Clinical practice guidelines for the maintenance of patient physical safety in the intensive care unit: Use of restraining therapies—American College of Critical Care Medicine Task Force 2001–2002

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Objective: **To develop clinical practice guidelines for the use of restraining therapies to maintain physical and psychological safety of adult and pediatric patients in the intensive care unit.**

Participants: **A multidisciplinary, multispecialty task force of experts in critical care practice was convened from the membership of the American College of Critical Care Medicine (ACCM), the Society of Critical Care Medicine (SCCM), and the American Association of Critical Care Nurses (AACN).**

Evidence: **The task force members reviewed the published literature (MEDLINE articles, textbooks, etc.) and provided expert opinion from which consensus was derived. Relevant published articles were reviewed individually for validity using the Cochrane methodology (http://hiru.mcmaster.ca/cochrane/ or www.cochrane.org).**

Consensus Process: **The task force met as a group and by teleconference to identify the pertinent literature and derive consensus recommendations. Consideration was given to both the weight of scientific information within the literature and expert opinion. Draft documents were composed by a task force steering committee and debated by the task force members until consensus was reached by nominal group process. The task force draft then was reviewed, assessed, and edited by the Board of Regents of the ACCM. After steering committee approval, the draft document was reviewed and approved by the SCCM Council.**

Conclusions: **The task force developed nine recommendations with regard to the use of physical restraints and pharmacologic therapies to maintain patient safety in the intensive care unit. (Crit Care Med 2003; 31:2665–2676)**

KEY WORDS: agitation; analgesia; chemical; delirium; ethical; evidence-based medicine; guidelines; intensive care unit psychosis; monitoring; moral; nursing assessment; pain; pharmacologic therapy; physical; restraints

RECOMMENDATION 1—LEVEL OF EVIDENCE C

Institutions and practitioners should strive to create the least restrictive but safest environment for patients in regard to restraint use. This is in keeping with the goals of maintaining the dignity and comfort of our patients while providing excellence in medical care.

RECOMMENDATION 2—LEVEL OF EVIDENCE C

Restraining therapies should be used only in clinically appropriate situations and not as a routine component of therapy. When restraints are used, the risk of untoward treatment interference events must outweigh the physical, psychological, and ethical risks of their use.

RECOMMENDATION 3—LEVEL OF EVIDENCE C

Patients must always be evaluated to determine whether treatment of an existing problem would obviate the need for restraint use. Alternatives to restraining therapies should be considered to minimize the need for and extent of their use.

RECOMMENDATION 4—LEVEL OF EVIDENCE C

The choice of restraining therapy should be the least invasive option capable of optimizing patient safety, comfort, and dignity.

RECOMMENDATION 5—LEVEL OF EVIDENCE C

The rationale for restraint use must be documented in the medical record. Orders for restraining therapy should be limited in duration to a 24-hr period.

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These practice guidelines have been developed by a task force assembled by the American College of Critical Care Medicine of the Society of Critical Care Medicine and have been reviewed by the Society's Council. These guidelines reflect the official opinion of the Society of Critical Care Medicine and should not be construed to reflect the views of the specialty boards or any other professional medical organization.

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New orders should be written after 24 hrs if restraining therapies are to be continued. The potential to discontinue or reduce restraining therapy should be considered at least every 8 hrs.

RECOMMENDATION 6—LEVEL OF EVIDENCE C

Patients should be monitored for the development of complications from restraining therapies at least every 4 hrs, more frequently if the patient is agitated or if otherwise clinically indicated. Each assessment for complications should be documented in the medical record.

RECOMMENDATION 7—LEVEL OF EVIDENCE C

Patients and their significant others should receive ongoing education as to the need for and nature of restraining therapies.

RECOMMENDATION 8—LEVEL OF EVIDENCE C

Analgesics, sedatives, and neuroleptics used for the treatment of pain, anxiety, or psychiatric disturbance of the intensive care unit patient should be used as agents to mitigate the need for restraining therapies and not overused as a method of chemical restraint.

RECOMMENDATION 9—LEVEL OF EVIDENCE C

Patients who receive neuromuscular blocking agents must have adequate sedation, amnesia, and analgesia. The use of neuromuscular blocking agents necessitates frequent neuromuscular blockade assessment to minimize the serious sequelae associated with long-term paralysis. Neuromuscular blocking agents should not be used as chemical restraints when not otherwise indicated by the patient's condition.

Restraints are widely used in the intensive care unit (ICU) to facilitate patient tolerance of invasive therapies and to avoid potentially life-threatening consequences associated with the abrupt discontinuation of such interventions (1–2). The use of restraints recently has come under increased scrutiny from institutions, external regulatory bodies, and the public (3). Some observers perceive that there is pervasive and inappropriate use of physical and chemical restraints in the ICU (4–6). Many critical care providers believe that opponents of restraint use have not satisfactorily considered the unique needs of and therapies for the critically ill patient that mandate the cautious use of restraints in appropriate clinical situations.

In view of this ongoing controversy, the American College of Critical Care Medicine of the Society of Critical Care Medicine assembled a task force of experts to evaluate the use of restraints in the ICU and to develop practice guidelines for the appropriate use of such restraints for both adult and pediatric patients. It is anticipated that the implementation of these guidelines will decrease the inappropriate use of restraints. These practice guidelines should serve as a benchmark for regulatory agencies in assessing the appropriate use of restraining interventions in the ICU.

ETHICAL CONSIDERATIONS

Restraints are used in ICUs to maintain ongoing invasive therapies when patients are unable to understand the need for such therapies. Clinicians should look for alternatives to restraints when possible, knowing the ethical questions that arise once they decide to apply restraints.

The clinician's use of restraints should not be derived from a purely utilitarian perspective. Such interventions require ethical justification. There is potential for conflict between the medical team's perception of the patient's best interest, what the team has been explicitly authorized to do by the patient or patient's legal guardian, and the patient's legal and socially accepted rights.

Over the past few decades, medical care in the United States has passed from an era when paternalistic physicians decided "what was best" into an era where patient autonomy supersedes most other issues. Mentally competent patients are not forced to accept treatment even when the decision results in a hastening of death. Patient autonomy is widely accepted and rarely opposed by the medical establishment.

