in "LPZ (Landelijke Prevalentiemeting Zorgkwaliteit) International". LPZ International performs an annual international prevalence measurement for different quality of care indicators (such as pressure ulcers, falls and restraints) in various settings, including hospitals (Van Nie-Visser et al., 2013, www.lpz-um.eu). As well as Switzerland and Austria, the Netherlands, the United Kingdom and Turkey are also participants in LPZ International. However, in these three countries, very few (or no) hospitals collect data on restraints. Therefore, only LPZ data from Switzerland and Austria were included in this study.

# 2.2. Setting and sample

For the LPZ International measurement, the national coordinator invites health-care institutions annually (via email, flyer, et cetera) to participate on a voluntary basis. In the hospital setting, all ward types (medical specialities) were eligible. Hospitalised patients aged 18+ with informed oral (Switzerland) or written (Austria) consent were included. Patients who were not available on the ward during the measurement (for example, as they were undergoing surgery) or who could not give informed consent (for instance, due to cognitive impairment or language barriers) and where no legal representative was available were excluded.

# 2.3. Variables and measurements

The LPZ 2.0 instrument, which is the revised version of the LPZ instrument, was used for data collection (Van Nie-Visser et al., 2013). It consists of a multi-module questionnaire with predefined answer options conceived as an online data entry program. For this study, data from the module on general patient characteristics and data from the module on restraints at three measurement points (08.11.2016, 14.11.2017 and 13.11.2018) were analysed.

The module on general patient characteristics included age, sex, surgical intervention in the two weeks prior to data collection, length of stay since admission to hospital, medical diagnosis groups according to ICD-10 (International Statistical Classification of Diseases and Related Health Problems 10th Revision) (World Health Organization, 2016) and care dependency. Care dependency was assessed using the Care Dependency Scale (CDS) (Dijkstra et al., 2012). The CDS consists of 15 items (for example, eating and drinking or mobility) that are rated on a Likert scale

from 1 to 5 (sum score 15–75). Lower scores indicate higher care dependency.

In the module on restraints the use of restraints within the institution was assessed regardless of restraint type for each patient retrospectively over a maximum period of 30 days (yes, no). Restraints were defined according to NICE (2015 – see background section). In regard to patients who had any restraint applied, the following criteria were surveyed:

- restraint type applied (multiple responses possible): mechanical (within this category bed rails, belt fixation, tabletop/chair table, other), electronic, pharmacological, physical, one-to-one supervision, locked ward or building, other (for definitions see Supplemental Material Table A)
- main reason for restraint use (single response possible): (preventing) falls, (preventing) wandering around, (preventing) aggressive behaviour, confusion or delirious behaviour, agitation, non-compliance with treatment, request of the patient and/or the family, other motive, unknown
- process indicators regarding restraint use (multiple responses possible): documentation, informing the patient/legal representatives about the entire process, evaluation, monitoring, use of alternatives, none.

The questionnaires are reviewed annually by the international research group of LPZ International and adapted where indicated, therefore answer options may differ across time. Because of this, the following restraint types were not available for all measurement points between 2016 and 2018 for the present study: the different types within mechanical methods (only assessed in 2018) and the answer option one-to-one supervision (only available for 2017 and 2018).

# 2.4. Data collection

All participating hospitals were requested to document restraint use during the 30-day period prior to the measurement (in case this was not normally completed in the patient's file or any other documentation system). On the measurement day data were collected by trained registered nurses on-site at the patient's bedside and/or through the patient's documentation (retrospective assessment). Training of the data collectors (the nurses) included recruitment of the patients for the measurement; information regarding the definitions, questions and answer options; and the use of the online data entry program. Additionally, a manual with all of the educational information, including a more detailed description, was available for the data collectors. Through their training along with the aid of the manual a uniform answering of the questions was ensured. The data collectors entered the data into the online data entry program, which only allowed questionnaire completion once all questions had been answered.

# 2.5. Country-specific regulations on restraint use

In the two countries (Switzerland and Austria) restraint use is regulated as follows. In Switzerland only the use of movement restriction measures for individuals in nursing and care homes who lack decision-making capacity, as well as for those with compulsory admission, is regulated by law (Bundesversammlung der Schweizerischen Eidgenossenschaft, 2018). As well as legal regulation, a medical-ethical guideline on coercive measures in medicine for all settings was developed (Swiss Academy of Medical Sciences, 2015). This guideline provides recommendations on coercive measures along with all other types of restraints. It focuses on ethical decision-making and considerations, as well as on process indicators such as evaluation and documentation. In Austria the use of restraints is regulated by the Nursing Home Residence Act and the Hospitalisation Act (Bundesministerium für Justiz, 1990, 2004). These acts regulate under which conditions, and by whom, restraints can be ordered and applied. The acts are applicable for mental health and long-term care settings, as well as for persons who have a mental illness or disability in hospital care. The reason, type, start and duration of the restraint must all be documented and immediately reported to the "Residential Advocacy Service".

