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Article

Novel Approaches Needed: A Suggestion for an Alternative to Mechanical Restraint in the 21st Century

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Abstract: Despite many calls to reduce or eliminate the use of mechanical restraint, it is still widely used in many countries. Studies using patient interviews have a very clear message: Patients experience mechanical restraint as the most humiliating intervention. There seems to be a lack of alternatives with violent patients if all other approaches to prevent the use of coercion have failed. We developed a method using 30 kg bags, originally designed for fitness purposes, to be attached to a patient's wrist or ankle under 1:1 supervision. The method was tested with 10 experienced nurses and de-escalation trainers. A video was made and presented to six outpatients who had previously experienced mechanical restraint. All participants were interviewed. Transcribed interviews were analysed using qualitative content analysis. All participants approved of the method as a milder and less humiliating alternative to mechanical restraint. Nurses' main concerns were the risk of falls and the use of the bags as a weapon. The latter could be controlled by using an additional bag. Patients were generally positive, especially if there was a history of abuse. The method should be further developed to replace at least part of mechanical restraints. As with all 'milder means', care should be taken to really replace restraint and not to introduce additional coercion.

Keywords: restraint; alternative; coercion; milder means; human dignity

1. Introduction

Mechanical restraint is used in most countries to control aggressive and violent inpatients. Surveys suggest that it is used in between 3% and 8% of all psychiatric admissions [1,2], amounting to millions of cases worldwide each year. The only alternatives are seclusion and, to some extent, the use of compulsory medication. A few countries, the United Kingdom, Ireland, the Netherlands, and Switzerland, have a clear preference for seclusion, with mechanical restraint used only in very exceptional cases [1,3]. Interviews with patients from different countries gave very clear results: Patients find mechanical restraint extremely humiliating and most (but not all) patients find it more intrusive and distressing than any other measure [4–9]. However, seclusion is also perceived as humiliating, staff contact and medical checks such as blood pressure measurement are difficult to realise during seclusion [4,6]. In Denmark, for example, seclusion is banned because it is considered inhumane [10]. The use of tranquilising medication is limited for medical reasons and their use is also controversial in many countries [11,12]. The UN Committee on the Convention on the Rights of Persons with Disabilities and the World Health Organisation strongly recommend that all countries abolish these practices and the corresponding domestic legislation [13,14], without, however, providing reasonable alternatives for people who are violent because of their mental disorder. In fact, convincing examples of a practice that eliminates seclusion and restraint have not yet been demonstrated in any country, and long-term data do not show a significant reduction [2]. The main reason is violence, observed in a significant proportion of psychiatric admissions [15,16], which has

been never discussed in the appeals to eliminate the use of coercion. If a sanitarian is attacked, the police are called to bring the guy away. If a nurse is attacked in a psychiatric ward, the respective patient will stay there. Therefore, it does not seem justified to wait until mechanical restraint is abolished. Given the undoubtedly humiliating nature of mechanical restraint, it can be considered a shame that in the 21st century we have not developed less humiliating and safer alternatives. There is an urgent need for novel approaches. Here we describe a pilot study of one such approach.

2. Methods

2.1. Technique

We developed a method with 30 kg bags, originally developed for purposes of fitness training, that can be attached with a length-adjustable belt at its handle to a patient's wrist or ankle. This allows patients to sit, to eat, or to go to the toilet. In case of severe agitation and danger of attacking the nurse present in the room, a second bag can be attached to the first bag in a row or at another wrist or ankle. A 4-minute video demonstration with subtitles in English is available at https://www.uniklinik-ulm.de/fileadmin/default/Kliniken/Psychiatrie-Psychotherapie-I/Bilder/2023-05-03_Fixierung_480_UT1.mp4.

2.2. Experimental Study

As long as these bags are not yet certified medical devices, they cannot be used with patients, even on a voluntary basis. Therefore we conducted a pilot study and tested the method with volunteering professionals and presented the video demonstration to patients who had previously experienced mechanical restraint. The aim of the pilot study was to explore potential risks and side effects as well as scenarios for appropriate use and to receive an ethical assessment, compared to mechanical restraint.

2.3. Test Scenario

Participants underwent experimental mechanical restraint in a bed with belts at five points. Then restraint belts were removed and, as an alternative, a 30 kg bag was attached to their wrist. Then they were encouraged to move, to eat, to go to the toilet, and to test the possibility of a violent attack towards the other nurse present in the room. This nurse was instructed to try to reach safe distance in the situation of an attack. For this situation, also the use of a second bag (in a row with the other or at the other wrist or at an ankle) was tried.