Autonomy presupposes a competent patient or an available surrogate to represent the patient's best interests. The determination of competency is often difficult. Language and cultural barriers, emotional distress, the presence of delirium, and the need for sensorium clouding medications are among the many factors that may impair a patient or a patient surrogate's decisions. An additional problem is that the incompetent patient rarely has a continuously available surrogate to determine minute-to-minute issues.

The ethical-legal system recognizes that when consent cannot be provided by the patient or a surrogate, the "reasonable person" rule applies. A critically ill patient brought into the hospital may be subjected to emergent procedures without formal informed consent based on the idea that a "reasonable person" would have consented to these procedures. The "reasonable person" rule is itself ambiguous and may at times unintentionally violate the rights of individuals (e.g., Jehovah's Witnesses, Christian Scientists) to decline standard medical care. Nevertheless, it is reasonable to assume that implied consent exists when a person seeks treatment and that clinicians might institute restraining therapies in appropriate situations when a patient or patient's surrogate is unable to provide consent.

The paradigm that most medical professionals adhere to is that of beneficence or doing good, nonmalfeasance or doing no harm, and respect for the patient's autonomy. Consensus regarding major medical decisions is reached between the medical team and the patient as the illness evolves. Usually this produces little disagreement between medical professionals and their patients or between the multiple medical professionals themselves. But the decision to implement restraints rarely is regarded as a major medical decision. Furthermore, the patients in question usually are unable to provide consent, and their surrogates often are not immediately available. Thus, the "reasonable person" rule frequently is applied in making the decision to restrain critically ill patients to prevent patients from harming themselves.

The result is a tension between the medical team's desire to further the best interests of the patient and the patient's own rights as an autonomous being.

An additional ethical concern is the need to protect the medical team and the patient's significant others from injurious acts that a delirious patient might unknowingly commit. Although the patient has the right to autonomy and quality health care, the members of the medical team also have the right to a safe working environment. Mitigating the reason for the patient's agitation (e.g., pain control) should be attempted first. However, in some situations, restraining

therapies may be required to protect caregivers and visitors alike.

Another concern is that the delirious but conscious patient will be aware of restraints and find them uncomfortable. The dilemma then arises of balancing discomfort vs. medical necessity. The providers involved may determine that patient autonomy must be overruled for the sake of safety for the patient and others. This often presents a situation that is both ethically difficult as well as psychologically unpleasant for the medical team.

There are many situations where patients can, and do, injure themselves if not restrained. Most patients and their significant others expect the medical team to protect patients from their own delirious behavior and would regard the failure to do so as negligence.

METHODS

The task force members individually and collectively undertook a systematic search of published literature pertaining to the use of restraints in the ICU using MEDLINE, CINAHL, and the Cochrane Library. In addition, the reference lists for each identified article were reviewed for additional published works. Key words used in these searches included *restraints*, *intensive care unit*, *self-extubation*, *physical*, *chemical*, *moral*, *ethical*, *sedation*, *pain*, *patient monitoring*, and *nursing assessment*. Searches were restricted to English language publications and primarily to citations published since 1990. The publications believed to be most pertinent to this review were identified by group consensus. To establish the relative scientific validity of these references, each publication was categorized according to the Cochrane methodology described in Table 1. Two members of the task force (GM, TD) independently reviewed and graded the literature with a third member (BB) acting as arbitrator where disagreement occurred. A summary of the literature selected is included in the reference list.

Based on this literature review and the expertise of the individual members, the task force met as a group and by teleconference to develop consensus recommendations. Consideration was given to the weight of scientific evidence in the literature as well as to individual expert opinion. Draft documents were composed by a task force steering committee and debated by the task force members until consensus was reached. The specific recommendations were assigned a "grade" (Table 2) based on the weight of scientific evidence on which the recommendation was based.

BACKGROUND

Although numerous publications regarding the use of restraints were identified, many did not specifically address the use of restraints in ICU patients. Most studies made general statements regarding the use of restraints in all hospitalized patients or in patients treated outside the acute care setting. Although some issues regarding the use of restraints may be relevant to all clinical settings, such as the role of restraints in preventing patient falls, many issues related to the use of restraints are unique to critical care practice.

The severity of illness manifested by patients in the ICU and the need for invasive devices and therapies account for many of the unique issues related to the use of restraint systems in the ICU. These invasive therapies are often uncomfortable but may lead to patient morbidity or death if interrupted in an uncontrolled manner. Traditional ICU practice has assumed that restraints enhance patient safety in the setting of high-risk interventions and severe physiologic disturbances. Unfortunately, the literature that has evaluated the risk-to-benefit ratio of restraining interventions is methodologically weak (i.e., poorly controlled, small sample sizes). The need for well-designed, adequately powered, multiple-center, prospective evaluations is great, but without federal sponsorship and funding, such studies of restraining therapies are unlikely to be performed.

Agitation in the ICU. A major factor driving the use of restraints in the ICU is the underlying confusion and agitation experienced by many critically ill patients. More than 70% of ICU patients may experience some degree of agitation during their ICU stay (7, 8). Mental status changes often make ICU patients unable to comprehend the purpose of the therapies that are a part of their care. The causes of agitation in the ICU are numerous. Some medical conditions like sepsis may directly cause patient confusion. Other factors resulting in agitation include discomfort associated with endotracheal intubation, surgical and diagnostic procedures (9, 10), anxiety, and sleep deprivation (7, 11).

Agitation can have deleterious consequences, including interference with mechanical ventilation, acute myocardial stress, and cerebral ischemia (12, 13). Agitation makes diagnostic evaluations more difficult and may interfere with the performance of procedures. The self-removal or disruption of devices used for diagnosis, treatment, or physiologic monitoring of the patient may have disastrous sequelae (14–17). Each such event may require redundant intervention and increase costs significantly (17). Patient agitation frequently contributes to the stress of family and friends and may effect their satisfaction with healthcare delivery (10, 18).

