Complete Summary

GUIDELINE TITLE

Clinical practice guidelines for the maintenance of patient physical safety in the intensive care unit: use of restraining therapies.

BIBLIOGRAPHIC SOURCE(S)

Maccioli GA, Dorman T, Brown BR, Mazuski JE, McLean BA, Kuszaj JM, Rosenbaum SH, Frankel LR, Devlin JW, Govert JA, Smith B, Peruzzi WT. 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. Crit Care Med 2003 Nov;31(11):2665-76. [43 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Conditions in critically ill patients requiring restraints, such as anxiety, agitation, delirious behavior, and violent behavior

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Critical Care
Emergency Medicine
Family Practice
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Emergency Medical Technicians/Paramedics
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

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

TARGET POPULATION

Adult and pediatric patients in the intensive care unit

INTERVENTIONS AND PRACTICES CONSIDERED

1. Physical and pharmacologic restraining therapies
2. Alternatives to restraining therapies
3. Documenting the rationale for restraint use in the medical record
4. Monitoring patients for complications from restraining therapies
5. Educating patients and their significant others about the need for and nature of restraining therapies
6. Agents to mitigate need for restraining therapies including analgesics, sedatives, and neuroleptics as needed
7. Adequate sedation, amnesia, and analgesia for patients receiving neuromuscular blockade, and frequent neuromuscular blockade assessment

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The task force members individually and collectively undertook a systematic search of published literature pertaining to the use of restraints in the intensive care unit (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.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1a

- *Therapy/Prevention, Etiology/Harm*: Systems research (SR) (with homogeneity*) of randomized, controlled trial (RCT)
- *Prognosis*: SR (with homogeneity) of inception cohort studies or a clinical prediction guide (CPG) validated on a test set
- *Diagnosis*: SR (with homogeneity) of level 1 diagnostic studies or a CPG validated on a test set

1b

- *Therapy/Prevention, Etiology/Harm*: Individual RCT (with narrow confidence interval*)
- *Prognosis*: Individual inception cohort study with $\geq$80% follow-up
- *Diagnosis*: Independent blind comparison of an appropriate spectrum of consecutive patients, all of whom have undergone both the diagnostic test and the reference standard

1c

- *Therapy/Prevention, Etiology/Harm*: All or none*
- *Prognosis*: All or none case-series*
- *Diagnosis*: absolute SpPins and SnNouts*

2a

- *Therapy/Prevention, Etiology/Harm*: SR (with homogeneity) of cohort studies
- *Prognosis*: SR (with homogeneity) of either retrospective cohort studies or untreated control groups in RCTs
- *Diagnosis*: SR (with homogeneity) of level $\geq$2 diagnostic studies

2b

- *Therapy/Prevention, Etiology/Harm*: Individual cohort study (including low-quality RCT; e.g., <80% follow-up)
- *Prognosis*: Retrospective cohort study or follow-up of untreated control patients in an RCT or CPG not validated in a test set
- *Diagnosis*: Any of:
    - Independent blind or objective comparison
    - 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
    - A diagnostic CPG not validated in a test set

2c

- *Therapy/Prevention, Etiology/Harm*: "Outcomes" research
- *Prognosis*: "Outcomes" research

3a

- *Therapy/Prevention, Etiology/Harm*: SR (with homogeneity) of case-control studies

3b

- *Therapy/Prevention, Etiology/Harm*: Individual case-control study
- *Diagnosis*: Independent blind comparison of an appropriate spectrum, but the reference standard was not applied to all study patients

4

- *Therapy/Prevention, Etiology/Harm*: Case-series (and poor quality cohort and case-control studies*)
- *Prognosis*: Case-series (and poor quality prognostic cohort studies*)
- *Diagnosis*: Any of:
    - Reference standard was not objective, unblended, or not independent
    - Positive and negative tests were verified using separate reference standards
    - Study was performed in an inappropriate spectrum of patients

5

- *Therapy/Prevention, Etiology/Harm*: Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"
- *Prognosis*: Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"

- *Diagnosis*: Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"

* Refer to Table 1 "Cochrane methodology: Levels of evidence and grades of recommendations" in the original guideline document for further explanation.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

To establish the relative scientific validity of the references, each publication was categorized according to the Cochrane Methodology described in Table 1 in the original guideline document. Two members of the task force independently reviewed and graded the literature, with a third member acting as arbitrator where disagreement occurred.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Nominal Group Technique)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

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.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

A. Levels of evidence 1a, 1b, 1c
B. Levels of evidence 2a, 2b, 2c, 3a, 3b
C. Levels of evidence 4
D. Levels of evidence 5

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The task force draft was reviewed, assessed, and edited by the Board of Regents of the American College of Critical Care Medicine (ACCM). After steering committee approval, the draft document was reviewed and approved by the Society of Critical Care Medicine (SCCM) Council.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Grades of recommendation (A-D) and levels of evidence 1a-1c, 2a-2c, 3a, 3b, 4, 5) are defined at the end of the "Major Recommendations" field.

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 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.