#### 2.6. Statistical analysis

The data from the two countries and the different measurement points were pooled into one data set. Descriptive statistics (numbers, percentages, 95% confidence interval [CI], median, interquartile range [IQR]) were used to describe the sample, the prevalence rate and types of restraints, the main reason for using restraints and the process indicators. Additionally, the results regarding restraints were analysed for differences according to country utilising cross tables.

Multivariate logistic regression analysis with a stepwise backwards procedure, based on the Akaike information criterion (AIC) (Akaike, 1974), was used to investigate the associations between patient characteristics and restraint use. The independent variables female sex, surgical intervention in the two weeks prior to data collection and each ICD-10 diagnosis group (World Health Organization, 2016) were included dichotomously (yes, no). Two ICD-10 diagnosis groups (congenital malformations, deformations and chromosomal abnormalities; certain conditions originating in the perinatal period) and the answer option unknown/no diagnosis had to be excluded because they were only present in less than 1% of patients. The inclusion of these variables would have led to convergence problems concerning the regression model. Age in years and number of days since admission to hospital were included as interval variables. In terms of care dependency, the five verified categories according to the Care Dependency Scale were utilised (15-24 completely dependant, 25-44 dependant to a great extent, 45-59 partially dependant, 60-69 independent to a great extent, 70-75 completely independent) (Dijkstra et al., 2012). Country was included as a character variable. Multicollinearity was tested using the variance inflation factor (VIF).

Since data were collected using an online data entry program in which all questions had to be answered in order to finish the survey there were no missing data. The statistical analysis was conducted utilising R Version 3.6.1 (R Core Team, 2019) and the R Packages "compareGroups" (Subirana et al., 2014), "jtools" (Long, 2019), "MASS" (Venables and Ripley, 2002), "questionr" (Barnier et al., 2018), "tableone" (Yoshida, 2020), "tidyverse" (Wickham et al., 2019) and "vcd" (Meyer et al., 2020). For data cleaning and pooling SPSS version 25 (IBM Corp., Released 2017) was used.

### 2.7. Ethical considerations

In Switzerland the Ethics Committee of the Canton of Bern declared that the present study did not fall under the Swiss Human Research Act (April 2019, BASEC-Nr: Req-2019-00259), therefore ethical approval was not required. In Austria the Ethics Committee of the Medical University of Graz approved the study protocol (approval nr. 20–192 ex08/09). All patients or their legal representatives received written information about the measurement and gave their oral (Switzerland) or written (Austria) informed consent. Data were collected pseudonymously so that identification of individual patients is almost impossible. Participation was voluntary.

#### 3. Results

# 3.1. Sample

A total of 29,477 patients hospitalised in 140 hospitals were surveyed regarding the use of restraints in Switzerland (CH) and