Patient-Initiated Treatment Interference. The best studied type of patient-initiated treatment interference in the ICU is agitation-related tracheal self-extubation. The reported incidence of self-extubation varies widely, ranging from 2% to 17% of intubated patients (19). The impact of this complication on mortality and morbidity rate has not been well delineated. The literature contains multiple reports of fatal self-extubations; however, well-designed studies to establish the mortality rate of self-extubation are lacking. The determination of morbidity related to patient self-extubation is even more poorly defined. The incidence of significant complications directly related to self-extubation and reintubation (e.g., aspiration pneumonia) has not been specifically evaluated in a prospective fashion. Adding to the confusion on the morbidity of self-extubation has been some authors' categorization of self-extubation as a morbid event in and of itself. However, between 63% and 89% (20, 21) of patients who extubate themselves do not require reintubation, casting doubt as to whether self-extubation itself should be regarded as a morbid event. These data also suggest that many patients should be considered for extubation earlier in the course of their illness. Prospective trials have shown that protocols to facilitate weaning are valuable in decreasing the duration of mechanical ventilation. It is plausible that the need for restraining therapies could be significantly reduced merely through the use of protocols designed to facilitate timely extubation.

Although some cohort analyses have identified the failure to use restraints as an important contributor to self-extubation (16, 20, 22, 23), the role of restraining therapy in preventing self-extubation

Table 1. Cochrane methodology: Levels of evidence and grades of recommendations, November 23, 1999

Grade of Recommendation	Level of Evidence	Therapy/Prevention, Etiology/Harm	Prognosis	Diagnosis
A	1a	SR (with homogeneity[a]) of RCTs	SR (with homogeneity) of inception cohort studies or a CPG[b] validated on a test set.	SR (with homogeneity) of level 1 diagnostic studies or a CPG validated on a test set.
	1b	Individual RCT (with narrow confidence interval[c])	Individual inception cohort study with ≥80% follow-up	Independent blind comparison of an appropriate spectrum of consecutive patients, all of whom have undergone both the diagnostic test and the reference standard.
	1c	All or none[d]	All or none case-series[e]	Absolute SpPins and SnNouts[f]
B	2a	SR (with homogeneity) of cohort studies	SR (with homogeneity) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity) of level ≥2 diagnostic studies
	2b	Individual cohort study (including low-quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT or CPG not validated in a test set.	Any of: 1. Independent blind or objective comparison 2. Study performed in a set of nonconsecutive patients or confined to a narrow spectrum of study individuals (or both), all of whom have undergone both the diagnostic test and the reference standard 3. A diagnostic CPG not validated in a test set
	2c	"Outcomes" research	"Outcomes" research	
	3a	SR (with homogeneity) of case-control studies		
	3b	Individual case-control study		Independent blind comparison of an appropriate spectrum, but the reference standard was not applied to all study patients.
C	4	Case-series (and poor quality cohort and case-control studies[g])	Case-series (and poor quality prognostic cohort studies[h])	Any of: • Reference standard was not objective, unblinded, or not independent • Positive and negative tests were verified using separate reference standards • Study was performed in an inappropriate spectrum** of patients
D	5	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"

SR, systems research; CPG; RCT, randomized, controlled trial.

[a]By homogeneity we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted, studies displaying worrisome heterogeneity should be tagged with a "−" at the end of their designated level; [b]Clinical Prediction Guide; [c]see note 2 for advice on how to understand, rate, and use trials or other studies with wide confidence intervals; [d]met when all patients died before the prescription became available, but some now survive on it; or when some patients died before the prescription became available, but none now die on it; [e]met when there are no reports of anyone with this condition ever avoiding (all) or suffering from (none) a particular outcome (such as death); [f]an Absolute SpPin is a diagnostic finding whose specificity is so high that a positive result rules in the diagnosis. An Absolute SnNout is a diagnostic finding whose sensitivity is so high that a negative result rules out the diagnosis; [g]by poor quality cohort study we mean one that failed to clearly define comparison groups or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and nonexposed individuals or failed to identify or appropriately control known confounders or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study, we mean one that failed to clearly define comparison groups or failed to measure exposures and outcomes in the same blinded, objective way in both cases and controls or failed to identify or appropriately control known confounders; [h]by poor quality prognostic cohort study, we mean one in which sampling was biased in favor of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, nonobjective way, or there was no correction for confounding factors.

has not been prospectively evaluated in a randomized, controlled trial. Other authors have noted that physical restraints may fail to prevent this complication. Reports exist of securely restrained patients who successfully managed to remove endotracheal tubes with their hands, and of other patients who succeeded in extubating themselves using facial and lingual maneuvers while their arms were restrained (20, 24). The use of physical restraints actually may increase patient agitation and increase the incidence of self-extubation (20). The literature reflects that physical restraints themselves are not uniformly successful in preventing self-extubation, and that their overall capability for decreasing the frequency of this event remains ill-defined.

Several cohort analyses have identified inadequate sedation and analgesia as important risk factors for self-extubation (15, 24, 25). A prospective trial of a protocol to promote effective sedation performed by Brook et al. (26) showed a decrease in the duration of mechanical

Table 2. Comparison of studies concerning restraining therapies and their ability to limit patient interference events for self-extubation in critical care

