RASSEGNA ITALIANA DI CRIMINOLOGIA ANNO XV N.3 2021

Società Italiana di Criminologia

Liability arising from restraint use in psychiatry

Responsabilità professionale derivante dall'uso della contenzione in psichiatria

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OPEN ACCESS

Double blind peer review

How to cite this article: R. Rinaldi, G. Bersani, A. Pastorini, A. di Luca, A. Del Rio, G. Montanari Vergallo (2021). Liability arising from restraint use in psychiatry. *Rassegna Italiana di Criminologia*, XV, 3, 192-202.
https://doi10.7347/RIC-032021-p192

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Received: 20.07.2020
Accepted: 19.04.2021
Published: 30.09.2021

Pensa MultiMedia
ISSN 1121-1717 (print)
ISSN 2240-8053 (on line)
doi10.7347/RIC-032021-p192

Abstract

This article aims to lay out an assessment of whether and when restraint use may be warranted in psychiatry. The authors lay out various types of restraints and the risks posed by such means for the patient's psychophysical well-being, wondering whether such practices really constitute forms of health care treatment. A negative response to that question would entail that restraint is never compulsory and can only be performed under the state of necessity. An affirmative answer, on the other hand, would mean that extraordinary conditions could make restraint mandatory. As a consequence of that, doctors may be held legally liable whether they fail to use restraint when necessary to keep patients from engaging in self-harm or harm against others. Since restraint *per se* entails heavy limitations to personal freedom (art. 13 Cost.) and serious risks for health (art. 32 Cost.) it can only be considered compulsory if the standards of an absolute state of necessity are met (under article 54 of Italian criminal statutes). Such parameters should be set on a national, rather than local, level.

Keywords: restraint, psychiatric patients, criminal liability, state of necessity, guidelines.

Riassunto

Lo scopo del presente articolo è quello di valutare se e quando l'uso della contenzione può essere giustificato in psichiatria. Gli autori espongono i vari tipi di costrizione e i rischi che tali mezzi comportano per il benessere psicofisico del paziente, soffermandosi ad analizzare se tali pratiche costituiscano realmente forme di cura sanitaria. Infatti, una risposta negativa a tale domanda comporterebbe che la contenzione non è mai obbligatoria e può essere eseguita solo in stato di necessità. Una risposta affermativa, invece, significherebbe che condizioni straordinarie potrebbero rendere obbligatoria la contenzione. Di conseguenza, i medici possono essere ritenuti legalmente responsabili se non usano la contenzione quando necessario per impedire ai pazienti di compiere atti di autolesionismo o danni ad altri. Poiché la contenzione di per sé comporta pesanti limitazioni alla libertà personale (art. 13 Cost.) e gravi rischi per la salute (art. 32 Cost.) essa può considerarsi obbligatoria solo se sono rispettati i criteri dello stato di assoluta necessità (ex art. 54 Cost. della legge penale italiana). Tali parametri dovrebbero essere fissati a livello nazionale e non locale.

Parole chiave: contenzione, paziente psichiatrico, responsabilità penale, stato di necessità, linee guida.

Liability arising from restraint use in psychiatry

Introduction: an overview of restraint's historical evolution

Public interest has always been linked to health care and coercion. Usually, public interest is considered as a factor which makes it compulsory to undergo treatment Sometimes, though, public interest can also prevent access to healthcare, as it is happening in this current pandemic, as infected people cannot leave their houses for health reasons.

Back in ancient times, doctors used to treat psychiatric and behavioral disorders through physical or psychological traumas. Hippocrates used to recommend ice cold showers for states of frenzy, Celsus went so far as to frighten and strike his patients. Indian Shamans scared them with vicious animals or by dipping them in cold river waters (Ferrannini, Peloso, Scapati & Maura, 2006). In the early 16th century, restraint was used in the Constantinopolis asylum, in the 17th century it was common practice in lazarettos, where the plague caused madness and delirium (Di Lorenzo, Miani, Formicola & Ferri, 2014). Hence, it is safe to say that restraint has always existed, in one form or another, being considered a necessary evil. During the Age of Enlightenment, a debate started as to the unorthodox use of restraint, viewed as a practice that ran afoul of fundamental human rights. In 1794, Philippe Pinel set out to study psychiatric diseases from a physiological perspective, freed psychiatric patients from the shackles and placed them into asylums, where they were restrained through novel tools: straightjackets, helmets, head straps, protective belts, hand mitts, handcuffs, bed rails. In 1856, psychiatrist John Connolly (2014) proposed to put an end to restraint use altogether. In 1904, the Italian legislature enacted law n. 36/1904 governing psychiatric institutions, based on custodial-repressive framework, in that it was grounded in the notion that mental diseases necessarily entailed a menace to society. Nevertheless, Royal Decree 16/08/1909 n. 615, which laid out the application standards of said law, stated under article 60 that the use of restraint had to be discontinued, or at least limited to extraordinary cases. Each institution's director was then required to authorize restraining and the specific type of restraints to be applied (R.D. n. 615, 16 august 1909).

