SQUIRE 2.0 Guidelines

Patients’ Experience of Delirium

CAM Validation for Cardiac Patients After Surgery

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**464**

- **e86** Semiquantitative Cough Strength Score for Predicting Reintubation After Planned Extubation
  Jun Duan, Lintong Zhou, Meling Xiao, Jinhua Liu, and Xiangmei Yang

- **e91** Peripheral Muscle Strength and Correlates of Muscle Weakness in Patients Receiving Mechanical Ventilation
  Linda L. Chlan, Mary Fran Tracy, Jill Guttormson, and Kay Savik

- **e99** Perceived Barriers to Anthropometric Measurements in Critically Ill Children
  Sharon Y. Irving, Stephanie Seiple, Monica Nagle, Shiela Falk, Maria Mascarenhas, and Vijay Srinivasan

- **e108** Being There: Inpatients’ Perceptions of Family Presence During Resuscitation and Invasive Cardiac Procedures
  Renee Samples Twibell, Shannon Craig, Debra Siela, Sherry Simmonds, and Cynthia Thomas

**Critical Care Research 466**

**SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence): Revised Publication Guidelines From a Detailed Consensus Process**
Greg Ogrinc, Louise Davies, Daisy Goodman, Paul Batalden, Frank Davidoff, and David Stevens

**On the Cover**
Detail from “The Mind Settling”
Jacqueline Roliardi
14" x 11"
Mixed media

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Visit her online gallery, http://jackieroliardiart.artsspan.com or at On The Edge Gallery in Scottsdale, AZ.

**Coming in January …**
Chapman and colleagues examine family and nurse satisfaction with elimination of all visitation restrictions in a mixed-profile intensive care unit.
Delirium Assessment 474 Lived Experience of the Intensive Care Unit for Patients Who Experienced Delirium
Karen Whitehorne, Alice Gaudine, Robert Meadus, and Shirley Solberg

480 Validation of the Confusion Assessment Method in Detecting Postoperative Delirium in Cardiac Surgery Patients
Nina Smulter, Helena Claesson Lingehall, Yngve Gustafson, Birgitta Olofsson, and Karl Gunnar Engström

Patient Safety 488 Use of Physical Restraints in Dutch Intensive Care Units: A Prospective Multicenter Study
Arendina W. van der Kooi, Linda M. Peelen, Rosa J. Raimakers, Renée L. Vroegop, Danique F. Bakker, Hilâl Tekatli, Mark van den Boogaard, and Arjen J.C. Slooter

496 Standardizing Communication From Acute Care Providers to Primary Care Providers on Critically Ill Adults
Kerri A. Ellis, Ann Connolly, Alireza Hosseinnezhad, and Craig M. Lilly

Pressure Ulcer Management 501 Vasopressors and Development of Pressure Ulcers in Adult Critical Care Patients
Jill Cox and Sharon Roche

Critical Care Evaluation 514 Validity and Sensitivity of 6 Pain Scales in Critically Ill, Intubated Adults
Mamoona Arif Rahu, Mary Jo Grap, Pam Ferguson, Patty Joseph, Sarah Sherman, and R. K. Elswick, Jr

Nutrition in Critical Care 525 Verifying Placement of Small-Bore Feeding Tubes: Electromagnetic Device Images versus Abdominal Radiographs
Vera Bryant, Jean Phang, and Kevin Abrams

Pediatric Critical Care 532 Increasing Parental Participation During Rounds in a Pediatric Cardiac Intensive Care Unit
Angela Blankenship, Sheila Harrison, Sarah Brandt, Brian Joy, and Janet M. Simsic

460 Editorial
Tough and Competent
Richard H. Savel and Cindy L. Munro

463 Clinical Pearls
Evidence-Based Review and Discussion Points
Ronald L. Hickman

539 Patient Care Page
Family Presence During Invasive Procedures
Linda Bell

540 Clinical Evidence Review
The “Cold Cord”: A Review of Therapeutic Hypothermia for Traumatic Spinal Cord Injuries
Brett Tracy, Rochelle Armola, and Jennifer Micham

545 ECG Puzzler
Bedside ECG Alarm Management
Michele M. Pelter, Teri M. Kozik, Salah S. Al-Zaiti, and Mary G. Carey

547 Education Directory
Visit AJCC’s Web site, www.ajcconline.org, to submit a manuscript or for author guidelines, full text of selected articles, OnlineNOW articles, digital edition access, eLetters, links to AACN’s online continuing education tests, and more.
It was a Friday afternoon: January 27, 1967, to be
precise. The United States and the Soviet Union
were in the middle of the Cold War. As a part of
this ideological standoff, these 2 superpowers were
engaged in a heated space race—a race that the United
States was losing. The Soviet Union had successfully
launched the first artificial space satellite, Sputnik 1, in
1957, and had beaten us by putting the first man in
space, the first man in orbit, the first woman in space,
and enabling the first person to perform a space walk.

A visionary and bold response was articulated by
President John F. Kennedy in 1961. Later, in 1962, he
expanded his remarks: “This nation should commit
itself to achieving the goal, before the decade is out,
of landing a man on the moon and returning him
safely to the Earth” as well as the famous words “We
choose to go to the moon in this decade and do the
other things, not because they are easy, but because
they are hard…”1

The United States had successfully completed
Project Mercury,2 proving we could put a human
into space, and Project Gemini,3 in which early Amer-
ican space pioneers (in a spacecraft just large enough
to contain 2 people) demonstrated how to actually
do the work of astronauts. Through trial, error, per-
severance, and tachycardia, these men learned how
to perform such tasks as working in space, navigating
their spacecraft, and, of greatest complexity and
importance, developing techniques to successfully
rendezvous spacecraft with each other (mandatory
for a successful moon landing), all with much less
computing power than each of us now carry in our
smartphones.

Apollo 1: Pressure to Succeed

It was in this context—during the Cold War,
the space race, and immense pressure to get to the
moon within the decade—that astronauts Virgil
“Gus” Grissom, Edward White, and Roger Chaffee
were working in their Apollo space capsule at Cape
Canaveral Air Force Station Launch Complex 34.
Grissom and White were veterans of space: the for-
mer having been involved in both Mercury and Gem-
ini missions, and the latter having performed the first
American spacewalk. Chaffee, the rookie, was a dec-
orated naval aviator. On that day, these men were
performing what was known as a “plugs out” sim-
ulation test to demonstrate whether the spacecraft
would function properly using its internal power and
life support systems. This was not considered to be a
hazardous test.

The astronauts entered the space capsule at around
1 PM and worked in their cramped quarters for hours.
There were problems, including strange odors and, of
greater concern, significant trouble with the commu-
nication system. Grissom was noted for having said
“How are we going to get to the moon if we can’t
The single greatest lesson from Apollo 1 that endures for us today is a lesson of leadership.

Talk between 2 or 3 buildings? Their simulated countdown continued into the early evening. At 6:31 PM, the fateful words “Fire! Fire in the cockpit!” were transmitted over the communications system. Seventeen seconds later, all 3 astronauts were dead. America’s space program came to an abrupt halt. The United States had lost its first casualties in the race for the moon. Catastrophe had occurred not during a complex mission thousands of miles from earth, but here on terra firma during a routine test.

Multiple investigations were launched, and the entire Apollo space program was frozen. There would not be another manned spaceflight until October 1968, some 21 months later. From a technical standpoint, the problems are now well known. The space capsule was routinely filled with pressurized 100% oxygen, the escape hatches opened in, and some wiring had lost insulation. A complete redesign of the spacecraft would be required, with hatches that opened outwards and with an atmosphere that was no longer pure oxygen, along with many other complex design changes. But in addition to a redesign of the spacecraft, a significant reassessment of the entire administrative culture at the National Aeronautics and Space Administration (NASA) also would be required.

The Kranz Dictum

The single greatest lesson from Apollo 1 that endures for us today is a lesson of leadership. At the time, the flight director was Eugene Francis “Gene” Kranz. On the Monday following the fire and death of the astronauts, Kranz gathered up his team. One can only imagine the immense psychological and emotional weight and pressure he must have felt. On his watch, the United States had lost 3 of its finest members of the astronaut corps, and it had happened during a routine simulation session. This could have easily been a statement of his resignation. Instead, however, Kranz found an opportunity to offer inspiration and leadership.

His speech articulated what became known as “The Kranz Dictum”:

Spaceflight will never tolerate carelessness, incapacity, and neglect. Somewhere, somehow, we screwed up. It could have been in design, build, or test. Whatever it was, we should have caught it. We were too gung ho about the schedule and we locked out all of the problems we saw each day in our work. Not one of us stood up and said, “Dammit, stop!” I don’t know what the committee will find as the cause, but I know what I find. We are the cause! We were not ready! We did not do our job!

From this day forward, Flight Control will be known by two words: “Tough” and “Competent.” Tough means we are forever accountable for what we do or what we fail to do. We will never again compromise our responsibilities. Every time we walk into Mission Control we will know what we stand for. Competent means we will never take anything for granted. We will never be found short in our knowledge and in our skills. Mission Control will be perfect. When you leave this meeting today you will go to your office, and the first thing you will do there is to write “Tough and Competent” on your blackboards. It will never be erased. Each day when you enter the room, these words will remind you of the price paid by Grissom, White, and Chaffee. These words are the price of admission to the ranks of Mission Control.

Kranz provided leadership during a dark, difficult time for America. He did not wither and become defeated by the challenges that faced him. Instead, he met these challenges head on. He became inspired and inspired others. He went on to become one of America’s great heroes, successfully leading the team on Apollo 11 that landed the first humans on the moon and providing inspirational leadership to the team that saved the crew during the Apollo 13 crisis—a situation that was a hair’s breadth away from becoming another fatal disaster.

Parallels to Critical Care

For those of us working in intensive care, there is much to be gained by contemplating these events.

About the Authors
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First of all, when we find ourselves in a challenging situation—something guaranteed in health care and clearly even more commonplace in critical care—we must think back to the leadership demonstrated by Kranz. One could easily imagine him shying away from the daunting situation that faced him. We critical care professionals are entrusted with the lives of our patients in much the same way NASA was with the lives of the astronauts. When we are working with a family situation that may be challenging, we must remember that we have chosen to do these things because they are noble, because they are worthy, because they are hard. When we are working with our colleagues to implement new guidelines or protocols to enhance the care and outcomes of our patients, we must not expect it will be easy. It is better if we expect it to be challenging. When we encounter conflict—no matter what kind of conflict it is—we must stay focused. We must not get caught up in the conflict; we must seek to manage it. We must take the high road.

**Our Search for Inspiration**

The search for inspiration in critical care nursing and medicine is of paramount importance. It is the why. It is why we do what we do. It is why we get up each day. It is why people continue to pursue critical care as a profession. We work as a team to provide comfort, to save lives, to fight death, to win. As critical care practitioners, it is not necessary for us to search for meaning in our professional lives; we have more meaning in our lives in one day than many have in a lifetime. Our problem is not one of finding meaning, but of reminding ourselves—and each other—how important what we do on a daily basis really is.

In conclusion, as part of our commitment to this profession, we must continually remind ourselves to be “tough and competent”: tough on ourselves because our patients deserve it, and competent because it is our price of admission to being part of the intensive care team. To paraphrase President Kennedy, we do not do what we do because it is easy; we do what we do because it is meaningful, because it is important, and “because it is hard.” We should all take a moment to remember the profound message of inspiration, leadership, passion, and courage that arose from the ashes of the tragedy that was Apollo 1.

The statements and opinions contained in this editorial are solely those of the coeditors in chief.

**REFERENCES**


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Clinical Pearls
Mary Jo Grap, RN, PhD, ACNP, Section Editor

Clinical Pearls is designed to help implement evidence-based care at the bedside by summarizing some of the most clinically useful material from select articles in each issue. Readers are encouraged to photocopy this ready-to-post page and share it with colleagues. Please be advised, however, that any substantive change in patient care protocols should be carefully reviewed and approved by the policy-setting authorities at your institution.

Assessing Pain for Patients Who Are Unable to Communicate

Pain is difficult to assess in noncommunicative patients who are being treated with mechanical ventilation or are sedated and unable to report pain. Use of a valid and reliable tool to assist health care providers in the management of pain in critically ill, sedated, and non-communicative patients is paramount. Arif Rahu and colleagues evaluated the validity and sensitivity of 6 pain scales to identify the most appropriate measure of pain in noncommunicative patients (ie, those who were mechanically ventilated and sedated). They found the following:
• All pain scales had moderate to high correlations with the patient’s self-report during suctioning.
• All scales were sensitive in capturing the patient’s pain response in all phases.
• Both subjects and investigators rated pain higher on FACES scale.
• Caregivers must be cautious in using the FACES scale because subjectivity may lead to over- or undertreating pain.

See Article, pp 514-524

Patients’ Perspectives on Family Presence

Patients’ families often want to be at the bedside of hospitalized loved ones during crisis events or invasive procedures. Health care professionals have mixed views about having family members present during invasive procedures, but little is known about patients’ perceptions of family presence. Twibell and colleagues examined this question and found the following:
• Most hospitalized adults experiencing crisis events prefer family presence, yet patient preferences may vary with the nature of the events.
• Having family “be there” during resuscitations and unplanned invasive cardiac procedures was described by patients as being both difficult and beneficial.
• Patients worried about their families getting in the way of the efforts of the health care team.
• Patients wanted to have control over family members’ behaviors during witnessed events but did not express concerns about confidentiality.
• Integrating family facilitators into family-centered care and developing hospital policies could alleviate decisional burdens on patients, provide support for families, and reduce anxiety of health care teams.

See Article, pp e108-e115

Barriers to Obtaining Anthropometric Measurements in the PICU

Anthropometric measurements (eg, weight, stature, head circumference) are vital for safe care in pediatric intensive care units (PICUs). Teams of PICU personnel should evaluate their practice and determine if barriers to obtaining anthropometric measurements exist in their environment and if so, develop innovative ways to remove these barriers from the provision of care. Irving and colleagues explored barriers to obtaining anthropometric measurements and determined:
• Ordering providers and nurses vary in their perceptions on the importance of these measurements.
• Estimated and/or reported measurements have a high likelihood of error and may have a harmful impact on patient care.
• Organization- and unit-based support to establish and maintain standards of practice in obtaining anthropometric measurements are essential to patient care.
• Targeted, multidisciplinary education strategies using evidence-based findings to create practice standards and establish guidelines on how to obtain anthropometric measurements are necessary to dispel myths regarding barriers to obtaining these measurements in the PICU population.

See Article, pp e99-e107

Intensive Care Unit–Acquired Weakness

Intensive care unit–acquired weakness is a frequent complication of critical illness because of patients’ immobility and prolonged use of mechanical ventilation. Understanding the causes, pathophysiology, and risk factors of ICU-acquired weakness is important for prevention. A study by Chlan and colleagues sought to describe daily measurements of peripheral muscle strength in patients receiving mechanical ventilation and explore relationships among factors that influence intensive care unit–acquired weakness. They found the following:
• Patients receiving mechanical ventilatory support are able to participate in handgrip dynamometry, which can be used to monitor peripheral muscle strength
• Older female patients may be a greater risk for muscle weakness
• Prolonged periods of mechanical ventilatory support contribute to peripheral muscle weakness
• Innovative, multidisciplinary interventions are needed to preserve muscle strength and to minimize muscle weakness in critically ill patients.

See Article, pp e91-e98

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**SEMIOQUANTITATIVE COUGH STRENGTH SCORE FOR PREDICTING REINTUBATION AFTER PLANNED EXTUBATION**

By Jun Duan, MD, Lintong Zhou, MD, Meiling Xiao, RN, Jinhua Liu, RN, and Xiangmei Yang, RN

**Background**  Semiquantitative cough strength score (SCSS, graded 0-5) and cough peak flow (CPF) have been used to predict extubation outcome in patients in whom extubation is planned; however, the correlation of the 2 assessments is unclear.

**Methods**  In the intensive care unit of a university-affiliated hospital, 186 patients who were ready for extubation after a successful spontaneous breathing trial were enrolled in the study. Both SCSS and CPF were assessed before extubation. Reintubation was recorded 72 hours after extubation.

**Results**  Reintubation rate was 15.1% within 72 hours after planned extubation. Patients in whom extubation was successful had higher SCSSs than did reintubated patients (mean [SD], 3.2 [1.6] vs 2.2 [1.6], \( P = .002 \)) and CPF (74.3 [40.0] vs 51.7 [29.4] \( \text{L/min} \), \( P = .005 \)). The SCSS showed a positive correlation with CPF (\( r = 0.69, P < .001 \)). Mean CPFs were 38.36 \( \text{L/min} \), 39.51 \( \text{L/min} \), 44.67 \( \text{L/min} \), 57.54 \( \text{L/min} \), 78.96 \( \text{L/min} \), and 113.69 \( \text{L/min} \) in patients with SCSSs of 0, 1, 2, 3, 4, and 5, respectively. The discriminatory power for reintubation, evidenced by area under the receiver operating characteristic curve, was similar: 0.677 for SCSS and 0.678 for CPF (\( P = .97 \)). As SCSS increased (from 0 to 1 to 2 to 3 to 4 to 5), the reintubation rate decreased (from 29.4% to 25.0% to 19.4% to 16.1% to 13.2% to 4.1%).

**Conclusions**  SCSS was convenient to measure at the bedside. It was positively correlated with CPF and had the same accuracy for predicting reintubation after planned extubation. (*American Journal of Critical Care. 2015;24:e86-e90*)

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**PERIPHERAL MUSCLE STRENGTH AND CORRELATES OF MUSCLE WEAKNESS IN PATIENTS RECEIVING MECHANICAL VENTILATION**

By Linda L. Chlan, RN, PhD, Mary Fran Tracy, RN, PhD, CCNS, Jill Guttormson, RN, PhD, and Kay Savik, MS

**Background**  Intensive care unit–acquired weakness is a frequent complication of critical illness because of patients’ immobility and prolonged use of mechanical ventilation.

**Objectives**  To describe daily measurements of peripheral muscle strength in patients receiving mechanical ventilation and explore relationships among factors that influence intensive care unit–acquired weakness.

**Methods**  Peripheral muscle strength of 120 critically ill patients receiving mechanical ventilation was measured daily by using a standardized handgrip dynamometry protocol. Three grip measurements for each hand were recorded in pounds-force; the mean of these 3 assessments was used in the analysis. Correlates of intensive care unit–acquired weakness (age, sex, illness severity, duration of mechanical ventilation, medications) were analyzed by using mixed models to explore the relationship to grip strength.

**Results**  Median baseline grip strength was variable yet diminished (7.7 pounds-force), with either a pattern of diminishing grip strength or maintenance of the baseline low grip strength over time. With controls for days of measurement, female sex (\( \beta = -10.4; P < .001 \)), age (\( \beta = -0.24; P = .004 \)), and days receiving mechanical ventilation (\( \beta = -0.34; P = .005 \)) explained a significant amount of variance in grip strength over time.

**Conclusions**  Patients receiving prolonged mechanical ventilation had marked decrements in grip strength, measured by hand dynamometry, a marker for peripheral muscle strength. Hand dynamometry is a reliable method for measuring muscle strength in cooperative critically ill patients and can be used to develop interventions to prevent intensive care unit–acquired weakness. (*American Journal of Critical Care. 2015;24:e91-e98*)

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PERCEIVED BARRIERS TO ANTHROPOMETRIC MEASUREMENTS IN CRITICALLY ILL CHILDREN

By Sharon Y. Irving, RN, PhD, CRNP, Stephanie Seiple, RD, CNSC, LDN, Monica Nagle, RD, CNSC, LDN, Shiela Falk, RD, LDN, Maria Mascarenhas, MBBS, and Vijay Srinivasan, MD

Background Anthropometric measurements are vital for safe care in pediatric intensive care units.

Objective To identify barriers to anthropometric measurements and determine if perceptions of barriers differ between ordering providers and nurses.

Methods A 21-item survey to elicit perceptions of barriers to obtaining anthropometric measurements was distributed via e-mail to societies with members who provide care in pediatric intensive care units.

Results Most of the 258 eligible respondents (46% ordering providers) were from North America (90%). Although 84% agreed that anthropometric measurements are important, only 3% knew if these measurements were obtained upon admission to their unit. Estimates of patients’ measurements by parents or caregivers were commonly used (72%) when actual measurements were not obtained. Leading barriers were presence of medical devices (57%), use of extracorporeal life support (54%), and unstable hemodynamic status (52%). More ordering providers than nurses considered osteopenia/fragile bones as a barrier to weight measurement (46% vs 29%; P=.007) and traumatic brain injury a barrier to measurement of head circumference (42% vs 24%; P=.002). More nurses than ordering providers perceived dialysis (21% vs 9%; P=.01) and obesity (26% vs 15%; P=.04) as barriers to measurement of stature. Ordering providers more than nurses perceived nurses’ workload (51% vs 33%; P<.001) and lack of importance (43% vs 20%; P<.001) as barriers.

Conclusions Barriers to obtaining anthropometric measurements exist in pediatric intensive care units; ordering providers and nurses have different perceptions of what constitutes a barrier. (American Journal of Critical Care. 2015;24:e99-e107)

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BEING THERE: INPATIENTS’ PERCEPTIONS OF FAMILY PRESENCE DURING RESUSCITATION AND INVASIVE CARDIAC PROCEDURES

By Renee Samples Twibell, RN, PhD, CNE, Shannon Craig, RN, MS, Debra Siela, RN, PhD, CCNS, ACNS-BC, CCRN-K, CNE, RRT, Sherry Simmonds, RN, BSN, CCRP, and Cynthia Thomas, EdD, RNC, CDONA

Background Although patients’ families want to be invited to the bedside of hospitalized loved ones during crisis events, little is known about patients’ perceptions of family presence.

Objective To explore adult inpatients’ perceptions of family presence during resuscitation, near-resuscitation, and unplanned invasive cardiac procedures shortly after the life-threatening event.

Methods In this qualitative study, data were collected by interviews at least 13 hours after a crisis event and before hospital discharge. Data were audio recorded, transcribed, and analyzed for themes.