Clinical Study	Research Question	Nature of Comparison	Setting	Results
Anid et al. (30)	Self-extubation: what is the problem?	Evaluate potential factors for self-extubation	ICU/CCU	Restless, sedated, but uncontrolled patients and patients intubated <24 hrs are at greater risk for self-extubation
Kapadia et al. (31)	Airway accidents in intubated ICU patients	Assess the rate of occurrence and nature of airway accidents	General adult ICU	Airway accidents occurred at low levels, with the most frequent being self-extubation of an endotracheal tube
Happ (32) (surveyed use of restraints and reasons in different parts of hospital, including critical care units)	Preventing treatment interference: the nurse's role in maintaining technologic devices	Describe the processes used by critical care nurses to prevent treatment interference	Medical and intermediate medical ICU	In addition to verbal strategies and other noninvasive techniques, nurses use assessment-driven physical and chemical restraining therapies to prevent treatment interference
Carrion et al. (16)	Accidental removal of endotracheal tubes	Characterize the rates of accidental removal of endotracheal tubes and assess efficiency of corrective measures aimed at reducing accidental removal of endotracheal tubes.	Medical/surgical ICU	Limiting upper extremity access to within 20 cm from the endotracheal tube significantly reduced patient-related removal of tubes.
Chevron (25)	Unplanned extubation: Risk factors of development and predictive criteria for reintubation	Nurse staffing levels and level of patient agitation	Medical/surgical ICU	Agitated patients who received insufficient sedation and were orally intubated presented the highest risk for unplanned extubation
Baer (20)	Is there an answer to preventing unplanned extubation?	Editorial comments on unplanned extubation	ICU	Delays in the weaning process may contribute to unplanned extubation
Winslow (21)	Do restraints really protect intubated patients?	Review of multiple studies involving unplanned extubations	ICU	Confine the use of restraints to intubated patients in the high-risk category who are delirious or agitated and are receiving high levels of oxygen or mechanical ventilation
Tominaga et al. (22) (Interventions to decrease unplanned extubations, suggested that restricting use of restraints contributed to increased risk of unplanned extubation. Prospective, observational data)	Decreasing unplanned extubations in the surgical ICU	Method of endotracheal tube fixation, use of chemical restraints, use of hand restraints.	Surgical ICU	Restricted use of hand restraints was associated with a significant increase in unplanned extubations. Endotracheal tubes secured with waterproof tape significantly reduced accidental extubation
Sessler and Listello (33)	Prevention of unplanned extubation	Literature review and editorial comments	ICU	Identity of patients at risk of an adverse outcome if unplanned extubation occurs. Secure endotracheal tube firmly, maximize patient acceptance of the endotracheal tube, control agitation, use effective restraints when necessary, perform timely extubation, and optimize patient surveillance

ICU, intensive care unit; CCU, critical care unit.

ventilation in the group sedated by protocol. Prospective, randomized trials confirming such a decrease in self-extubation by the use of sedation protocols have not been performed. Sedation therapy must be used judiciously, as the excessive use of sedation in ventilated ICU patients may increase duration of mechanical ventilation (27). Protocols for the periodic interruption of intravenous sedation have been shown to avoid this complication (28). Further discussion of sedation is outside the scope of this practice guideline. For more information, the reader is referred to the Clinical Practice Guide-

lines for Sustained Use of Sedatives and Analgesics (29).

Patient discontinuation of other devices and therapies in the ICU has not been as well studied as self-extubation, but it is likely that many of the same considerations apply (30, 31). Carrion et al. (16) studied patient removal of nasogastric tubes, arterial catheters, and central venous catheters and concluded that restraints substantially decreased the removal of such devices. However, the complications of the restraining therapies used were not clearly described, so that a risk to benefit assessment for the use of restraints was difficult to make for these clinical scenarios.

No studies have been designed to study patients at high risk for morbidity or death in the event of abrupt loss of their airway or other therapies. It is in such high-risk patients that restraint use is most likely to prove beneficial. High risk should include patients with difficult airways, facial edema, cervical spine injuries, and halos, as well as the hemodynamically unstable, the hypoxemic, and those experiencing myocardial ischemia. The fact that most studies have included patients at low risk for serious sequelae if important therapies were suddenly discontinued may have led authors to incorrectly conclude that restraint therapies were of no benefit in preventing harm (Table 2).

A number of well-designed, prospective trials regarding the use of pharmacologic therapies to treat ICU patients' pain and anxiety have been performed. These studies suggest that the use of analgesic, sedative, and neuroleptic agents to treat pain, anxiety, and delirium is associated with numerous benefits. These trials usually have not assessed the impact of sedation therapy on the use of restraints in the ICU. Rather, the use of sedation and analgesia therapy to decrease the use of restraints has been inferred by the efficacy of these therapies in reducing patient agitation, pain, anxiety, or psychiatric disturbance.

Alternatives to the Use of Physical Restraints. Although a number of alternatives to physical restraints in the ICU have been proposed, the efficacy and safety of these interventions have not been prospectively evaluated. Unfortunately, most of these studies have been conducted outside the ICU setting, and the applicability of these alternatives to restraints for critically ill patients remains unproven. Alternatives have included pharmacologic agents to treat the patient's agitation. An additional strategy is the identification of problems causing patient discomfort and agitation that can be easily corrected. Urinary retention, malposition of an endotracheal tube, and discomfort related to body position all can be remedied, decreasing agitation. Another strategy is the use of diversionary activities that may reduce the level of agitation. Music, providing scheduled activities, allowing the family greater access to the patient, frequent reorienting, and personal attention to the patient by caregivers have been suggested as methods to lessen the use of restraints. Other interventions have included altering the ICU environment to decrease agitation-producing stimuli and using alternative methods for securing endotracheal tubes.

High noise levels in the ICU disrupt sleep and contribute to patient agitation. Environmental modifications to reduce noise levels and alterations of ICU routines to facilitate more normal sleep-wake cycles may reduce the need for restraining therapies. The use of bed exit alarms, relocating patients closer to central monitoring areas, and increasing inpatient observation (i.e., video cameras) may permit early identification of increasing agitation, allowing intervention before critical events occur. The use of family members or friends as "sitters" also may facilitate closer observation and provide a calming influence on the patient.

Finally, evolving techniques and devices may decrease the patient's ability to interfere with treatment. Improved methods of securing endotracheal tubes may lessen their chance of being inadvertently removed. The use of a stockinet over the site of an intravenous catheter or bulky dressings covering devices to reduce access to gastrostomy tubes may decrease inadvertent dislodgment of these devices (32–36).