Law n.180, passed in 1978 has marked a turning point, by affirming a novel principle: mental patients must not be detained because viewed as dangerous, but rather treated and granted the same rights as any other patient(Foot, 2014, 2015). The centrality of law n.180/1978 is confimed by the fact that its content is entirely merged into the fundamental law establishing the National Health Service, No. 833 of 1978. Undergoing treatment and voluntary hospitalization then became free choices; only under extraordinary circumstances can patients be involuntarily hospitalized, if they refuse to undergo urgent treatments. In particular under articles 33, 34 and 35 of law n. 833/1978. The criteria for involuntary psychiatric hospitalization (IPH) "in Italy are the following: (a) the patient is suffering from psychic alterations that need immediate treatment; (b) the patient refuses treatment; and (c) the patient cannot be adequately treated by other non-hospital-based means. The IPH decision involves 4 subjects, two doctors (one for the IPH proposal and one for the IPH confirmation), the city mayor and the magistrate, with the latter having the duty to evaluate the correctness and lawfulness of the treatment, having the certifications and ordinance available" (Ferracuti et al., 2020). Involuntary psychiatric hospitalization, however, is to be viewed as a health care measure, rather than a means to exert social control (Altamura & Goodwin, 2010).

Types of restraints: definitions, classifications and nature

In psychiatric practice, a protective restraint is a device intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others (Food and Drug Administration, Code of Federal Regulations Title 21). There are many different forms of restraint, namely physical, mechanical, environmental, chemical and "relational". Physical restraint entails the use of force for the purpose of immobilizing patients in a state of extreme agitation (Putkonen et al, 2013), mechanical restraints may involve a variety of different devices, which the patient cannot remove, meant to limit freedom of movement (Knutzen et al, 2014). The most widespread of such tools are wristlet, anklet, or other type of strap secured to the patient's bed. Such measures undoubtedly entail heavy limitations to personal freedom, which is enshrined in article 13 of the Italian Constitution and article 5 of the European Convention on Human Rights. Bed rails are applied for safety reasons, in order to reduce the risk of patients rolling over and falling out of their beds; when used for that purpose, bed rails are not deemed to be restraint devices, although they may function as such when applied to prevent patients from getting out of bed (Martin, Bernhardsgrutter, Gobel & Steinert, 2007). Environmental restraint consists of keeping patients within a given

environment, a room or a closet, by locking its doorways (Bowers, Alexander, Simpson, Ryan & Carr-Walker, 2004). Chemical restraint is the administration of drugs such as tranquilizers and sedatives, not for strictly therapeutic purposes, but rather to change the patient's behavioral patterns and limit mobility, stunting their sense of awareness and vigilance (Wong et al. 2019). The health team is tasked with verifying the accurate administration of such drugs, taking into account the effects and possible side effects and monitoring symptoms during remission or new onset. Nursing staff therefore plays a major role in the clinical supervision of drug administration (de Bruijn et al, 2020). Relational restraint involves listening and empathetic observation aimed at reducing patient aggressiveness (i.e. de-escalation) (Spencer, Johnson & Smith, 2018); it is therefore effective for controlling or limiting the patient's movements without physically preventing them.

Various circumstances may lead operators to resort to restraint: the patient's state of confusion, violent behaviors, risk of falling, tendency to wander, the need to prevent the tampering with therapeutic devices, postural support for hypokinetic disorders, inadequate facilities and understaffing (Italian Society of Gerontology and Geriatrics, Manuale di competenze in geriatria).

Restraint is used in many health care settings: operating rooms, neurology, anesthesia and resuscitation, general medicine intensive care units, psychiatric wards within hospitals and private clinics, inpatient care units and even nursing homes, therapeutic communities, emergency rooms, residential facilities for the elderly and disabled, in addition to psychiatric patients. As a matter of fact, the rising life expectancy has led to higher rates of debilitating diseases and age-related dementia, which call for hospitalization in facilities for the mentally or physically disabled (Bicego, 2011; Vlayen et al, 2012).