# Table 1Patient characteristics.

Characteristics	Total $(n = 29,477)$		Switzerlar	nd $(n = 20,561)$	Austria ( $n = 8916$ )		
	median	IQR	median	IQR	median	IQR	
Age in years	70	24	70	23	69	23	
Number of days since admission to hospital	5	9	5	9	5	10	
Care Dependency Scale (sum score)	71	15	70	15	74	11	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	
Female sex	14,504	49.2 (48.6-49.8)	9902	48.2 (47.5-48.8)	4602	51.6 (50.6-52.7)	
Surgical intervention in the two weeks prior to data collection (yes)	10,542	35.8 (35.2-36.3)	8318	40.5 (39.8-41.1)	2224	24.9 (24.0-25.9)	
ICD-10 diagnosis groups (multiple responses)							
Diseases of the circulatory system	16,245	55.1 (54.5-55.7)	11,756	57.2 (56.5-57.9)	4489	50.3 (49.3-51.4)	
Endocrine, nutritional and metabolic diseases	9886	33.5 (33.0-34.1)	7023	34.2 (33.5-34.8)	2863	32.1 (31.1-33.1)	
Diseases of the musculoskeletal system and connective tissue	9834	33.4 (32.8–33.9)	7543	36.7 (36.0–37.3)	2291	25.7 (24.8-26.6)	
Diseases of the genitourinary system	8333	28.3 (27.8-28.8)	6389	31.1 (30.4-31.7)	1944	21.8 (21.0-22.7)	
Diseases of the digestive system	7214	24.5 (24.0-25.0)	5185	25.2 (24.6-25.8)	2029	22.8 (21.9-23.6)	
Diseases of the respiratory system	7137	24.2 (23.7-24.7)	5224	25.4 (24.8-26.0)	1913	21.5 (20.6-22.3)	
Neoplasms	6118	20.8 (20.3-21.2)	4540	22.1 (21.5-22.7)	1578	17.7 (16.9-18.5)	
Mental and behavioural disorders	5831	19.8 (19.3-20.2)	4249	20.7 (20.1-21.2)	1582	17.7 (17.0-18.6)	
Diseases of the blood and blood-forming organs and	4283	14.5 (14.1-14.9)	3539	17.2 (16.7-17.7)	744	8.3 (7.8-8.9)	
certain disorders involving the immune mechanism							
Diseases of the nervous system	4118	14.0 (13.6-14.4)	3064	14.9 (14.4-15.4)	1054	11.8 (11.2-12.5)	
Certain infectious and parasitic diseases	3559	12.1 (11.7-12.5)	2997	14.6 (14.1-15.1)	562	6.3 (5.8-6.8)	
Diseases of the skin and subcutaneous tissue	2450	8.3 (8.0-8.6)	1712	8.3 (8.0-8.7)	738	8.3 (7.7-8.9)	
Factors influencing health status and contact with health services	2413	8.2 (7.9–8.5)	1641	8.0 (7.6-8.4)	772	8.7 (8.1-9.3)	
Injury, poisoning and certain other consequences of external causes	1800	6.1 (5.8-6.4)	1462	7.1 (6.8–7.5)	338	3.8 (3.4-4.2)	
Diseases of the eye and adnexa	1769	6.0 (5.7-6.3)	1247	6.1 (5.7-6.4)	522	5.9 (5.4-6.4)	
Symptoms, signs and abnormal clinical and laboratory	1304	4.4 (4.2-4.7)	1100	5.3 (5.0-5.7)	204	2.3 (2.0-2.6)	
findings, not elsewhere classified							
Diseases of the ear and mastoid process	684	2.3 (2.2-2.5)	551	2.7 (2.5-2.9)	133	1.5 (1.3-1.8)	
External causes of morbidity and mortality	491	1.7 (1.5-1.8)	448	2.2 (2.0-2.4)	43	0.5 (0.3-0.6)	
Pregnancy, childbirth and the puerperium	290	1.0 (0.9–1.1)	171	0.8 (0.7–1.0)	119	1.3 (1.1-1.6)	
Congenital malformations, deformations and	148	0.5 (0.4–0.6)	114	0.6 (0.5-0.7)	34	0.4 (0.3-0.5)	
chromosomal abnormalities							
Unknown/no diagnosis	112	0.4 (0.3-0.5)	78	0.4 (0.3-0.5)	34	0.4 (0.3-0.5)	
Certain conditions originating in the perinatal period	28	0.1 (0.1-0.1)	25	0.1 (0.1-0.2)	3	<0.1 (<0.1-0.1)	

IQR=interquartile range, 95% CI=95% confidence interval,

ICD-10=International Statistical Classification of Diseases and Related Health Problems 10th Revision.

Austria (AT) at three measurement points between 2016 and 2018. The sample consisted of 20,561 (69.8%) patients from Switzerland and 8916 (30.2%) patients from Austria (Table 1). The 29,477 participants corresponded to 75.4% (95% confidence interval [CI] 74.9%–75.8%) of all patients hospitalised (N = 39,106) on the measurement days in the 140 hospitals (CH 76.3% [95% CI=75.8%–76.8%] N = 26,934; AT 73.3% [95% CI=72.5%–74.0%] N = 12,172).

Approximately half of the patients were female (49.2%, n = 14,504) and 35.8% (n = 10,542) had a surgical intervention in the two weeks prior to data collection. Their median age was 70 years, their median length of stay since admission to the hospital was 5 days and the median score of the CDS was 71 (indicating that most of the patients were completely independent in their care). The three most frequent ICD-10 diagnosis groups were diseases of the circulatory system (55.1%, n = 16,245), endocrine, nutritional and metabolic diseases (33.5%, n = 9886) and diseases of the musculoskeletal system and connective tissue (33.4%, n = 9834). Differences between countries are shown in Table 1.