Results From the bedside interviews (N=48), the overarching theme of “being there” was explained more specifically as “being there is beneficial,” “being there is hard,” “families in the way,” and “desire for control.” Most participants preferred family presence, although preferences varied with types of crisis events, patients’ predictions of family members’ responses, and the nature of family relationships. New perspectives emerged about patients’ decision making related to family presence.

Conclusions This study extends existing knowledge about factors that influence the decision-making processes of hospitalized patients regarding family presence during a crisis event. Health care professionals can provide support as patients ponder difficult decisions about who to have present and can reduce patients’ fears that families might interfere with the life-saving efforts. (American Journal of Critical Care. 2015;24:e108-e115)

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Do you have a QR scanner app on your iPhone or Android? Scan this QR code with your phone to access this article instantly.
Since the publication of Standards for Quality Improvement Reporting Excellence (SQUIRE 1.0) guidelines in 2008, the science of the field has advanced considerably. In this manuscript, we describe the development of SQUIRE 2.0 and its key components. We undertook the revision between 2012 and 2015 using (1) semistructured interviews and focus groups to evaluate SQUIRE 1.0 plus feedback from an international steering group, (2) two face-to-face consensus meetings to develop interim drafts, and (3) pilot testing with authors and a public comment period. SQUIRE 2.0 emphasizes the reporting of 3 key components of systematic efforts to improve the quality, value, and safety of health care: the use of formal and informal theory in planning, implementing, and evaluating improvement work; the context in which the work is done; and the study of the intervention(s). SQUIRE 2.0 is intended for reporting the range of methods used to improve health care, recognizing that they can be complex and multidimensional. It provides common ground to share these discoveries in the scholarly literature (www.squire-statement.org). *(American Journal of Critical Care. 2015;24:466-473)*
In 2005, draft publication guidelines for quality improvement reporting debuted in *Quality and Safety in Health Care*. At that time, publications of scholarly work about health care improvement were often confusing and of limited value. Leaders in the field were working to consolidate the evidence for a science of improvement and without guidance on how to write their findings, authors struggled to report their improvement work in a reliable and consistent way. These factors influenced the initial publication in 2008 of the Standards for Quality Improvement Reporting Excellence (SQUIRE), which we will refer to as SQUIRE 1.0. The guidelines were developed in an effort to reduce uncertainty about the information deemed to be important in scholarly reports of health care improvement, and to increase the completeness, precision, and transparency of those reports.

In the intervening years, the reach of systematic efforts to improve the quality, safety, and value of health care has grown. Health professions education worldwide now includes improvement as a standard competency. The science of the field also continues to advance through guidance on applying formal and informal theory in the development and interpretation of improvement programs; stronger ways to identify, assess, and describe context; recommendations for clearer, more complete descriptions of interventions; and development of initial guidance on how to study an intervention.

In this setting, we have undertaken a revision of SQUIRE 1.0. When we began, it rapidly became apparent that a wide variety of approaches had developed for improving health care, ranging from formative to experimental to evaluative. Rather than limit the revised guidelines to only a few of these, we fashioned them to be applicable across the many methods that are used. We aimed to reflect the dynamic nature of the field, and support its further development. This article describes the development and content of SQUIRE 2.0 (Table 1).

**SQUIRE 2.0 Developmental Path**

We developed SQUIRE 2.0 between 2012 and 2015 in 3 overlapping phases: (1) evaluation of the initial SQUIRE guidelines, (2) early revisions, and (3) pilot testing with late revisions.

We began the evaluation of SQUIRE 1.0 by collecting data to assess its clarity and usability. Semistructured interviews and focus groups with 29 end-users of SQUIRE 1.0 revealed that many found SQUIRE 1.0 helpful in planning and doing improvement work, but less so in the writing process. This issue was especially apparent in efforts to write about the cyclic, iterative process that often occurs with improvement interventions. SQUIRE 1.0 was seen by many as unnecessarily complex with too much redundancy and lacking a clear distinction between “doing improvement” and “studying the improvement.” A recent independent study and editorial also documented and addressed some of these challenges.

In the second phase, we convened an international advisory group of 18 experts that included editors, authors, researchers, and improvement professionals. This group met through 3 conference calls, reviewed SQUIRE 1.0 and the results of the end-user evaluation, and provided detailed feedback on successive revisions. This advisory group and additional participants attended 2 consensus conferences in 2013 and 2014 where they engaged in intensive analysis and made recommendations that further guided the revision process.
The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve health care.

The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of health care, and used methods to establish that observed outcomes were due to the intervention(s).

A range of approaches exists for improving health care. SQUIRE may be adapted for reporting any of these.

Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript.

The SQUIRE Glossary contains definitions of many of the key words in SQUIRE.

The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item.

Please cite SQUIRE when it is used to write a manuscript.
In the third phase, 44 authors used an interim draft version of the updated SQUIRE guidelines to write sections of a manuscript. Each author then provided comments on the utility and understandability of the draft guidelines, and in their submitted section, identified the portions of their writing sample that fulfilled the items of that section.22 We also obtained detailed feedback about this draft version through semistructured interviews with 11 biomedical journal editors. The data from this phase revealed areas needing further clarification and which specific items were prone to misinterpretation. Finally, a penultimate draft was e-mailed to over 450 individuals around the world, including the advisory group, consensus meeting participants, authors, reviewers, editors, faculty in fellowship programs, and trainees. This version was also posted on the SQUIRE website with an invitation for public feedback. We used the information from this process to write SQUIRE 2.0 (Table 1).

**SQUIRE 2.0**

Many publication guidelines, including CONSORT (randomized trials), STROBE (observational studies), and PRISMA (systematic reviews) focus on a particular study methodology (www.equator-network.org). In contrast, SQUIRE 2.0 is designed to apply across the many approaches used for systematically improving the quality, safety, and value of health care. Methods range from iterative changes using Plan-Do-Study-Act (PDSA) cycles in single settings to retrospective analyses of large-scale programs to multisite randomized trials. We encourage authors to apply other publication guidelines—particularly those that focus on specific study methods—along with SQUIRE, as appropriate. Authors should carefully consider the relevance of each SQUIRE item but recognize that it is sometimes not necessary, nor even possible, to include each item in a particular manuscript.

SQUARE 2.0 retains the IMRaD (Introduction, Methods, Results, and Discussion) structure.23 Although used primarily for reporting research within a spectrum of study designs, this structure expresses the underlying logic of most systematic investigations and is familiar to authors, editors, reviewers, and readers. We continue to use A. Bradford Hill’s 4 fundamental questions for writing: Why did you start? What did you do? What did you find? What does it mean?24 In our evaluation of SQUIRE 1.0, novice authors found these questions to be straightforward, clear, and useful.

SQUIRE 2.0 contains 18 items, but omits the multiple subitems that were a source of confusion for SQUIRE 1.0 users.19 A range of approaches exists for improving health care and SQUIRE may be adapted for reporting any of these. As stated earlier, authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE item in a particular manuscript. In addition, authors need not use items in the order in which they appear. Major changes between SQUIRE 1.0 and 2.0 are concentrated in 4 areas: (1) terminology, (2) theory, (3) context, and (4) studying the intervention(s).

**Terminology**

The elaborate detail in SQUIRE 1.0 was seen by users as both a blessing and a curse19: helpful
in designing and executing quality improvement work but less useful in the writing process. The level of detail sometimes led to confusion about what to include or not include in a manuscript. Consequently, we made the items in SQUIRE 2.0 shorter and more direct.

A major challenge in the reporting of systematic efforts to improve health care is the multiplicity of terms used to describe the work, which is challenging for novices and experts alike. Improvement work draws on the epistemology of a variety of fields, and depending on one’s field of study, the same words can carry different connotations, a particularly undesirable state of affairs. Terms such as “quality improvement,” “implementation science,” and “improvement science” refer to approaches that have many similarities but can also connote important (and often-debated) differences. Other terms such as “health care delivery science,” “patient safety,” and even simply “improvement” are also subject to surprising variation in interpretation. To address this problem in semantics, we created a glossary of terms used in SQUIRE 2.0 (Table 2). The glossary provides the intended meaning of certain key terms as we have used them in SQUIRE 2.0 (Table 1). These definitions may be helpful in other endeavors, but are not necessarily intended to be adopted for use in other contexts. Overall, we sought terms and definitions that would be useful to the largest possible audience. For example, we chose “intervention(s)” to refer to the changes that are made. We decided not to use the word “improvement” in the individual items (although it remains in the SQUIRE acronym) to encourage authors to report efforts that did not lead to changes for the better. Reporting well-done, negative studies is vital for the learning in this discipline.

Theory
SQUIRE 2.0 includes a new item titled “Rationale.” Biomedical and clinical research is driven by iterative cycles of theory building and hypothesis testing. Health care improvement work has not consistently based the planning, design, and execution of its programs solidly in theory, to the detriment of the work. For this reason, SQUIRE 2.0 explicitly includes an item devoted to theory, although we chose to use the broader and less technical label “Rationale,” to encourage authors to be explicit in reporting formal and informal theories, models, concepts, or even hunches as to why they expected a particular intervention to work in a particular context. A plain language interpretation of “Rationale” might be, “Why did you think this would work?” A recent narrative review of the nature of theory and its use in improvement describes the many types and applications of theory, and considers pitfalls in using, and not using, theory.12

The addition of the “Rationale” item is intended to encourage clarity around assumptions about the nature of the intervention, the context, and the expected outcomes. The presence of a well-thought-out rationale will align with appropriate measures and with the study of the intervention; it may also be the starting point for the next round of work. The “Summary” item in the Discussion section encourages authors to revisit the original rationale in the light of its findings and in the larger context of similar projects.

Context
SQUIRE 2.0 accepts “context” as the key features of the environment in which the work is immersed and which are interpreted as meaningful to the success, failure, and unexpected consequences of the intervention(s), as well as the relationship of these to the stakeholders (eg, improvement team, clinicians, patients, families).13-16 Systematic efforts to improve health care should contain clear descriptions and acknowledgement of context, rather than efforts to control it or explain it away. SQUIRE 1.0 included context with items in all sections of the manuscript, but context did not rise to the level of a distinct item itself. SQUIRE 2.0 recognizes context as a fundamental item in the Methods section, but its relevance is not limited to this section. In addition to affecting the development of the rationale and subsequent design of the intervention(s), context plays a key role in the iterations of intervention(s) and the outcomes. While it is often not simple to capture or describe context, understanding its impact on the design, implementation, measurement, and results make it a vital contributor in identifying and reporting the factors and mechanisms responsible for the success or failure of the intervention(s).

Studying the Intervention(s)
The study of the intervention is, perhaps, the most challenging item in SQUIRE. In the evaluation of SQUIRE 1.019 and in the pilot testing,22 many were perplexed by this item and its subelements. This item was intended to encourage a more formal assessment of the intervention and its associated outcomes. In SQUIRE 2.0, this section is called, “Study of the Intervention(s)” (Table 1).

“Doing” an improvement project is fundamentally different from “studying” it. The primary purpose of “doing” improvement is to produce better local processes and outcomes, rather than contribute to new generalizable knowledge. In contrast, the reason for “studying” the intervention is mainly to contribute to the body of knowledge about the
Table 2
Glossary of key terms used in SQUIRE 2.0. This glossary provides the intended meaning of selected words and phrases as they are used in the SQUIRE 2.0 guidelines. They may, and often do, have different meanings in other disciplines, situations, and settings.

<table>
<thead>
<tr>
<th>Assumptions</th>
<th>Reasons for choosing the activities and tools used to bring about changes in health care services at the system level.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Context</td>
<td>Physical and sociocultural makeup of the local environment (for example, external environmental factors, organizational dynamics, collaboration, resources, leadership, and the like), and the interpretation of these factors (“sense-making”) by the health care delivery professionals, patients, and caregivers that can affect the effectiveness and generalizability of intervention(s).</td>
</tr>
<tr>
<td>Ethical aspects</td>
<td>The value of system-level initiatives relative to their potential for harm, burden, and cost to the stakeholders. Potential harms particularly associated with efforts to improve the quality, safety, and value of health care services include opportunity costs, invasion of privacy, and staff distress resulting from disclosure of poor performance.</td>
</tr>
<tr>
<td>Generalizability</td>
<td>The likelihood that the intervention(s) in a particular report would produce similar results in other settings, situations, or environments (also referred to as external validity).</td>
</tr>
<tr>
<td>Health care improvement</td>
<td>Any systematic effort intended to raise the quality, safety, and value of health care services, usually done at the system level. We encourage the use of this phrase rather than “quality improvement,” which often refers to more narrowly defined approaches.</td>
</tr>
<tr>
<td>Inferences</td>
<td>The meaning of findings or data, as interpreted by the stakeholders in health care services—improvers, health care delivery professionals, and/or patients and families.</td>
</tr>
<tr>
<td>Initiative</td>
<td>A broad term that can refer to organization-wide programs, narrowly focused projects, or the details of specific interventions (for example, planning, execution, and assessment).</td>
</tr>
<tr>
<td>Internal validity</td>
<td>Demonstrable, credible evidence for efficacy (meaningful impact or change) resulting from introduction of a specific intervention into a particular health care system.</td>
</tr>
<tr>
<td>Intervention(s)</td>
<td>The specific activities and tools introduced into a health care system with the aim of changing its performance for the better. Complete description of an intervention includes its inputs, internal activities, and outputs (in the form of a logic model, for example), and the mechanism(s) by which these components are expected to produce changes in a system’s performance.</td>
</tr>
<tr>
<td>Opportunity costs</td>
<td>Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion of resources needed to introduce, test, or sustain a particular improvement initiative.</td>
</tr>
<tr>
<td>Problem</td>
<td>Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a health care service delivery system that adversely affects patients, staff, or the system as a whole, or that prevents care from reaching its full potential.</td>
</tr>
<tr>
<td>Process</td>
<td>The routines and other activities through which health care services are delivered.</td>
</tr>
<tr>
<td>Rationale</td>
<td>Explanation of why particular intervention(s) was chosen and why it was expected to work, be sustainable, and be replicable elsewhere.</td>
</tr>
<tr>
<td>Systems</td>
<td>The interrelated structures, people, processes, and activities that together create health care services for and with individual patients and populations. For example, systems exist from the personal self-care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the macrosystem, and all the way to the market/social/insurance system. These levels are nested within each other.</td>
</tr>
<tr>
<td>Theory or theories</td>
<td>Any “reason-giving” account that asserts causal relationships between variables (causal theory) or that makes sense of an otherwise obscure process or situation (explanatory theory). Theories come in many forms, and serve different purposes in the phases of improvement work. It is important to be explicit and well-founded about any informal and formal theory (or theories) that are used.</td>
</tr>
</tbody>
</table>

Efficacy and generalizability of efforts for improving health care. Both “doing” and “studying” are required for a deep understanding of the nature and impact of the intervention(s) as well as the possible underlying mechanisms. “Study of the Intervention(s)” focuses mainly on whether and why an intervention “works.” It should align with the rationale and may include, but is not limited to, pre-planned formal testing of the proposed theory that the intervention(s) actually produced the observed
changes, as well as the impact of the intervention(s) on the context in which the work was done.

SQUIRE 2.0 asks authors to be as transparent, complete, and as accurate as possible about reporting “doing” and “studying” improvement work as both aspects of the work are key to scholarly reporting. The “Summary” and “Interpretation” items in the Discussion encourage authors to explain potential mechanisms by which the intervention(s) resulted (or failed to result) in change, thereby developing explanatory theories that can be subsequently tested.

Conclusions

The development of SQUIRE 2.0 consisted of a detailed analysis of SQUIRE 1.0, input from experts in the field, and thorough pilot testing. Many methods and philosophical approaches to improve the quality, safety, and value of health care are available. The systematic efforts to improve health care are often complex and multidimensional, and their effectiveness is inherently context dependent. SQUIRE 2.0 provides common ground on which the discoveries contributed by the various approaches can advance the field by sharing them in the published literature.

At the same time, we recognize that simply publishing SQUIRE 2.0 will not effect this change; additional efforts and resources are required. For example, we have created an explanation and elaboration (E&E) document (Goodman D, Ogrinc G, Davies L; personal communication, 2015) to accompany this article. For each item in SQUIRE 2.0, the E&E provides one or more examples from the published literature and a commentary on how the example(s) meets or does not meet the item’s standards; this information brings the content of each item to life. The SQUIRE website (www.squire-statement.org) contains a number of resources in addition to the guidelines themselves, including interactive E&E pages and video commentaries. The website supports an emerging online community for the continuous use, conversation about, and evaluation of the guidelines.

Writing about improvement can be challenging. Sharing successes, failures, and developments through scholarly literature is an essential component of the complex work required in order to improve health care services for patients, professionals, and the public.

Acknowledgments

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APPENDIX

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AMERICAN ASSOCIATION of CRITICAL-CARE NURSES
A Community of Exceptional Nurses
LIVED EXPERIENCE OF THE INTENSIVE CARE UNIT FOR PATIENTS WHO EXPERIENCED DELIRIUM

By Karen Whitehorne, RN, MN, CPMHN(C), Alice Gaudine, RN, PhD, Robert Meadus, RN, PhD, and Shirley Solberg, RN, PhD

Background  Delirium is a common occurrence for patients in the intensive care unit and can have a profound and lasting impact on them. Few studies describe the experience of intensive care patients who have had delirium.

Objective  To understand the lived experience of intensive care for critically ill patients who experienced delirium.

Methods  The study participants consisted of 7 men and 3 women, 46 to 70 years old, who had delirium according to the Confusion Assessment Method for the Intensive Care Unit. The van Manen method of hermeneutic phenomenology was used, and data collection entailed audio recorded semistructured interviews.

Results  Four themes were detected: “I can’t remember,” “Wanting to make a connection,” “Trying to get it straight,” and “Fear and safety concerns.”

Conclusion  Nurses working in intensive care units need to assess patients for delirium, assess the mental status of patients who have delirium, and help patients and patients’ families learn about and deal with the psychological effects of the intensive care unit experience. (American Journal of Critical Care. 2015;24:474-479)
A stay in an intensive care unit (ICU) includes the experience of delirium for up to 89% of patients. Delirium has a fluctuating course that includes acute alteration in mental status, inattention, disorganized thinking, and altered level of consciousness. Delirium in the ICU is associated with increased mortality, and patients with delirium who survive may have long-term adverse effects. In several studies on the ICU experience and delirium, researchers have found associations between recall of delusional memories of the ICU and the incidence of anxiety, depression, decreased quality of life, and posttraumatic stress disorder.

Knowledge about the ICU experience of patients who had delirium is incomplete. Historically patients with delirium were excluded from research because they could not communicate, were uncooperative, or could not be assessed if they were nonverbal. Follow-up research on patients who had delirium in the ICU has focused on the effects of a particular symptom experience, such as dreams and hallucinations, and not on the experience as a whole. Progress in understanding the experience of the ICU for patients who have experienced delirium is limited; thus, ICU clinicians might not recognize delirium or the distress experienced by patients who have delirium. We designed a study to add to the literature on the ICU experience of patients who have experienced delirium during their ICU stay. Specifically, our research question was as follows: What is the lived experience of the ICU for patients who have experienced delirium?

Methods

The study was approved by the appropriate research ethics boards of the hospitals where the study was done.

Design

The method used for this study was Heideggerian hermeneutic phenomenology based on the research of van Manen. This phenomenological approach enables researchers to understand life experiences “pathetically,” that is, the “felt sense of being in the world,” and through the presentation of findings for others to gain this understanding. Because an individual’s being in the world is spatial, embodied, temporal, and relational, van Manen’s suggested lifeworld themes or existentials were used to produce rich descriptions of the experience: lived space, lived body, lived time, and lived human relations.

Study Participants and Procedure

Patients were included in the study if they were adults admitted to the ICU who had been identified as positive for delirium while in the ICU by using the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU). Patients who had previously had dementia, were unable to read or speak, or were unable to speak English were excluded. The participants consisted of 7 men and 3 women, 46 to 70 years old, from 2 acute care hospitals in eastern Canada. They were interviewed after transfer from the ICU to a medical or surgical unit. This time frame allowed for a thorough description of the experience before debriefing took place and while the participant was in a supportive environment if recall of the experience might be distressing.

Data Collection

The clinical educator for the ICU approached patients after they were no longer delirious according to results of the CAM-ICU and determined if the patients were physically and mentally able and willing to take part in the research. Participants provided signed informed consent. Data were collected via open-ended questions within a semi-structured interview that was audio recorded (see Table). Interviews continued until rich descriptions of the ICU experience were obtained or participants had nothing to add to the recounting of the experience.

Analysis

Data were analyzed, and findings were written and rewritten on the basis of van Manen’s guidelines for phenomenological analysis. The highlighting or selective approach to data analysis was used: the
I can’t remember” captures the lack of memory for a period in the unit.

This lack of memory was experienced as relief to some and as distress to others, who wanted details of what had happened. Family members and friends of a patient told the patient about their observations of the delirium if the patient wanted that information. Some participants had feelings of guilt and shame when told how they had behaved and what they had said during the delirium. The knowledge often led to a need to apologize. One participant commented: “I’ve got to face them. . . . I’ve got to deal with it [behavior] somehow. . . . I still need to apologize for it.” Participants could feel hurt when family members joked about the participants’ behavior during this time: “They still have to make a bit of fun. . . . They’re trying to make me feel better I suppose. . . . It makes me feel bad. . . . It’s not funny.” When participants were told what had happened during the lost time, they experienced doubt about the accuracy of the description because of their lack of recall of the event or disbelief about how ill they had been.

**Trustworthiness of the Data**

In order to improve the rigor of the study, a thematic summary of transcripts was mailed to each participant. Follow-up telephone interviews allowed for phenomenological reflection with the participants and refinement of the thematic analysis. Rigor was achieved by using the framework of Whitemore et al, which includes 4 primary criteria: credibility, authenticity, criticality, and integrity. The framework also includes 6 secondary criteria: explicitness, vividness, creativity, thoroughness, congruence, and sensitivity. These criteria were applied throughout the research process.