Restraint use in Italy: relevant data

Surveys on the use of restraint in psychiatric and geriatric facilities are relatively few, since such a phenomenon is hardly ever monitored and analyzed from a clinical and methodological standpoint.

Nowadays, in Italy, the most recent piece of research is the PROGRES-Acuti (PROgetto RESidenze per pazienti acuti), funded by the Italian Ministry of Health in 2004, which has highlighted that as many as 60% of psychiatric intensive care unit in civil hospitals (PICU) had resorted to mechanical restraint, and in over 70% restraint devices were available (Dell'Acqua et al, 2007). A more recent study has found that in Italy, 20 cases of restraint occur for every 100 hospitalized psychiatric patients, which accounts for 11% of patients in psychiatric care (Ferioli, 2013). A survey centered around Rome's hospitals has also shown that restraints have been used on 11 patients for every 100 discharged (Rossi, 2015; Sangiorgio & Sarlatto, 2008/2009). The situation is quite heterogeneous: some diagnostic and care facilities adamantly refuse to use restraints of any kind, whereas in other hospitals, restraint is widely used for the management of aggressive patients. A 2009 survey carried out by the SPDC (Servizi psichiatrici di diagnosi e cura, i.e. public psychiatric services) coordination body in the central region of Latium, which focused on 20 out of 22 facilities in the region, produced alarming data: 9.5% of hospitalized patients had been restrained, for an average time length of 18 hours. Half of the patients who had been involuntarily hospitalized was also restrained. Hence, it is safe to assume that the data on restraint use are somewhat conflicting; a national research study has pointed out that restraint in Italy is far more widespread than in other European countries (Kalisova et al, 2014), while other studies have put the Italian rate at about the same level as the average international rate (for instance, Italy: 6,3% of hospitalized psychiatric patients; Switzerland: 6,6%, Finland: 5,7%; USA: 8,5%; Germany: 9,5%) (Kallert et al, 2005).

On the other hand, it is necessary to underline how the same clinical indications to the restraint are undergoing evolutions over the years.

At the time of Laws 180 / 833, in fact, the vast majority of compulsory health treatments, in which restraining measures could be implemented, occurred for patients suffering from acute psychotic states, both schizophrenic and affective, with only much less incidence of cases of agitated, aggressive or confused behavior related to other diseases.

In the course of the last decades, instead, it was possible to observe a phenomenon of enormous increase in acute psychiatric conditions, even of extreme clinical, somatic and behavioural severity induced by the use of abuse substances of various kinds, such as strong psychostimulants, hallucinogens, drugs with dissociative action, etc. (Corazza et al., 2020), as well as the huge increase in the diffusion of cannabinoids and cocaine (Zaami, et al, 2018). This has led to the development of new comorbidities and (even beyond the questionable concept of "double diagnosis") to the very clear increase in the frequency of acute and severe psychotic states in subjects totally unable to recognize their condition and to accept therapeutic interventions, so as to be frequently subject to compulsory treatment and, consequently, to the possibility of restraint.

In parallel, the mandatory treatment in practice is justified by the recognition of the central importance with respect to the long-term outcome of early intervention in the onset of psychotic disorders, even acute and of any nature.

Nor should there be negligence in considering the clinical attention given to pathological conditions previously underestimated, such as neuroevolutionary or cognitive disorders of various kinds in young subjects, or also moderate cognitive manifestations in subjects with neurodegenerative diseases, for which obligatory intervention, in case of acute decompensation, often forces to evaluate also the hypothesis of the restraint.

This is clearly a varied clinical overview, much wider, by type and number, than that one considered by the legislators of the psychiatric reform.

The attempt to customize treatment programs, such as that of providing an Individual Rehabilitation Treatment Plan for each individual patient, able to predict every possible stage of treatment, including those that may be mandatory, often encounters in real clinical practice with insurmountable operational difficulties which are essentially linked to the variety and unpredictability of individual clinical stages.

Psychophysical risks for patients

Various forms of restraint are often combined in one intervention, a modality that could amplify the risk of negative impact on the patient's health. Restraint in fact entails psychophysical risks for patients arising to the length, way of execution and the patient's preexisting health conditions. In addition to numerous physical hazards (asphyxia, deep vein thrombosis, pulmonary embolism, joint and skin trauma, respiratory infections, death as a result of prolonged psychomotor agitation, etc...) (Kersting, Hirsch & Steinert, 2019; Rakhmatullina, Taub & Jacob, 2013; Ishida et al., 2014), aspiration pneumonia, rhabdomyolysis, pressure ulcer, urinary tract infection, Sepsis, urinary retention and gastrointestinal bleeding (Funayama & Takata, 2020), psychological risks cannot be overlooked: prolonged confusion, loss of personal dignity and sense of shame, depression, terror, severe sense of frustration and helplessness, coupled with even worse aggressive fits and agitation arising from attempts to break free, a deterioration of social and cognitive processes; such developments may ultimately lead to a chronicization of the mental disease rather than improvement (Italian Committee for Bioethics, 2000; Yu, Topiwala, Jacoby & Fazel, 2019).