# 3.2. Prevalence rate and type of restraints

The 30-day prevalence rate of patients with at least one restraint was 8.7% (n = 2577), with differences between countries being detected (CH 10.6%, n = 2171; AT 4.6%, n = 406). Mechanical methods were the most frequently used type of restraint (55.0%, n = 1417). Within this category (data available only for the measurement point in 2018 n = 10,305, mechanical restraint n = 570), bed rails were most commonly cited (86.7%, n = 494). Apart from mechanical methods, electronic (33.2%, n = 856) and pharmacological (24.6%=633) methods were frequently used (see Table 2). Differences between countries were evident. For example, in Switzerland more electronic methods were used but there were fewer locked wards or buildings than in Austria.

# 3.3. Reasons for restraint use

The main reason for restraint use was fall prevention (43.8%, n = 1129), followed by confusion or delirious behaviour (20.4%, n = 525). Patient or family request was far more often the main reason for restraint use in Austria than in Switzerland (see Table 3).

#### 3.4. Process indicators

Overall, the use of restraints was documented in the patients' files for 64.3% (n = 1657) of patients affected by restraint use (n = 2577). In 51.0% (n = 1315) of the cases the patient and/or the legal representatives were informed about the entire process surrounding the use of the restraint. A regular evaluation with all persons involved, including the patient, was part of the restraint procedure in 42.9% (n = 1105) of the cases. In 42.1% (n = 1084) of the cases, in each shift someone was responsible for monitoring the patient undergoing the restraining. Alternatives to minimise the use of restraints (for example, delirium prevention) were primarily used in 37.1% (n = 957) of the cases. There were small differences between countries, as shown in Table 4.

#### Table 2

Prevalence rate and type of restraint.

	Total $(n = 29,477)$		Switzerland $(n = 20,561)$		Austria ( <i>n</i> = 8916)	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Restraint (yes)	2577	8.7 (8.4-9.1)	2171	10.6 (10.1-11.0)	406	4.6 (4.1-5.0)
Proportion restraint type (multiple responses)						
Mechanical restraints	1417	55.0 (53.0-56.9)	1224	56.4 (54.3-58.5)	193	47.5 (42.6-52.5)
Proportion type of mechanical restraint (multiple responses, only 2018)						
n participants 2018	10,305	6923	3382			
n restraint (yes) 2018	570	495	75			
Bed rails	494	86.7 (83.6-89.3)	428	86.5 (83.1-89.4)	66	88.0 (78.4-94.4)
Other mechanical restraint	100	17.5 (14.5-20.9)	92	18.6 (15.3-22.3)	8	10.7 (4.7-19.9)
Belt fixation	65	11.4 (8.9-14.3)	48	9.7 (7.2-12.7)	17	22.7 (13.8-33.8)
Tabletop/chair table	56	9.8 (7.5-12.6)	49	9.9 (7.4-12.9)	7	9.3 (3.8-18.3)
Electronic restraints	856	33.2 (31.4-35.1)	798	36.8 (34.7-38.8)	58	14.3 (11.0-18.1)
Pharmacological restraints	633	24.6 (22.9-26.3)	549	25.3 (23.5-27.2)	84	20.7 (16.9-25.0)
Other	388	15.1 (13.7-16.5)	302	13.9 (12.5-15.4)	86	21.2 (17.3-25.5)
One-to-one supervision <sup>a</sup>	227	8.8 (7.7-10.0)	223	10.3 (9.0-11.6)	4	1.0 (0.3-2.5)
Locked ward or building	164	6.4 (5.5-7.4)	82	3.8 (3.0-4.7)	82	20.2 (16.4-24.4)
Physical restraints (keeping someone restrained with human physical force)	75	2.9 (2.3-3.6)	70	3.2 (2.5-4.1)	5	1.2 (0.4–2.9)

<sup>a</sup> Answer option was only available for 2017 and 2018 (*n* participants=20,012).

95% CI=95% confidence interval; for definitions of the different restraint types see Supplemental Material Table A.

#### Table 3

Main reason for restraint use.