**Results**

A total of 4 themes were identified from the 10 interview transcripts: “I can’t remember,” “Wanting to make a connection,” “Trying to get it straight,” and “Fear and safety concerns.”

**I Can’t Remember**

The theme “I can’t remember” describes the lack of memory for a period during the ICU experience.
they were unable to speak. Staff members talking to patients helped create feelings of connection, such as when a nurse explained what she was doing step by step in providing care. Connecting with staff improved participants’ feelings of safety and of being in touch with reality.

**Trying to Get It Straight**

The theme “Trying to get it straight” refers to attempts to make sense of the experience of delirium both during and after being in the ICU. Differentiating between what was real or not was difficult. In addition, the experience was difficult to understand because it was a weird occurrence, with unusual phenomena such as hallucinations, disorganized thinking, and periods of disorientation. These experiences were compounded by an impaired ability to communicate, which was a barrier to seeking explanations from staff or family members. Participants searched for cues in the environment to help them understand what was happening and where they were.

Some thought they were dreaming, whereas others thought they were awake or were dreaming while awake. Sleep-wake states were confused. As described in the following quotation, the combination of reality and things that were not real coupled with the temporary nature of some experiences added to the confusion.

> You didn’t know what to believe like . . . are they [monkeys] really up there in the lights or is that just your mind and then you look at [sister’s name], is she really there or is that just my mind? . . . I couldn’t get . . . what’s real and what’s fake right. . . . It’s confusing.

Other perceptual disturbances such as hallucinations were described, such as hearing music, going through a tunnel with dark colors, and feeling the motions of a ship and hearing the ocean waves. These hallucinations added to the real-life quality of what seemed to be happening. Other vivid visual hallucinations included frozen turkeys in a kitchen, car lights on the wall, large black birds, savage monkeys in the lights, fairies, and a lady picking flowers.

Participants often did not realize they were in the ICU but thought they were in a boat, a nightclub, a beauty parlor, a building downtown, a psychiatric facility, or a race track. They could describe in detail what each place looked like. When they finally were able to talk about the strange experiences with staff, the talking helped them figure out if an experience was real or not. At times, participants felt the staff’s assessment of their orientation was not accurate. As one participant said, “Nurses would come and ask me ‘do you know where you are?’ . . . And, ah, I would say [place], and they would say well that’s very good. But I thought [place] was the name of this boat that I was on.”

The memories of these experiences and feelings often came back in “flashes.” Recall of these unusual experiences was accompanied by the participant’s concern that he or she might be perceived as weird or abnormal or that the experience was indicative of a “mental condition.”

**Fear and Safety Concerns**

The theme “Fear and safety concerns” represents feelings that either the participant or the participant’s family members were in danger. These memories evoked strong emotions. The fear was caused by unexplained experiences, including vivid hallucinations, concern of reexperiencing delirium, feelings of helplessness and weakness from the effects of medication, illness, and being restrained. In one participant, disorientation created a feeling that the participant was in World War II and had been picked up by Japanese soldiers on another ship. He thought that the ICU staff members were these soldiers. He felt that staff members were trying to harm him when they were giving him a bath. He did not understand what was happening or why and resisted being cared for by staff members.

Feelings of fear were compounded by the unusual experiences such as hallucinations. Some of the visual hallucinations were described as vivid and very frightening, and this experience could have a lasting effect even after a participant had been out of the ICU for weeks. One participant said the following:

> The one that was most upsetting was the monkeys . . . up in the lights . . . You could hear them jumping up and down, and they were bawling like they were trying to get at me. They were on all the lights, not just at the one that was at my bed but all around the room. . . . They were savages . . . I didn’t know . . . if they wanted to get out or get at me . . . I’m still afraid to look up at the lights . . . And I always . . . whisper because I’m afraid they’ll hear me.

The delirium experiences were so disturbing that participants feared reexperiencing them and avoided or planned to avoid behaviors that might trigger a further episode. An example of a strategy used was refusing a sleeping pill because the sleep induced by the pill might lead to delirium. Other participants feared any future surgery that might
Delirium distorted the person’s sense of bodily and relational experiences.

...
in obtaining participants because of patients’ critical illness, difficulty of participants in describing unusual events, and a lack of recall of the ICU experience. These factors might have influenced the nature of data collected. Another limitation may be that no specific type of delirium was targeted. Delirium can be classified as hypoactive, hyperactive, or mixed hypoactive and hyperactive. Hypoactive delirium often goes unrecognized, whereas the agitation of hyperactive delirium is more obvious. The majority of the participants in our sample probably had hyperactive delirium, which may be associated with different experiences than are other types of delirium.

Conclusion

The effects of an experience in the ICU that includes delirium can be long lasting and can continue after transfer out of the ICU. Health care personnel must consider the impact of the ICU experience and the experience of delirium on patients who had delirium during the ICU stay. Our findings contribute to the body of knowledge about the impact of the ICU and the delirium experience and can facilitate development of treatment plans for ICU survivors who had delirium.

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This study was performed in 2 acute care hospitals in eastern Canada. We thank the ICU Delirium and Cognitive Impairment Study Group (http://www.icudelirium.org) for teaching hospital staff how to use the CAM-ICU.

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VALIDATION OF THE CONFUSION ASSESSMENT METHOD IN DETECTING POSTOPERATIVE DELIRIUM IN CARDIAC SURGERY PATIENTS

By Nina Smulter, RN, MSc, Helena Claesson Lingehall, RN, MSc, Yngve Gustafson, MD, PhD, Birgitta Olofsson, RN, PhD, and Karl Gunnar Engström, MD, PhD

Background Early detection, prevention, and treatment of delirium after cardiac surgery are important for quick postoperative recovery. The Confusion Assessment Method (CAM) may be an easy-to-use instrument for detecting delirium in clinical practice.

Objectives To compare the congruent validity of the CAM with the results from repeated assessments by using a combination of the Organic Brain Syndrome Scale and the Mini-Mental State Examination according to the Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition, Text Revision) criteria for delirium.

Methods Patients aged 70 years or older undergoing cardiac surgery were assessed on postoperative days 1 and 4, and the 2 diagnostic methods were compared. The sensitivity and specificity of the CAM were examined. The reference method allowed categorization of delirium into subgroups of psychomotor activities and psychiatric symptom profiles, which were compared with the CAM results.

Results Postoperative delirium was diagnosed in 78 of 141 patients (55.3%). According to the CAM, 59 patients (41.8%) were categorized as delirious, 53 correctly. Thus, the sensitivity was 68% and the specificity was 90%, indicating false-negative rather than false-positive observations.

Conclusion Patients with psychomotor hyperactivity and mixed psychotic-emotional symptoms were more likely to have delirium detected via the CAM than were patients with less obvious clinical manifestations of delirium. Repetitive cognitive testing and psychogeriatric experience are probably necessary to improve the results obtained with the CAM. (American Journal of Critical Care. 2015;24:480-487)
Delirium is common after cardiac surgery, with a prevalence of 23% to 52%.\textsuperscript{1-3} Delirium can lead to complications, prolonged hospitalization, and increased morbidity and mortality.\textsuperscript{4,7} Early detection, prevention, and treatment are important for a quick postoperative recovery.\textsuperscript{8-10} Delirium is a neuropsychiatric syndrome characterized by attention disturbance and a change in cognition.\textsuperscript{11} The syndrome can occur in both medical and surgical patients of any age but is more common among older patients.\textsuperscript{12} Delirium is associated with a disturbance in psychomotor activity, which can be classified into various clinical types, such as hyperactive, hypoactive, and mixed hyperactive and hypoactive.\textsuperscript{13,14} Psychotic and emotional signs and symptoms are also common in older patients with delirium.\textsuperscript{14,15} Delirium develops rapidly, within a few hours or days, and fluctuates.

By definition, delirium also has an underlying cause.\textsuperscript{11} The risk factors for delirium can be divided into predisposing and precipitating contributors. In patients undergoing cardiac surgery, predisposing factors include advanced age, previous cerebrovascular disease, and diabetes. Examples of precipitating factors are electrolyte disturbances, anemia, postoperative infections, and volume overload during surgery.\textsuperscript{16,17}

As primary caregivers, nurses play an important part in recognizing and identifying postoperative delirium.\textsuperscript{18,19} However, nurses often misread the clinical signs of delirium, especially hypoactive delirium.\textsuperscript{1,19,20} Possibly, nurses lack the sufficient knowledge required to detect subtle indications of delirium and to correctly interpret signs and symptoms of cognitive impairment.\textsuperscript{19,20} Nevertheless, nurses detect and document delirium more correctly than do physicians.\textsuperscript{21} As might be intuitively realized, the detection rate can be improved by using assessment scales,\textsuperscript{19,20,22} but many of the scales available are both time-consuming and require extensive training.\textsuperscript{23,24} These assessment scales must also have adequate monitoring details with respect to sensitivity and specificity, and the findings should also be different for the different delirium subtypes.

The Organic Brain Syndrome (OBS) Scale is widely used among research professionals in a variety of patients.\textsuperscript{1,6,14,15,25,26} The OBS Scale is based on comprehensive assessments and was developed to detect disturbances in awareness and orientation of older patients, as well as to detect indications of delirium.\textsuperscript{27} The scale addresses a variety of signs and symptoms, including both psychomotor and psychiatric symptom profiles.\textsuperscript{1,26,27} The Confusion Assessment Method (CAM) is another commonly used instrument for detection of delirium in both clinical care and research.\textsuperscript{28-30} The CAM is described as an observational instrument, appreciated for being quick to use in daily practice, requiring as little interviewing as possible.\textsuperscript{31} Another factor that has contributed to its widespread use is its translation into several languages. The instrument has also been widely recommended in clinical guidelines.\textsuperscript{29} In previous studies,\textsuperscript{29,32} the CAM has generally had high sensitivity and high specificity. The CAM was developed by Inouye et al\textsuperscript{31} on the basis of the Diagnostic and Statistical Manual of Mental Disorders (Third Edition Revised; DSM-III-R) criteria and is intended for the detection of delirium by nursing staff and research professionals.

The aim of this study was to evaluate the congruent validity of the English version of the CAM with the results of repeated combined assessments done by using the OBS Scale and the Mini-Mental State Examination (MMSE) according to the Diagnostic and Statistical Manual of Mental Disorders (Fourth Revision, Text Revision; DSM-IV-TR) criteria for delirium. The sensitivity of the CAM in detection of various delirium subtypes was also investigated.

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Methods

The study was approved by the appropriate regional ethical review board.

Population and Design

The study population consisted of patients who had surgery in the cardiothoracic surgery department at Umeå University Hospital, Umeå, Sweden, between February and October 2009. During this period, 199 patients aged 70 years or older scheduled for routine cardiac surgery were eligible for inclusion in the study. Exclusion criteria were emergency procedures, planned deep hypothermic circulatory arrest, known psychiatric disease; and severe communication difficulties, including hearing and vision impairment (n = 6). A total of 15 patients were excluded because of administrative reasons, resulting in 178 eligible patients. Of these, 153 patients gave their oral and written consent for participation in the study. Of these, 12 patients did not complete the study protocol for various reasons (eg, intubated at the time of discharge, no indication for surgery, misunderstanding of the study). In the final sample, 141 patients were assessed for delirium by using the MMSE, OBS Scale, and CAM on days 1 and 4 after surgery. The 37 patients whose data were not analyzed did not differ in sex, age, or procedural type from the cohort whose data were analyzed.

The surgical procedures included coronary artery bypass grafting (CABG), mitral valve and aortic valve surgery with and without ascending aorta procedures, and combinations of both CABG and valve surgery. Postoperative care in the cardiothoracic surgery department is divided into 3 units: the intensive care unit, the step-down unit, and the general unit. The study did not interfere with the patients’ clinical care. The study schedules and the timing of assessments were independent of the care level. Time spent in the intensive care unit after surgery was kept as short as possible; therefore the first assessment (day 1) was, in most instances, performed in the step-down unit. The second assessment (day 4) took place mostly in the general unit.

Measurements

The diagnosis of delirium was based on DSM-IV-TR criteria. The combined results of assessments made by using the OBS Scale and the MMSE were reviewed for findings that met the criteria.

The MMSE was used to assess cognitive state both before and after surgery. Scores on the instrument range from 0 to 30; scores less than 24 are considered an indication of cognitive impairment. The MMSE is a clinically and scientifically accepted instrument with confirmed validity. In particular, with repeated MMSE assessments, the diagnostic precision for detection of cognitive fluctuations increases, especially when patients can be assessed in the preoperative period.

The OBS Scale was used to detect delirium and to categorize delirium subtypes. The scale has 2 main parts, with subscales for disorientation and confusion. The assessment is based on observations and interviews of patients and their caregivers. In this study, the MMSE assessment replaced the first subscale (information on cognitive status); hence, only the second part of the OBS Scale was used. The second subscale covers 39 clinical items, including different time-related variations and fluctuations of the clinical state, emotional reactions, suspiciousness, hallucinations, paranoid symptoms and delusion, language and speech disturbances, neurological signs and symptoms, spatial orientation and recognition, and physical and practical ability. In comparisons with other delirium assessment scales, the OBS Scale has good concurrent validity and effectiveness. The results also allow subdivision into various psychomotor and psychiatric subtypes of delirium, which may have importance for treatment of delirium.

The CAM is a screening instrument used to assess 9 clinical features of delirium: acute onset and fluctuating course, inattention, disorganized thinking, altered level of consciousness, disorientation, memory impairment, perceptual disturbance, increased or reduced psychomotor activity, and disturbance in the sleep-wake cycle. The CAM results are interpreted in accordance with the DSM-III-R criteria for delirium. A diagnosis of delirium requires the presence of both acute onset and fluctuating course and inattention, together with an observation of either disorganized thinking or altered level of consciousness. According to Inouye et al, the remaining 5 features are not considered crucial for a diagnosis of delirium. In the study reported here, the English version of the CAM was used because no validated Swedish version is available.

Study Procedures

A protocol was designed to follow the patients during their hospital stay. Medical, social, and functional data were obtained from clinical records and from interviews with patients and health care professionals.

Patients were assessed by using the MMSE the day before surgery. Patients were then assessed on day 1 after surgery by using the MMSE together with the OBS Scale and the CAM (accepted interval 1-2).
and on day 4 (accepted interval 3-5). Most of the day 1 assessments were done in the step-down unit, not the intensive care unit. Only 1 patient had a duration of mechanical ventilation greater than 24 hours (93 hours). For this particular patient, the time frame refers to the time of extubation rather than the day of surgery.

All assessments were performed by 2 study nurses experienced in dealing with patients who have cardiothoracic surgery. Before the study began, the nurses received specialized training, with lectures on delirium and practical training in the use of assessment instruments such as the MMSE, the OBS Scale, and the CAM. The study nurses did not participate in the final interpretation of the results and diagnostic decisions. Instead, delirium was diagnosed en bloc after the observation period by 2 specialists in psychogeriatric medicine. The evaluation process followed a protocol. First, the results of the MMSE and the OBS Scale were analyzed separately and independently by the 2 specialists. Then the combination of the results of the MMSE and the OBS scale was analyzed independently. During the third step, consensus was reached on the diagnosis of delirium in accordance with DSM-IV-TR criteria.

The results of CAM assessments were analyzed separately, but the analysis followed a similar pattern. The results were first reviewed by the 2 psychogeriatric specialists separately, and then consensus was reached. The diagnosis was made on the basis of recommendations published by Inouye et al.31

Delirium was further divided into subtypes, such as psychomotor activity or psychiatric symptom profiles. The indications of psychomotor activity were used to separate patients into groups with hypoactive, hyperactive, or mixed hyperactive-hypoactive signs and symptoms and patients whose delirium could not be classified by using this approach.14 Only a few patients had solely hyperactive delirium; they were therefore grouped together with patients who had mixed symptom profiles, collectively defined as hyperactive delirium. The psychiatric symptom profile was divided into emotional and psychotic signs and symptoms. Emotional delirium is characterized by depressed mood, emotional lability, and anxiety. Psychotic delirium involves hallucinations, paranoia or illusions, and delusions.14,15 Some of the patients could not be characterized according to these dimensions; these patients were instead considered non-classifiable, similar to the situation described for signs and symptoms of psychomotor activity.

### Statistical Analysis

Microsoft Excel was used for data overview and calculations. PASW Statistics, version 18, for Windows (IBM SPSS Inc) was used for statistical analyses.

The study was focused on cross-table diagnostic comparisons between the CAM and an evaluation based on the combination of the results of the OBS Scale and MMSE assessments, which was considered the reference. The McNemar test was used for binominal comparisons. Sensitivity and specificity between methods were determined. A value of P less than .05 was considered significant.

### Results

The mean age of the 141 patients in the sample was 76.7 years, and 35.5% of the patients were women (Table 1). According to the repeated assessments with the OBS Scale combined with the MMSE, 78 patients (55.3%) had postoperative delirium. This number applies to delirium that occurred any time during the observational period (day 1 and/or day 4 overall delirium; Table 2). According to CAM results, 59 of the 141 patients (41.8%) were delirious; 6 of these diagnoses were false-positive observations. Thus, the CAM results correctly indicated that 53 patients (37.6%) were delirious, for a sensitivity of 68% and a specificity of 90%.

Persistent delirium, identified on day 1 and persisting until day 4 (day 1 and/or day 4, overall delirium; Table 2), occurred in 35 of the 141 patients (24.8%). Of these 35, the CAM results indicated that 22 had persistent delirium; 2 of the

### Table 1

Patient demographics and preoperative observations

<table>
<thead>
<tr>
<th>Characteristica</th>
<th>Valueb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), years</td>
<td>76.7 (4.4)</td>
</tr>
<tr>
<td>Women</td>
<td>35.5</td>
</tr>
<tr>
<td>Diabetes</td>
<td>16.3</td>
</tr>
<tr>
<td>History of cerebrovascular accident</td>
<td>14.9</td>
</tr>
<tr>
<td>Hypertension</td>
<td>83.7</td>
</tr>
<tr>
<td>Left ventricular function (reduced)</td>
<td>32.6</td>
</tr>
<tr>
<td>NYHA (class IV)</td>
<td>17.7</td>
</tr>
<tr>
<td>CABG only</td>
<td>59.6</td>
</tr>
<tr>
<td>Valves only</td>
<td>19.9</td>
</tr>
<tr>
<td>Combined CABG and valve</td>
<td>20.6</td>
</tr>
<tr>
<td>MMSE score, mean (SD)</td>
<td>27.0 (2.6)</td>
</tr>
<tr>
<td>GDS score, mean (SD)</td>
<td>2.5 (2.2)</td>
</tr>
<tr>
<td>P-ADL (dependent; n = 140)</td>
<td>3.6</td>
</tr>
<tr>
<td>I-ADL (dependent; n = 140)</td>
<td>39.3</td>
</tr>
</tbody>
</table>

Abbreviations: CABG, coronary artery bypass grafting; GDS, Geriatric Depression Scale (range, 0-15); I-ADL, instrumental activities of daily living; MMSE, Mini-Mental State Examination (range, 0-30); NYHA, New York Heart Association functional classification; P-ADL, personal activities of daily living.

a Number of patients = 141 unless indicated otherwise.
b Data are presented as percentages unless indicated otherwise.

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[Note: The Table 1 markdown format is not displayed here as it is a plain text representation.]
results were false-positive. Thus, the CAM results were somewhat worse in terms of sensitivity (63%) but had better specificity (98%).

On day 1, the reference method indicated that 64 of the 141 patients (45.4%) were delirious. The corresponding figure on day 4 was 49 patients (34.8%).

On the basis of the findings with the OBS Scale, these 49 patients were classified into 2 groups: those with a psychomotor symptom profile and those with a psychiatric symptom profile (Table 3). The ability to use the CAM results to detect these delirious patients was of interest. CAM findings on their own cannot be used to provide a subdiagnosis of psychiatric symptom profiles, ruling out comparisons in terms of specificity. Instead, true-positive and false-negative CAM results allowed the calculation of sensitivity. In this context, patients with hyperactive signs and symptoms appeared to be more easily detected by using the CAM than did those with a hypoactive profile (Table 3). Some delirious patients were difficult to characterize for psychomotor activity by using the OBS Scale and are referred to as nonclassifiable. This group of patients was less likely to be indicated as delirious by the CAM results, yielding a sensitivity of less than 40%.

Psychiatric symptom profiles describe another dimension of delirium (Table 3). In these terms, the CAM results had good sensitivity for detection of patients with emotional symptoms on day 1. CAM results also had high sensitivity for detection of patients with symptoms of mixed emotional and psychotic symptoms.

Discussion

In this study, we compared diagnosis of delirium based on CAM results among older patients undergoing routine cardiac surgery with a diagnosis based on repeated OBS Scale and MMSE assessments, according to DSM-IV-TR criteria. According to the repeated assessments with the OBS Scale and the MMSE, 78 of the 141 patients had postoperative delirium, an incidence comparable to the incidence in other studies.36,37 The CAM had a relatively high specificity of 90% or greater for detection of delirium but yielded an underestimation of the occurrence of delirium, with a high proportion of false-negatives and hence a relatively low sensitivity of about 60% to 70%.

Table 2
Delirium and subgroups by different diagnostic methods: Confusion Assessment Method versus Organic Brain Syndrome scale and the Mini-Mental State Examination (MMSE/OBS) according to the criteria for delirium in the Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition, Text Revision) in 141 patients

<table>
<thead>
<tr>
<th>Day</th>
<th>MMSE/OBS</th>
<th>P</th>
<th>True-positive</th>
<th>True-negative</th>
<th>False-positive</th>
<th>False-negative</th>
<th>Sensitivity, %</th>
<th>Specificity, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 and/or 4</td>
<td>78</td>
<td>.001</td>
<td>53</td>
<td>57</td>
<td>6</td>
<td>25</td>
<td>68</td>
<td>90</td>
</tr>
<tr>
<td>1</td>
<td>64</td>
<td>.001</td>
<td>46</td>
<td>74</td>
<td>3</td>
<td>18</td>
<td>72</td>
<td>96</td>
</tr>
<tr>
<td>4</td>
<td>49</td>
<td>.004</td>
<td>29</td>
<td>87</td>
<td>5</td>
<td>20</td>
<td>59</td>
<td>95</td>
</tr>
<tr>
<td>1 and 4</td>
<td>35</td>
<td>.007</td>
<td>22</td>
<td>104</td>
<td>2</td>
<td>13</td>
<td>63</td>
<td>98</td>
</tr>
</tbody>
</table>

*McNemar test.