Severe physical complications may arise in «at risk» patients such as smokers, individuals with physical malformations that might get in the way of the correct applications of restraints, and patients held in facilities unsupervised by medical personnel (Castle & Mor, 1998).

Is restraint a form of medical treatment?

There is currently no consensus in the scientific community as to whether restraint may serve a therapeutic purpose or if, on the contrary, it should be deemed a means to prevent self harm or harm against others, but devoid of any measurable clinical effectiveness (Cioffi & Tomassini, 2019). According to the Italian Supreme Court (2018), the Italian Code of Ethics for Nurses (under article 35) (2019), and the prevalent scientific doctrine (Dell'Acqua, 2015), restraint cannot be thought of as a therapeutic intervention; the very notion of medical intervention, in fact, comprises direct actions aimed at diagnosing or treating diseases, or at least allaying the physical or psychological sufferings stemming from them. Restraint has no therapeutic function whatsoever. In fact, it runs counter to the very notion of therapy, in that it entails adverse psychological effects and risks for the patient's physical well-being (Taddei, 2017).

There is a doubt however, arising from the fact that self-harming or the tendency to harm others do show the mental disease getting worse. Since restraint can prevent such conducts, it is useful in terms of preventing their health consequences. In other words, restraint is not therapeutic, as it does not cure the causes of the state of agitation, but it can be beneficial because it can prevent the psychiatric patient from injuring himself or others.

That explains the conflicting positions on the issue that can be observed internationally. The authors of the "Royal Australian and New Zealand College of Psychiatrists", for instance, argue in favor of the supposed therapeutic value of restraining practices; they even went so far as to amend the recommendations (Bloch, Kenn & Smith, 2018) and introduce as a new rationale for arguing in favor of restraint the awareness that less invasive interventions cannot guarantee the same degree of safety and effectiveness, in addition to the need to prevent the risk of violent acts on the part of patients. The Danish Council of Ethics on the other hand has concluded that it is possible to reduce restraint use without negatively affecting therapeutic quality and effectiveness. The Council has backed up that point pointing to evidence drawn from national psychiatric institutions used as sources of data, which entered into a partnership with the Council itself for the realization of the study. Based on such findings, it has been concluded that the most useful means to make restraint almost unnecessary may be the creation of a therapeutic culture solidly grounded in a peer relationship between doctors and their patients; on such basis, it could be feasible to reduce restraint use without compromising the quality of treatment and care (The Danish Council of Ethics, 2012).

In keeping with a restrictive position, the Council of Europe (2017) has stressed that resorting to restraint is only acceptable to prevent imminent harm to themselves or others and restraints should always be used for the shortest possible time, under constant medical supervision and in appropriate facilities. Using restraints is to be deemed ethically illegitimate, in that they limit the patient's freedom and are used against his or her will, hence pose a glaring violation of the principle of autonomy (Hammervold, Norvoll, Aas & Sagvaag, 2019). Overall, most codes of ethics do not believe that patients can really benefit from the use of coercion and violence, and decry such practices as outdated left-overs of an asylum-centered culture (Council of Europe, 2004). That position is also shared by the Italian Committee for Bioethics (2015).

Nonetheless, doctors have an obligation to preserve both human life and psychophysical well-being (Italian code of medical ethics, 2014; Ricci, di Luca & di Luca, 2016). By virtue of that duty, health care personnel may put in place «cautionary measures», under specific circum-

stances. Hence, restraint has no therapeutic value in and of itself, since it is not aimed at treating any disease; yet such measures may be instrumental in preventing acts of violence, either self-harm or harm against others, and are therefore meant to preserve the lives and health of patients. But patient's aggressiveness is not always a manifestation and symptom of the mental illness (Catanesi 2017, 186-187). In specific cases in which the violent or aggressive behavioral manifestations that lead to restraint are direct expressions of a mental disorder (including neurocognitive disorders), which pose an immediate risk that cannot otherwise be safely managed, a certain therapeutic role of restraint could also be hypothesized. In that case, coercive measures are a necessary preventive tool for the purpose of keeping patients from hurting themselves or others, as long as the risks of harm or death related to the disease's manifestations are higher than those arising from restraint use. Such measures are obviously not forms of therapy, but they may be part of a broader health care approach meant to avoid even worse damages. Let us consider the following example: a psychiatrist has been treating a suicidal patient with depression.