	Total		Switze	rland	Austria		
Patients with restraint $(n)$	2577		2171		406		
Main reason for restraint use (single response)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	
(Preventing) Falls	1129	43.8 (41.9-45.8)	1029	47.4 (45.3-49.5)	100	24.6 (20.5-29.1)	
Confusion or delirious behaviour	525	20.4 (18.8-22.0)	465	21.4 (19.7-23.2)	60	14.8 (11.5-18.6)	
Other motive	308	12.0 (10.7-13.3)	211	9.7 (8.5-11.0)	97	23.9 (19.8-28.3)	
Request of the patient and/or family	188	7.3 (6.3-8.4)	119	5.5 (4.6-6.5)	69	17.0 (13.5-21.0)	
Agitation	123	4.8 (4.0-5.7)	111	5.1 (4.2-6.1)	12	3.0 (1.5-5.1)	
Non-compliance with treatment	71	2.8 (2.2-3.5)	68	3.1 (2.4-4.0)	3	0.7 (0.2-2.1)	
(Preventing) Wandering around	56	2.2 (1.6-2.8)	42	1.9 (1.4-2.6)	14	3.4 (1.9-5.7)	
(Preventing) Aggressive behaviour	33	1.3 (0.9-1.8)	19	0.9 (0.5-1.4)	14	3.4 (1.9-5.7)	
Unknown	24	0.9 (0.6-1.4)	19	0.9 (0.5-1.4)	5	1.2 (0.4-2.9)	

95% CI=95% confidence interval.

#### Table 4

Process indicators.

	Total		Switzerland		Austria		
Patients with restraint $(n)$	2577		2171		406		
Process indicators (multiple responses)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	
The restraining was documented in the patient file	1657	64.3 (62.4-66.2)	1403	64.6 (62.6-66.6)	254	62.6 (57.7-67.3)	
The patient and/or the legal representatives were informed about the entire process surrounding the use of restraints	1315	51.0 (49.1-53.0)	1093	50.3 (48.2–52.5)	222	54.7 (49.7-59.6)	
The use of restraints was evaluated with all persons involved (including the patient)	1105	42.9 (41.0-44.8)	919	42.3 (40.2-44.4)	186	45.8 (40.9–50.8)	
In each shift a person/nurse was appointed to monitor the patient undergoing restraining regularly, according to the defined prescription	1084	42.1 (40.1-44.0)	954	43.9 (41.8-46.1)	130	32.0 (27.5-36.8)	
Primarily alternatives were used to minimize the use of restraints	957	37.1 (35.3–39.0)	821	37.8 (35.8–39.9)	136	33.5 (28.9–38.3)	
None	265	10.3 (9.1-11.5)	229	10.5 (9.3-11.9)	36	8.9 (6.3-12.1)	

95% CI=95% confidence interval.

# 3.5. Associated patient characteristics

In the multivariate analysis with AIC backward selection the strongest association with restraint use was detected for patients' care dependency, with an almost exponentially increasing odds ratio (OR). Completely dependant patients, according to the Care Dependency Scale, had a 25-fold higher risk (OR=25.00, 95% CI=21.01-29.78) of undergoing restraint during their hospital stay than completely independent patients. Various ICD-10 diagnosis groups were associated with a slightly higher risk of being re-

strained (see Table 5). The most important ICD-10 diagnosis group with an OR of 2.36 (95% Cl=2.15-2.59) was mental and behavioural disorders. The variables female sex, diseases of the digestive system and diseases of the musculoskeletal system and connective tissue were found to be significant risk-decreasing variables with ORs of around 0.8. The different prevalence by country described above is also reflected in the regression analysis. In Switzerland the risk of experiencing the use of a restraint is 2.23 times higher (95% Cl 1.98–2.51) than in Austria. The model fit is 0.28 according to Cragg-Uhler, or 0.22 according to McFadden (p < 0.000).