Definitions:

Grades of Recommendation

A. Levels of evidence 1a, 1b, 1c
B. Levels of evidence 2a, 2b, 2c, 3a, 3b
C. Levels of evidence 4
D. Levels of evidence 5

Levels of Evidence

1a

- *Therapy/Prevention, Etiology/Harm*: Systems research (SR) (with homogeneity*) of randomized, controlled trial (RCT)
- *Prognosis*: SR (with homogeneity) of inception cohort studies or a clinical prediction guide (CPG) validated on a test set
- *Diagnosis*: SR (with homogeneity) of level 1 diagnostic studies or a CPG validated on a test set

1b

- *Therapy/Prevention, Etiology/Harm*: Individual RCT (with narrow confidence interval*)
- *Prognosis*: Individual inception cohort study with $\geq$80% follow-up

- *Diagnosis*: Independent blind comparison of an appropriate spectrum of consecutive patients, all of whom have undergone both the diagnostic test and the reference standard

1c

- *Therapy/Prevention, Etiology/Harm*: All or none*
- *Prognosis*: All or none case-series*
- *Diagnosis*: absolute SpPins and SnNouts*

2a

- *Therapy/Prevention, Etiology/Harm*: SR (with homogeneity) of cohort studies
- *Prognosis*: SR (with homogeneity) of either retrospective cohort studies or untreated control groups in RCTs
- *Diagnosis*: SR (with homogeneity) of level $\geq$2 diagnostic studies

2b

- *Therapy/Prevention, Etiology/Harm*: Individual cohort study (including low-quality RCT; e.g., <80% follow-up)
- *Prognosis*: Retrospective cohort study or follow-up of untreated control patients in an RCT or CPG not validated in a test set
- *Diagnosis*: Any of:
    - Independent blind or objective comparison
    - 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
    - A diagnostic CPG not validated in a test set

2c

- *Therapy/Prevention, Etiology/Harm*: "Outcomes" research
- *Prognosis*: "Outcomes" research

3a

- *Therapy/Prevention, Etiology/Harm*: SR (with homogeneity) of case-control studies

3b

- *Therapy/Prevention, Etiology/Harm*: Individual case-control study
- *Diagnosis*: Independent blind comparison of an appropriate spectrum, but the reference standard was not applied to all study patients

4

- *Therapy/Prevention, Etiology/Harm*: Case-series (and poor quality cohort and case-control studies*)
- *Prognosis*: Case-series (and poor quality prognostic cohort studies*)

- *Diagnosis*: Any of:
    - Reference standard was not objective, unblended, or not independent
    - Positive and negative tests were verified using separate reference standards
    - Study was performed in an inappropriate spectrum of patients

5

- *Therapy/Prevention, Etiology/Harm*: Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"
- *Prognosis*: Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"
- *Diagnosis*: Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"

* Refer to Table 1 "Cochrane methodology: Levels of evidence and grades of recommendations" in the original guideline document for further explanation.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved physical and psychological safety of patients in the intensive care unit

POTENTIAL HARMS

Physical or psychological complications of restraining therapies

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines reflect the official opinion of the Society of Critical Care Medicine and do not necessarily reflect, and should not be construed to reflect, the views of certification bodies, regulatory agencies, or other medical review organizations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Maccioli GA, Dorman T, Brown BR, Mazuski JE, McLean BA, Kuszaj JM, Rosenbaum SH, Frankel LR, Devlin JW, Govert JA, Smith B, Peruzzi WT. 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. Crit Care Med 2003 Nov;31(11):2665-76. [43 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Nov

GUIDELINE DEVELOPER(S)

Society of Critical Care Medicine - Professional Association

SOURCE(S) OF FUNDING

Society of Critical Care Medicine (SCCM)

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Gerald A. Maccioli, MD, FCCM, Critical Health Systems, Raleigh Practice Center, Raleigh, NC; Todd Dorman, MD, FCCM, Departments of Anesthesiology/Critical Care Medicine, Medicine, Surgery, and Nursing, Johns Hopkins Hospital, Baltimore, MD; Brent R. Brown, MD, Internal Medicine Program, University of Oklahoma College of Medicine; John E. Mazuski, MD, PhD, FCCM, Washington University School of Medicine; Barbara A. McLean, MN, CCRN, CCNS-NP, FCCM, Atlanta Medical Center, Atlanta, GA; Joanne M. Kuszaj, MSN, RN, CCRN, Medical Surgical Intensive Care Unit, Rex Healthcare, Raleigh, NC; Stanley H. Rosenbaum, MD, FCCM, Department of Anesthesiology, Yale University School of Medicine; Lorry R. Frankel, MD, FCCM, Stanford University; John W. Devlin, PharmD, BCPS, FCCM, Tufts—New England Medical Center, Boston, MA; Joseph A. Govert, MD, Duke University Medical Center, Durham, NC; Brian Smith, RCP, RRT, Northwestern Memorial Hospital, Chicago, IL; William T. Peruzzi, MD, FCCM, Section of Critical Care Medicine

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Society of Critical Care Medicine (SCCM) Web site.

Print copies: Available from the Society of Critical Care Medicine, 701 Lee Street, Suite 200, Des Plaines, IL 60016; Phone: (847) 827-6869; Fax: (847) 827-6886; on-line through the SCCM Bookstore.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Dorman T, Angood PB, Angus DC, Clemmer TP, Cohen NH, Durbin CG Jr, Falk JL, Helfaer MA, Haupt MT, Horst HM, Ivy ME, Ognibene FP, Sladen RN, Grenvik AN, Napolitano LM. Guidelines for critical care medicine training and continuing medical education. Crit Care Med 2004 Jan;32(1):263-72.

Electronic copies: Available in Portable Document Format (PDF) from the Society of Critical Care Medicine (SCCM) Web site.

Print copies: Available from the Society of Critical Care Medicine, 701 Lee Street, Suite 200, Des Plaines, IL 60016; Phone: (847) 827-6869; Fax: (847) 827-6886; on-line through the SCCM Bookstore.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on June 22, 2004. The information was verified by the guideline developer on August 9, 2004.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 9/29/2008