Waiting for the depression treatment to produce resolving effects, the doctor must prevent the patient from acting on his or her suicidal ideation. A pharmacological therapy is usually necessary, in addition to implementing various other measures: removing belts and strings that could be used to commit suicide, instructing nurses to closely follow the patient's behavior. Such precautions do not cure the patient's depressive disorder, yet preserve his or her life (Montanari Vergallo, Rinaldi, Bersani & Marinelli, 2017). Furthermore, in some situations, restraint use have an even clearer clinical purpose, for it is part of a broader therapeutic intervention: casts applied by orthopedics to treat fractures, scoop stretchers or spinal boards, designed to provide rigid support and containment during movement of a person with suspected spinal or limb injuries, or various surgical tools. All in all, it would be an inaccurate generalization to consider restraint a therapeutic act or categorically deny such a definition: it is necessary to establish whether such coercive measures are aimed at patient care, i.e. preventing worse injuries; only in that case can restraint be deemed a medical act.

Restraint: obligation or choice? Possibility of criminal charges arising from unwarranted use

Restraint is in itself a limitation to personal freedom. It can therefore be argued that it is always unlawful, especially without a therapeutic objective, and may lead to an indictment.

Firstly, health care operators may be charged with assault and battery if they prevent patients from moving freely (under article 610 of Italian Criminal Code), for instance by locking them up in a room. If patients are bound over substantial periods of time, that may lead to abduction charges, given that the patient's freedom is taken away by the operators (under article 605 of Italian Criminal Code). Hence, in order for the professionals involved to be cleared of charges, a solid reason justifying such measures has to be offered. Specifically, health care providers may not be indicted if they acted in self-defence and in emergency circumstances, as stated by article 54 of the Italian Criminal Code: "those who acted out of necessity to save themselves or others from imminent danger of serious harm are not punishable, provided that the danger was not otherwise avoidable or directly caused by those who committed the crime".

Still, from a different perspective, it can be argued that all health care operators must act as guarantors in behalf of their patients, and therefore have a duty to protect their health against any danger that could threaten its integrity (art. 2 and 32 of the Italian Constitution) (Cass. Pen. sez. IV, sent. n. 97391, 1 december 2004; Dodaro, 2011). Psychiatrists and treating staff play a uniquely critical role: in addition to the duty to care, in fact, they have a duty to supervise and keep, even to the point of using restraints. Law n. 180/1978 has marked a departure from the principle of mental patients synonymous with dangerous patients, (Dodaro, 2011); still, patients can in fact turn "dangerous", i.e. capable of inflicting violence on themselves or others. From that perspective, psychiatric operators have a duty to resort to mechanical restraints, in emergency circumstances and when no alternative exists, in order to prevent harm.

If doctors are derelict in their duties of diligence and caution, failing to prevent incapable patients from harming themselves or others, they may be charged with abandonment of incapable patient (under article 591 of Italian Criminal Code). In such cases, operators may be convicted even if their patients suffer no damage at all. In fact, for a conviction to be handed out, it is enough to prove that a danger came into being as a result of the operator's conduct. If the patient dies or sustains injuries following the operator's failure to intervene, the health care personnel may be convicted for manslaughter or accidental injuries (art. 590-sexies of Italian Criminal Code), in addition to abandonment of incapable patients, on account of their failure to prevent an incident that they had a duty to prevent, by virtue of their status as guarantors, which entails obligations to protect and supervise (Cass. Pen. Sez. IV, Sent. n. 48292, 27 November 2008; Catanesi, Manna & Ventriglio, 2016; Catanesi et al. 2012).

Also, the failure of operators to notify to the authorities any instance of mistreatment or deprivations against patients is punishable as well (Royal College of Psychiatrists, 2014), as spelled out in article 22 of the Italian Code of Ethics for Nurses: any health team member who realizes that mistreatment or violence have occurred against patients must take all necessary steps to ensure proper action is taken in a timely fashion in the interest of the damaged patients themselves.

A "diligent" form of restraint

Regardless of whether restraint is intended as a choice or a duty, scientific sources largely agree on the fact that restraint use cannot be justified by a generic need to protect patients' health: in fact, specific clinical conditions need to be met.

