Refraint vs. Restraint

Delirium, Immobility, PICS and the Impact of Patient Restraints

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Contents

INTRODUCTION

Restraint is a double-edged sword. It can keep patients and staff safe, but can also cause physical and emotional trauma, and even death. Restraints have unique application in psychiatric wards and prisons but for the purpose of this paper, we will focus on the patient requiring restraint to maintain vital tubes and lines. Both physical and chemical restraints will be considered and their interactions examined.

For centuries, restraints were utilized indiscriminately to control psychiatric patients. In the 1960s, medical literature warned the healthcare community against the use of restraints, citing psychological, physical, physiological, and ethical concerns[1]. In 1991, the U.S. Food & Drug Administration (FDA) issued a medical bulletin entitled "Potential Hazards with Protective Restraint Devices" and beginning in 1992, restraints were required to be labeled as "prescription-only" devices. In January 1996, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) published a new chapter of its standards for hospitals for the use of physical restraints and seclusion, containing requirements about detailed policies and procedures[2].

PHYSICAL RESTRAINT OVERVIEW

The overall prevalence of restraint use varies geographically between 0-87%. Nordic countries, the UK, and Iberia utilize virtually no physical restraints, while North America, Asia, Africa and other parts of Europe report heavier usage[3]. It is important to recognize that a decrease in usage of one type of restraint is often accompanied by an increase in another. For example, a deeply chemically restrained patient often does not require physical restraint; however, while physical restraints restrict movement, chemical restraints restrict cognitive function as well.

There is claim that physical restraints are not effective in preventing self-discontinuation of medical equipment[4]. Patients in wrist restraints often self-extubate, as they are able to slide their body downward, bringing their face toward the restrained hand for easy endotracheal tube (ETT) extraction. Patients in mitt restraints that are not tied to the bed, squeeze their mitts on either side of the ETT for extraction. With enough maneuvering, patients are often able to free themselves from mitt and sleeve-type restraints.

CHEMICAL RESTRAINT OVERVIEW

Minimizing restraint is important for many reasons, all of which one might imagine while being physically restrained oneself. While being restrained, one could surmise that human rights and personal freedoms are at issue. Conclusion could be reached that while restrained, there would be less unwanted movement AND less wanted movement, and that in order to tolerate any

length of time physically restrained, chemical restraint might be welcomed. These traumatic events become less obvious when it is another individual being restrained.

As chemical restraint is introduced, less movement occurs, including internal movement such as muscle contraction and general tone as for vascular health, secretion clearance, and gut motility, Not only are these physical complications occurring but also the mind is adversely affected. Hallucinations and errant experiences are introduced, resulting in confusion and false memories which can morph into long-lasting impressions and long-term dysfunction.

Types of chemical restraint vary considerably including short-acting, long-acting, hemodynamically destabilizing, pain-controlling, anti-psychotic, and by route of administration and cost. Physical restraints also come in varying forms including wrist, mitt, sleeves, arm boards and splints, bedrails and sheets as well as sitters. Even some safety equipment can be categorized as restraints including body straps that keep patients from falling out of verticalizing hospital beds.

RESTRAINT COMPLICATIONS

In addition to the movement-reducing deleterious effects of restraints, other common complications include pressure injury; skin maceration and tears; bruising; localized edema and vascular compromise at the site of constriction, especially if the restraint is applied before third-spacing presents; and dislodgement of intravenous and intra-arterial catheters.

There are also emotional complications such as learned helplessness which can plague patients who have been ill for extended periods of time. Patients who have survived prolonged illness often still feel they are a subject pithed for examination and that their survival continues to depend on others, manifested by the sense that things should be done for and to them.

Staff may also experience emotional trauma related to the sense that restraints cause their patients to suffer while they are powerless to intervene. This can culminate in dissatisfaction, burnout, or a propensity to promote discontinuation of care at an early stage. Alternatively, staff can develop a hardening to the anxiety of a restrained patient if they are aggressive or uncooperative due to their restraints.