#### Table 5

Model					
p<0.000; Pseudo-R <sup>2</sup> Cragg-Uhler=0.28, McFadden=0.	22; AIC=13,657.27				
Patient characteristics	OR (95% CI)				
(Intercept)	0.01 (0.01-0.01)*				
Country					
Austria	Reference				
Switzerland	2.23 (1.98-2.51)*				
Age in years	1.00 (1.00-1.01)*				
Female sex	0.80 (0.73-0.87)*				
Number of days since admission to hospital	1.00 (1.00-1.00)*				
Care Dependency Scale (CDS)					
$\geq$ 70 completely independent	Reference				
$\geq$ 60–69 independent to a great extent	2.56 (2.22-2.96)*				
$\geq$ 45–59 partially dependant	6.36 (5.53-7.32)*				
$\geq$ 25–44 dependant to a great extent	14.84 (12.78-17.25)*				
24 completely dependant	25.00 (21.01-29.78)*				
Mental and behavioural disorders	2.36 (2.15-2.59)*				
External causes of morbidity and mortality	1.46 (1.12-1.88)*				
Factors influencing health status and contact with health services	1.29 (1.12-1.48)*				
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	1.24 (1.04-1.47)*				
Diseases of the eye and adnexa	1.24 (1.05-1.46)*				
Diseases of the blood and blood-forming organs	1.18 (1.06–1.32)*				
and certain disorders involving the immune mechanism	(				
Injury, poisoning and certain other consequences of external causes	1.14 (0.97–1.33)				
Diseases of the nervous system	1.10 (0.98-1.23)				
Diseases of the digestive system	0.85 (0.76-0.94)*				
Diseases of the musculoskeletal system and connective tissue	0.78 (0.71-0.86)*				

\* statistically significant based on the 95% CI.OR=odds ratio, 95% CI=95% confidence interval, AIC=Akaike Information Criterion.

#### 4. Discussion

In our cross-sectional study on restraint use in Swiss and Austrian hospitals, we found that approximately every 11th patient was affected by restraint use. Most frequently mechanical methods (for example, bed rails) were applied followed by electronic and pharmacological restraints. Restraints seem to be used in complex care situations such as with patients at risk of falling or with delirium. When using restraints, processes such as documentation and regular evaluation do not appear to be systematically implemented. The strongest association for restraint use was found with patients' care dependency and mental and behavioural disorders. This indicates that a very vulnerable patient group was most affected by restraint use.

# 4.1. Prevalence rate and type of restraints

The prevalence rate for the use of at least one restraint over a 30-day period was 8.7%. Since this rate includes different restraint types and does not, as in most other studies (in the hospital setting), include only mechanical (physical) methods a comparison of the prevalence rates is not possible. Internationally there seems to be conceptual ambiguity concerning restraints (Xyrichis et al., 2018); an international consensus in regard to a research definition only exists for physical (mechanical) restraints (Bleijlevens et al., 2016). However, the results show how important comprehensive research on restraints is, especially regarding various interventions limiting a person's human rights.

Both in the literature (Barton-Gooden et al., 2015; Enns et al., 2014) and in this study bed rails are the most common restraint type. The frequent use of bed rails could be related to the fact that bed rails are increasingly often permanently installed on

the bed (Hignett et al., 2013; Ó Flatharta et al., 2014) and that they are (therefore) viewed as a standard operational procedure (Barton-Gooden et al., 2015). However, there is no evidence regarding the benefit of bed rails (for instance, in fall prevention) (LeLaurin and Shorr, 2019; Sze et al., 2012). In contrast, there is intense discussion about the risks of bed rail use (LeLaurin and Shorr, 2019; Ó Flatharta et al., 2014). For example, more severe fall injuries could occur if a patient tried to climb over the bed rail and then fell from a higher level than if the bed rail were down, therefore frequent use of bed rails should be critically reflected.

Two forms of restraint other than bed rails that were identified in this study as being frequently used were electronic and pharmacological restraints. To date, electronic restraints in hospitals have hardly been investigated. There are indications that bed/chair alarms, for example, are often used to prevent falls. However, a positive effect regarding fall rate or reduced use of mechanical restraints has yet to be detected (LeLaurin and Shorr, 2019). Pharmacological restraints have to some extent been described in the literature. They seem to be frequently applied measures, even though side effects from the medication and a negative impact on rehabilitation (after hospitalisation) have been reported (Agens, 2010; Mott et al., 2005). Often pharmacological restraints are not recorded as restraints, for example the off-label use of antipsychotic medication to address agitation in people with delirium or dementia. However, in the long-term care setting an association was found between the (off-label) use of antipsychotic medication and various adverse events such as hip fractures and infections (Chiu et al., 2015).