According to the Italian Code for Bioethics (under article 31), doctors can impose physical, pharmacological and environmental restraints only in cases of documented clinical necessity and only for as long as strictly necessary, with respect for human dignity and safety (2014). To buttress that point, Italian jurisprudence (Cass. pen. Sez. V sent. n. 50497, 20 June 2018), the 2019 Italian Code of Ethics for Nurses (under article 35) and the guidelines issued in 2010 by the Italian Conference of Regions all agree on the fact that restraint use is only acceptable in emergency situations of imminent danger, for the purpose of averting severe damage to the health of the patient or others, not preventable otherwise.

The time length and the use of restraints need to be accurately regulated and limited, given that restrained patients run physical risks. Restraint must be prescribed by a physician. Restraint measures must be proportionate to the health conditions and diseases of the individual patient, and be part of a protocol in writing, thoroughly documented, and have to be replaced with other measures, more acceptable for patients, as soon as the emergency conditions are no longer there (Council of Europe, 2000). The health team is required to specify in the patient records all the reasons why the physician chose to apply restraints on the patient, the exact time when such measures were applied, the overall length of the treatment and the treatment specifics, in addition to all directives and instructions provided by the doctor to the nursing staff. If the need arises for restraint to be prolonged, it is necessary to motivate such a decision, and the request for that needs to be signed by the physician and the ward management; the same process must be complied with when restraint is discontinued (Cacace, 2013).

Should adverse outcomes arise from restraint use, the measures must be ceased at once. Any coercive measure has to be implemented with respect for human dignity at all times (Council of Europe, 2017; Italian Committee for Bioethics, 1999, 2015). Moreover, restraint interventions may be carried out only as part of a broader therapeutic pathway, which needs to entail an effective and consistent provision of care by health services.

For those reasons, mechanical restraint use, even when applied to patients in involuntary psychiatric hospitalization, is to be considered an *extrema ratio* (last resort) intervention, meant to prevent imminent danger such as patients engaging in harmful behaviors against themselves or others (Cass. Pen. Sez. V sent. n. 50497, 20 June 2018; Royal College of Nursing, 2008; Zaami, Rinaldi, Bersani & Marinelli 2020).

Moreover, when choosing what type of restraint to use, the patient's will has to be taken into account as well (Council of Europe, 2004; European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment, 2017). That recommendation, however, needs to be clarified. The need to resort to restraint is hardly compatible with gaining a valid informed consent. As a matter of fact, the Swiss Academy of Medical Sciences (2017) has drawn a clear distinction between the way to deal with cognitively capable patients as opposed to incapable ones: the former may never be subjected to restraint, whereas incapable patients may be restrained, provided that an objective situation of imminent danger exists which cannot be prevented otherwise. Still, it is still highly advisable to start a discussion with the patient as to what situations may lead to the need for restraint before such situations come into being; that way, prior consent could be gained in the form of advance directives (di Luca, Del Rio, Bosco & di Luca, 2018; Montanari Vergallo & Spagnolo, 2019). Such consent does not make an unnecessary (therefore illicit) content lawful, but it is necessary to make the patient aware of his situation, and to reduce the risk that the dispute may affect the fiduciary relationship between the professional and the patient.

When situations of emergency and imminent danger do occur, restraint use may be chosen and applied by the nursing staff or caregivers directly (Italian Code of Ethics for Nurses, 2019).

Once the emergency has ceased, the nurses have a duty to inform doctors about the decision to resort to restraint (Fascio, 2004). If the healthcare personnel decides to apply restraints, the least invasive options should be applied, in a manner consistent with the patient's real needs and in keeping with therapeutic continuity; restraints should be kept in place for as long as necessary to overcome the critical crisis situation that made their use necessary in the first place. As soon as there is no longer any danger, restraints ought to be removed, since by that time, their use would be unjustifiable, and could even be criminally relevant (European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment, 2017). It needs to be considered, in fact, that restraint is applied without a valid informed consent from the patients, who are incapable of expressing their will in a legal fashion (Fascio, 2004).

It is advisable to remove the restraints at least once every two hours, for about ten minutes at least, except for night hours, so as to enable patients to move regularly (Conference of the Autonomous Regions and Provinces, 2010). After the expiration of such a term, doctors might decide to prolong restraint if deemed necessary; it is however impossible to determine in advance for how long the restraints should be kept on: that determination always depends on the patient's conditions (Italian Committee for Bioethics, 2015). There must be constant supervision of the patient's conditions following the application of restraints, and the situation has to be regularly monitored at all times by the health care personnel.

