ORIGINAL ARTICLE

Deaths Due to Physical Restraint

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SUMMARY

Background: Physical restraint is used primarily for patients at risk of falling, those with motor unrest and agitated behavior, and those who manifest an intention of doing harm to themselves or are at risk of suicide. The use of freedom-restraining measures (FRM), and, in particular, the use of physical restraints against the patient's will, can be a serious intrusion of basic human rights and, as such, an act of violence against the patient. The improper use of physical restraints can cause injuries of varying severity, which can sometimes be fatal.

<u>Methods:</u> We analyzed all cases of death under physical restraint that were recorded in the autopsy reports of the Institute of Forensic Medicine in Munich from 1997 to 2010.

Results: Among the 27 353 autopsies conducted over the period of the study, there were 26 cases of death while the individual was physically restrained. Three of these cases involved patients who died of natural causes while restrained, and one was a suicide. The remaining 22 deaths were caused solely by physical restraint; all of them occurred in patients under nursing care who were not continuously observed. The immediate cause of death was strangulation (11 cases), chest compression (8 cases), or dangling in the head-down position (3 cases). In 19 of these 22 patients, the restraints were incorrectly fastened, including two cases in which improvised non-standard restraints were used. One nursing-home patient died because of an abdominal restraint even though it had been correctly applied: She was mobile enough to slip through the restraint till it compressed her neck, and then unable to extricate herself from it, so that she died of strangulation.

<u>Conclusion:</u> To prevent such deaths, we recommend from a forensic medical standpoint that all possible alternatives to FRM should be used instead. If direct-contact restraints are truly necessary, they must be applied as recommended and the restrained person must be closely observed.

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reedom-restraining measures (FRM) to prevent falls, to control the movement of patients with behavioral disorders or motor unrest, and to enable treatment to be carried out are employed principally in geriatric medicine and in general care of the elderly (1–3). In psychiatry, these measures are most often used to prevent self-harm and suicide attempts (4–6). Restriction of the freedom of movement of care-home residents and patients is usually achieved by means of mechanical restraint, most frequently in the form of side rails (1, 2). These count as FRM when they are used without the consent or against the will of the person concerned. Direct-contact restraints (restraints in the true sense of the word) include straps, bandages, protective blankets, and restraining trays (1).

Sleep-inducing drugs and psychopharmaceuticals constitute restriction of freedom if they are given with the primary aim of reducing motor activity to such an extent that the person concerned is unable to leave the room or the facility (7). Administration of medication for therapeutic purposes, however, does not constitute FRM, even if it has the side effect of reducing mobility. Locking someone inside a ward or a room is also FRM. Other "hidden" or "disguised" methods include removal of shoes, visual aids, and walking frames and the installation of special door locks intended to restrict the movements of care-home residents or patients. The admissibility of transmitters or tracking devices is controversial. Transmitters trigger an alarm if the wearer leaves the facility. Electronic devices can be viewed as an infringement of human rights (8), but various courts have deemed them admissible provided appropriate consent has been obtained (9, 10).

Complications of physical restraint

Restraint by straps, particularly around the torso, is associated with loss of freedom and autonomy and hampers social relationships. The immobility enforced by regular and long-lasting restraint can lead to muscular atrophy or worsen existing atrophy (11). The restrained person's ability to stand and walk after the period of restraint is impaired, considerably hindering or, in the worst case, completely preventing effective long-term measures to avoid falls. In addition, physical restraint promotes typical complications of immobilization such as decubitus ulcers, pneumonia, and leg vein thrombosis (11, 12). Immobilization often causes stress and has a negative impact on cognitive skills (13).

Improper application of restraining straps can lead to injuries such as cutaneous abrasions, bruises, soft tissue

compression, neural lesions, and fractures (14), possibly even to death by asphyxiation (e1–e3, 15, 16). Even if the straps have been properly applied, fatal accidents may occur in the event of insufficient vigilance (17).

Legal Requirements

The term "FRM" embraces all restraints to freedom of movement that cannot be removed by the restrained person and/or impede the person's access to their own body (see Box) (3).

Section 1906 of the German Civil Code (7) stipulates that such interventions are permissible only to stop the person concerned committing suicide or causing themselves severe damage to health. The same applies to medical treatments or interventions that are necessary but cannot be carried out owing to the home resident's/patient's behavior or mental state (e.g., danger of self-removal of an infusion needle or urinary catheter).