Some authors have suggested that lower caregiver-to-patient ratios increase the use of restraints and related therapies including heavy sedation (19, 27, 37, 38). Some self-extubation studies have observed increased self-extubations in association with decreased nurse staffing ratios (25). The value of alternatives to physical restraints in the ICU principally has been derived from testimonial data and has received little prospective assessment. In other healthcare settings, particularly in nursing homes, caregiver education in the use of alternative modalities has resulted in a decreased use of physical restraints, generally without an increase in morbidity from falls or other adverse events (36, 39–41). Given the paucity of data documenting the safety and efficacy of these alternatives compared with traditional restraint techniques, there is no assurance that alternative strategies would be embraced by critical care practitioners (2). However, critical care providers should initiate trials comparing these alternative strategies to traditional restraint techniques to provide better evidence for the development of future guidelines.

Psychological Aspects of Restraint Use. Caregiver attitudinal factors may drive the use of restraints in the ICU as identified in a study by Happ (32) on the attitudes of ICU nurses toward the prevention of patient treatment interference. The need to prevent life-threatening events was perceived as the justification for the use of restraints, but nurses expressed ambivalence as to the use of these devices. In this study, ICU nurses preferred the use of sedative and other pharmacologic therapies in lieu of physical restraints for most of their patients (32). Little information has been published regarding the attitudes of ICU physicians toward the use of restraining therapies. It might be expected that there would be differences between nurses and physicians in the perceived need for restraints, but no studies exist evaluating such differences. Perhaps the most important perceptions to consider are those of restrained patients. Leith (38) noted the negative attitudes of hospitalized patients toward being restrained, but the perceptions of ICU patients who have been restrained have not been well documented. Minnick et al. (2) described the results of interviews with 15 ICU patients about their perceptions of restraints after they were discharged from the ICU. Only 40% of the patients remembered being physically restrained, and these patients did not report undue distress related to the process. Much of the distress of these patients related to the discomfort of intubation and to their hallucinations. Although the applicability of this small study to the general ICU population is uncertain, these results provide some evidence that physical restraints in the ICU do not commonly produce patient psychological distress.

Posttraumatic stress disorder (PTSD) occurs in many ICU patients (42). PTSD results from an exposure to a traumatic

event and evokes intense fear, horror, and a feeling of helplessness. The aftermath may affect patients' ability to cope with daily life. In studies of ICU patients, PTSD has been recognized as a frequent sequela of a prolonged ICU stay. Symptoms of PTSD include anxiety attacks, hypervigilance, nightmares, insomnia, intrusive thoughts, flashbacks, and depression that may manifest during ICU care. Intensive care professionals must recognize the symptoms of PTSD and minimize patient stressors. The role that restraints play in the development of PTSD-related disorders is unknown, but there is an association between the use of sedatives and neuromuscular blocking agents and the development of this disorder (42). Whether this reflects causation or simply the identification of the most seriously ill patients is unclear but points to the need for careful consideration of the potential sequelae of such therapies.

THE OBJECTIVES OF RESTRAINING THERAPIES

The objective of restraining therapies in the ICU is to provide optimal patient safety while maintaining comfort and individual dignity as much as possible. The subsequent discussion focused on this overall objective by addressing several questions related to the use of these modalities:

- What defines restraining therapy in the ICU?
- What are the indications for the use of restraining therapies in the ICU?
- How do we determine which patients need restraining therapies?
- What alternatives to restraining therapy should be considered?
- How should restraining therapies be initiated?
- How frequently should patients be reassessed with regard to their need for restraining therapies?
- How frequently should monitoring for complications be performed in patients subjected to restraining therapies?
- How should restraint use be documented in the medical record?

What Defines Restraining Therapy in the ICU? A *restraining therapy* is a treatment aimed at improving a medical condition (e.g., hypoxemia) or preventing complications by restricting a patient's movement or access to his or her body. Such therapies may be physical or pharmacologic. *Physical restraints* are mechanical devices that restrict patients' movements. Many devices commonly used in the intensive care unit could incorrectly be considered physical restraints. These include *medical protective devices*, which protect the patient from further exacerbating the underlying illness or injury. An example is a splint applied to a fractured extremity. Such a device is standard medical therapy and does not constitute a restraining therapy although it restricts the patient's free movement. Although these devices are not considered further in these guidelines, their use may necessitate monitoring for the development of complications similar to those that may develop with physical restraints.

Another form of restraint used in the ICU is *medical immobilization*, defined as a temporary immobilization for the performance of and recovery from a medical or surgical treatment (e.g., surgical positioning, intravenous arm boards, protection of surgical treatment sites by bulky dressings in pediatric patients). These restraints both facilitate performance of the procedure and prevent complications that might occur during recovery. The use of restraints in these circumstances is generally of limited duration. As with the use of medical protective devices, this form of immobilization should not be considered a restraining therapy. Nevertheless, precautions must be made to prevent patient injury when medical immobilization is used.

Occasionally, physical restraints are applied to patients who have been legally detained. The use of restraints under these circumstances is considered *forensic restraint*. This use of forensic restraints is outside the purview of this document. However, the clinician must monitor these patients for complications related to the use of such restraints. Although law enforcement officials need to maintain careful surveillance of the incarcerated patient, medical care of the patient must not be compromised by the use of forensic restraints.

The restraining therapies relevant to these guidelines are the mechanical and pharmacologic mechanisms to limit or in some cases totally prevent patient movement where patient interference with treatment could have life-threatening consequences. Typical physical restraining devices used in the ICU include, but are not limited to, soft wrist and ankle restraints, upper body-vests, two- to five-point leather restraints, No-No arm boards when tied to the bed or crib (in pediatric patients), and body webs.

Pharmacologic restraints are medications used to control agitation or in some cases induce coma and paralysis (e.g., for extracorporeal treatment of severe respiratory failure). Under this definition, a number of commonly used pharmaceutical agents could be included. Among them are analgesics, particularly opioid analgesics, benzodiazepines and other sedative agents, major tranquilizers, dissociative agents, and neuromuscular blocking agents. An extensive description of the use of analgesics, sedatives, and neuroleptic agents is available in the revised clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult (29). Practice guidelines for the appropriate use of neuromuscular blocking agents in the ICU also have been developed by the ACCM (43), and these currently are undergoing revision.