RESTRAINT INTENT

It can be argued that patients are restrained because they are agitated from illness, baseline mental condition, or insertion of tubes and lines. Indeed, it may be the empathetic response of caregivers who believe they would be more bothered by being in the situation of the patient which results in over-treatment of agitation. But there are things to consider: 1) Patient

agitation may be significantly allayed by explanation, soothing, company, and other non-physical methods to either reduce or prevent restraint and 2) It is a natural response to want to move more when restraint is enforced.

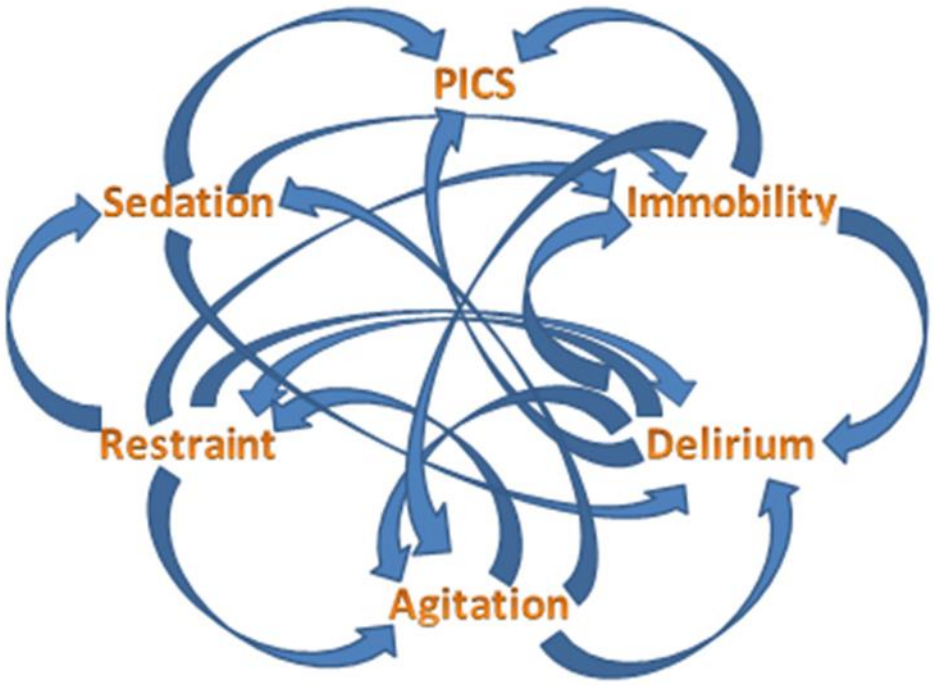
A supportive argument for restraint is inability of the nurse to be with each patient at all times. While a patient may be reminded that they should not dislodge their tubes and lines, they are often forgetful, unfocused, confused, and clumsy. If the nurse is not physically with the patient, it is quite possible that an emergent situation may ensue. For this reason, even when a patient demonstrates comprehension and cooperation, nurses are understandably not comfortable leaving the room to perform other duties unless the patient is restrained.

RESTRAINT ALTERNATIVES

A vast number of alternatives have been utilized in physical restraint minimization programs. Examples include: quiet single rooms; familiar staff; physical, occupational and recreational therapies; increased staffing level; additional supervision and observation; active listening; and increased visiting and companionship using family, friends or volunteers. Many other alternatives have been suggested based on expert opinion. However, no individual alternative has been shown to be effective and most have not been subject to any evaluation. While a number of studies have demonstrated that physical restraint can be reduced using a variety of interventions, it has not yet been determined which interventions are effective.