# 4.2. Reasons for restraint use

Findings showed that fall prevention is the main reason for restraint use in this study, which is consistent with the literature (Farina-Lopez et al., 2014; Freeman et al., 2016; Gu et al., 2019; Perez et al., 2019); however, there is growing evidence that restraints are ineffective for preventing falls (Enns et al., 2014; LeLaurin and Shorr, 2019; Sze et al., 2012). Interestingly the second-most common reason for using restraints was confusion or delirious behaviour. This is contrary to the literature, in which the avoidance of therapy interruption is mentioned as the second-most common reason for restraint use (Farina-Lopez et al., 2014; Freeman et al., 2016; Gu et al., 2019; Perez et al., 2019). As confusion or delirious behaviour is often linked with a risk of therapy interruption the difference in results could be influenced by definitions/personal interpretations of what the main reason for restraint use is. However, similarly to fall prevention there are negative indications regarding the use of restraints in that they could lead to the development of delirium (Lach et al., 2016; Rose et al., 2016). Therefore their use could be counterproductive in terms of therapy interruption, prevention, et cetera, at least over the longer term. Overall, there are indications that restraints are often used in complex care situations (fall risk, delirium), in which preventive measures and/or alternative approaches would be challenging and difficult to implement. Since the reasons for restraint use are similar to those in the long-term care setting (Hofmann and Hahn, 2014; Möhler et al., 2011; Scheepmans et al., 2020) it would be worth examining whether restraint reduction strategies in this setting could be adapted to the hospital setting (Abraham et al., 2020).

# 4.3. Process indicators

The process indicators for restraint usage show great potential for improvement since even the documentation of restraint use in the patients' files is complete in only 64.3% of the cases. This supports the assumption that there is a lack of knowledge regarding legal and ethical regulations when using restraints (De Bellis et al., 2013; Eskandari et al., 2017; Farina-Lopez et al., 2014; Möhler and Meyer, 2014; Ó Flatharta et al., 2014; Rose et al., 2016). This is especially evidenced by the incomplete or sometimes totally missing documentation of the use of restraints, which is widely discussed in the literature (Beysard et al., 2018; Gu et al., 2019; Perez et al., 2019; Suliman, 2018; van der Kooi et al., 2015). Indeed, Freeman et al. (2016) emphasise that poor documentation also leads to a lack of systematic reassessment/evaluation of the use of restraints. The even lower occurrence (42.9%) of regular evaluations of restraint use with all individuals involved could be related to this assumption.

Findings showed that alternatives to restraints (for example, for fall prevention) were used in only 37.1% of cases. Möhler and Meyer (2014) state that restraints are routine nursing interventions and that because of this routine, alternatives are not sufficiently considered, even though it is a legal and ethical requirement. Additionally, since health professionals often see restraints as solely a mechanical fixation with a belt, it may be assumed that not all measures are correctly identified as being a restraint (Kong et al., 2017). If health professionals do not realise that a certain intervention is a restraint they likely will not document and evaluate its use or consider alternatives before using it. Standardisation of the processes along with education could help to ensure that ethical and legal requirements are met and at the same time promote awareness. Those health professionals who have to evaluate restraint use regularly and document their decisions are then required to think about the necessity of the use of restraints. In this respect, interprofessional training programmes for all health professionals, which focus on the different restraint types, their use and their possible alternatives, could be beneficial for a more conscious restraint management (Abraham et al., 2020; Lach et al., 2016).

#### 4.4. Associated patient characteristics

The results of the regression analysis are highly relevant from an ethical point of view. They show that very vulnerable and careintensive patients (older, completely care dependant, with mental and behavioural disorders) have an increased risk of being restrained. This means that the patients who are most affected are those who often cannot speak up for themselves, therefore ethical considerations become even more important. In view of the demographic trend, an increase in the number of patients at risk of restraint use in the hospital setting must be assumed. It is therefore essential that health professionals show increased awareness of restrictive practices and use restraints in a more reflective and targeted manner (including for the long term) instead of basing practice on routine and intuition (Li and Fawcett, 2014; Möhler and Meyer, 2014; Xyrichis et al., 2018). The results of this study can contribute to stimulating (critical) discussions about restrictive practice and to identifying possibilities for quality improvement approaches.

The differences between Switzerland and Austria could have been influenced by the availability of the different restraint equipment (for example, for body fixation) in the hospital and on the ward (Hignett et al., 2013), as well as by their different legal situations (Kong et al., 2017). Although more restraints were used in Switzerland these tended to be potentially less restrictive than those in Austria. For example, the proportion of electronic measures and one-to-one supervision is considerably higher in Switzerland, whereas the proportion of locked wards and buildings is higher in Austria. However, these potentially less drastic measures have hardly been studied to date, either in terms of benefits or risks. As regards fall prevention, LeLaurin and Shorr (2019) state that alarms and sitters (one-to-one supervision) seem to be ineffective.