Home residents/patients who are capable of giving consent make their own decisions regarding the use and duration of FRM. Additional legal authorization is unnecessary. For consent to be valid, the person concerned must be able to understand the importance and the consequences of their decision. The consent always applies only to a concrete situation and can be revoked at any time. Legal competence is not a precondition for valid consent.

For home residents and patients who cannot give consent and are in care, the above-mentioned § 1906 para. 4 of the Civil Code (7) comes into effect in cases where regular (e.g., every night) or long-lasting (>2 days) FRM are essential for their wellbeing. Before FRM can be applied, however, the following must be obtained: a medical recommendation—or, preferably, an independent expert opinion—the agreement of the resident's/patient's appointed representative, and the approval of the responsible court. Only in urgent cases and emergencies may FRM be authorized by home/ hospital managers, physicians, nurses, or relatives. Care must be taken to ensure that the measures used for restraint are appropriate to the situation and are clearly documented. If it is apparent from the outset that longterm FRM will be required, then by legal definition (section 34 of the German Criminal Code) no emergency exists and court approval should be urgently sought.

Even if the person requiring restraint was admitted to the care facility under § 1906 para. 1 of the Civil Code (7), employment of additional restraints requires court approval.

A court decision approving the use of measures to ensure the safety of a person in care does not expressly require these measures to be applied. Whether FRM are actually necessary and how often the restrained person should be monitored depend on the latter's health and general condition. These decisions are generally made by the members of staff with direct responsibility for the person concerned. Permanent monitoring (by video or a sitter at the bedside) and care during the period of

restraint is obligatory for patients in psychiatric wards, but not in homes for the elderly or care homes.

The legal regulations cover persons in residential homes, hospitals, or other institutions (supervised groups, external residential facilities), but not those being cared for in their own home. German law requires clear documentation of the form and duration of every application of FRM in inpatient facilities.

Frequency

Measures that restrict the individual freedom of movement of elderly and/or mentally ill, usually demented persons are still routine in homes for the elderly, care homes, and hospitals.

The number of such measures receiving court approval under § 1906 para. 4 of the Civil Code in German residential homes, hospitals, and other institutions has almost doubled in the space of a decade, from 52 536 in 2000 to 96 092 in 2009 (e4).

Various surveys (1, 18, 19) indicate that FRM are used in the care of 5% to 70% of all inhabitants of residential homes, with straps being used for restraint in 5% to 10% of these cases. This wide variation in frequency can be explained by the heterogeneity of both the study populations and the methods employed (e.g., written surveys, direct observation, retrospective capture of FRM from case records). Moreover, country-and facility-specific guidelines and the attitudes of individual institutions and their staff are decisive in determining whether and to what extent FRM are used (6).

No central registry for FRM has yet been established in Germany, so there are no nationwide electronic data on the use of restraining measures in homes for the elderly and care homes.

Our own ongoing surveys of all inpatient facilities for care of the elderly in the German federal states of Bavaria, Baden-Württemberg, Hesse, and Rhineland-Palatinate, together with the records of the responsible courts in Bavaria and Rhineland-Palatinate, have recently yielded the first data on frequency and type of FRM (e5, e6).

Assessment of deaths associated with mechanical restraint

Forensic pathologists repeatedly encounter cases of death under mechanical restraint. The central question is then whether or not the death was natural. Death caused by illness is natural. However, the death agony may result in an abnormal position of the body in the restraining device, which can lead to suspicion of unnatural death. Death is unnatural when caused primarily by restraint.

Study findings

The Institute of Forensic Medicine in Munich performed a total of 27 353 autopsy examinations at the request of the state attorney's office and the administrative authority between 1 January 1997 and 31 December 2010. Twenty-six of the deceased had been restrained by straps at the time of death (*Table 1*). The

BOX

Legal provisions for freedom-restraining measures

- Under what circumstances may freedom-restraining measures be used?
 - To prevent suicide or self-harm
 - To avoid serious impairment of health, e.g., in movement or postural disorders associated with high danger of falls, pronounced motor unrest, agitated/aggressive behavior
 - To promote the success of medical treatments/interventions, e.g., to prevent self-removal of an infusion needle or urinary catheter or to ensure immobilization of a fracture

• Who decides on the use of freedom-restraining measures?