Time periods must also be set, beyond which restraint will have to be monitored by an outside psychiatrist acting as an independent guarantor, particularly in situations

where restraint use draws out considerably (Italian Society of Psychiatry, 2009).

A qualified operator should steadily be in the room with the patient, so as to consolidate the therapeutic alliance. The constant presence of a professional cannot and should not be replaced by video surveillance (European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment, 2017). Evidence has in fact shown that a high quality relationship between patients and health care professionals positively affects the patient's ability to withstand restraints (Aguilera-Serrano, Guzman-Parra, Garcia-Sanchez, Moreno-Küstner & Mayoral-Cleries, 2018).

Consequently, patients should be thoroughly explained the reasons why restraints are being used and the non-punitive nature of such interventions. The most suitable communicative approaches should be adopted for the purpose of reassuring patients and setting their minds at ease. After the restraints have been discontinued, a further conversation needs to be started with the patient and with any other party involved as witnesses, such as other patients, relatives, and staff members, who may even draw upon such episodes to grow professionally; similar situations may in fact be managed in the future without the need to restrain (Italian Society of Psychiatry, 2009).

In case of reports leading to litigation, it will be up to the court to establish whether restraint has been used in a professionally sound fashion, in light of the pivotal principle of proportionality and as a last resort. Therefore, choices must be made as to the best type of restraint, the timing and length, and the applications most consistent with the degree of gravity and urgency, in order to stave off the damages that might arise from the unorthodox or overlong use of restraints. The use of restraints will likely be judged as justifiable only if the right types are chosen based on the specifics of each individual case, and only if the restraint devices are patented and authorized for use. In the United States, all types of restraints have to be approved and labeled as «prescription only» devices (Catanesi, Troccoli & Carabellese, 2003). Nurses who avail themselves of makeshift or improvised devices, such as bandages or ropes never approved as restraints, are punishable by law.

Ultimately, health care personnel are required to provide constant oversight as to the quality of care for each patient, and ensure the least invasive therapeutic interventions are undertaken. That way, they can discharge their moral duty to respect the patient's dignity and humanity, which are enshrined in a great deal of codes of ethics (The British Psychological Society, 2018).

Can restraint really be performed out of necessity?

The advantages and value of the no-restraint approach have been increasingly acknowledged in scientific literature. Such a methodology is mainly characterized by two fundamental principles: a) patients are never bound to their beds; b) doors should remain open during any procedure. The relationship between patients and operators is key. No-restraint wards aim to allay and soothe states of anguish, when a state of agitation is manifested, rather than tie up and immobilize patients through restraints. In order to achieve that, a solid, straightforward relationship needs to be established between patients and the health team (De Benedictis, 2011; Taddei, 2017; Toresini, 2007).

That is utterly relevant, since a provable state of necessity makes a crime not punishable, as long as that act was the only way to avoid an even worse outcome (under articles 54 of the Italian Criminal Code and 2045 of the civil code). Consequently, before the state of necessity can be invoked, it is necessary to prove that an imminent risk of damage to the patient could not be avoided through the no-restraint approach. However, such proof is difficult to produce. Since that element is closely linked to facility management, rather than the single choices made by operators, hospital managers and high-ranking officials should be held accountable. However, a review of the literature has shown that behaviors for which restraint is deemed necessary are: agitation, anxiety, restlessness, delirium, confusion, disorientation, drowsiness, aggression and violence (Teece et al., 2020). It should be clarified that the assessment of the state of necessity is conducted by the physician, but it is for the judge to determine whether the choice of the physician is correct. For the reasons explained above, the judge does not consider any state of agitation or aggressiveness sufficient to justify the contention, but only those conditions that cannot be faced otherwise. This leads to the belief that professionals must always try to prevent critical situations at first and, in case of failure, solve them in a non-contentious way.

The need for national legislation

The report titled "Restraint in psychiatric care: a possible strategy of prevention", issued on 29th July 2010 by the Italian Conference of Regions, has laid out a set of recommendations. Firstly, monitoring and data collection are key points, and should include all relevant information on restraint such as the duration of each intervention, nightly restraint cases, frequency of restraint use, the number of patients who have been restrained and the diagnosis associated with each one of them.