Table 3
Psychomotor activity symptom and psychiatric symptom profiles with diagnostic comparisons

<table>
<thead>
<tr>
<th>Profile</th>
<th>Confusion Assessment Method</th>
<th>MMSE/OBS</th>
<th>True-positive</th>
<th>True-negative</th>
<th>False-positive</th>
<th>False-negative</th>
<th>Sensitivity, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychomotor activity symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypoactive only</td>
<td></td>
<td>40</td>
<td>31</td>
<td>9</td>
<td>78</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td></td>
<td>30</td>
<td>19</td>
<td>11</td>
<td>63</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 4</td>
<td></td>
<td>11</td>
<td>10</td>
<td>1</td>
<td>91</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperactive</td>
<td></td>
<td>10</td>
<td>7</td>
<td>3</td>
<td>70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonclassifiable</td>
<td></td>
<td>13</td>
<td>5</td>
<td>8</td>
<td>38</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td></td>
<td>9</td>
<td>3</td>
<td>6</td>
<td>33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatric symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional only</td>
<td></td>
<td>17</td>
<td>14</td>
<td>3</td>
<td>82</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td></td>
<td>9</td>
<td>4</td>
<td>5</td>
<td>44</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 4</td>
<td></td>
<td>10</td>
<td>6</td>
<td>4</td>
<td>60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychotic only</td>
<td></td>
<td>9</td>
<td>4</td>
<td>5</td>
<td>44</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixed emotional and psychotic</td>
<td></td>
<td>9</td>
<td>7</td>
<td>2</td>
<td>78</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td></td>
<td>16</td>
<td>13</td>
<td>3</td>
<td>81</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 4</td>
<td></td>
<td>28</td>
<td>19</td>
<td>9</td>
<td>68</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonclassifiable</td>
<td></td>
<td>15</td>
<td>8</td>
<td>7</td>
<td>53</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: MMSE/OBS, Mini-Mental State Examination/Organic Brain Syndrome Scale.

*a Variations in detection rate of patients with delirium (counts) with the Confusion Assessment Method for different symptom profiles of delirium with regard to activity patterns and different psychotic symptom profiles. The group hyperactive symptoms consists of merged isolated hyperactive and mixed (hyperactive and hypoactive) symptoms.
Classification of delirium into psychotic and emotional symptom profiles was of interest, particularly how these subgroups were identified or not identified as delirious on the basis of CAM results. Delirium could be divided into subcategories by using the OBS Scale, but the CAM does not provide this option. In our study, most patients were classified as having a hypoactive symptom profile, confirming the results of previous studies. In the early postoperative period, more patients had emotional rather than psychotic symptoms. The sensitivity of the CAM in detecting various subtypes of delirium was tested. Our findings suggested that the CAM was better for detecting patients with hyperactive symptoms and patients with emotional or mixed psychotic and emotional symptoms. In contrast, patients with hypoactive “silent” delirium and those with less obvious symptoms were less likely to be detected by using the CAM.

The CAM was originally developed as an observation scale for the quick detection of delirium in care environments. However, CAM assessments performed by nurses have revealed problems with precision. In our study, sensitivity and specificity rates of CAM for detection of delirium overall were 68% and 90%, respectively. Other investigators have had similar results. Moreover, our results confirm those obtained in a previous study in which Rolfson et al analyzed the validity of the CAM in detecting postoperative delirium in patients undergoing isolated CABG. To our knowledge, the study by Rolfson et al is the only previous study validating the CAM in cardiac surgery patients. Rolfson et al reported a sensitivity of 70% and a specificity of 100% for the CAM. However, our results are not strictly comparable with those of Rolfson et al, because in their study physicians rather than nurses assessed the patients. Rolfson et al reported a low precision for the CAM when nurses administered the instrument, with a sensitivity of only 13%. Similarly, Lemiengre et al reported a low sensitivity when nurses in geriatric care used the CAM without concomitant cognitive testing, with difficulties identified in recognizing acute onset, fluctuation, and altered level of consciousness. In a palliative care setting, Ryan et al reported that these problems were not limited to nurses; physicians also had problems recognizing these characteristics on the basis of CAM results. Because of the findings of low precision when CAM is used alone, combining the CAM with cognition testing might be a desirable practice to improve the detection of delirium, especially when CAM assessments are performed by caregivers who are not specialists in geriatric psychiatry. In our study, nurses administered the CAM, but specialists in psychogeriatric medicine reviewed the observations. In these circumstances, the CAM results were good for detecting the overall occurrence of delirium.

Of note, CAM refers to an older diagnostic manual (DSM-III-R), a characteristic that possibly adds a discrepancy, because the OBS Scale and MMSE are based on DSM-IV-TR criteria. Laurila et al have suggested that criteria in the Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition, Text Revision) offer a higher sensitivity for detecting delirium than do both Diagnostic and Statistical Manual of Mental Disorders (Third Edition) and DMS-III-R. The OBS Scale covers a wider range of psychiatric symptoms than does the CAM. As a result, the OBS Scale provides a more comprehensive overview of a patient’s mental status, including changes between assessments.

Our study has limitations. Only 2 interviews were conducted after surgery. The CAM is described as an observational instrument that requires as little interviewing as possible, but repeated assessments are required, preferably more than 2 assessments. The OBS Scale has a more detailed protocol and is more robust in this respect. Another issue in our study was the lack of continuity. Because of logistic reasons, not all the patients were interviewed by the same research nurse, a situation that may have reduced the possibility of detecting fluctuations. The CAM and the reference method (OBS Scale and MMSE assessments) refer to different manuals (DSM-III-R vs DSM-IV-TR), a difference that may have affected the comparison. Finally, our study sample consisted of only 141 patients, and the sample was limited to older patients undergoing cardiac surgery.

Preoperative testing with the MMSE offers the possibility of detecting impaired cognition before surgery that can then be compared with cognition recorded postoperatively, as we did in our study. However, in an emergency, preoperative cognitive testing is not always possible. If preoperative cognitive testing is not feasible, detection of postoperative delirium with the combined use of the MMSE and the OBS-Scale is not necessarily better than detection with the CAM.

Conclusions

In conclusion, the CAM was associated with a high specificity but a fairly low sensitivity for detection of postoperative delirium after cardiac surgery. CAM results were better for detection of patients with hyperactive, emotional, and mixed psychotic symptoms and patients with emotional or mixed psychotic and emotional symptoms. In contrast, patients with hypoactive “silent” delirium and those with less obvious symptoms were less likely to be detected by using the CAM.

The CAM had high specificity but underestimated the occurrence of delirium.
and emotional symptoms than for patients with other subcategories of delirium. Repetitive cognitive testing and psychogeriatric experience are probably necessary if detecting the more subtle forms of hypovigilant and psychotic delirium by using the CAM is to be improved.

ACKNOWLEDGMENTS
This research was performed at Heart Centre, Cardiac Surgery unit, Umeå University Hospital. We thank the creator of the CAM instrument, Professor Sharon Inouye, for permission to use the scale for the purposes of this study. The instrument was adapted from Inouye SK, vanDyck CH, Alessi CA, Balkin S, Siegal AP, Horwitz RI. Clarifying confusion: the Confusion Assessment Method. A new method for detection of delirium. *Ann Intern Med.* 1990;113:941-948. Confusion Assessment Method: Training Manual and Coding Guide, copyright 2003, Hospital Elder Life Program, LLC. We also thank the participants and the staff at the Cardiothoracic Surgery Department Heart Centre for their cooperation in this study.

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Use of Physical Restraints in Dutch Intensive Care Units: A Prospective Multicenter Study

By Arendina W. van der Kooi, PhD, Linda M. Peelen, PhD, Rosa J. Raijmakers, BSc, Renée L. Vroegop, BSc, Danique F. Bakker, BSc, Hilâl Tekatli, MSc, Mark van den Boogaard, PhD, and Arjen J.C. Slooter, MD, PhD

Background Increasing evidence indicates that harmful effects are associated with the use of physical restraint. Objectives To characterize the use of physical restraint in intensive care units. Prevalence, adherence to protocols, and correlates of the use of physical restraint were determined. For comparisons between ICUs, adjustments were made for differences in patients’ characteristics. Methods A prospective, cross-sectional, observational multicenter study with a representative sample (n=25) of all Dutch intensive care units, ranging from local hospitals to academic centers. Each unit was visited twice, and all 379 patients admitted during these visits were included and were examined for use of physical restraint. Results Physical restraint was used in 23% of all patients (range, 0%-56% for different units). Of all 346 nurses interviewed, 31% reported using a protocol when applying physical restraint. When corrections were made for clustering within units, the risk for use of physical restraint was increased in patients with delirium or coma, in patients who could not communicate verbally, and in patients receiving psychoactive or sedative medications. Sex, severity of illness, and nurse to patient ratio were not independently related to use of physical restraint. In 11 units (44%), use of physical restraint was more frequent than expected on the basis of patients' characteristics, although this finding was not significant. Conclusions Physical restraint is frequently used in Dutch intensive care units. The differences in frequency between units suggest that opportunities exist to limit the use of physical restraint. (American Journal of Critical Care. 2015;24:488-495)
For patients who are in the intensive care unit (ICU), physical restraint (ie, the mechanical restriction of movements) can be used with the intention to prevent accidental removal of endotracheal tubes, catheters, and drains and to allow essential treatment.1 Physical restraint can be used alone or in combination with chemical restraint (ie, sedation).2 The effectiveness of physical restraint has never been studied in a randomized clinical trial, and evidence of harmful effects associated with physical restraint is increasing. In addition to local injury of the skin and peripheral nerves,3 the use of physical restraint has been associated with risk for delirium4,5 and posttraumatic stress disorder.2-6 Furthermore, the use of physical restraint may be regarded as humiliating by awake patients and their relatives.7,8 Although physical restraint is intended to prevent accidental removal of devices, it may actually increase agitation and accidental self-removal of endotracheal tubes.9

The Society of Critical Care Medicine has created guidelines10 for the use of restraining therapies to decrease inappropriate use of physical restraint. The scope of the use of physical restraint is still unclear; however, frequencies between 0% and 100% have been reported.2,10-13 In previous studies,2,10 the frequency of physical restraint was estimated by using surveys, a method that may be subject to bias. In observational studies11-14 in which patients were individually examined, few different centers or ICUs were included. A recent French investigation10 indicated that in 82% of ICUs, physical restraint was used at least once during mechanical ventilation in more than 50% of the patients. However, this study10 was based on answers to a questionnaire sent to ICU physicians only, and therefore the results may not reflect actual practice. Moreover, an outcome measure that describes the percentage of ICUs that used physical restraint at least once in more than 50% of the patients may be difficult to translate to actual clinical practice. Because of these limitations, the pattern of use of physical restraint in ICUs remains unclear.

The objective of this study was to characterize the use of physical restraint in the ICU. We therefore studied the prevalence, adherence to protocols, and correlates of the use of physical restraint and compared these between different ICUs, with adjustments made for differences in patients’ characteristics.

Materials and Methods

Study Design and Sample

This prospective, cross-sectional, observational multicenter study was performed in 25 ICUs of 25 different hospitals in the Netherlands. In the Netherlands, 3 different levels of ICU exist: level 1, small-sized ICU in a local hospital; level 2, medium-sized ICU in a teaching hospital; and level 3, large-sized ICU in a university or large teaching hospital. In order to ensure generalizability, the selection of study centers was proportional to the distribution of all 92 level 1, level 2, and level 3 ICUs in the Netherlands (ie, 5 to 3 to 2). In order to increase the sample size per ICU, thereby increasing the generalizability of the findings, each participating ICU was visited twice. The study population included mixed populations of ICU patients who were admitted to a participating ICU during the visits of the investigators. None of these patients were excluded. The study design was approved by the Medical Ethics Committee of the Radboud University Nijmegen Medical Center, the Netherlands (registration number 2012/107), and a waiver for informed consent was obtained. All patient data were recorded anonymously.

Data Collection

All patients were individually examined by the investigators for use of physical restraint during the investigators’ visit. When restraint was used, the location (eg, both arms) and technique were recorded.
The technique could be either professional (eg, using aids designed to restrain a patient) or provisional (eg, using bed sheets to restrain a patient). Furthermore, during their visits, the investigators assessed the level of sedation or agitation by using the Richmond Agitation-Sedation Scale (RASS)\textsuperscript{15} and the presence of delirium by using the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU).\textsuperscript{16} The ability of the patient to communicate verbally was also recorded. Patients could not be screened by using the CAM-ICU when they had a RASS score less than -3, and these patients were classified as comatose.

In addition, the investigators checked patients’ medical and nursing records for the following parameters: age, sex, admitting service, severity of illness (based on scores on the Acute Physiology and Chronic Health Evaluation [APACHE]\textsuperscript{17} II or IV, depending on the hospital), score on the Sepsis-related Organ Failure Assessment (SOFA),\textsuperscript{18} and administration of psychoactive or sedative medication (ie, antipsychotics, \textalpha_2-agonists, benzodiazepines, or propofol) during the 24 hours before the investigators’ visit. Also, the nurse to patient ratio for each patient was recorded, and the patient’s record was checked for whether the use of physical restraint was documented and whether consent was obtained from the patient or the patient’s legal representative.

The attending ICU nurses and physicians were interviewed by using a questionnaire on the use of and indications for physical restraint in the admitted patients. For the interview, 2 standard forms were used. The first form included 4 questions about the patient: Is the patient restrained at the moment? Was the patient restrained in the past 24 hours? Does the ICU have consent for the use of the restraints for this patient (only in instances when restraint was used)? What is the reason for the use of restraints for this patient (only in instances when restraint was used). The last question was a multiple-choice question. The health care provider could choose a first, second, and third reason from the following options: patient pulling on catheters or tubes; possible threat to airway; prevent patient from falling; patient has an unstable fracture; danger to self; danger to others or aggression; delirium, or other. The second form consisted of 3 questions about awareness of a protocol and implementation of a protocol for use of restraint: Does a protocol for use of restraint exist in your ICU? Do you use this protocol? Do you know where to find this protocol?

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Data Analysis

All continuous variables were tested for normality by using the Kolmogorov-Smirnov test. Continuous variables were examined by using a t test for normal distributions and the Mann-Whitney test otherwise. For comparison of categorical variables, \( \chi^2 \) analysis or the Fisher exact test (when categories contained 5 or fewer expected cases) was used.

Univariate and multivariate log binomial regression analyses were used to investigate the associations of various factors with the use of physical restraint. Sex, use of psychoactive or sedative medications (yes/no), mental status classification (delirious, not delirious, comatose), ability to verbally communicate (yes/no), and nurse to patient ratio (\( \leq 1 \) to \( >1 \)) were included as categorical variables. Because some of the hospitals’ used APACHE II scores and others used APACHE IV scores, the scores were transformed into a single severity of illness score by normalizing and standardizing the original variables. This severity of illness score was subsequently included as a continuous variable. The RASS score was not included in the models because it was highly correlated with mental status classification. Estimates from the models are presented as relative risks with accompanying 95% CIs. In order to account for clustering of multiple patients within ICUs, all analyses were conducted by using generalized estimation equations.

In order to account for the differences between ICUs in policies on use of physical restraint and patient populations, the observed prevalence of use of physical restraint was compared with the expected prevalence for each ICU. In order to calculate the expected prevalence, a logistic regression model was developed on the basis of patients’ characteristics (sex, severity of illness, use of psychoactive or sedative medication, mental status classification, ability to communicate verbally, and nurse to patient ratio) to estimate an individual patient’s risk for use of physical restraint. The model was subsequently applied to the patients in the data set. The observed vs expected ratio (O:E ratio) per ICU was then calculated as the observed number of physically restrained patients divided by the sum of the predicted probabilities for the patients of that particular ICU. A 95% CI for the O:E ratio was calculated on the basis of a Poisson distribution. An O:E ratio greater than 1 indicates that the prevalence of physical restraint was higher than expected on the basis of patients’ characteristics; an O:E ratio less than 1 indicates that physical restraint was used less often than expected.

Missing values were imputed by using multiple imputation with 10 data sets. All analyses were repeated for each imputed data set and subsequently combined into a single estimate according to the
Table 1
Characteristics of the study population

<table>
<thead>
<tr>
<th>Characteristicb</th>
<th>All (n = 379)</th>
<th>Physically restrained (n = 87)</th>
<th>Not physically restrained (n = 292)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, No. (%) of patients</td>
<td>234 (62)</td>
<td>53 (61)</td>
<td>181 (62)</td>
<td>.77</td>
</tr>
<tr>
<td>Age, median (IQR), y</td>
<td>67 (56-75)</td>
<td>69 (60-77)</td>
<td>67 (55-74)</td>
<td>.13</td>
</tr>
<tr>
<td>APACHE IV score, median (IQR)</td>
<td>83 (61-101)</td>
<td>89 (60-110)</td>
<td>83 (61-100)</td>
<td>.30</td>
</tr>
<tr>
<td>APACHE II score, median (IQR)</td>
<td>22 (16-26)</td>
<td>22 (16-26)</td>
<td>21 (17-27)</td>
<td>.58</td>
</tr>
<tr>
<td>Admitting service, No. (%) of patients</td>
<td></td>
<td></td>
<td></td>
<td>.20</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>161 (42)</td>
<td>41 (47)</td>
<td>120 (41)</td>
<td></td>
</tr>
<tr>
<td>General surgery</td>
<td>94 (25)</td>
<td>16 (18)</td>
<td>78 (27)</td>
<td></td>
</tr>
<tr>
<td>Cardiology/cardiothoracic surgery</td>
<td>68 (18)</td>
<td>13 (15)</td>
<td>55 (19)</td>
<td></td>
</tr>
<tr>
<td>Neurology/neurosurgery</td>
<td>47 (12)</td>
<td>13 (15)</td>
<td>34 (12)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>9 (2)</td>
<td>4 (5)</td>
<td>5 (2)</td>
<td></td>
</tr>
<tr>
<td>Medication given in prior 24 hours, No. (%) of patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>124 (33)</td>
<td>43 (49)</td>
<td>81 (28)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>α2-Agonists</td>
<td>15 (4.0)</td>
<td>5 (6)</td>
<td>10 (3)</td>
<td>.35</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>146 (39)</td>
<td>46 (53)</td>
<td>100 (34)</td>
<td>.002</td>
</tr>
<tr>
<td>Propofol</td>
<td>71 (19)</td>
<td>23 (26)</td>
<td>48 (16)</td>
<td>.04</td>
</tr>
<tr>
<td>RASS score, median (IQR)</td>
<td>0 (-3 to 0)</td>
<td>-2 (-4 to 0)</td>
<td>0 (-3 to 0)</td>
<td>.05</td>
</tr>
<tr>
<td>Mental status, No. (%) of patients</td>
<td></td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Comatose</td>
<td>135 (36)</td>
<td>43 (49)</td>
<td>92 (32)</td>
<td></td>
</tr>
<tr>
<td>Delirious</td>
<td>75 (20)</td>
<td>31 (36)</td>
<td>44 (15)</td>
<td></td>
</tr>
<tr>
<td>Hypoactivec (RASS score &lt; 0)</td>
<td>59 (88)</td>
<td>20 (77)</td>
<td>39 (95)</td>
<td></td>
</tr>
<tr>
<td>Hyperactivec (RASS score &gt; 0)</td>
<td>8 (12)</td>
<td>6 (23)</td>
<td>2 (5)</td>
<td></td>
</tr>
<tr>
<td>Awake and not delirious</td>
<td>169 (45)</td>
<td>13 (15)</td>
<td>156 (33)</td>
<td></td>
</tr>
<tr>
<td>Verbal communication possible, No. (%) of patients</td>
<td>164 (43)</td>
<td>13 (15)</td>
<td>151 (52)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Nurse to patient ratio, No. (%) of patients</td>
<td></td>
<td></td>
<td></td>
<td>.77</td>
</tr>
<tr>
<td>≥ 1 to 1</td>
<td>251 (66)</td>
<td>58 (67)</td>
<td>193 (66)</td>
<td></td>
</tr>
<tr>
<td>&lt; 1 to 1</td>
<td>124 (33)</td>
<td>27 (31)</td>
<td>97 (33)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; IQR, interquartile range; RASS, Richmond Agitation-Sedation Scale.

a Because of rounding, not all percentages total 100.

b The following variables had missing observations: restraint use (n = 6), sex (n = 3), age (n = 3), APACHE IV score (n = 165), medication given in preceding 24 hours (n = 1), RASS (n = 35), mental status (n = 13), verbal communication (n = 5), nurse to patient ratio (n = 4). Patients were classified as comatose when they had a RASS score less than -3.

c At research visit, 8 patients unknown because RASS scores were missing.

Results

The sample included 379 patients from 25 different adult ICUs (12 level 1, 8 level 2, and 5 level 3) in the Netherlands. Of all 379 patients, 87 (23%) were physically restrained during the visit of the investigator. Restrained patients received antipsychotics, benzodiazepines, or propofol in the preceding 24 hours more often than did nonrestrained patients (Table 1). Furthermore, during the visit of the researcher, restrained patients had lower RASS scores, were more often delirious or comatose, and were more often unable to communicate verbally. Upper limb restraint was used in the majority (98%) of physically restrained cases; leg restraint (5%) and torso restraint (1%) were rarely used. In 98% of the restrained patients, the technique used was professional.

The most common reasons for applying restraint were possible threat to airway and pulling on catheters or the endotracheal tube (Table 2). In 39 of the 87 restrained patients (45%), the use of physical restraint was documented in the patient’s record, and in 40 instances (46%) informed consent was obtained from the patient or the patient’s legal representative. A total of 23 of the ICUs (92%) had a restraining protocol. Of the 346 interviewed ICU nurses, 108 (31%) reported using a protocol when applying physical restraint in any situation. In other instances, the protocol was broken, for example, by not documenting the use of physical restraint in the medical record or by not asking for consent before applying the physical restraint.