- Residents of homes for the elderly/care homes and hospital patients who are capable of giving consent decide for themselves on the use and duration of freedom-restraining measures
- For residents/patients who are not capable of giving consent, the assent of the legally appointed representative and the
 approval of the responsible court are required
- In urgent cases and emergencies, freedom-restraining measures may be authorized by home/hospital managers, physicians, nurses, and relatives
- Court approval of freedom-restraining measures is indispensable if they are to be used regularly or for a long period of time; court approval authorizes safety measures, but does not obligate their use

cause of death in these cases had been recorded as "unclear" or "unnatural" by the physician who performed the post mortem external examination. The autopsy findings, medical history, case notes and court documents, including police reports, were analyzed retrospectively.

In 22 cases death was due solely to the restraint. In three inpatients who died while restrained by an abdominal strap the causes of death were pancreatitis, coronary sclerosis with myocardial induration, and aspiration of chyme during an epileptic fit. In these cases the restraining strap had caused slight cutaneous abrasions in the chest and axillary region. Systemic signs associated with asphyxiation were not found, however. Therefore, the restraint was no more than a relevant factor in the patients' death from disease. One further patient suffered from metastatic stomach cancer and episodes of depression. He died of extensive burns after setting his bedding on fire with suicidal intent

Of the 22 home residents/patients whose death was caused solely by the restraint, 13 were female and nine male. Their mean age was 75.8 years (range 39 to 94 years), and six were over 90. Most of them (n = 15) were demented, and two had Huntington's chorea with marked motor unrest and slight intellectual impairment but intact cognitive skills.

Sixteen of the 22 deaths occurred in homes for the elderly and care homes, five in hospitals, and one in the patient's own home.

The straps had been employed because the deceased were at risk of falling (n = 18), in danger of harming themselves (n = 2), or tended to walk out of the facility (n = 2). In most cases there was court approval of re-

straint (n = 14), and two of the persons concerned had given consent. In one home resident and in all five hospital inpatients there was neither written consent nor court approval, although in most cases restraints had been applied regularly (n = 1) or continuously for a long period (n = 4).

According to the case notes, the shortest time between the last living contact and the discovery of the dead body was 15 min, while the longest interval, in a patient being cared for in his own home, was 3 days. In homes for the elderly or care homes, the typical time was 3 to 4 h, reflecting the frequency of repositioning. The hospital patients were last seen alive 2 h (range 0.5 to 4.4 h) before death.

In essence the study revealed three mechanisms of death: dangling in head-down position (n = 3), chest compression (n = 8), and strangulation (n = 11).

In 19 of the 22 deaths due to restraint the restraining devices had not been applied properly ($Table\ 2$). In most of these cases the abdominal strap had been correctly put on and secured, but the side straps had not been fastened and the side rail was raised only on one side of the bed or not at all (n = 9). In one case each, a belt and a bedsheet were used for restraint. Only in one case, a home resident in a wheelchair, was the restraining device applied correctly; however, her mobility and ultimately her physique led to strangulation by the abdominal strap (17).

In the majority of cases police investigations revealed no evidence of a criminal offense, so no legal action ensued. In three cases, however, the responsible nurses were convicted of negligent homicide (§ 222 of the German Criminal Code) and sentenced to pay a fine equivalent to 90 days' income. One treating physician

TABLE 1		
Type of physical restraint		
Type of restraint	n = 26	
Abdominal strap in bed	22	
Abdominal strap in wheelchair	1	
Pelvic strap in armchair	1	
Belt in wheelchair	1	
Sheet in bed	1	

TABLE 2	
Accident analysis	
Incorrect use of restraints	n = 19
Abdominal strap without side straps, without bedrail, or with bedrail raised on only one side	9
Abdominal strap with side straps, without bedrail or with bedrail raised on only one side	5
Abdominal strap without side straps, with bedrail raised on both side	3
Abdominal strap without side straps, with divided bedrail	1
Pelvic strap too loose	1
Unusual means of restraint (belt, bedsheet)	n = 2
Correct use of restraint	n = 1

was also fined 90 days' income because he had ordered removal of the side rails from the bed of a restrained home resident. The carers who had actually applied the restraints were not charged because they had expressly drawn attention to the necessity of raising the side rails after application of an abdominal strap.