RESTRAINT INTERACTIONS

There are feedback loops and perpetuating cycles that exist around restraints as shown here in the SPIDAR Web diagram:



SPIDAR Web

Sedation leads to: Immobility, Delirium and PICS

PICS (Post-intensive care syndrome) results from: Sedation, Immobility, and Delirium

Immobility leads to: PICS, Delirium, and Agitation

Delirium leads to: PICS, Agitation (active), Immobility (passive), and Restraint

Agitation leads to: Sedation, Delirium and Restraint

Restraint leads to: Sedation, Immobility, Agitation, and Delirium

LITERATURE

Literature supports this diagram, clarifying links between restraint, post-traumatic stress, delirium, agitation, sedation, and immobility. In long-term outcomes studies, results show that

restraint heightens agitation and many patients who remember being restrained are moderately to severely bothered by it[5] and six times more likely to have post-traumatic stress[6]. We know that physical restraint is an independent precipitating factor for delirium[7] and that restrained patients are more agitated and over-sedated[8]. Other studies tell us that clinicians feel that physical restraint, chemical restraint[9], and patient and staff safety concerns are all barriers to early mobilization[10]. Supporting the notion of the ineffectiveness of restraints, studies show that patients who are restrained have more device removal and more reintubation despite having lower APACHE II scores[11].

LEGAL AND REGULATORY CONCERNS

While the medical community focuses on physical and emotional harm, the legal community debates ethics. It is argued that even though there is a dearth of evidence for their effectiveness, if the empirical evidence supported their effectiveness, the use of physical restraints would nevertheless be unethical; The argument continues that ethically justifiable restraint use demands certain necessary and sufficient conditions: that the physician obtain informed consent, that their application be medically appropriate, and that restraints be the least liberty-restricting way of achieving the intended benefit[12].

Regulatory institutions attempt to optimize and standardize the use of physical restraint though make no recommendations about chemical restraint. This rewards over-sedation which is arguably more detrimental to well-being than physical restraint. As with any attempt to protocolize and standardize in the hope of improving a flawed system, some gaps are bound to appear. In the case of restraints, in which several critical segments must unite to create best practice, the end result is a work in progress.

In the United States, the Centers for Medicare & Medicaid Services (CMS) has made changes to restraint protocols, mostly in the area of definitions, and documentation for reimbursement. Medical centers scramble to implement new and improved methods for satisfying changing regulations while striving to provide best care to patients and not unduly stress an already over-burdened patient-care team.

The result is finding a way to connect regulatory dots in the safest way possible in order to keep the hospital system operational. This is realized by time-consuming documentation or overuse of chemical restraint which is not regulated, and creation of specialty committees to oversee restraint regulation. In response, mobility teams and physical/occupational/speech/respiratory therapists do their best to coordinate for specified times to work with patients before they are once again restrained.

WHAT IS A RESTRAINT?

The CMS definition of Restraints is delineated in CFR §482.13(e) (1) Definitions. (i) A restraint is—(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely. Per CFR 482.13(e)(1)(i)(c), A restraint does not include devices, such as…protective helmets, or other methods…to permit the patient to participate in activities without the risk of physical harm[13].

Unification of terms is difficult which creates confusion in the medical community as to what is and is not considered a restraint. For the most part, wrist restraints and mitt restraints tied to a bed are termed restraints. The status of mitt restraints that are not tied to the bed is less clear among institutions as it is debated whether mitts prohibit movement and whether patients can take them off. If a patient can remove a device, it is not a restraint but presumably that defeats the purpose of its application. Often, the requirement of documentation plays a part in the debate.

While sitters or patient guards are not deemed restraints, they indeed restrain patients. In fact, sitters may restrain patients even more by prohibiting leg movement as well as arm movement and can be viewed by patients as guards or captors. In the US, these regulations can lead to unintended consequences such as long-term acute care hospitals (LTACHs) utilizing sitters to restrain patients who are attempting to extract tracheostomies and feeding tubes, in order to document that the patient was not restrained with a device. In this way, the patient can be discharged to a nursing home or a rehabilitation center where they are free to dislodge their vital equipment and be counted among the vast number of readmissions where the cycle of restraint, sedation and delirium can begin again.