What Are the Indications for the Use of Restraining Therapies in the ICU? The primary goal for the use of restraining therapies in the ICU is to ensure patient safety. The most common indication is to decrease the risk of deliberate or inadvertent removal of an essential medical device. This includes circulatory assist devices, endotracheal tubes, tracheotomy tubes, intracranial catheters, nasogastric or orogastric tubes, enteral feeding tubes, central venous catheters, arterial catheters, chest tubes, surgical drains, intravenous lines, and urinary catheters. Restraining therapies also may be necessary to limit the patient's movements if movement might lead to a new or exacerbate an existing injury. An example is a patient with a spinal fracture who might suffer a spinal cord injury by moving before stabilization of the spine has been established.

Restraining therapies also may facilitate the performance of bedside procedures in patients who cannot cooperate. For instance, such therapies might be used during the insertion of an arterial catheter in a delirious patient, both to allow placement of the device and to ensure that the patient is not injured during its placement.

Another use of restraining therapies in the ICU is for patients with primary behavioral or psychiatric disorders. Occasionally such patients may be housed in an ICU because it is the only setting avail-

able where the patient can be closely monitored. More often these patients are admitted to the ICU because of an acute medical condition, such as a drug overdose or suicide attempt. On improvement, these patients may remain in the ICU awaiting transfer to an appropriate psychiatric facility. Because of their underlying psychopathology, these patients have the potential to injure themselves or others. Under such circumstances restraining therapies may be indicated, but their use should be in accordance with local institutional ICU policy and contemporary standards of psychiatric care.

How Do We Determine Which Patients Need Restraining Therapies? Restraining therapies should be used only when they have been deemed a clinical necessity and when alternative measures have been unsuccessful or cannot be employed without jeopardizing patient safety or care. Several factors should be considered in determining the patient's need for restraining therapies. Careful patient examination may reveal a cause for agitation that is remediable without restraining therapy.

The possibility of hypoxemia, hypercapnia, electrolyte imbalances, and untoward effects of medications should be considered in any agitated patient. Malfunction of mechanical devices, such as endotracheal tubes, urinary catheters, intravenous infusion pumps, or epidural catheters may create discomfort or stop ongoing analgesia leading to agitation. Patients should be evaluated for untreated pain, anxiety, or delirium and appropriate therapy instituted if needed. Toxicity from medications or illicit substances may manifest itself by altered mental status. Acute withdrawal from ethanol or other addictive substances should always be considered.

The ventilator settings of agitated patients should be reassessed and confirmed to be appropriate to ensure that patient-ventilator dyssynchrony is not the cause of the patient's distress. Patients undergoing "noninvasive" ventilation should be evaluated to optimize mask fit and padding to ensure this is not a source of agitation. In patients who are intubated, the literature clearly identifies ongoing intubation of the "weanable" patient as a perturbation with a high likelihood of treatment interference. Patients should be frequently reassessed for their suitability for extubation, as the timely extubation of the patient avoids the risks of prolonged intubation and may eliminate the source of the patient's agitation.

The patient also should be evaluated with regard to the consequences of treatment interference events and therefore the risk of withholding restraining therapies. A patient whose only invasive device is an intravenous catheter is at far less risk from treatment interference than the patient on extracorporeal membrane oxygenation. Because of the critical nature of the latter patient's therapies, the preemptive institution of restraining therapies is more compelling than in most situations.

What Alternatives to Restraining Therapies Should Be Considered? The most important alternative therapies are pharmacologic agents used to treat the patient's agitation (Table 3). Sedatives and analgesics are commonly used to treat pain and anxiety in the ICU patient. Neuroleptic agents such as haloperidol also should be considered since they relieve agitation and distressing hallucinations. Neuromuscular blockers should not be considered as alternatives to restraining therapies. These agents may be necessary in patients with severe respiratory dysfunction to optimize mechanical ventilation, use extracorporeal techniques, and reduce patient oxygen consumption. However, when their primary purpose is to prevent movement of a patient, they should be considered chemical restraints. Their use as restraining therapy should be as a last resort when all other methods have proven unsuccessful or not feasible. Neuromuscular blockade must always be accompanied by adequate sedative and analgesic medications.

Nonpharmacologic methods are also available as alternatives to the use of restraints (Table 4). These include diversionary tactics to calm the agitated patient or to redirect the patient's attention away from a medical device producing distress. Altering the local environment to decrease sensory stimuli may be useful. This could include limiting noise from alarms, avoiding unnecessary arousal of the patient, and scheduling activities during waking hours so the patient attains a more normal sleep-wake cycle. Increased vigilance of the patient may allow for the elimination of physical restraints. Using family members and other healthcare personnel ("sitters") may allow reduction of restraints. Nonrestraining techniques that interfere with the patient's ability to remove a device may reduce the need for full physical restraints. Methods to better secure endotracheal tubes are included in this category, as are bulky dressings that make it less likely that the patient will notice and remove the device. The removal of devices from the oropharynx and nasopharynx may lessen patient discomfort. Thus, if a patient is likely to require long-term ventilatory or nutritional support, tracheostomy or gastrostomy may lessen patient discomfort.

If alternatives fail, restraints then may be necessary. Determination of restraint type must include an evaluation of potential for restraint-induced injury. The least restrictive restraint should be used for the shortest duration necessary.

How Should Restraining Therapies Be Initiated? The physician, nurse, and other members of the critical care team should concur on the patient's need for restraining therapy before its initiation and on the form of restraining therapy to use (Tables 3 and 5). The initial physician order may be a verbal order based on the assessment of the patient by a registered nurse that has been communicated to the physician. The verbal order should be followed by a bedside assessment by the physician as soon as possible (Table 6). When restraints are initiated for marked agitation or violence, the physician should be notified of restraint use within 1 hr of restraint application, and physicians should personally examine such patients within 4 hrs. Patients restrained to prevent treatment interference alone should have their physician notified within 12 hrs and should be examined by the physician within 24 hrs of restraint application.