The high autopsy rate at the Institute of Forensic Medicine in Munich shows that employment of physical restraints can have fatal consequences not only when the devices are incorrectly applied but also, exceptionally, in the case of correct use.

Prevention

Danger of falling and psychomotor unrest are the most common indications for FRM (3, 12, 13). The desire to avoid falls in general does not justify FRM per se. Moreover, recent studies cast doubt on whether restraints and the resulting restriction of mobility actually prevent falls (2, 3, 20). Behavioral problems such as agitation may even be reinforced by restraining measures (21), which can constitute a subjectively traumatic experience (22). Therefore, each individual person who requires physical restraint should be allowed to retain as much freedom of movement as possible in the circumstances.

Doctors, nurses, and care-home staff should always strive to establish and eliminate the underlying reasons why persons in their care are agitated, at risk of falling, or tend to walk out. The guidelines of the Bavarian Care Commission (Bayerischer Landespflegeauschuss) offer comprehensive advice on responsible use of FRM in care and have been adopted and implemented by the Ministry of Work, Family and Health in the state of Hesse. The compendium includes alternatives to FRM, suggestions on how to avoid incorrect or illegal forms of restraint, and internal and external quality assurance. Furthermore, it contains checklists and specific advice designed to help all those concerned decide whether or not restraint is indicated (23). Another source of information is a teaching DVD recently produced for the Bavarian State Ministry of Work and Social Affairs, Family, and Women (e7).

If the causes of the abnormal condition or state of health cannot be eliminated or at least minimized, FRM are by no means the method of choice. All available alternatives must first be considered. For example, special beds, bed nests, hip protectors, and training to improve strength and balance have all proved effective. Use of such devices and techniques is successful in reducing the frequency of FRM without increasing the danger of injury (24, 25). If no alternative methods are feasible, FRM may be employed, but only if they are indispensable to the wellbeing of the person concerned (7).

The use of FRM does not decrease the carers' workload. The restrained person must be closely monitored and cared for, and the administrative burden is high; every instance of FRM has to be clearly and painstakingly documented. Moreover, staff are required to attend training courses.

It is essential that the restraining straps be applied correctly, following the manufacturer's recommendations. Therefore, not only must carers receive special instruction but institution-specific guidelines must be drawn up.

The manufacturers advise that the bed straps be secured tightly to the frame of the bed or to adjustable head or foot sections. Care must be taken that the adjustment mechanisms of the bed (or chair) are not compromised. The appropriate length of strap must be selected, depending on height and waist size. Straps that are too short or too long affect not only comfort but also safety. Abdominal straps should be fitted closely around the waist and secured with a magnetic fastener, taking care not to interfere with breathing. An open hand should just fit between strap and body. To avoid accidents, the side rails of the bed should be raised (exception: five-point restraint); divided side rails should not be used. Restraining systems should also never be used without side straps, which prevent the restrained person from turning diagonal to the axis of the body. Without side straps, the restrained person may succeed in climbing over the side rail. Regular checks must be carried out to ensure the strap is still properly fitted.

The use of restraint systems in Germany is regulated by § 5 of the Operation of Medical Devices Ordinance (Medizinprodukte-Betreiberverordnung), according to which medical devices may be employed only for their intended use and by specially trained staff (e8). Section 11 para. 2/2 of the Homes Law (Heimgesetz) states that operators of care homes are responsible for the personal suitability and professional qualification of their staff (e9). The local Trade Supervisory Office is responsible for enforcing the Operation of Medical Devices Ordinance.

Conflict of interest statement

The authors declare that no conflict of interest exists

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KEY MESSAGES

- Freedom-restraining measures (FRM) are a form of violence and should therefore be a means of last resort, restricted to an indispensable minimum.
- The basic rule is that the potential benefit of FRM must outweigh the potential harm.
- The overall use of FRM, particularly of strap systems, should be reduced in order to prevent the occurrence of health impairment, injury, or even death.
- Before FRM are applied, all persons concerned must be made well aware that they constitute a severe restriction of personal freedom; alternative courses of action must be discussed and whenever possible identified and followed.

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