Of the 72 ICU physicians who participated in this study, 26 (36%) knew which patients on their unit were physically restrained.
Table 2
Motivations for use of physical restraint in 87 patients

<table>
<thead>
<tr>
<th>Motivation</th>
<th>No. (%) of patients³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient is pulling on catheters/tubes</td>
<td>49 (56)</td>
</tr>
<tr>
<td>Possible threat to airway</td>
<td>59 (68)</td>
</tr>
<tr>
<td>Prevent patient from falling</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Patient has an unstable fracture</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Danger to self</td>
<td>21 (24)</td>
</tr>
<tr>
<td>Danger to others or aggression</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Delirium</td>
<td>9 (10)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (18)</td>
</tr>
</tbody>
</table>

³ Total number is 162 because each patient could have up to 3 reasons for use of physical restraints listed. No primary reason was given in 5 cases of applied physical restraint. No second reason was given in 35 cases. No third reason was given in 59 cases.

As shown in Figure 1, the percentage of restrained patients varied widely between different hospitals (0%-56%). Use of physical restraint, when corrected for clustering per ICU, was associated with a delirious or comatose mental status, use of psychoactive or sedative medication, and inability to communicate verbally (Table 3). Sex, severity of illness, and nurse to patient ratio were not independently associated with use of physical restraint.

The O:E ratios for all 25 ICUs are shown in Figure 2. In 11 ICUs (44%), the use of physical restraint was more frequent than was expected on the basis of patients' characteristics (O:E ratio > 1), although this value was not significant.

Discussion

In this large multicenter study, use of physical restraint in the ICU was characterized on the basis of examinations of individual patients. Our results indicated that 23% of the ICU patients were physically restrained and that this proportion differed widely between different ICUs even after correction for differences in patients' characteristics. Use of physical restraint was associated with a delirious or comatose mental status, use of psychoactive or sedative medication, and inability to communicate verbally. For 44% of the ICUs, more patients were physically restrained than was expected on the basis of patients' characteristics.

Use of physical restraint may have harmful effects, and our findings provide a starting point for strategies to decrease its use. Because physical restraint is used more often in delirious patients than in nondelirious patients, reducing the occurrence of delirium may decrease the use of physical restraint. This reduction may be achieved by using the so-called ABCDE bundle20 (Awakening and Breathing Coordination, Delirium monitoring, and Exercise/Early mobility), which can reduce the risk for delirium.21 Alterations in a patient's
Table 3

Risk factors for use of physical restraint

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariate</th>
<th>Multivariate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1.06 (0.72-1.54)</td>
<td>1.07 (0.76-1.49)</td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Severity of illness (per SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of psychoactive or sedative medica<strong>b</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>2.27 (1.54-3.33)</td>
<td>1.45 (1.06-1.96)</td>
</tr>
<tr>
<td>Mental status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comatose<strong>c</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delirious</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Awake and not delirious</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verbal communication possible</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>4.21 (2.53-7.01)</td>
<td>2.84 (1.56-5.20)</td>
</tr>
<tr>
<td>Nurse to patient ratio</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥1 to 1</td>
<td>1.08 (0.82-1.42)</td>
<td>0.89 (0.64-1.23)</td>
</tr>
<tr>
<td>&lt;1 to 1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

*All models were based on generalized estimation equations with log binomial regression analysis, taking into account clustering of patients within intensive care units. Univariate: all 6 variables (sex, severity of illness, use of psychoactive or sedative medication, mental status, ability to communicate verbally, and nurse to patient ratio) were included separately in the model. Multivariate: all 6 variables were included in the model simultaneously.

Use of psychoactive or sedative medication included antipsychotics, propofol, &-agonists, and benzodiazepines.

Patients were classified as comatose when they had a score less than -3 on the Richmond Agitation-Sedation Scale.

Figure 2

Physical restraint per intensive care unit (ICU): observed:expected ratios. The black circles represent the observed:expected ratio on the use of physical restraint per ICU, and the whiskers represent 95% CIs. The total number of patients examined during the 2 visits per ICU is shown below the name of the ICU (A through Y) on the x-axis. The names of the ICUs are similar to the names in Figure 1.
then several investigators have reported harmful effects of sedation. We think that chemical restraint should be used with caution, and in accordance with current sedation guidelines.

ICU nurses play an important role in strategies to decrease the use of physical restraint. In our study population, the decision to apply physical restraint was primarily made by the nursing staff, and almost two-thirds of the ICU physicians did not know which patients on their unit were restrained. Documentation of the use of restraint was low, entered in the patient’s medical record in less than half of the cases (45%). In a minority of cases, informed consent was obtained from the patient or the patient’s legal representative. Therefore, in order to implement the Society of Critical Care Medicine guidelines to limit the use of physical restraint, more efforts should be made to alert nursing staff on the harmful effects of using physical restraint and to suggest alternatives.

One of the strengths of our study is that the study population is a good representation of the Dutch ICU population. A large number of patients were included from 25 ICUs, creating a study sample of a quarter of all Dutch ICUs. The selection of ICUs was in proportion to the nationwide distribution of types of ICUs, and all admitted patients in the ICUs were included in the study. All ICUs were visited twice by an independent investigator. The investigator who collected the data was not involved in the care of the included patients. Anonymity of institutions was guaranteed, thus decreasing the risk of a change in the physical restraint policy because of the upcoming visit of the investigator. Furthermore, this study is the first one in which the use of physical restraint was compared across different ICUs. Differences in patients’ characteristics between ICUs were taken into account by using an O:E ratio. This approach allowed for a fairer comparison between physical restraint rates of different ICUs. Nevertheless, considerable differences were found.

Limitations

Some limitations need to be addressed. First, patients were examined in the daytime. During the night, delirium may be more common when fewer nurses are taking care of these patients. More patients may therefore be physically restrained during the evenings and nights. Hence, the prevalence of physical restraint and the effect of nurse to patient ratio on physical restraint may have been underestimated. Second, although we guaranteed anonymity of study centers, we cannot exclude that the use of physical restraint was reduced because of an upcoming visit by one of the investigators. Per site, only a single person was informed about the time of the research visit. Although the majority of the ICU staff were not informed about the research visit, we cannot exclude the possibility that ICU personnel adjusted the use of physical restraint because of the upcoming visit. This adjustment would also have led to an underestimation of the use of physical restraint. Third, although this study is one of the largest studies on the prevalence of use of physical restraint in ICUs on the level of individual patients, in some hospitals, only a few patients were evaluated. This situation occurred mainly because some of the ICUs were level 1 ICUs (n = 12), with a small number of ICU beds. Fourth, our results provide an analysis of the use of physical restraint in the Netherlands. Therefore, generalizing these results to other countries must be done cautiously. Fifth, the use of opioids was not documented, a situation that may have affected the association observed between the use of psychoactive or sedative medication and the use of physical restraint. However, this association was consistent with the association of a comatose state with use of physical restraint. Sixth, in our multivariable models, we adjusted our estimates for use of psychoactive or sedative medication in the preceding 24 hours. However, we cannot entirely exclude the possibility that physical restraint was started before psychoactive or sedative medication was started. Last, the questionnaire used to interview the nurses and physicians was created specifically for this study and was therefore not validated in another population.

Conclusion

Use of physical restraint is common in Dutch ICUs. However, the frequency of use differs considerably between different ICUs, suggesting that opportunities exist to reduce the use of physical restraint.

ACKNOWLEDGMENTS

This work was performed at Antoni van Leeuwenhoek Hospital-Netherlands Cancer Institute, Amsterdam; Boven IJ Hospital, Amsterdam; Diakonessenhuis, Utrecht; Erasmus Medical Center, Rotterdam; Flevo Hospital, Almere; Groene Hart Hospital, Gouda; Haven Hospital, Rotterdam; IJsselstein Hospital, Capelle aan de IJssel; Ikazia Hospital, Rotterdam; Jeroen Bosch Hospital, Den Bosch; Meander Medical Center, Amersfoort; Onze Lieve Vrouwe Gasthuis, Amsterdam; Rijnstate Hospital, Arnhem; Sint Anna Hospital, Geldrop; Sint Franciscus Gasthuis, Rotterdam; Sint Lucas Andreas Hospital, Amsterdam; Slotervaart Hospital, Amsterdam; Spaarne Hospital, Hoofddorp; Radboud University Nijmegen Medical Center; University Medical Centre Utrecht; Vlietland Hospital, Schiedam; Hospital Amstelland, Amstelveen; Hospital Rivierland, Tiel; Hospital Group Twente, Almelo; Zuwe Hofpoort Hospital, Woerden. We thank all participating intensivists of the hospitals for their hospitality and cooperation.

FINANCIAL DISCLOSURES

None reported.
REFERENCES


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STANDARDIZING COMMUNICATION FROM ACUTE CARE PROVIDERS TO PRIMARY CARE PROVIDERS ON CRITICALLY ILL ADULTS

By Kerri A. Ellis, DNP, Ann Connolly, NP, Alireza Hosseinnezhad, MD, and Craig M. Lilly, MD

Objective  To increase the frequency of communication of patient information between acute and primary care providers. A secondary objective was to determine whether higher rates of communication were associated with lower rates of hospital readmission 30 days after discharge.

Methods  A validated instrument was used for telephone surveys before and after an intervention designed to increase the frequency of communication among acute care and primary care providers. The communication intervention was implemented in 3 adult intensive care units from 2 campuses of an academic medical center.

Results  The frequency of communication among acute care and primary care providers, the perceived usefulness of the intervention, and its association with 30-day readmission rates were assessed for 202 adult intensive care episodes before and 100 episodes after a communication intervention. The frequency of documented communication increased significantly (5/202 or 2% before to 72/100 or 72% after the intervention; P<.001) and the communication was considered useful by every participating primary care provider. Rates of rehospitalization at 30 days were lower for the intervention group than the preintervention group, but the difference was not statistically significant (41/202 or 23% vs 16/88 or 18% of discharged patients; P=.45; power 0.112 at P=.05).

Conclusions  The frequency of communication episodes that provide value can be increased through standardized processes. The key aspects of this effective intervention were setting the expectation that communication should occur, documenting when communication has occurred, and reviewing that documentation during multiprofessional rounds. (American Journal of Critical Care. 2015;24:496-500)

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doi: http://dx.doi.org/10.4037/ajcc2015332
More frequent communication among acute care providers and primary care providers (PCPs) has been associated with better outcomes for patients.\textsuperscript{1,2} However, research thus far indicates that communication across health care settings is less frequent than expected by PCPs.\textsuperscript{3,4} Effective transfer of information about patients when they arrive at the hospital reduces the risk of medication errors, unnecessary diagnostic testing, and rehospitalization rates and is associated with improved quality of life for patients.\textsuperscript{1,5} Furthermore, successful communication strengthens relationships among providers and may increase patient referral rates across health care settings.\textsuperscript{3} It is increasingly clear that the frequency of communication among providers across health care settings is lower than the optimal levels that our patients expect.\textsuperscript{4,6}

Ineffective communication adds to the patient’s disease burden and the costs of care. Cost savings from improved communication, specifically at times of care transitions, were estimated to be $25 to $45 billion for the United States in 2011.\textsuperscript{7} Realizing these cost savings depends, in part, on identifying achievable methods for more effective communication among acute care providers and PCPs.

Our prior study\textsuperscript{4} of the epidemiology of communication among acute care providers and PCPs suggested that communication could be improved by implementing a standardized communication protocol. That study\textsuperscript{4} also provided qualitative data that were used to design the intervention that was used for this study and provided a validated instrument to make the required measurements. In the present study, we measured the effects of a novel communication intervention that can be implemented at little incremental cost or effort when it is integrated into daily multiprofessional rounds.

The hypothesis tested in this study was that a standardized communication protocol would increase the rate of documentation on mode of communication from acute care providers to PCPs at the time of an unscheduled admission to an adult ICU. The perceptions of PCPs about the usefulness of direct communication also were evaluated, the sustainability of the intervention was assessed, and the association of the intervention with rehospitalization rates was measured.

Materials and Methods

Study Design

We designed and conducted a pre-post study to evaluate the frequency of communication among providers of acute care and PCPs. The effect of a standard communication process on the frequency of communication was measured after a 2-month washout period and a 4-week training and implementation transition period for the care providers in intensive care units (ICUs). The PCP was contacted by the ICU provider who was caring for the patient when the patient was admitted, rather than a member of the study team. Once the ICU provider completed the communication with the PCP, the ICU provider then documented the process in the patient’s electronic medical record. This study was conducted on each campus of a 2-campus academic tertiary care center. The PCPs of patients admitted to any of 3 adult medical ICUs that used a closed staffing model from June 2, 2012, to July 25, 2012 were enrolled in the study. We then expanded the intervention to all 7 adult ICUs across the 2 campuses from January 1, 2013, to December 31, 2013. From January 1, 2013, to December 31, 2013, we performed weekly chart audits to assess the sustainability of this intervention.

Study Participants

All ICU admissions were reviewed to identify the patient’s PCP from the electronic medical record. When recent visits of a patient with a PCP were confirmed, the study staff contacted the PCP and invited him or her to participate in a telephone survey. We...
used a validated and published instrument to collect data during telephone surveys. Study staff made up to 3 attempts to contact the patients’ PCPs; if all attempts were unsuccessful, that PCP was excluded from the study. Verbal consent was obtained from each PCP before enrollment. We conducted 100 interviews to provide 80% power for detecting an increase in the frequency of communication from 5% to 20% of eligible episodes of care at a significance level of .05. In addition, we held focus groups throughout the implementation phase with the acute care providers to obtain feedback on the intervention and interactions with the PCPs.

The Intervention

The communication intervention was designed and implemented in our previous study by using the Plan-Do-Study-Act model from the Institute for Healthcare Improvement (IHI, with permission). The medical record was modified to accommodate recording of how and when acute care providers communicated with the ICU patients’ PCPs (Figure 1). The documentation elements included the identity of the PCP who was notified, the method and date of notification, and what information was communicated, namely, ICU admission or a decline in a patient’s health status. Implementation of this standardized process of communication by an acute care provider occurred in a 1-month period. The study staff also performed an inclusive chart review from June 11, 2012, to July 25, 2012, to compare the documentation of communication in the electronic medical record with that obtained during the telephone interview.

The review of sustainability of the communication intervention was measured by weekly chart audits using the checklist method conducted from January 1 to December 31, 2013. This chart review included 7 adult ICUs (3 medical, 2 surgical, 1 cardiac, 1 neurosciences). The findings of the chart reviews of the intervention were shared with the on-service attending intensivists. This study was performed under a waiver of the requirement for written informed consent by the University of Massachusetts Human Subjects Committee (docket #14260).

Statistical Analyses

Rates of communication, documentation, and rehospitalization were compared by using the \( \chi^2 \) test or the Fisher exact test to compare data from before and after the intervention by using a prespecified 2-sided significance level of .05 (SPSS version 22, IBM Corp). Qualitative data from PCPs of their perceptions were parsed by question, tabulated, coded, and summarized.

Results

We identified 302 encounters in which a patient had a PCP who we could contact among 512 ICU encounters for the entire study (Figure 2). Every PCP who was contacted on the first attempt agreed to participate in the study. The groups were well balanced with regard to demographic characteristics (Table 1). The intervention was associated with a significant increase in direct (interactive) communication events from acute care providers to PCPs (8% to 37%; \( P < .001 \)). Concordantly, all forms of documented communication (including unidirectional electronic communications) also increased significantly (2% to 72%; \( P < .001 \)). These improvements

Figure 1 Protocol for communication from the acute care provider to the primary care provider (PCP).

Figure 2 Enrollment of primary care providers (PCPs) in the study. Thirty-three primary care providers had more than 1 patient who required admission to a medical intensive care unit.
in the frequency of communication were not only sustainable, but also increased for the calendar year following study completion. Acute care providers’ documentation of communication with their patient’s PCP increased to levels greater than 90% most of the time, which was consistently higher than the levels observed during the study.

The frequency of communication with PCPs for the intervention group increased primarily because telephonic contact increased from 16 of 202 cases (8%) to 37 of 100 cases (37%). We identified several barriers to contacting PCPs; verified e-mail transmissions from acute care providers failed to reach the PCP in 10 out of 39 cases (26%) because of inactive, incorrect, or unused e-mail accounts. Telephonic contact failed to reach the PCP in 5 of 11 cases (45%) because of inability of the answering service to transfer messages (3 cases, 27%) or delay in communication between covering providers (2 cases, 18%).

Our qualitative analyses were obtained from an open-ended question to the PCPs about how the direct communication from the acute care team was useful to them in caring for their patients. This analysis revealed that every PCP in this study perceived the communication from acute care providers to be useful. Responses were coded by the study team before analysis. Analysis suggested segregation of the responses into 4 subgroups:

1. The direct communication will assist the PCP in follow-up care of the patient.
2. The PCP identified limitations for direct communication with the acute care team.
3. Rehospitalization assistance was requested by the PCP.
4. The PCP appreciates the opportunity to have direct communication with the acute care team.

We were able to identify 2 primary themes regarding why the communication was valued. PCPs remarked that the information shared would help them to reengage with the patient after discharge and they appreciated the opportunity to have an active role in their patient’s plan of care. Many of the PCPs who had direct communication with the acute care team commented that they also felt welcomed in the ICU environment, which matched the observations of the acute care team of having PCPs visit their ICU patients. We also collected qualitative data from acute care ICU providers regarding the ease of program implementation. They reported that input from the patient’s PCPs was helpful in providing pertinent medical history that was otherwise not known that directly affected the patient’s ICU plan of care and for transitioning patients to home. They reported that the intervention required a mean of 5 minutes of the ICU provider’s time.

We also analyzed 30-day rehospitalization rates. The intervention was associated with an 18% rate of readmissions at 30 days, which was lower than but not significantly different ($P = .45$) from the baseline rate of 23% (Table 2).

**Discussion**

The main finding of this study is that the frequency of communication among acute care providers and PCPs was significantly increased by the intervention. Moreover, when this standardized communication intervention was integrated into daily multiprofessional ICU rounds, the frequency of communication increased further and was sustained during a 1-year follow-up period. The mutual value of the information exchange was self-reinforcing. The ICU providers noted more visits by PCPs to our ICUs resulting in interactions with their patients. In addition, setting uniform expectations for documenting communication in the electronic medical record and providing feedback to each responsible clinician most likely fostered adherence.

Communication with PCPs at the time of a patient’s

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### Table 1
**Demographics of patients and primary care providers**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Before intervention</th>
<th>After intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients admitted to intensive care unit</td>
<td>202</td>
<td>100</td>
</tr>
<tr>
<td>Age, median (SIQR), y</td>
<td>68 (25)</td>
<td>66 (25)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>103 (51)</td>
<td>50 (50)</td>
</tr>
<tr>
<td>Female</td>
<td>99 (49)</td>
<td>50 (50)</td>
</tr>
<tr>
<td>Communication event from acute care provider to PCP documented in patient’s electronic medical record</td>
<td>5 (2)</td>
<td>72 (72)</td>
</tr>
<tr>
<td>PCP aware of admission</td>
<td>118 (58)</td>
<td>72 (72)</td>
</tr>
</tbody>
</table>

*Abbreviations: PCP, primary care provider; SIQR, semi-interquartile range.*

### Table 2
**Readmission to hospital before and after intervention**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Before intervention</th>
<th>After intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients admitted to intensive care unit</td>
<td>202</td>
<td>100</td>
</tr>
<tr>
<td>No. of patients who died during initial hospitalization</td>
<td>24</td>
<td>12</td>
</tr>
<tr>
<td>No. (%) of patients readmitted to hospital within 30 days of hospital discharge</td>
<td>41 (23)</td>
<td>16 (18)</td>
</tr>
</tbody>
</table>

*Values in second and third column are number (percentage) of patients unless otherwise noted.*
transition into an adult ICU proved to be achievable and sustainable at little incremental cost.

Our findings that PCPs perceived that direct communication was useful, assisted them with follow-up care, and allowed them to participate in the plan of care is consistent with the results of many other studies.1,3,6 The PCPs commented during the survey interview that they preferred communication by telephone, which has been previously reported.3 However, some PCPs reported that e-mail was just as informative and convenient and could be bidirectional. Many e-mail responses included, “thank you for taking the time to notify me.” and at other times, the PCP provided information that assisted the ICU team in plan of care, such as providing the patient’s baseline creatinine level or blood pressure. Our findings are consistent with results reported by other researchers, who also note the limitations of a nonstandardized approach to communication with PCPs.1,3,9 Our findings support a standardized and interprofessional team-integrated approach to communication with the PCPs of adult ICU patients.

A secondary aim of our study was to explore the impact of the communication intervention on 30-day hospital readmission rates. In accord with our expectations, the differences in readmission rates from this 100-encounter study were not statistically significant, and we cannot tell if these differences were due to chance or were not detected as significant because of the small sample size of the study. The study results do allow us to estimate that groups of 1200 encounters would allow an 80% probability of achieving significance at the .05 level.

The rate of nonresponse by PCPs to 3 communication attempts that were made during regular working hours was higher than we expected. We identified coverage and communication system issues specific to certain PCP’s practices that prevented 17% of initial contact attempts, suggesting that improvement efforts may be of value. Further research will be helpful for understanding practice-specific factors that prevent office-delivered notifications from reaching PCPs and why some calls are not returned.

This study has important limitations that must be considered when interpreting its findings, including bias inherent to its pre-post design. First, although the study was adequately powered to detect achievable increases in communication frequency, it was not large enough to interrogate effects of the intervention on 30-day readmission rates. Moreover, the study provides limited information about the impact of the intervention in settings where the frequency of communication with PCPs is high or in settings where most patients do not have a PCP. The scope and size of the study also prevented inferences regarding outcomes that we know are important, including mortality, length of stay, and functional status over time. In addition, the study provides only limited information regarding the impact of the intervention on the relationships among acute care providers and PCPs. Furthermore, PCPs who could not be reached may have had different opinions on the importance of communicating with acute care providers, decreasing our findings of the usefulness of the intervention. Additional studies to evaluate whether this communication and documentation intervention affects morbidity and mortality, hospital costs, rehospitalization rates, and provider-to-provider relationships are needed.