The report has also illustrated various other indications, such as to oversee all instances of aggressive behavior, improve personnel training for managing critical situations, assess the facility's organization when the number of patients is considerably high, foster transparency in order to improve accessibility to the wards, increase the degree of livability and facilitate communication with the outside. Many such recommendations appear to be sensible to us; overall, however, they strike us as somewhat generic and vague, leaving too much discretionary power to regional councils. That impression is confirmed by the

indications laid out in regional plans: the inconsistencies among different regions are quite glaring; Tuscany, for instance, in its 2012-2015 health care and social plan, has put in place a total ban on any form of physical restraint, mandating that all doors be left open in SPDC facilities and recommending constant attention as to the appropriate implementation of pharmacological therapies.

The 2004-2012 Lombardy regional plan on mental health has interpreted the Conference's report as a prod to "regulate" restraint use, and tasked local health care agencies to outline related protocols. The region has acknowledged that such practices should only be applied in well documented emergency circumstances, and yet recognized that restraint use is quite widespread. Restraint guidelines issued from one of the most prominent health care institution in Milan, the Niguarda hospital, have also highlighted the overall ambiguity of the Commission's recommendations. Such guidelines have defined restraint as a common practice, which may be necessary through various stages of several mental illnesses; they do not however explore the ethical and therapeutic reasons not to use restraints. Such guidelines have spelled out a long and diverse list of "high-risk situations and behaviors that call for restraint use": they range from anxiety disorders to psychomotor agitation, delirium and hallucinatory states, sleep cycle disorders and fall prevention. Still, it is worth noting that many of those scenarios, e.g. anxiety disorders, do not meet the requirement of urgency and necessity (Niguarda Ca' Granda Hospital, 2008).

In Italy, regional governments are charged with regulating health care, but such regulations must be consistent with national legislation (under article 117 of the Italian Constitution). In addition, restraint impacts fundamental rights such as personal freedom, dignity and health, which are comprised in national statutes, both criminal and civil, and are therefore nationally upheld and regulated (again, under article 117 of the Italian Constitution) (European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment, 2017).

Hence, it is safe to conclude that setting the conditions on which restraint can be legally used cannot be part of health care management and cannot be influenced by factors such as staff shortages or availability of adequate facilities at the regional level. Clear national legislation is not sufficient to avoid unequal treatment. Uniform application provisions in all regions and investments in structures and staff are also needed. This is the only way to solve the problem of the excessive use of urgent hospitalization, which forces the patient to undergo treatment before the procedure required by law is completed.

Conclusion

Both legal statutes and codes of ethics stand in opposition to restraint use. Restraint is in fact not deemed a health care measure. After all, even when it can be viewed as a medical act, its main goal is to deprive patients of their freedom to move, and that makes it usable only under conditions of absolute necessity. Consequently, putting in place restraints when such a requirement is not met may entail being held liable for the crimes of accidental injuries, kidnapping, assault and battery. Since those are all felonies, no insurance would cover for the compensatory damages awarded to aggrieved patients. Although operators may mistakenly invoke a state of necessity to justify their carrying out restraint measures, under article 55 of Italian Criminal Code, they may still be charged with misdemeanor accidental injuries, rather than criminal liability, which would still bind them to pay compensatory damages arising from the injuries and the deprivation of liberty.

The tenability of invoking the state of necessity defence is quite disputable as well. Based on articles 54 of the Criminal Code and 2045 of the Civil Code, unwarranted restraint is not criminally punishable only if the risk of severe damage to the patient was not avoidable in any other way. The no-restraint model, however, may go a long way towards avoiding restraint use altogether. Consequently, one of the requirements of the "state of necessity" based argument would be unmet.

At any rate, the choice of the types of restraints and related implementation methods cannot be left up to the regional governments or even worse, to each hospital, since restraint entails the violation of fundamental rights that must be uniformly upheld nationwide. To that end, restraint could be effectively regulated through the guidelines laid out in law n. 24/2017, article 5 (Mazzariol, Karaboue, di Luca & di Luca, 2018; Montanari Vergallo & Zaami, 2018; Pastorini, Karaboue, di Luca, di Luca & Ciallella, 2018) or through the implementation of the above-mentioned cautionary measures, which constitute good clinical health care practices, and should therefore be taken into account in malpractice trials (Montanari Vergallo, Zaami, di Luca, Bersani & Rinaldi, 2017).

Lastly, since there is a pressing regulatory and legal need to reduce restraint use to a minimum, or even ban it, a national monitoring body ought to be instituted, based on regional data and aimed at drawing comparisons of regional policies, in order to eliminate all regulatory inconsistencies. Just as importantly, forgoing restraint should be considered a quality factor for the assessment of health care services and a requirement for accreditation.

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