When physical restraints are applied,

Table 3. Pharmacological alternatives to physical restraints

- Analgesics
- Sedatives
- Major tranquilizers (neuroleptic agents)
- Dissociative agents
- Other

Revised Clinical Practice Guidelines for the Sustained Use of Sedatives and Analgesics in the Critically Ill Adult (29)

Table 4. Alternatives to restraining therapies

Environmental	Therapy	Communication
Alter environmental stimuli	Manage pain and hypoxemia, evaluate ventilator settings	Maximize communication
Keep objects necessary for daily living close at hand	Maximize activities of daily living	Provide communication aids
Use support devices that are not so restrictive	Eliminate bothersome treatments as soon as possible	Provide reality links and reorientation cues
Decrease bed rail use if patient is climbing over them	Begin oral feedings as soon as possible	Involve patient in care planning if possible
Use more frequent or constant supervision	Remove catheters as soon as possible	Use anxiety reduction techniques
Increase the caregiver supervision ratio	Review medications for any possible contributors to delirium or anxiety	Involve family and others in care planning
Use one-to-one supervision	Encourage physical exertion, exercise, mobility	

Modified from Fletcher (36).

Table 5. Categories of physical restraining therapies

Types of Restraints	Most Restrictive → Least Restrictive			
Chest/body				
Limb plus vest	*			
Papoose board	*			
Posey vest			*	
Extremities				
4-point (felt)	*			
2-point soft wrist		*		
2-point diagonal soft			*	
Elbow (restraints)			*	
Mittens				*
Environment				
Seclusion		*		
High climber			*	
Side rails				*
Vail bed or Craig bed			*	
Geri chair				*

an RN or LV(P)N must do so or supervise application by other qualified staff. The application of the device should be done in such a way that upholds the patient's rights and dignity. The patient and significant others must be given appropriate information regarding the need for the restraining therapy. Restraining therapies must be easy to remove in case of an emergency.

To ensure that patient care staff understand the use of alternative therapies and safe application of the restraining devices, training programs must be completed with initial employment and an annual competency review should be required of staff thereafter.

Each healthcare organization should develop internal monitoring or quality assurance programs to ensure that the staff is compliant with the principles and policies surrounding the appropriate use of restraining devices.

How Frequently Should Patients Be Reassessed With Regard to Their Need for Restraining Therapies? Reassessment of the need for the therapy to continue should be based on the same principles used in the determination to initiate restraining therapy. Since the goal is to only use such therapy when there is no suitable alternative, the critical care team should assess readiness of the patient for restraint reduction or removal at least every 8 hrs (Table 6) The frequency of reassessments should be based on the clinical circumstances of the patient and the predetermined plan of care.

The bedside nurse must constantly be aware of the possibility that the patient may have recovered from the clinical conditions that necessitated the use of restraints in the first place. The critical care team should reassess the patient at least every 24 hrs to determine whether the order for restraints should remain active.

During reassessment, the nurse should continue to attempt use of the alternatives to restraints listed in Table 4.

How Frequently Should Monitoring for Complications Be Performed in Patients Subjected to Restraining Therapies? Restraining therapies themselves can pose a threat in the form of complications. Complications may occur not only in a physical sense but also from a psychological perspective. Not only does the patient need to be monitored for complications from the restraints, but the patient's care needs also must be addressed (Table 6). A restrained patient can no longer provide for his or her basic needs of turning, eating, drinking, and toileting. The staff caring for the patient must be skilled in providing for these needs while at the same time monitoring for complications from the restraining therapies in use. The frequency of monitoring should be determined by the clinical condition of the patient. In general, a calm patient receiving restraining therapies must be monitored for complications at least every 4 hrs. Agitated patients need more frequent monitoring, and reevaluation every 15 mins is recommended until the patient becomes calm.

How Should Restraint Use Be Documented in the Medical Record? Documentation in the medical record should include the assessment of the need for restraints, what alternatives to restraints were unsuccessfully used, and the findings of ongoing monitoring of the patient for complications (Table 6). How restraining therapy fits into the plan of care should be included in the progress notes. Education of the patient and significant others about restraint use must be documented.

At each institution, a quality assurance system should review medical records pertaining to the use of restraints to develop quality improvement strate-

Table 6. Recommendations for the initiation, monitoring, and documentation of physical restraints

Emergent Behavioral Indication	Nonemergent Medical Indication
Justification: Patient exhibits violent behavior.	Justification: Limit mobility to provide safe care
Restraint Initiation	**Restraint Initiation**
1. Physician notification within 1 hr of application for verbal order	1. Physician notified within 12 hrs for verbal order
2. Must be seen by physician or LIP within 4 hrs of application	2. Patient must be seen by physician or LIP within 24 hrs of restraint application
3. Orders cover a 24-hr period	3. Orders cover a 24-hr period
4. Daily entries justifying restraint must be entered into medical record	4. Daily entries justifying restraint must be entered into the medical record
Reorder	**Reorder**
Must be redocumented every 24 hrs	Must be redocumented every 24 hrs
Bedside Monitoring	**Bedside Monitoring**
When patient is agitated: every 15 mins	**When patient is agitated: every 15 mins**
1. Chest skin color, capillary refill, pulse of restrained extremities	1. Check skin color, capillary refill, pulse of restrained extremities
2. Check for extremity movement and sensation	**When patient is calm: at least every 4 hrs**
3. Proper body alignment	1. Check skin color, capillary refill, pulse on each restrained extremity
4. Document in record	2. Check for extremity movement and sensation
When patient is agitated: every 2 hrs	3. Proper body alignment, reposition
1. Evaluation of pharmacotherapeutics used to control pain, anxiety, agitation, and delirium	4. Document in record
2. Offer toileting or assess elimination needs at least every 2 hrs	**When patient is calm: every 2 hrs**
3. Offer food and fluids for those who can take oral nutrition at least every 2 hrs	1. Check LOC, vital signs, ventilator indicators (if applicable)
4. If patient is unable to have oral nutrition, assess adequate hydration and nutrition	2. Monitor the patency and/or mechanical function of drainage tubes, position of endotracheal tubes
5. Extremity release/ROM	3. Evaluate pharmacotherapeutics used to control pain, anxiety, agitation, and delirium
Assess readiness for restraint reduction or removal at least every 8 hrs	4. Effect of adjunctive therapies (e.g., music therapy, dim lights, family present)
	5. Extremity release/ROM
	Assess readiness for restraint reduction or removal at least every 8 hrs

LIP, licensed independent practitioner; ROM, range of motion; LOC, level of comfort.

gies. Review of the following components of monitoring and documentation should be a part of the quality review and improvement program:

1. The record should contain adequate documentation in the nursing and physician progress notes of the need to initiate restraints.
2. If restraints were applied by nursing personnel under the institution's *pro re nata* urgent restraint use policy, the record should reflect a written or verbal order for the restraints used from a physician including the date and time of the order.
3. Documentation should be made of ongoing assessments and monitoring for complications during each restraint use episode.