This new paradigm of communication is an achievable low-cost remedy that can sustainably increase the frequency of communication among acute care providers and PCPs. Communication when a patient is being transferred into an adult ICU increases opportunities for providers to work together to bridge the gaps that can occur when patients move between health care settings.

FINANCIAL DISCLOSURES
The authors acknowledge UMass Memorial Medical Center for their generous support of this study, which was conducted without extramural support.

REFERENCES

To purchase electronic or print reprints, contact American Association of Critical-Care Nurses, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 889-1712 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.
Background

Vasopressors are lifesaving agents used to raise mean arterial pressure in critically ill patients in shock states. The pharmacodynamics of these agents suggest vasopressors may play a role in development of pressure ulcers; however, this aspect has been understudied.

Objective

To examine associations between type, dose, and duration of vasopressors (norepinephrine, epinephrine, vasopressin, phenylephrine, dopamine) and development of pressure ulcers in medical-surgical and cardiothoracic intensive care unit patients and to examine predictors of the development of pressure ulcers in these patients.

Methods

A retrospective correlational design was used in a sample of 306 medical-surgical and cardiothoracic intensive care unit patients who received vasopressor agents during 2012.

Results

Norepinephrine and vasopressin were significantly associated with development of pressure ulcers; vasopressin was the only significant predictor in multivariate analysis. In addition, mean arterial pressure less than 60 mm Hg in patients receiving vasopressors, cardiac arrest, and mechanical ventilation longer than 72 hours were predictive of development of pressure ulcers. Patients with a cardiac diagnosis at the time of admission to the intensive care unit were less likely than patients without such a diagnosis to experience pressure ulcers while in the unit.

Conclusion

The addition of vasopressin administered concomitantly with a first-line agent (often norepinephrine) may represent the point at which the risk for pressure ulcers escalates and may be an early warning to heighten strategies to prevent pressure ulcers. Conversely, because vasopressors cannot be terminated to avert development of pressure ulcers, these findings may add to the body of knowledge on factors that potentially contribute to the development of unavoidable pressure ulcers. (American Journal of Critical Care. 2015;24:501-511)
More than 5 million patients are treated annually in intensive care units (ICUs) across the United States. Contemporary ICUs manage the sickest of the sick in the health care system in a technologically demanding environment. As a result, patients are surviving illnesses that mere decades ago would have resulted in certain death. The severity of illness experienced by ICU patients and use of multiple lifesaving treatments place these patients at great risk for development of pressure ulcers. ICU patients have the highest nosocomial rates of pressure ulcers among hospitalized patients, between 12% and 42%, and the estimated attributable costs are $1.99 billion annually.2-5

The major causes of a pressure ulcer are pressure and tissue tolerance.6 Although the intensity and duration of pressure experienced contribute to tissue ischemia, tissue tolerance determines the ability of the skin and underlying structures to withstand pressure successfully. Tissue tolerance is influenced by both extrinsic risk factors such as friction, shear, and moisture and intrinsic factors such as nutritional status, age, hypotension, comorbid conditions, and poor oxygen perfusion.6

Although development of pressure ulcers in a hospitalized patient has been deemed a “never event” since 2008,7 the premise that pressure ulcers are unavoidable, especially in patients who are extremely medically compromised, is gaining acknowledgment and acceptance. In a recent consensus conference of the National Pressure Ulcer Advisory Panel, intrinsic and nonmodifiable factors, including unstable hemodynamic status with repositioning, marked cardiopulmonary compromise leading to impaired tissue oxygenation and poor tissue perfusion, shock states, and the initiation of life-saving treatments for which either the implementation of pressure ulcer prevention strategies would be contraindicated or would take priority over pressure ulcer prevention, were all cited as potential contributors to unavoidable pressure ulcers.8

Vasopressors are lifesaving drugs used to increase mean arterial pressure (MAP) in critically ill patients with hypoxia and impaired tissue perfusion.9,10 The pharmacodynamics of vasopressors suggests that these medications may play a role in altering tissue tolerance and may contribute to development of pressure ulcers. The vasoconstriction that occurs in response to both the administration of the agent and the hypotension that necessitates use of the agent can induce inadequate perfusion of the extremities, mesenteric organs, and kidneys.9 Although vasopressors are not new medications, they have reemerged as important agents for treatment of shock states.11,12

**Review of the Relevant Literature**

The role of vasopressor administration in development of pressure ulcers has been understudied, but use of these agents may be an important risk factor. Investigations that included vasopressors as a variable in ICU patients have yielded various degrees of empirical evidence.

In a few studies,13-15 no significant relationship between vasopressor use and development of pressure ulcers was detected. In other studies,16,17 relationships between vasopressor administration and development of pressure ulcers was significant; however, the specific vasopressors used were not identified. In still other studies, the specific vasopressors were indicated, but a generic variable was used for analysis, yielding significant relationships with development of pressure ulcers in both multivariate18 and univariate19 analyses. In 2 studies with multivariate analyses,20,21 norepinephrine was significantly associated with development of pressure ulcers, whereas in another study,22 moderate doses of norepinephrine were significantly related to development of pressure ulcers.

In summary, emerging evidence supports use of vasopressors as a potential risk factor for pressure ulcers, with preliminary evidence indicating that use of norepinephrine is a risk factor. Because of the lack of clarity about the vasopressors used in many studies, discerning the agents that may pose
the greatest risk is difficult. Minimal evidence exists on the effect of dose and duration of administration of individual agents, because the physiological effects can vary according to the dose delivered and the receptors targeted9,10,23-26 (Table 1). Last, concomitant administration of more than a single vasopressor, as is the standard of care in the treatment of refractory vasodilatory shock states such as septic shock,12 has not been studied in relation to the risk for pressure ulcers.

The purpose of this study was to examine the associations between type, dose, and duration of administration of vasopressor agents (norepinephrine, epinephrine, vasopressin, phenylephrine, dopamine) and development of pressure ulcers in ICU patients in medical-surgical and cardiovascular units and to examine factors significantly predictive of development of pressure ulcers in these patients.

### Methods

#### Study Design and Setting

A retrospective, descriptive correlational design was used for the study. The setting was a 12-bed medical-surgical ICU and a 6-bed cardiovascular ICU, both intensivist led, in Englewood Hospital and Medical Center, Englewood, New Jersey, a 500-bed Magnet teaching hospital.

#### Sample

All adult patients admitted to the 2 ICUs during 2012 were considered for participation according to the following criteria. Patients were included if they were 18 years or older, were in the ICU more than 24 hours, and were given a vasoressor during the ICU admission. Patients were excluded if they were younger than 18 years, were in the ICU for 24 hours or less, were not given a vasoressor during the ICU admission, or had a preexisting pressure ulcer of any stage on the time of ICU admission. In order to achieve statistical power, a sample size of 300 was calculated for multivariate analysis, according to the accepted rule of 10 participants for each predictor variable under investigation (10 to 1).27

### Data Collection

All variables abstracted from electronic medical records and used for analysis are summarized in Table 2. The dependent variable was the presence or absence of a pressure ulcer at the time of discharge from the ICU.

Staff ICU nurses were recruited and trained to assist with the data abstraction. All staff nurses at Englewood Hospital and Medical Center are required to participate in annual mandatory education on pressure ulcers. This study was approved by the appropriate institutional review boards.

### Data Analysis

SPSS, version 21.0 for Windows, software (IBM SPSS), was used for data analysis. Descriptive statistics including frequency distributions for all study variables were calculated. Differences between patients in whom pressure ulcers did and did not develop were determined by using t tests and $\chi^2$ analyses. The Pearson product moment correlation was used for correlational analyses of the study variables. Direct logistic regression was used to determine the model that yielded the best prediction of the development of pressure ulcers.

### Results

#### Description of the Sample

Demographic variables are summarized in Table 3. The final sample for data analysis consisted of 306 patients. The mean age was 71 (SD, 13.8) years, 57% of the patients (n = 175) were men, and 78% (n = 238) were white. The mean ICU length of stay was 6.7 (SD, 7) days. The top 2 ICU admitting diagnoses were cardiac conditions (59%) and infection or sepsis (16%). The most common shock
states were cardiogenic shock (26%) and septic shock (22%). Compliance with the evidence-based protocol for preventing pressure ulcers was documented for 92% of the study sample. All ICU beds were equipped with low-air-loss mattresses.

**Descriptive Statistics of the Study Variables**

Table 4 is a summary of the descriptive statistics of the study variables. The occurrence rate of pressure ulcers for this study sample was 13% (n = 41). Of these, 39% (n = 16) were staged as suspected deep tissue injury. The most common anatomical location reported was the sacrum (56%; n = 23; Table 5).

Of the 306 patients, 84% (n = 257) received norepinephrine. Statistically significant differences between the groups were found for norepinephrine for the total number of infusion hours, highest dose received of the agent, and the number of hours of infusion at each dose range. Of the 41 patients in whom pressure ulcers developed, 37 (90%) received norepinephrine. Vasopressors administered for the entire sample and for each subgroup (acquired pressure ulcers vs no pressure ulcers) are summarized in Table 6.

The following variables, for which correlational analyses indicated a significant relationship to development of pressure ulcers, were included in the final regression equation: length of stay before the ICU admission \( (r = 0.134; P = 0.02) \), cardiac surgery diagnosis \( (r = 0.189; P = 0.001) \), score on the Braden scale at ICU admission \( (r = -0.182; P = 0.002) \), ICU admitting diagnosis \( (r = 0.127; P = 0.03) \), peripheral necrosis due to vasopressor use \( (r = 0.176; P = 0.002) \), cardiac arrest \( (r = 0.184; P = 0.001) \), cardiovascular disease \( (r = 0.151; P = 0.008) \), mechanical ventilation greater than 72 hours \( (r = -0.479; P < 0.001) \), hours of MAP less than 60 mm Hg while receiving vasopressor agents \( (r = 0.342; P < 0.001) \), norepinephrine \( (r = 0.119; P = 0.04) \), and vasopressin \( (r = 0.372; P < 0.001) \). According to direct logistic regression, the following variables were significant predictors of the development of pressure ulcers (Table 7): cardiac arrest \( (B = 1.359; P = 0.05; \text{OR} = 3.894; 95\% \text{CI} = 0.998-15.118) \), mechanical ventilation longer than 72 hours \( (B = 3.161; P < 0.001; \text{OR} = 23.604; 95\% \text{CI} = 6.427-86.668) \), hours of MAP less than 60 mm Hg while receiving vasopressors \( (B = 0.092; P = 0.01; \text{OR} = 1.096; 95\% \text{CI} = 1.020-1.178) \), administration of vasopressin \( (B = 1.572; P = 0.004; \text{OR} = 4.816; 95\% \text{CI} = 1.666-13.925) \), and cardiac diagnosis at time of ICU admission \( (B = -3.360; P = 0.03; \text{OR} = 0.035; 95\% \text{CI} = 0.002-0.764) \).

**Discussion**

We found that norepinephrine and vasopressin were significantly associated with development of...
pressure ulcers; in multivariate analysis, vasopressin was the only agent that was a significant predictor. Development of a pressure ulcer was almost 5 times more likely in patients who received vasopressin than in patients who did not receive the drug.

Whereas norepinephrine, epinephrine, and phenylephrine are sympathomimetic agents, vasopressin (antidiuretic hormone) is not. Rather, it is categorized as a peptide hormone. At higher doses, vasopressin induces potent vasoconstriction in the systemic, splanchnic, renal, and coronary arteries. Vasopressin is often used as a second-line agent in refractory vasodilatory shock states such as septic shock and can reduce the dosage levels required for the first-line agent, commonly norepinephrine. In our study, 15 of the 41 patients (37%) who had a pressure ulcer had a diagnosis of septic shock, the most frequently occurring shock state in these patients. Compared with ulcer-free patients, patients in whom pressure ulcers developed also had statistically significant longer infusion times of vasopressin (32 hours vs 87 hours; \( P = .005 \)) and longer infusion times of high-dose vasopressin (20 hours vs 57 hours; \( P = .03 \)).

In patients who received 2 vasopressors concurrently, the difference between patients with and without pressure ulcers was significant for the combination of norepinephrine and vasopressin (\( \chi^2 = 39.3; \ P < .001 \)). More than 50% of the patients in whom a pressure ulcer developed had received this combination. It is plausible that the need to add vasopressin, a second-line drug, to a patient’s treatment might represent a “tipping point,” increasing the risk for development of pressure ulcers, especially in patients who had longer infusion times for vasopressin at rates greater than 0.03 U/min.

Examination of the interaction between vasopressin and other vasopressors revealed significant differences between the combinations of phenylephrine plus vasopressin and epinephrine plus vasopressin, also suggesting that the need for a second vasopressor agent may indicate the point at which the risk for pressure ulcers escalates (Table 8). The need for a second vasopressor may be an early warning for nurses to increase pressure ulcer prevention strategies. Moreover, because administration of these agents cannot be stopped to avert development of pressure ulcers, this finding may add to the knowledge about factors that potentially contribute to the development of unavoidable pressure ulcers.

Longer duration of MAP less than 60 mm Hg while receiving vasopressor agents was also a significant predictor of pressure ulcers in our sample. Hypotension has been significantly associated with development of pressure ulcers in previous studies in ICU patients. However, we examined hypotension refractory to treatment with vasopressors. Hypotension is the most common indicator that perfusion is inadequate. In a hypotensive state, blood is shunted to the central circulation to preserve end-organ function, thus away from the peripheral circulation supporting the skin. This shunting decreases the tissue tolerance of the skin to pressure and shear forces, contributing to development.

### Table 3

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), range, y</td>
<td>71 (13.8), 21-98</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>175 (57)</td>
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<tr>
<td>Female</td>
<td>131 (43)</td>
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<tr>
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</tr>
<tr>
<td>White</td>
<td>238 (78)</td>
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<tr>
<td>Hispanic</td>
<td>19 (6)</td>
</tr>
<tr>
<td>Black/African American</td>
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<tr>
<td>Other</td>
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<td>Cardiac</td>
<td>171 (56)</td>
</tr>
<tr>
<td>Infection/sepsis</td>
<td>42 (14)</td>
</tr>
<tr>
<td>Respiratory</td>
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<tr>
<td>Gastrointestinal</td>
<td>23 (8)</td>
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<td>Surgery</td>
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<td>Vascular</td>
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<td>8 (3)</td>
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<td>Septic shock</td>
<td>67 (22)</td>
</tr>
<tr>
<td>Hypovolemic</td>
<td>24 (8)</td>
</tr>
<tr>
<td>Multiple organ dysfunction syndrome</td>
<td>4 (1)</td>
</tr>
<tr>
<td>Neurogenic</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Cardiac surgery</td>
<td></td>
</tr>
<tr>
<td>Coronary artery bypass graft (CABG)</td>
<td>68 (22)</td>
</tr>
<tr>
<td>Valve replacement surgery</td>
<td>44 (14)</td>
</tr>
<tr>
<td>CABG and valve replacement</td>
<td>28 (9)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (3)</td>
</tr>
<tr>
<td>Thoracic aneurysm repair</td>
<td>7 (2)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Unless otherwise indicated, data in the table are expressed as number (percentage). Because of rounding, not all percentages total 100.
Table 4
Comparison of study variables between patients with acquired pressure ulcers and patients without pressure ulcers

<table>
<thead>
<tr>
<th>Variablea</th>
<th>All patients (N = 306)</th>
<th>Pressure ulcer acquired (n = 41)</th>
<th>No pressure ulcer (n = 265)</th>
<th>Test statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>71 (14)</td>
<td>74 (10)</td>
<td>71 (14)</td>
<td>t = -1.39 (P = .17)</td>
</tr>
<tr>
<td>Total hospital length of stay, days</td>
<td>13 (11)</td>
<td>20 (12)</td>
<td>12 (11)</td>
<td>t = -5.80 (P &lt; .001)</td>
</tr>
<tr>
<td>Total length of stay before ICU admission, days</td>
<td>2 (3)</td>
<td>3 (6)</td>
<td>2 (3)</td>
<td>t = -2.35 (P = .02)</td>
</tr>
<tr>
<td>Total ICU length of stay, days</td>
<td>7 (7)</td>
<td>15 (10)</td>
<td>5 (5)</td>
<td>t = -5.80 (P &lt; .001)</td>
</tr>
<tr>
<td>Body mass index&lt;18.5, No. (%) of patients</td>
<td>26 (8)</td>
<td>4 (10)</td>
<td>22 (8)</td>
<td>χ² = 0.2 (P = .89)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>80 (21)</td>
<td>74 (23)</td>
<td>78 (21)</td>
<td>t = 0.85 (P = .34)</td>
</tr>
<tr>
<td>Prealbumin, mg/dL (n = 54)</td>
<td>8 (5)</td>
<td>8 (5) (n = 19)</td>
<td>7 (6) (n = 35)</td>
<td>t = -0.66 (P = .51)</td>
</tr>
</tbody>
</table>

Score on Braden Scale

| At hospital admission | 18 (12), range 7-21 | 15 (4) | 18 (13) | t = 2.00 (P = .05) |
| At ICU admission      | 13 (3), range 7-23  | 12 (2) | 13 (3)  | t = 3.96 (P < .001) |

APACHE II score, No. (%) of patients

| Entire sample | 109 (36) | 6 (15) | 103 (39) | χ² = 8.8 (P = .003) |
| Noncardiac patients | 197 (64) | 35 (85) | 162 (61) | χ² = 4.5 (P = .05) |
| ≤ 19 | 48 (32) | 5 (16) | 43 (36) | |
| ≥ 20 | 102 (68) | 26 (84) | 76 (64) | |

Comorbid conditions, No. (%) of patients

| Severe anemia | 46 (15) | 9 (22) | 37 (14) | χ² = 1.8 (P = .24) |
| Peripheral necrosis due to vasopressor use | 5 (2) | 3 (7) | 2 (1) | χ² = 9.5 (P = .002) |
| Cardiac arrest | 36 (12) | 13 (32) | 33 (12) | χ² = 10.3 (P < .001) |
| Diabetes mellitus | 106 (35) | 13 (32) | 93 (35) | χ² = 0.2 (P = .67) |
| Peripheral arterial disease | 28 (9) | 6 (15) | 22 (8) | χ² = 1.7 (P = .20) |
| Cardiovascular disease | 230 (75) | 24 (59) | 206 (78) | χ² = 7.0 (P = .008) |

Mechanical ventilation>72 hours, No. (%) of patients

| 91 (30) | 35 (85) | 56 (21) | χ² = 70.1 (P < .001) |

No. of hours of MAP<60 mm Hg on vasopressors

| 3 (9) | 11 (21) | 2 (4) | t = -2.72 (P = .01) |

Died in the ICU, No. (%) of patients

| 79 (26) | 26 (63) | 53 (20) | χ² = 34.9 (P < .001) |

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; ICU, intensive care unit; MAP, mean arterial pressure.

* Unless otherwise indicated, data in the table are expressed as mean (SD). Because of rounding, percentages may not total 100.

** Calculated as weight in kilograms divided by height in meters squared.

of pressure ulcers. Hypotension that persists despite these agents may be an indication of a severely and possibly terminally compromised patient. Persistent hypotension in combination with administration of a vasopressor may also be a warning sign that a patient is experiencing prolonged diminished perfusion to the skin, elevating the risk for pressure ulcers. Although repositioning strategies can be implemented in patients with unstable hemodynamic status, the success of the intervention depends on stabilization of blood pressure after a position change. Caregivers should be aware that the potential damage to the skin due to hypotension may be nonmodifiable in some instances, even with the use of current evidence-based prevention strategies, because the underlying condition (hypotension refractory to vasopressors) cannot be successfully abated.

Patients who required mechanical ventilation for more than 72 hours were 23 times more likely than patients who did not to have a pressure ulcer, a finding supported in the literature. In our study, 35 of the 41 patients with pressure ulcers received mechanical ventilation for more than 72 hours. Perhaps the need for prolonged mechanical ventilation is an indication of both immobility (due to sedation) and severe illness, both of which are required during mechanical ventilation may predispose a patient to shear forces and elevate the risk for pressure ulcers. Although health care practice is moving away from deep sedation and toward early

Norepinephrine and vasopressin were associated with pressure ulcer development.

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mobility, current guidelines recommend that sedative medications be titrated to maintain a lighter rather than a deeper level of sedation.\textsuperscript{36,39} However, these guidelines clearly recognize that clinical situations exist for which lighter levels of sedation would be contraindicated.\textsuperscript{38} Additionally, 80\% (n = 73) of the patients treated with prolonged mechanical ventilation had an APACHE II score of 20 or higher, representing a higher severity of illness.\textsuperscript{28} Even with the consistent implementation of prevention strategies, the association between need for prolonged mechanical ventilation and development of pressure ulcers was significant.

Cardiac arrest was also a significant predictor of pressure ulcers in our study. Among the sample of 306 patients, 46 had a cardiac arrest, with a survival rate of 22\%, higher than the reported survival rate of 15\%.\textsuperscript{28} A pressure ulcer developed in 13 of these 46 patients, representing 32\% of the 41 patients

### Table 5

Analysis of pressure ulcers (N = 306)

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%) of patients\textsuperscript{a}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure ulcer stage</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>5 (12)</td>
</tr>
<tr>
<td>II</td>
<td>15 (37)</td>
</tr>
<tr>
<td>III</td>
<td>0 (0)</td>
</tr>
<tr>
<td>IV</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Unstageable</td>
<td>5 (12)</td>
</tr>
<tr>
<td>Suspected deep tissue injury</td>
<td>16 (39)</td>
</tr>
<tr>
<td>Location</td>
<td></td>
</tr>
<tr>
<td>Sacrum</td>
<td>23 (56)</td>
</tr>
<tr>
<td>Buttocks</td>
<td>14 (34)</td>
</tr>
<tr>
<td>Heel</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Days to pressure ulcer detection</td>
<td></td>
</tr>
<tr>
<td>1-3</td>
<td>16 (39)</td>
</tr>
<tr>
<td>4-6</td>
<td>10 (24)</td>
</tr>
<tr>
<td>7-9</td>
<td>5 (12)</td>
</tr>
<tr>
<td>&gt;9</td>
<td>10 (24)</td>
</tr>
</tbody>
</table>

\textsuperscript{a} Because of rounding, percentages may not total 100.