In regard to the legal situation in the two countries, in Switzerland only movement restriction measures for a subpopulation and/or specific settings are regulated. In Austria, however, all restraint types are included in the legislation and there is also a focus on subpopulation and/or specific settings. Furthermore, in Austria the documentation of restraints is mandatory, whereas in Switzerland only recommendations from the SAMS (Swiss Academy of Medical Sciences, 2015) exist. Interestingly in this study there was no difference regarding the documentation of restraint use between the countries. However, in both countries clear legal regulations that are independent of specific populations and settings are lacking, especially for the hospital setting. It is therefore uncertain whether the different regulations had an influence on the differences in restraint use detected between these two countries (for instance, restraint type or reason for restraint use). Nevertheless, in terms of restraint reduction, it is important to have clear policies and to monitor and benchmark the use of restraints (Lach et al., 2016; Scheepmans et al., 2020).

# 4.5. Strengths and limitations

The strengths of the study are the large sample sizes of the two countries and their many similarities (including their healthcare systems), the inclusion of all medical specialities of all hospital types, the annually reviewed questionnaire and the highly standardised data collection. There are also some limitations, however. The first is the exclusion of a potentially very vulnerable patient group and thus the possibility of a selection bias. Patients who could not give their informed consent (for instance, due to cognitive impairment) and where no legal representative was present had to be excluded from the study, therefore it is possible that the restraint prevalence was underestimated and that the results might be biased with respect to restraint types and the main reasons for their use. In both countries for a variety of reasons approximately a quarter of all hospitalised patients on the measurement days did not participate in the survey. In addition, the results also depend on the data quality within the hospital. Since data were collected retrospectively over a period of the previous 30 days, patient files were also used as a data source. However, as the results show, documentation is only available for about two-thirds of restraints, therefore it is possible that a documentation and/or recall bias exists, and again that the restraint prevalence is underestimated. Additionally, it is also possible that only hospitals that were already engaged in restraint reduction participated in the study. However, due to the large sample size and the high participation rate it can be expected that the results of this study will be generalisable.

In the regression analysis based on the model fit it must be assumed that there are additional factors influencing restraint use that are not represented in this model (for example, contextual factors such as nurse-to-patient ratio and skill mix are not assessed with LPZ 2.0). Additionally, the cross-sectional study design favours fluctuations in the group of patients examined and limits the causality of the results. At this point it should also be mentioned that due to the cross-sectional design, the direction of the association of the patient characteristics with the restraint use is not clear. For example, care dependency can be the cause and/or the consequence of restraint use.

One limiting condition of the survey is the answer option "other", which represents a large number of responses in all questions. Since this response option is not very meaningful in terms of quality improvement efforts, future studies should investigate what has been recorded under "other". On the one hand, a more refined picture of restraint use could be obtained, while on the other hand, the questionnaire could be adapted. Given these limitations, longitudinal designs and/or observational studies seem to be necessary in future research.

# 5. Conclusions

Restraints are frequently used in hospitals, even though there is growing evidence regarding their negative effects on patients and on their lack of benefits (for instance, with fall prevention). This study reveals that a very vulnerable patient group (older, completely care dependant and/or with mental and behavioural disorders) is most affected by restraint use. Therefore, and in light of the demographic trend, a more conscious usage of restraints based upon the legal and ethical requirements will become even more important. The standardisation of processes such as documentation and evaluation as well as the education of the interprofessional team could be beneficial for raising awareness and for ensuring the sustainable reduction of restraint use. Overall, this first study on different restraint types, irrespective of medical specialities in hospitals, provides insight into possibilities for quality improvement approaches.

#### **CRediT authorship contribution statement**

**Silvia Thomann:** Conceptualization, Methodology, Resources, Data curation, Formal analysis, Writing - original draft, Writing review & editing. **Sandra Zwakhalen:** Conceptualization, Writing review & editing, Supervision. **Dirk Richter:** Methodology, Validation, Writing - review & editing. **Silvia Bauer:** Resources, Writing - review & editing. **Sabine Hahn:** Conceptualization, Writing - review & editing, Supervision.

# **Conflict of Interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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# **Ethical Approval**

In Switzerland the Ethics Committee of the Canton of Bern declared that the present study did not fall under the Swiss Human Research Act (April 2019, BASEC–Nr: Req-2019-00259), therefore ethical approval was not required. In Austria the Ethics Committee of the Medical University of Graz approved the study protocol (approval nr. 20192 ex08/09).

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# Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ijnurstu.2020.103807.

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