2.4. Ethics

A positive ethical vote was obtained from the Medical Chamber of Baden Wuerttemberg (F-2023-016). All participants received a written study information and signed informed consent on their participation, including recording the interview and using the data.

2.5. Participants

Professional participants were recruited among the centres of psychiatry Suedwuerttemberg, a hospital group with 10 sites in the Federal State Baden-Wuerttemberg. Inclusion criteria were \geq three years work in acute psychiatry, experience with using mechanical restraint, and experience with de-escalation training.

The inclusion criterion for patients was having experienced at least one mechanical restraint. Being an in-patient was an exclusion criterion. Patients were recruited among the centres' outpatient services and self-help groups.

2.6. Interviews

All interviews were conducted by TS, using a previously developed interview guideline. First, the scenario was clarified: The bags technique should replace mechanical restraint conducted before, with a nurse 1:1 present continuously, and nobody else in the room. Then participants were asked which risks for patients they could imagine under these conditions, and which risks for staff. Subsequently, they were asked to imagine the method for different types of patients and to judge whether this could be appropriate: Agitated patients with psychotic disorders or mania, violent patients with delirium and dementia, intoxicated patients, patients with mental retardation and violent behaviour towards self or others, and patients with borderline personality disorder and repeating severe self-harm. Finally, participants were encouraged to express their ethical opinions in terms of human dignity, fairness, and humiliation. Interview were recorded and then transcribed.

2.7. Analysis

All interviews were analysed by TS and SH separately with qualitative content analysis [14] according to themes. No 'vote counting' was done; instead, we attempted to represent the diversity of opinions. Quotations are presented for typical opinions.

3. Results

Professional participants were eight male and two female nurses. Two worked as de-escalation trainers, eight as nurses on acute psychiatric wards. Their median age was 45 years (34-59) and they had a median of 20 years of professional experience (4-33). Patients were four females and two males with a median age of 40 years (30-55). They had a median of 15 psychiatric admissions (4- estimated 100) and had experienced a median of 2 mechanical restraints (1-estimated 100).

3.1. Risks for patients

According to the professionals, falls were assumed to be the major risk of the technique. "Because at that moment he might trip over his own legs because he's dangerous to others, you're a few steps away, and I can't get there that quickly". This risk was also rated as high because the patients could not easily catch themselves with the bags on their hands in the event of a fall: "I see the risk that he could injure himself and then possibly hit his face head-on, a head injury". As a minor risk, some professionals imagined patients could hurt their shoulders or their back with abrupt movements. "I could imagine it, but I would be worried that he forgets that something is attached to him and gets up suddenly and wants to run after me, for example, and that something happens with the shoulder or the patient falls down" or that the belts could cut in. One nurse worried that the bag could fall on the patient "because it can also be dangerous if he drops something on his foot from these weight bags". Further comments referred to the material: Seams must be stable and robust, and aspects of hygiene have to be considered (washable material etc.). Some professionals expressed concerns that patients with risk of severe self-harm could strangle themselves with long belts, but conceded that this risk could be averted by the presence of a nurse in 1:1 supervision.

One of the patients feared that self-harm could not be prevented as safely with this technique as with others. Another was concerned that the belts could cut. Overall, however, fewer concerns were expressed by the patients than by the staff.

3.2. Risk for Staff

All interviewed professionals and some of the patients saw the major risk for staff in the bags being used as a weapon, attacking the nurse present in the room. Some said that they would not use it for very strong and agitated patients for this reason. But all conceded that this risk could be minimised by use of a second bag in a row or at the other wrist. However, they mentioned that this would then be rather similar with traditional mechanical restraint. The somewhat surprising own experience for participants was that they were well able to move, but rather slowed down and soon exhausted. "Of course, the radius is such that you could be hit, but you can always keep a safe

distance if you work a bit ahead". „It's about the speed of the patient, you are out of the area so quickly where you would be at risk". Staff expressed the concern that patients could kick with their legs, as these are not restrained in contrast to conventional restraints "right after overpowering him, I'm just a bit worried that the legs are free and that someone else could get hurt". Another concern of some participants was the weight of the devices for transportation. This could hurt the back, especially among those with lower body weight. There were controversial opinions on the appropriate shape of the bags. Good handles would be useful for transportation, but could also facilitate violent acts by patients. The form of a cone instead of a bag would enhance friction on the ground and help to slow down the patient, but would be more difficult for transportation. Less or more weight of the bag could be more appropriate for individual patients, but the aspect of transportation should be taken into account. "Of course, it should not be so heavy that it makes movement completely impossible, but at the same time it should have enough weight so that the patient has difficulty, for example, in hurling it or somehow being able to misuse it so easily".