### Table 6

Vasopressor agents and comparison of patients with and without acquired pressure ulcers

<table>
<thead>
<tr>
<th>Agent</th>
<th>All patients</th>
<th>Pressure ulcer acquired</th>
<th>No pressure ulcer</th>
<th>Test statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norepinephrine</td>
<td>n = 257</td>
<td>n = 37</td>
<td>n = 218</td>
<td>$\chi^2 = 4.3$ (P = .04)</td>
</tr>
<tr>
<td>Total hours of infusion</td>
<td>49 (55)</td>
<td>98 (109)</td>
<td>31 (30)</td>
<td>t = -3.81 (P &lt;.001)</td>
</tr>
<tr>
<td>Highest dose received, $\mu$g/min</td>
<td>10 (8.5)</td>
<td>17 (10)</td>
<td>9 (8)</td>
<td>t = -4.66 (P &lt;.001)</td>
</tr>
<tr>
<td>Lowest dose received, $\mu$g/min</td>
<td>2 (2.7)</td>
<td>2.5 (4)</td>
<td>2.3 (2)</td>
<td>t = -0.34 (P = .51)</td>
</tr>
<tr>
<td>No. of hours of high dose ($\geq 15.1 \mu$g/min)</td>
<td>6 (22)</td>
<td>26 (50)</td>
<td>2 (7)</td>
<td>t = -2.90 (P &lt;.001)</td>
</tr>
<tr>
<td>No. of hours of midrange dose (5.1-15 $\mu$g/min)</td>
<td>15 (27)</td>
<td>39 (54)</td>
<td>11 (16)</td>
<td>t = -3.16 (P &lt;.003)</td>
</tr>
<tr>
<td>No. of hours of low dose (1-5 $\mu$g/min)</td>
<td>18 (21)</td>
<td>28 (29)</td>
<td>17 (18)</td>
<td>t = -2.31 (P = .02)</td>
</tr>
<tr>
<td>Vasopressin</td>
<td>n = 54</td>
<td>n = 22</td>
<td>n = 32</td>
<td>$\chi^2 = 42.3$ (P &lt;.001)</td>
</tr>
<tr>
<td>Total hours of infusion</td>
<td>54 (61)</td>
<td>87 (80)</td>
<td>32 (29)</td>
<td>t = -3.04 (P &lt;.005)</td>
</tr>
<tr>
<td>Highest dose received, U/min</td>
<td>0.05 (0.02)</td>
<td>0.04 (0.02)</td>
<td>0.04 (0.02)</td>
<td>t = -0.66 (P = .51)</td>
</tr>
<tr>
<td>Lowest dose received, U/min</td>
<td>0.02 (0.02)</td>
<td>0.02 (0.00)</td>
<td>0.06 (0.20)</td>
<td>t = 1.40 (P = .17)</td>
</tr>
<tr>
<td>No. of hours of high dose ($\geq 0.03$ U/min)</td>
<td>35 (52)</td>
<td>57 (73)</td>
<td>20 (23)</td>
<td>t = -2.29 (P = .03)</td>
</tr>
<tr>
<td>No. of hours of low dose (&lt;0.03 U/min)</td>
<td>20 (20)</td>
<td>29 (44)</td>
<td>12 (17)</td>
<td>t = -1.68 (P = .10)</td>
</tr>
<tr>
<td>Epinephrine</td>
<td>n = 61</td>
<td>n = 8</td>
<td>n = 53</td>
<td>$\chi^2 = 0.0$ (P = .57)</td>
</tr>
<tr>
<td>Total hours of infusion</td>
<td>45 (49)</td>
<td>124 (86)</td>
<td>33 (25)</td>
<td>t = -2.97 (P = .02)</td>
</tr>
<tr>
<td>Highest dose received, $\mu$g/min</td>
<td>8 (7)</td>
<td>16 (6)</td>
<td>6 (6)</td>
<td>t = -4.42 (P &lt;.001)</td>
</tr>
<tr>
<td>Lowest dose received, $\mu$g/min</td>
<td>2.4 (3)</td>
<td>5 (4)</td>
<td>2 (2)</td>
<td>t = -1.60 (P = .15)</td>
</tr>
<tr>
<td>No. of hours of high dose ($\geq 15.1 \mu$g/min)</td>
<td>5 (15)</td>
<td>25 (35)</td>
<td>2 (6)</td>
<td>t = -1.93 (P = .09)</td>
</tr>
<tr>
<td>No. of hours of midrange dose (5.1-15 $\mu$g/min)</td>
<td>20 (35)</td>
<td>78 (47)</td>
<td>11 (22)</td>
<td>t = -3.93 (P &lt;.005)</td>
</tr>
<tr>
<td>No. of hours of low dose (1-5 $\mu$g/min)</td>
<td>20 (20)</td>
<td>20 (31)</td>
<td>20 (17)</td>
<td>t = 0.06 (P = .95)</td>
</tr>
<tr>
<td>Phenylephrine</td>
<td>n = 22</td>
<td>n = 4</td>
<td>n = 18</td>
<td>$\chi^2 = 0.5$ (P = .51)</td>
</tr>
<tr>
<td>Total hours of infusion</td>
<td>39 (72)</td>
<td>89 (140)</td>
<td>24 (29)</td>
<td>t = -1.04 (P = .35)</td>
</tr>
<tr>
<td>Highest dose received, $\mu$g/min</td>
<td>67 (60)</td>
<td>101 (107)</td>
<td>57 (38)</td>
<td>t = -1.46 (P = .14)</td>
</tr>
<tr>
<td>Lowest dose received, $\mu$g/min</td>
<td>12 (13)</td>
<td>10 (9)</td>
<td>12 (15)</td>
<td>t = 0.29 (P = .71)</td>
</tr>
<tr>
<td>No. of hours of high dose ($\geq 100$ $\mu$g/min)</td>
<td>9 (38)</td>
<td>38 (79)</td>
<td>0.4 (1.4)</td>
<td>t = -1.08 (P = .33)</td>
</tr>
<tr>
<td>No. of hours of midrange dose (51-100 $\mu$g/min)</td>
<td>10 (25)</td>
<td>13 (29)</td>
<td>9 (25)</td>
<td>t = -0.29 (P = .80)</td>
</tr>
<tr>
<td>No. of hours of low dose (1-50 $\mu$g/min)</td>
<td>17 (23)</td>
<td>25 (39)</td>
<td>14 (17)</td>
<td>t = -0.94 (P = .57)</td>
</tr>
<tr>
<td>Dopamine</td>
<td>n = 55</td>
<td>n = 4</td>
<td>n = 51</td>
<td>$\chi^2 = 2.2$ (P = .10)</td>
</tr>
<tr>
<td>Total hours of infusion</td>
<td>28 (63)</td>
<td>139 (210)</td>
<td>19 (22)</td>
<td>t = -4.20 (P &lt;.001)</td>
</tr>
<tr>
<td>Highest dose received ($\mu$g/kg per minute)</td>
<td>8 (5)</td>
<td>11 (5)</td>
<td>8 (5)</td>
<td>t = -1.18 (P = .24)</td>
</tr>
<tr>
<td>Lowest dose received ($\mu$g/kg per minute)</td>
<td>3 (3)</td>
<td>3 (1)</td>
<td>3 (3)</td>
<td>t = 0.26 (P = .79)</td>
</tr>
<tr>
<td>No. of hours of high dose ($\geq 15.1 \mu$g/kg per minute)</td>
<td>1 (5)</td>
<td>2 (3)</td>
<td>1 (5)</td>
<td>t = -0.14 (P = .89)</td>
</tr>
<tr>
<td>No. of hours of midrange dose (5.1-15 $\mu$g/kg per minute)</td>
<td>8 (17)</td>
<td>31 (42)</td>
<td>6 (13)</td>
<td>t = -2.99 (P = .004)</td>
</tr>
<tr>
<td>No. of hours of low dose (1-5 $\mu$g/kg per minute)</td>
<td>19 (51)</td>
<td>107 (170)</td>
<td>12 (15)</td>
<td>t = -4.07 (P &lt;.001)</td>
</tr>
</tbody>
</table>

\textsuperscript{a} Data in the second, third, and fourth column are expressed as mean (SD).
who had pressure ulcers. Cardiac arrest induces the ultimate hypoperfusion state. Resuscitation efforts are aimed at improving central circulation and oxygenation and preserving brain function; hence, flow of oxygenated blood to the skin and the extremities is decreased.40 Care during and after the cardiac arrest is focused on lifesaving therapies, including administration of vasopressor agents. Thus, development of pressure ulcers may be attributed to the hypoperfusion state that occurs as a result of the cardiac arrest or the inability to apply interventions to prevent pressure ulcers or both during the cardiac arrest and immediately after as care priorities are shifted to life preservation.

Among the subset of 41 patients in whom a pressure ulcer developed, 16 had suspected deep-tissue injury, and in 14 of those the ulcers were located on the sacrum and buttocks. One of the most common anatomical locations for pressure ulcers is the sacrococcygeal region because of the lack of soft-tissue mass (muscle, fascia) between the bone and skin layers.4-35 Suspected deep-tissue injury was added to the National Pressure Ulcer Advisory Panel Staging System in 2007.11 Deep-tissue injuries begin in the deep layers at the muscle-bone interface and progress outward to the epidermal layers and sometimes are not visible for many days.42-45 Muscle is a highly vascularized tissue, with high metabolic demands and low tissue tolerance for sustained compression, increasing its susceptibility to pressure and development of pressure ulcers.35,46 The peripheral vasoconstriction induced by vasopressors further shunts blood away from the skin and underlying structures and may further contribute to deep-tissue injury, especially in the already susceptible anatomical areas of the sacrococcygeal region.

**Limitations**

The retrospective design of this study may be considered a limitation; however, all of the variables abstracted reflected objective clinical assessment parameters documented for all ICU patients who received vasopressor agents. Use of a single site is also a limitation because it can decrease the generalizability of the study findings. Inclusion of the APACHE II variable for the entire sample may also be a limitation, because the APACHE II is a poor prognostic indicator among cardiac surgery patients47-49; consequently, we eliminated this variable from the main analysis.

**Conclusion**

Prevention of pressure ulcers is part of routine patient care in every ICU. Consistent application of

---

**Table 7**

Logistic regression analysis*

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>SE</th>
<th>Wald</th>
<th>P</th>
<th>Exp (B)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac arrest</td>
<td>1.359</td>
<td>0.605</td>
<td>3.831</td>
<td>.05</td>
<td>3.894</td>
<td>0.998-15.188</td>
</tr>
<tr>
<td>Mechanical ventilation &gt; 72 hours</td>
<td>3.161</td>
<td>0.664</td>
<td>22.686</td>
<td>&lt;.001</td>
<td>23.604</td>
<td>6.427-86.668</td>
</tr>
<tr>
<td>Hours of MAP &lt; 60 mm Hg while receiving vasopressors</td>
<td>0.092</td>
<td>0.037</td>
<td>6.199</td>
<td>.01</td>
<td>1.096</td>
<td>1.020-1.178</td>
</tr>
<tr>
<td>Use of vasopressin</td>
<td>1.572</td>
<td>0.542</td>
<td>8.423</td>
<td>.004</td>
<td>4.816</td>
<td>1.666-13.925</td>
</tr>
<tr>
<td>Cardiac diagnosis at ICU admission</td>
<td>-3.360</td>
<td>1.577</td>
<td>4.539</td>
<td>.03</td>
<td>0.035</td>
<td>0.002-0.764</td>
</tr>
</tbody>
</table>

Abbreviations: ICU, intensive care unit; MAP, mean arterial pressure. * Nagelkerke $R^2 = 0.571$; Hosmer and Lemeshow test: $\chi^2 = 5.3; df = 8; P = .73$.

**Table 8**

Significant vasopressor interaction variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pressure ulcer acquired (n = 41)</th>
<th>No pressure ulcers (n = 265)</th>
<th>Test statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norepinephrine/vasopressin (n = 52)</td>
<td></td>
<td></td>
<td>$\chi^2 = 39.3 (P &lt; .001)$</td>
</tr>
<tr>
<td>Yes</td>
<td>21 (51)</td>
<td>31 (12)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>20 (49)</td>
<td>234 (88)</td>
<td></td>
</tr>
<tr>
<td>Phenylephrine/vasopressin (n = 10)</td>
<td></td>
<td></td>
<td>$\chi^2 = 6.3 (P = .03)$</td>
</tr>
<tr>
<td>Yes</td>
<td>4 (10)</td>
<td>6 (2)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>37 (90)</td>
<td>259 (98)</td>
<td></td>
</tr>
<tr>
<td>Epinephrine/vasopressin (n = 17)</td>
<td></td>
<td></td>
<td>$\chi^2 = 11.9 (P = .003)$</td>
</tr>
<tr>
<td>Yes</td>
<td>7 (17)</td>
<td>10 (4)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>34 (83)</td>
<td>255 (96)</td>
<td></td>
</tr>
<tr>
<td>Epinephrine/phenylephrine (n = 5)</td>
<td></td>
<td></td>
<td>$\chi^2 = 9.5 (P = .02)$</td>
</tr>
<tr>
<td>Yes</td>
<td>3 (7)</td>
<td>2 (1)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>38 (93)</td>
<td>263 (99)</td>
<td></td>
</tr>
</tbody>
</table>

Test statistic: No pressure ulcers (n = 265) / Pressure ulcer acquired (n = 41).
eLetters
Now that you’ve read the article, create or contribute to an online discussion on this topic. Visit www.ajcconline.org and click "Submit a response" in either the full-text or PDF view of the article.

REFERENCES
1. Which of the following is the estimated annual cost of nosocomial pressure ulcers in the intensive care unit (ICU)?
   a. $1.99 billion  
   b. $1.99 million  
   c. $2.5 billion  
   d. $2.5 million

2. Pressure ulcers were deemed a “never event” in which of the following years?
   a. 1999  
   b. 2002  
   c. 2008  
   d. 2010

3. The purpose of this study was to examine associations between type, dose, and duration of administration with how many vasopressor agents?
   a. 5  
   b. 2  
   c. 4  
   d. 3

4. To be included in the study, patients must have been admitted to the ICU for more than which of the following hours?
   a. 5  
   b. 4  
   c. 2  
   d. 3

5. The final sample for data analysis consisted of how many patients?
   a. 175  
   b. 238  
   c. 257  
   d. 306

6. In this study, which of the following was the most common location for a suspected deep tissue injury?
   a. Trochanters  
   b. Sacrum  
   c. Heels  
   d. Ischial tuberosities

7. Which of the following vasopressors is often used as a second-line agent in refractory vasodilatory shock states?
   a. Norepinephrine  
   b. Phenytoin  
   c. Epinephrine  
   d. Vasopressin

8. According to this and other studies, which of the following hemodynamic factors is significantly associated with the development of pressure ulcers?
   a. Increased systemic vascular volume  
   b. Hypotension  
   c. Hypertension  
   d. Increased heart rate

9. Current guidelines recommend that sedative medications be titrated to maintain a lighter rather than a deeper level of sedation.
   a. True  
   b. False

10. What was the mean age of the patients in this study?
    a. 80  
    b. 65  
    c. 71  
    d. 59

11. In this study sample, the rate of pressure ulcer occurrence was which of the following?
    a. 13%  
    b. 23%  
    c. 51%  
    d. 16%

12. According to Table 5, thirty-nine patients developed pressure ulcers in which of the following time frames?
    a. 4 to 6 days  
    b. 7 to 9 days  
    c. 1 to 3 days  
    d. > 9 days
Critically ill patients are at risk for alterations in skin integrity and pressure ulcer formation. The administration of vasopressors, used to increase arterial blood pressure, is a life-sustaining therapy that can influence the incidence of pressure ulcer formation among critically ill patients. Vasopressors are pharmacologic agents (eg, nesnephrine, norepinephrine, and vasopressin) that constrict arterial blood vessels, thus predisposing the critically ill recipient to tissue ischemia and a heightened risk for pressure ulcer development. Despite the emerging research that links vasopressor administration and pressure ulcer development, prior research has not examined the influence that the type of vasopressor agent, its dose, and duration of administration has on the occurrence of pressure ulcer formation among critically ill patients.

To examine the association between vasopressor administration (eg, type of agent, dose, and duration) and pressure ulcer development, the authors conducted a retrospective, descriptive study. They identified 306 critically ill adults who were admitted to a medical-surgical or cardiothoracic intensive care unit (ICU) for more than 24 hours, and received a vasopressor agent during the ICU stay. Data were collected on clinical characteristics such as comorbidities, descriptors of vasopressor administration (eg, type of agent, dose, and duration) and pressure ulcer characteristics (eg, Braden score, time to development, location, and stage). Bedside critical care nurses were recruited and trained to abstract the data from the electronic medical records. The findings of this study confirmed that vasopressin administration along with other clinical characteristics predicted a critically ill patient's likelihood for pressure ulcer formation. In addition to vasopressin, the authors report that cardiac arrest, mechanical ventilation for more than 72 hours, prolonged hypotension (mean arterial blood pressure).
pressure < 60 mm Hg), and a cardiovascular ICU admission were significant predictors of pressure ulcer formation. The authors conclude that vasopressor administration, in particular vasopressin, is linked to pressure ulcer formation among the critically ill.

Information From the Authors

Jill Cox, PhD, APN-C, CWOCN, lead author on this EBR article provides additional information about the study. Cox is an advanced practice nurse in the acute care setting with a specialty in wound, ostomy and continence care. In her clinical role, Cox is responsible for pressure ulcer prevention and treatment among hospitalized patients.

According to Cox, “The ICU is truly the epicenter for pressure ulcer development among hospitalized patients. Our journey began about 10 years ago with one burning question, ‘What are we missing with respect to pressure ulcer prevention?’” says Cox. Over the years, Cox and her colleagues have implemented evidence based pressure ulcer guidelines, and monitored compliance to the guidelines but pressure ulcer rates remained high.

To address the rates of pressure ulcer development at her institution, Cox partnered with her colleague, Sharon Roche, RN, PhD, APN-C, CCRN, an advanced practice nurse in critical care, to explore the relationship between vasopressor administration and pressure ulcer development in critically ill patients. “While the literature did support to varying degrees the relationship between vasopressor administration and pressure development, we wanted to explore whether certain certain doses, durations and combinations of these drugs contributed to pressure ulcer development,” Cox adds.

Implications for Practice

Cox encourages readers of the American Journal of Critical Care to continue to conduct pressure ulcer risk assessments and implement evidence-based prevention strategies for critically ill patients receiving vasopressors, with an awareness that risk factors such as vasopressor administration may potentially contribute to the development of unavoidable pressure ulcers.

She points out, “In this study, vasopressin as a second-line agent emerged as the only significant predictor among the 5 vasopressor agents and may represent the ‘tipping-point’ at which the patient’s risk for pressure ulcers significantly increases.” Cox hopes that the study findings heighten the awareness of critical care clinicians regarding vasopressor administration as a risk factor for pressure ulcer development.

Now that you’ve read the article, create or contribute to an online discussion on this topic. Visit www.ajcconline.org and click “Submit a response” in either the full-text or PDF view of the article.
Validity and Sensitivity of 6 Pain Scales in Critically Ill, Intubated Adults

By Mamoona Arif Rahu, RN, PhD, CCRN, Mary Jo Grap, RN, PhD, ACNP, Pam Ferguson, RN, BSN, CCRN, Patty Joseph, RN, BSN, CCRN, Sarah Sherman, NP, MSN, and R. K. Elswick, Jr, PhD

Background
Self-report is the best indicator of pain; however, pain is more difficult to assess in noncommunicative patients who may be receiving mechanical ventilation or sedated and unable to report pain.

Objectives
To evaluate the validity and sensitivity of 6 pain scales (Adult Nonverbal Pain Scale; Behavior Pain Scale [BPS]; Comfort Scale; FACES; Face, Legs, Activity, Cry, and Consolability scale; Pain Assessment Behavioral Scale with Numeric Rating Scale [NRP]) to identify the best measure of pain in noncommunicative patients.

Methods
Fifty communicative and 100 noncommunicative patients receiving mechanical ventilation were observed before and during routine physical examination and endotracheal tube suctioning.

Results
All pain scales had moderate to high correlations with the patient’s self-report during suctioning. The FACES score reported by the patient had the highest correlation with the patient’s NRP score ($r=0.76$, $P<.001$) during suctioning; associations between the BPS and NRP scores during physical examination were the weakest ($r=0.21$, $P=.20$). All scales were sensitive in capturing the patient’s pain response in all phases ($P<.001$); sensitivity was higher during suctioning ($P<.001$). Both participants and investigators rated pain higher on the FACES scale.

Conclusions
These pain scales commonly used in noncommunicative critically ill adult patients are valid and sensitive for capturing changes in pain response during suctioning in both communicative and noncommunicative patients. However, caution must be used when using the FACES scale because subjectivity may lead to overtreatment or undertreatment of pain. (American Journal of Critical Care. 2015;24:514-524)
Critically ill patients are subjected to a variety of uncomfortable and painful experiences during the course of hospitalization. Critically ill patients often experience inadequate pain relief. Not only do critically ill patients suffer pain that is due to their illness and disease state, but they also have pain caused by common procedures such as suctioning and repositioning. Self-reporting is the best method for evaluation of pain, but pain is more difficult to assess in noncommunicative patients, who may be receiving mechanical ventilation or sedated and unable to report pain. The American College of Critical Care Medicine has developed expert guidelines for preventing and treating pain in noncommunicative patients. In meeting these standards, health care agencies have instituted procedures to assess, diagnose, and treat pain systematically. However, these guidelines are difficult to implement without a single valid and reliable pain scale, especially for noncommunicative patients.