In addition, the following policies are recommended for patients restrained by physical restraints:

1. The provision of ongoing psychological and spiritual support for both the patient and significant others.
2. Trials of release of restraining therapies.

If a death occurs while a patient is in physical restraints, the death should undergo institutional review.

Leather restraints occasionally are used in the ICU for patients who are severely agitated or suffer from behavioral disorders. When these restraints are used, more frequent monitoring is required. Based on the patient's level of agitation and clinical condition, assessments of the patient's condition and safety should be performed every 15–30 mins. As with other restraints, the patient's condition should be reevaluated several times a day and less dangerous and restrictive restraints substituted when the patient's condition permits such a change.

Assessment of Pediatric Patients. Pediatric patients in restraint by seclusion or mechanical devices should be observed at intervals of ≤15 mins. Written orders for physical restraints or seclusion for behavioral health patients should be limited to 2 hrs for children ages 9–17 and 1 hr for patients <9 yrs.

With pediatric patients, the critical care team should be particularly attentive to maintaining proper body alignment and correct device positioning when physical restraints are used. The restrained child should be monitored every 30 mins for evidence of respiratory distress. The nursing staff should evaluate the child's level of consciousness and assess restrained extremities for pressure-related injury or impaired circulation at least every 2 hrs. Physical restraints should be removed for extremity range of motion, patient repositioning, the offering of food/fluids, and patient hygiene every 4 hrs or more frequently if clinically indicated.

CONCLUSIONS

Despite the numerous questions that exist about the risks, benefits, and practical use of restraining therapies in critically ill people, there is currently little prospective information in the literature that can be used for development of evidence-based guidelines to promote the scientific application of these modalities.

The task force developed nine recommendations with regard to the use of physical restraints and pharmacologic therapies to maintain patient safety in the intensive care unit.

The overwhelming majority of the studies reviewed were uncontrolled case series or case reports and were graded as Cochrane level 4 and 5. Thus, these guidelines reflect the consensus of the task force following their review of the existing literature regarding the prevailing standard of medical care for restraint use in the ICU as well as the ethical framework on which their use is based. Restraining therapies in the ICU are used primarily to maintain patient safety. The principal concern of care providers is the inadvertent discontinuation of life support therapy or invasive monitoring devices and the prevention of injury from falls. The principle rationale for restraint use should be the maintenance of patient safety; rarely should behavior control be the primary goal of restraining therapy.

SUMMARY

Task Force Recommendations for Maintenance of Patient Physical Safety Using Restraining Therapies

Recommendation 1—Level of Evidence C. Institutions and practitioners should strive to create the least restrictive but safest environment for patients in regard to restraint use. This is in keeping with the goals of maintaining the dignity and comfort of our patients while providing excellence in medical care.

Recommendation 2—Level of Evidence C. Restraining therapies should be used only in clinically appropriate situations and not as a routine component of therapy. When restraints are used, the risk of untoward treatment interference events must outweigh the physical, psychological, and ethical risks of their use.

Recommendation 3—Level of Evidence C. Patients must always be evaluated to determine whether treatment of an existing problem would obviate the need for restraint use. Alternatives to restraining therapies should be considered to minimize the need for and extent of their use.

Recommendation 4—Level of Evidence C. The choice of restraining therapy should be the least invasive option capable of optimizing patient safety, comfort, and dignity.

Recommendation 5—Level of Evidence C. The rationale for restraint use must be documented in the medical record. Orders for restraining therapy should be limited in duration to a 24-hr period. New orders should be written after 24 hrs if restraining therapies are to be continued. The potential to discontinue or reduce restraining therapy should be considered at least every 8 hrs.

Recommendation 6—Level of Evidence C. Patients should be monitored for the development of complications from restraining therapies at least every 4 hrs, more frequently if agitated or otherwise clinically indicated. Each assessment for complications should be documented in the medical record.

Recommendation 7—Level of Evidence C. Patients and their significant others should receive ongoing education as to the need for and nature of restraining therapies.

Recommendation 8—Level of Evidence C. Analgesics, sedatives, and neuroleptics used for the treatment of pain, anxiety, or psychiatric disturbance of the ICU patient should be used as agents to mitigate the need for restraining therapies and not overused as a method of chemical restraint.

Recommendation 9—Level of Evidence C. Patients who receive neuromuscular blocking agents must have adequate sedation, amnesia, and analgesia. The use of neuromuscular blocking agents necessitates frequent neuromuscular blockade assessment to minimize the serious sequelae associated with long-term paralysis. Neuromuscular blocking agents should not be used as chemical restraints when not otherwise indicated by the patient's condition.

FUTURE CONSIDERATIONS

The development of these guidelines has been made difficult by the critical lack of carefully performed prospective trials assessing the risks and benefits of restraining therapies in the ICU setting. Although many issues are open for evaluation, the task force has identified three areas that seem most needful of investigation to develop more evidence-based guidelines for the use of restraining therapies in critically ill patients:

1. We recommend randomized, controlled trials to assess the efficacy of various restraining therapies in reducing the incidence of inadvertent device removal.
2. We recommend randomized, controlled trials to assess the optimal methods for safely weaning or discontinuing restraining therapies (a "release trial").
3. We recommend a randomized, controlled trial to assess the hypothesis that ICU staffing patterns affect the need for and implementation of restraining therapies.

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