Patients only addressed the aspect of possible violent acting against staff.

3.3. *Indications*

The professional participants agreed that they would not apply the method in elderly patients with risk of falls and in severely intoxicated patients due the same reasons. "I could well imagine with aggressive patients with psychosis or mania" was a frequent comment. However, there were also concerns expressed relating to very aggressive and agitated, vigorous patients. For patients with mental retardation and aggressive behaviour towards self and others, opinions were inconsistent. Some participants were sceptical, others positive: "This method would perhaps also be an addition to the spectrum in this respect, I could well imagine that". With regard to patients with severe self-harm, different views were expressed. Some saw no use and supposed, such type of patients would try to strangle themselves or bang their head on the ground. Others expressed more positive opinions: "But to relieve tension, those who inflict pain and wounds on themselves, you would have to weigh it up, yes that would perhaps also be something you could discuss with the patient". Several participants said that introducing a new method would require new standards of quality to be established: „Yes, I think you have to discuss with the team beforehand which patient would be suitable". Many professionals stated that they could well imagine the bags as a loosening or interim solution after the end of a restraint or seclusion in order to reduce its duration.

Interviewed patients were less able to differentiate different types of patients from their own experience. They expressed less concerns with possible violence: "I really believe that those who are so excited, so agitated, that they then lash out with 30 kg bags, that is a vanishingly small minority. So I think so, I can well imagine it with most of them". One patient expressed a strong opinion that the method should be absolutely preferable for those who had been victims of abuse: "So I speak for all victims of abuse and I don't think there is an exception, that this restraint on the back is the most terrible situation..."

3.4. *Human Dignity*

Without exception, professionals stated that they found the novel approach less humiliating and ethically preferable for those to whom the procedure could be applied without undue risk to themselves or staff. "One has an association that it is a bit like the iron ball on the foot and reminds one of the convict camp. But actually mechanical restraint is much more restrictive and humiliating. In this respect, it is a milder means in comparison. I think it's very good that people are thinking about such alternatives and would like to try it out if it were possible". "Coercion is coercion, but if I imagine many of our patients are secluded, restrained with belts, and then have to pee and go to the toilet, they could do that with it and I think that's a point that convinces many. Need of a bedpan is undignified for all". The nurses interviewed had the idea that the measure could be helpful in returning people to the community on the ward, but were concerned that they could be stigmatized or ridiculed if they wore the bags: "At first I thought that the idea might be that the patient could sit

at the table properly outside the seclusion room, for example, that he could eat. [...] However, I see the risk of stigmatization if patients see it that way."

Patients interviewed were very positive about an alternative and often referred to their own negative experiences with mechanical restraint: "That's why I find this alternative a thousand times better from my point of view, that I wouldn't have these choking attacks because I could sit and wouldn't have to lie on my back". Also psychotic experiences during restraint played a role: "Exactly, you're not tied down on a bed and then facing the lethal injection or something. That's much more pleasant here. Because that's another association". Negative associations like an "iron ball" were not expressed. Compared to seclusion, the possibility of contact was emphasised: "Yes, it's a good thing, because you can stay in touch". Patients also mentioned the aspects of eating and going to the toilet: "So you could still eat yourself and if necessary also go to the toilet yourself, so you feel completely inhumane when you are fed or things like that are done with you".

4. Discussion

The findings of our experimental study show that this new approach could be promising. In terms of human dignity, all participants rated it positively compared to mechanical restraint. No undue risks or serious safety concerns were expressed. However, participants were divided on whether it could replace a small or large proportion of mechanical restraints, with the main concern remaining serious violence against accompanying carers. This is not surprising given the lack of clinical experience.