RESTRAINT GUIDELINES

The 2018 Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU (PADIS) Guidelines state that the effect physical restraints have on the care and outcomes of critically ill adults remains controversial; that studies report higher rates of unplanned extubations and frequent reintubations, greater unintentional device removal, longer Intensive Care Unit (ICU) length of stay (LOS), increased agitation, higher benzodiazepine, opioid, and antipsychotic medication use, and increased risk for delirium or disorientation. The Guidelines further inform that patients' perceptions of being physically restrained during an ICU stay vary but often provoke strong emotional responses that persist after the ICU stay. They warn that although certain countries report a "restraint-free" ICU environment, it may be possible that their use of bedside sitters and/or pharmacologic restraints is increased. The guidelines call for randomized controlled trials to study outcomes related to restraints[14].

CMS publishes that 'Patient care staff must demonstrate through their documentation in the patient's medical record that the restraint intervention used is the least restrictive intervention that protects the patient's safety'. They cite that 'The use of restraint is based on individual assessments of the patient', offering that 'A patient's clinical needs often change over time'[11].

REFRAINT

Refraint is a new concept which promotes a level of avoidance of invasive equipment dislodgement while allowing movement, freedom and less need for sedation. Given that the medical, legal, and regulatory communities are beneficent, it is likely that each of these concerns also promotes least restraint necessary and alternative modalities when feasible. In practice, feasibility depends on staff availability, cost, documentation burden, safety and efficacy.

Refraint strives to occupy a notch below restraint and find a common ground for regulatory bodies that work to protect patients' rights and safety. Refraint is a preferred option for patients who require reminding to leave vital tubes and lines in place while alone in their rooms, yet hold dear their freedom to move; for staff who, in pursuit of best practice, hope to minimize sedation and reduce the risk of delirium and PICS; for institutions that require regulatory compliance; and for a common goal of healing as fast as possible in a humane manner.

EXERSIDES™ AND HEALTHY DESIGN

The *Exersides*™ Refraint System, made by Healthy Design, is a combination of Refraint and restraint with some unique features. It contacts the patient gently at the wrist and shoulder, allows comfort bending at the elbow and full range of motion at the wrist and hand while permitting total use of the shoulder. In comparison to traditional restraints, *Exersides*™ loosens with edema. Unlike wrist restraints, *Exersides*™ does not need to be tied to the bed. Unlike mitt restraints, there is full view and access to the back of the hand for intravenous lines, front of the wrist for arterial lines, and fingers for pulse oximeters, capillary refill checks and finger stick glucose checks. Unlike sleeve restraints, there is no constant skin contact with or obstruction of the upper or lower arm, and unlike arm boards, there is no hard surface in contact with the patient.

There are multiple levels of Refraint and restraint to choose from in one device, all of which can be changed quickly and easily. There is a 'No Bed Tie' configuration, a flexible 'Exercise Bed Strap' which allows more controlled and effective movement, and a rigid bed tie option for those patients who require full restraint. Each configuration provides protection of vital tubes and lines. Such versatility allows the *Exersides*™ Refraint System to match patient needs and always be minimum restraint necessary for each individual patient at every point in their illness and recovery.

ABOUT THE AUTHOR

Marie T Pavini MD is a Critical Care physician in Vermont. Dr. Pavini launched Healthy Design to develop products that improve the ICU experience for patients and staff. Exersides™ is the flagship product of Healthy Design.

Dr. Pavini had always thought there was something inherently wrong with awakening a patient for team rounds only to re-sedate them afterward. She felt it was not enough to provide physical, occupational and cognitive therapy sporadically and return the patient to immobility and/or sedation for the rest of the day. Dr. Pavini believed that patients should be as awake and interactive as comfortably possible throughout the day while keeping them and staff safe.

Furthermore, while a patient may require one level of sedation and restraint at one moment, this can change throughout their stay. Considering this, Dr. Pavini wanted there to be one device that could change according to patient needs, always providing the least restraint necessary -so she created one.

To learn more about Exersides™,
visit www.Exersides.com or email Dr. Pavini at hello@exersides.com.

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