It is necessary to place this proposed alternative to mechanical restraint in context. There is a huge amount of literature on 'alternatives' to mechanical restraint. Most of these 'alternatives' are interventions to prevent and avoid mechanical restraint, which are undoubtedly necessary and effective. We have previously published a systematic review of this type of intervention [11]. In a subsequent scoping review on alternatives to the use of mechanical restraints in the management of agitation or aggression in psychiatric patients [18], the authors found more or less the same studies and approaches, but now call them 'alternatives', following the political discussion to develop alternatives to the use of seclusion and eventually to abolish the use of coercion in psychiatry [13,14]. The 'alternatives' identified in 21 included articles were staff training in de-escalation techniques, risk assessment tools, data monitoring, patient involvement, appropriate physical environment, organisational change and complex programmes such as Six Core Strategies or Safewards. It is also not surprising that patients least appreciate mechanical restraints and prefer 'soft' interventions such as listening to music, being accompanied in 1:1 supervision, soft rooms, etc. [19,20]. However, we believe that it blurs the boundaries and is like comparing apples and oranges to call these important approaches 'alternatives'. Fire prevention is important, but it is not a cure for burns. Similarly, an alternative to mechanical restraint is a practice that can be used when all preventive approaches have failed and a patient is still imminently or openly violent. In these situations, alternatives are very limited. The most commonly used restraint is seclusion, with considerable backrest to limit contact with the patient and to make medical assessments, such as blood pressure monitoring, more difficult. Subjective distress during seclusion is only slightly less than during mechanical restraint [4,6,21]. Physical restraint, i.e., holding the patient by physical force, is a practice predominantly used in the UK and Ireland, where mechanical restraint is not permitted [1]. It can be considered a good alternative, but requires extensive staff training and carries risks for staff and patients [22]. To our knowledge, physical restraint could not be implemented broadly as an alternative to mechanical restraint in any of the countries where mechanical restraint is permitted. Another recently developed alternative is the so-called restraint chair, which is basically a technical variant of the traditional belt-to-bed mechanical restraint. A first qualitative study reported positive patient experiences [23]. Whether this could be a humane advance, whether there are advantages over traditional mechanical restraint and whether there are safety issues remains to be investigated. Some further interesting alternatives to mechanical restraint have been developed in geriatric psychiatry, where there is evidence that mechanical restraint is harmful and can lead to serious somatic consequences. Although not supported by strong evidence, technical devices to prevent falls or mitigate their

consequences, such as hip protectors [25,26], low-low beds [27], bedchair pressure sensors [28], gait stabilisers [29] and physical training [30,31] may be alternatives to restrictive interventions. However, these alternatives to mechanical restraint can only be considered in frail patients, not in those with overt violent behaviour.

Therefore, we believe that our proposed approach could be an alternative to the use of mechanical restraint for patients with overt or imminent violence when all other measures to prevent violence and coercion in inpatient psychiatric settings have failed.

The next steps in gaining such further experience with the technique, always accompanied by 1:1 staff supervision, should be similar to the introduction of new drugs. A certified medical device must be developed for any clinical use. Well-designed randomised controlled trials should be conducted before any introduction into clinical routine. These trials must be designed to ensure that the novel approach does in fact replace mechanical restraint and does not result in additional restraint of patients who would not have been restrained in typical clinical practice.

5. Conclusions

As mechanical restraint is widely used in clinical practice worldwide, and there is a strong call for milder alternatives, the impact on clinical practice in mental health care could be significant. The surprisingly positive comments from former patients underline the need to test this approach in real-life practice. An obstacle to take into account, at least in some countries, is the need to obtain a label as a licensed medical product. We caution against uncontrolled use and emphasise the need for rigorous studies and the development of practice guidelines.

Author Contributions: Tilman Steinert developed the technique, wrote the ethical application and the study design, conducted the interviews, participated in the qualitative analysis, and wrote the manuscript. Bernd Maierhofer developed the technique further, recruited the professional study participants, introduced the technique to them, and conducted and supervised their self-experience with the technique. Peter Schmid produced the video demonstration. Sophie Hirsch recruited outpatients for the study, did the qualitative analysis together with Tilman Steinert and participated in drafting the manuscript.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and a positive ethical vote was obtained from the Medical Chamber of Baden Wuerttemberg (Approval code: F-2023-016; Approval date: 28/03/2023).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

Conflicts of Interest: Tilman Steinert and Sophie Hirsch have received funding from the German Association for Psychiatry and Psychotherapy for the development of a national guideline on prevention of coercion. Tilman Steinert has received funding from the German Innovationsausschuss for a RCT on the implementation of this guideline. The other authors declare that they have no conflicts of interest.

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