The ability to assess and document a patient’s pain correlates directly with the ability to manage pain. Therefore having a valid and reliable tool to use in managing pain in critically ill, sedated, noncommunicative patients is essential for health care providers. Although several behavioral pain tools have recently gained favor for use in intensive care units, no one tool is used universally in such patients. A systematic review describing instruments developed for pain assessment in noncommunicative patients revealed 5 pain assessment tools. Of those 5 tools, the Behavioral Pain Scale (BPS), the Critical-Care Pain Observation Tool (CPOT), and the Adult Nonverbal Pain Scale (ANVPS) had the highest psychometric score based on quality judgment criteria relating to validity and reliability. Scales such as the BPS, CPOT, and ANVPS show good interrater reliability and discriminant validation, although the degree of correlation with patients’ self-reports of pain vary.

Therefore, the purpose of this study was to evaluate the validity and sensitivity of 6 pain scales in an effort to identify the most appropriate measure of pain in noncommunicative patients (ie, patients receiving mechanical ventilation or sedated).

**Methods**

**Setting and Sample**

The study was conducted at Virginia Commonwealth University Medical Center, an academic medical center, and the sample of 150 patients receiving mechanical ventilation was drawn from patients more than 18 years old who were admitted to a medical respiratory intensive care unit. The sample of 150 consisted of 100 patients who were noncommunicative (unable to speak, write, or use eye or hand motions) and 50 communicative patients. This observation study was reviewed by the institutional review board, and a waiver of informed consent was approved. Patients requiring neuromuscular blocking agents and those with overt disease affecting the brain (head trauma, intracranial hemorrhage, and meningitis) were excluded because manifestations of pain may vary in such patients. Male and female patients from all ethnicities and racial backgrounds were recruited.

**Measurement of Key Variables**

**Characteristics of Patients.** Age, sex, ethnicity, duration of intubation, and reason for admission to the intensive care unit were collected from the medical record. To describe the sample, a measure of severity of illness was documented on admission to the study by using the Acute Physiology. Age, and Chronic Health Evaluation (APACHE) III. The APACHE III score was recorded from the medical record by using data from the 24 hours of data.
Pain was assessed before and during noxious and non-noxious procedures. Each patient enrolled in the study received 4 packets of pain assessment tools for the 4 phases of pain assessment. The nurse investigator assessed pain during 4 phases: (1) before physical examination (a procedure that is not noxious) when the patient appeared to be at rest and was comfortable, (2) during routine physical examination, (3) before routine endotracheal suctioning when the patient appeared to be at rest and was comfortable, and (4) during routine endotracheal suctioning (a noxious procedure). The patient’s nurse informed the investigator when the patient required suctioning according to clinical assessments and also when routine physical examination was to occur. The investigator observed the patient for 2 minutes and recorded pain assessments for phase 1 or phase 3. A period of at least 30 minutes separated phase 2 and phase 3 to reduce the effect of one procedure on the other.

Endotracheal suctioning did not occur simply for study purposes. Endotracheal tube suctioning is a noxious event. Heart rate and mean arterial pressure increase significantly during and after suctioning, returning to baseline approximately 5 minutes later. Therefore, it is reasonable to use a routine nursing intervention such as endotracheal suctioning in this study as a noxious procedure.

Communicative Patients. In the 50 patients who could communicate, the investigator used 6 pain assessment tools (ANVPS, BPS, COMFORT, FACES-Nurse, FLACC, and PABS) to evaluate pain, and the patients used the NRS and the FACES scale to rate their pain. Before the physical examination and the suctioning procedure, the investigator observed the patient for 2 minutes to assess pain level and then completed each tool. Second, the investigator asked the patient to rate his or her pain as a self-report measure by using the NRS and FACES scale and pointing to the corresponding image. The investigator and the patients used the same FACES scale. FACES-patient indicates results obtained from the patients and FACES-nurse indicates results obtained by the investigator. During the physical examination and suctioning procedure, the investigator observed the duration of the event and then completed each tool. Then the investigator asked the patient to rate his or her pain by using the NRS and FACES-patient.

Noncommunicative Patients. Noncommunicative patients were unable to rate their pain by using the NRS, so this tool was omitted for the 100 noncommunicative patients. The sensitivity of each of the 6 pain assessment tools (ANVPS, BPS, COMFORT, FACES-Nurse, FLACC, and PABS) was assessed by identifying changes in pain level during the 4 phases. The investigator followed the same steps to observe the patient for 2 minutes to obtain the patient’s pain level before the procedure and then

Level of Pain. The patient’s pain level was recorded by using the pain tools listed in Table 1. The Numeric Rating Scale (NRS) and the FACES scale are routinely used for pediatric and adult patients to rate their own pain level. Both of these scales have been successfully used to evaluate pain in older adults. However, data to support the efficacy of those scales compared with other pain tools in patients receiving mechanical ventilation are limited. In addition, 5 other pain tools, (ANVPS; BPS; Comfort Scale; Face, Legs, Activity, Cry, and Consolability (FLACC); Pain Assessment Behavioral Scale [PABS]) commonly used with noncommunicative patients, were selected on the basis of variations in behavior descriptors and physiological parameters (Table 1).

Procedures
This study was conducted in an 18-bed medical intensive care unit. Four nurse investigators (P.F., M.R., P.J., S.S.) with more than 5 years of critical care experience (3 clinical nurses and 1 clinical nurse specialist in the target unit) selected all patients for the study on the basis of the study’s inclusion and exclusion criteria. Training for each tool was conducted, and inter-rater reliability was established by having all investigators assess the same patient at the same time (10 communicative and 10 noncommunicative patients). Overall interrater reliability between principal investigator P.F. and the other investigators (M.R., P.J., S.S.) was high (Cronbach α: 0.89, 0.88, and 0.92, respectively). Packets of pain assessment tools were prepared before the start of the study. In order to minimize influence of the results and prevent bias, each pain tool in the packet was randomly organized and only behavioral descriptors (no numeric values) were listed.

The 4 nurse investigators independently enrolled patients by using a random computer-generated enrollment list during periods when the investigators were available to collect data. Once study patients were selected, descriptive data concerning their demographics and information about their admission to the intensive care unit were gathered from the medical record.

preceding study enrollment. In addition, sedation level was measured by using the Richmond Agitation-Sedation Scale (RASS). The RASS is a 10-point scale, ranging from -5 (unarousable) to 0 (calm and alert) to +4 (combative), based on observation of specific behaviors of the patient. This scale has been validated against a visual analogue scale of sedation and agitation and tested for interrater reliability in 5 adult intensive care units.15

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Pain was assessed before and during noxious and non-noxious procedures.
### Table 1
Summary of original studies on pain assessment tools

<table>
<thead>
<tr>
<th>Pain assessment tools</th>
<th>Psychometric testing</th>
<th>Behavior and physiological parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Communicative</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FACES(^{15})</td>
<td>Adaptation of the picture projection technique in which 6 faces are shown to the child</td>
<td>Drawing of 6 schematic faces depicting changes in severity of expressed pain (score range 0-10, smiling</td>
</tr>
<tr>
<td></td>
<td>Concurrent validity tested with 5 different scales; children ages 3-18 years preferred</td>
<td>“no hurt” face on the left to a crying “hurts worst” face on the right)</td>
</tr>
<tr>
<td></td>
<td>the FACES scale</td>
<td>Score range 0-10, with lower scores indicating less pain</td>
</tr>
<tr>
<td>Numeric Rating Scale (NRS)(^{12})</td>
<td>Well-tested tool of self-report of pain rating; originally validated in postoperative</td>
<td>Combination of horizontal numeric rating scale and word anchors</td>
</tr>
<tr>
<td></td>
<td>adult patients</td>
<td>Score range 0-10, with word anchors “no pain” at one end of the scale, “moderate pain” in the middle,</td>
</tr>
<tr>
<td></td>
<td>Concurrent validity tested with Faces Pain Scale, the Verbal Descriptor Scale, and the</td>
<td>and “worst possible pain” at the opposite end of the scale</td>
</tr>
<tr>
<td></td>
<td>Iowa Pain Thermometer ((r = 0.78) to 0.86 in the cognitively impaired group, except</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Faces Pain Scale) and ((r = 0.96) to 0.97 cognitively intact group) (n = 66, P &lt; .01)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>selected scales</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Noncommunicative</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult Nonverbal Pain Scale (ANVPS)(^{9})</td>
<td>Modified the Face, Legs, Activity, Cry, and Consolability (FLACC) scale to reflect</td>
<td>Five-item scale:</td>
</tr>
<tr>
<td></td>
<td>components appropriate to an adult population; content validated by nursing and medical</td>
<td>Face</td>
</tr>
<tr>
<td></td>
<td>experts in critical care</td>
<td>Activity/movement</td>
</tr>
<tr>
<td></td>
<td>Concurrent validity tested with FLACC during rest, turning, or suctioning ((r = 0.86),</td>
<td>Guarding</td>
</tr>
<tr>
<td></td>
<td>(n = 59, P &lt; .001).</td>
<td>Physiologic I (vital signs)</td>
</tr>
<tr>
<td></td>
<td>Internal consistency Cronbach (\alpha = 0.78)</td>
<td>Physiologic II (skin temperature, pupil dilatation)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Score range 0-10, with lower scores indicating less pain</td>
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<tr>
<td>Behavioral Pain Scale (BPS)(^{7})</td>
<td>Developed from staff survey and literature review</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test-retest reliability tested during rest and procedure ((r = 0.71) at rest and (r</td>
<td>Three items:</td>
</tr>
<tr>
<td></td>
<td>= 0.50 during procedure, (n = 31), both (P &lt; .01))</td>
<td>Facial expression</td>
</tr>
<tr>
<td></td>
<td>Internal consistency: Cronbach (\alpha = 0.78)</td>
<td>Movements of upper and lower extremities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Compliance with mechanical ventilation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pain indicator scored 1 (no response) to 4 (full response); score range 3-12, with lower scores</td>
</tr>
<tr>
<td></td>
<td></td>
<td>indicating less pain</td>
</tr>
<tr>
<td>COMFORT(^{20})</td>
<td>Designed for assessment of pain, no pain, related distress, and sedation in pediatric</td>
<td>Eight items:</td>
</tr>
<tr>
<td></td>
<td>intensive care unit (PICU); developed from literature review and survey of PICU nurses</td>
<td>Alertness</td>
</tr>
<tr>
<td></td>
<td>Concurrent validity tested with visual analog scale ((r = 0.75), (n = 50, P &lt; .01))</td>
<td>Calmness</td>
</tr>
<tr>
<td></td>
<td>Internal consistency: Cronbach (\alpha = 0.90)</td>
<td>Respiratory distress</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Physical movement</td>
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<tr>
<td></td>
<td></td>
<td>Muscle tone</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Facial tension</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Blood pressure (mean arterial pressure) baseline</td>
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<tr>
<td></td>
<td></td>
<td>Heart rate baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Each category scored from 1 to 5 points; score range 8-40:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8-16 = oversedated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>17-26 = optimally sedated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>27-40 = inadequately sedated</td>
</tr>
<tr>
<td>FLACC(^{21})</td>
<td>Developed by clinicians on the basis of categories of behavior included in other scales</td>
<td>Five items:</td>
</tr>
<tr>
<td></td>
<td>to evaluate pain in children</td>
<td>F: face</td>
</tr>
<tr>
<td></td>
<td>Concurrent validity tested with Objective Pain Scale ((r = 0.80), (n = 89, P &lt; .001))</td>
<td>L: legs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A: activity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: cry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C: consolability</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Each equally weighted from 0 to 2; score range 0-10, with lower scores indicating less pain</td>
</tr>
<tr>
<td>Pain Assessment Behavioral Scale (PABS)(^{22})</td>
<td>Modified FLACC to reflect components appropriate to an adult population</td>
<td>Five items:</td>
</tr>
<tr>
<td></td>
<td>Concurrent validity tested with verbal report ((r = 0.69), (n = 305, P &lt; .001))</td>
<td>Face</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restlessness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Muscle tone</td>
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<td></td>
<td></td>
<td>Vocalization</td>
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<td></td>
<td>Consolability</td>
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<tr>
<td></td>
<td></td>
<td>Score range 0-10, with lower scores indicating less pain</td>
</tr>
</tbody>
</table>
completed each tool. Then the investigator observed during the procedure for the duration of the event and then completed each tool.

Data Analysis

The purpose of this study was to evaluate the validity and sensitivity of pain scales in an effort to identify the most appropriate measure of pain in noncommunicative patients (ie, patients receiving mechanical ventilation or sedated). The questions of validity and sensitivity were answered with 2 separate samples. The first sample, intended to address validity, was taken from communicative intubated patients. Each patient’s pain was measured with the following pain scales: ANVPS, BPS, COMFORT, FACES-nurse, FLACC, and PABS and patient self-report using the FACES-patient and NRS for the 4 phases of assessment. The NRS served as the reference standard tool for patients’ self-reports of pain. A Spearman correlation coefficient (ρ) was calculated for each scale with the NRS. Before data collection, the power was estimated assuming use of the Pearson correlation coefficient and the Fisher z test. Thus, for the planned sample size of 50 (sample of communicative patients), the 2-sided Fisher z test of the null hypothesis that the Pearson correlation coefficient equals 0 was estimated to have 82% power to detect correlations as small as 0.4.

The second sample, intended to assess sensitivity, was taken from 100 noncommunicative intubated patients. Each patient’s pain was measured with the following pain scales (ANVPS, BPS, COMFORT, FACES-nurse, FLACC, and PABS) for the 4 phases of assessment. A mixed-effects linear model was used to test for changes from before the stimulus (poststimulus minus prestimulus) for both the noxious stimulus and the stimulus that was not noxious (poststimulus minus prestimulus) for both the noxious stimulus and the stimulus that was not noxious for the 4 phases of assessment. A mixed-effects linear model was used to test for changes from before the stimulus (poststimulus minus prestimulus) for both the noxious stimulus and the stimulus that was not noxious and for each of the pain scales. The fixed effects included time (before and during stimulus), stimulus (not noxious and noxious), time by stimulus interaction, and the RASS score as a covariate. Patient was modeled as a random effect. The homogeneity of the covariates assumption and model assumptions was checked. Because no preliminary data are available, no power calculations were possible. However, a sample of 100 noncommunicative intubated patients is thought to be adequate for assessing sensitivity.

Results

Patients

The sample consisted of 50 communicative and 100 noncommunicative patients and was evenly divided between males and females (Table 2). Most patients were African American, with no difference in race and ethnicity between the communicative and noncommunicative groups. The mean age was 56 (SD, 12.7) years in the communicative patients and 52 (SD, 16.6) years in noncommunicative patients, with no significant difference in age between the 2 groups ($F_{149} = 2.29; P = .13$). Severity of illness was higher in the noncommunicative patients than in the communicative patients ($F_{149} = 22.71; P < .001$). The RASS scores at baseline differed significantly between the 2 groups; noncommunicative patients were more sedated ($Z = 8.35, P < .001$). Ninety-six percent of the communicative patients were alert or mildly sedated, whereas 61% of noncommunicative patients were moderately to deeply sedated.

Pain Level

Validity, Communicative Intubated Patients. The mean scores of the investigators’ ratings of the pain scales (ANVPS, BPS, COMFORT, FACES-nurse, FLACC, and PABS) and patients’ ratings using FACES-patient and NRS are reported in Table 3. The pain intensity score before and during physical examination increased slightly, whereas a significant increase was seen during suctioning. However, patients pointed to higher pain intensity on the FACES scale than they communicated as a numeric value during the suctioning procedure (mean score during suctioning NRS = 3.88, FACES-patient = 5.22). Interestingly, investigators’ ratings of pain were even higher than patients’ self-reports (NRS = 3.88, FACES-Nurse = 6.73) during the suctioning procedure.

In addition, the pain scales varied in their association with the NRS before and during the 2 procedures (Table 4). All pain scales had significant moderate to high correlations with the patient’s self-rating by using the NRS during the suctioning procedure. However, before physical examination, only the FACES-patient and FACES-nurse had significant correlations with the NRS. As expected, patients’ self-rating by using the FACES-patient, where the patients chose the face that best represented their pain level, had the highest correlation with the NRS (ρ = 0.76, $P < .001$) during the suctioning procedure. Interestingly, only BPS had a non-significant correlation of 0.21 ($P = .20$) with patient self-report during physical examination, whereas all other tools showed significant moderate correlation. Interestingly, 68% of the communicative patients rate pain during physical assessment as “0” when using the NRS (mean score, 1.95; SD, 3.21; median, 0; range, 0–10), whereas nurses rated patients’ pain level as 4 or greater when using the BPS 71% of the time (mean score, 4.2; SD, 1.09; median, 4.0; range,
## Table 2
Sample characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Yes (n = 50)</th>
<th>No (n = 100)</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Sex&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>27</td>
<td>54</td>
<td>45</td>
</tr>
<tr>
<td>Male</td>
<td>23</td>
<td>46</td>
<td>55</td>
</tr>
<tr>
<td>Ethnicity&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>50</td>
<td>100</td>
<td>96</td>
</tr>
<tr>
<td>Race&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>33</td>
<td>66</td>
<td>58</td>
</tr>
<tr>
<td>White</td>
<td>17</td>
<td>34</td>
<td>35</td>
</tr>
<tr>
<td>American Indian or Alaskan Native</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory disorders</td>
<td>20</td>
<td>40</td>
<td>22</td>
</tr>
<tr>
<td>Neurological disorders/alter mental status</td>
<td>10</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Gastrointestinal, genitourinary, or hematological disorders</td>
<td>5</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>Cardiovascular disorders</td>
<td>5</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>Sepsis</td>
<td>3</td>
<td>6</td>
<td>14</td>
</tr>
<tr>
<td>Trauma, motor vehicle accidents</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Unclear cause, other</td>
<td>7</td>
<td>14</td>
<td>16</td>
</tr>
<tr>
<td>RASS categories&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate/deeply sedated</td>
<td>1</td>
<td>2</td>
<td>61</td>
</tr>
<tr>
<td>Alert/mildly sedated</td>
<td>48</td>
<td>96</td>
<td>37</td>
</tr>
<tr>
<td>Restless/agitated</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Age,&lt;sup&gt;a&lt;/sup&gt; years</td>
<td>56</td>
<td>12.7</td>
<td>52</td>
</tr>
<tr>
<td>Duration of intubation,&lt;sup&gt;a,c&lt;/sup&gt; days</td>
<td>5.2</td>
<td>4.4</td>
<td>4.3</td>
</tr>
<tr>
<td>Score on Acute Physiology and Chronic Health Evaluation III&lt;sup&gt;d&lt;/sup&gt;</td>
<td>65.8</td>
<td>19.2</td>
<td>85.7</td>
</tr>
<tr>
<td>RASS baseline score&lt;sup&gt;d&lt;/sup&gt;</td>
<td>-0.3</td>
<td>0.7</td>
<td>-2.8</td>
</tr>
</tbody>
</table>

<sup>a</sup> No significant difference among communicative and noncommunicative categories.

<sup>b</sup> RASS = Richmond Agitation-Sedation Scale; we have further summarized the RASS’s 10 levels of sedation as moderate/deeply sedated (RASS score of -5, -4, or -3), alert/mildly sedated (RASS score of -2, -1, or 0), or restless/agitated (RASS score of +1, +2, +3, or +4)<sup>11, 28</sup>

<sup>c</sup> Duration of intubation = days of intubation before enrollment in the study.

<sup>d</sup> P < .001.

## Table 3
Mean (SD) scores for the 50 communicative patients

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>NRS</th>
<th>FACES-patient</th>
<th>ANVPS</th>
<th>BPS</th>
<th>COMFORT</th>
<th>FACES-nurse</th>
<th>FLACC</th>
<th>PABS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>1.51 (2.88)</td>
<td>3.35 (3.40)</td>
<td>0.75 (1.06)</td>
<td>3.86 (1.30)</td>
<td>17.48 (3.08)</td>
<td>1.86 (2.52)</td>
<td>0.45 (1.00)</td>
<td>0.43 (0.85)</td>
</tr>
<tr>
<td>During</td>
<td>1.95 (3.21)</td>
<td>2.54 (2.48)</td>
<td>0.88 (0.95)</td>
<td>4.17 (1.09)</td>
<td>17.88 (2.06)</td>
<td>1.38 (1.79)</td>
<td>0.71 (0.90)</td>
<td>0.68 (0.93)</td>
</tr>
<tr>
<td>Suctioning</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>1.29 (2.35)</td>
<td>3.80 (3.32)</td>
<td>0.64 (0.78)</td>
<td>3.89 (1.02)</td>
<td>17.68 (2.23)</td>
<td>1.26 (1.45)</td>
<td>0.43 (0.79)</td>
<td>0.41 (0.69)</td>
</tr>
<tr>
<td>During</td>
<td>3.88 (3.55)</td>
<td>5.22 (3.05)</td>
<td>3.08 (1.63)</td>
<td>7.08 (1.71)</td>
<td>23.40 (4.04)</td>
<td>6.73 (2.51)</td>
<td>2.76 (1.67)</td>
<td>2.96 (1.81)</td>
</tr>
</tbody>
</table>

Abbreviations: ANVPS, Adult Nonverbal Pain Scale; BPS, Behavior Pain Scale; FACES-patient, use of FACES scale by the patient as a self-report measure by pointing to the corresponding image; FACES-nurse, use of FACES scale by the investigator to score patients’ pain level by selecting the corresponding image; FLACC, Face, Legs, Activity, Cry, and Consolability scale; NRS, Numeric Rating Scale; PABS, Pain Assessment Behavioral Scale.
Table 4
Correlations (Spearman \( \rho \)) of pain scales with the Numeric Rating Scale in communicative patients during 4 evaluations

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Scale</th>
<th>ANVPS</th>
<th>BPS</th>
<th>COMFORT</th>
<th>FLACC</th>
<th>PABS</th>
<th>FLACC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>FACES-patient</td>
<td>0.4684</td>
<td>0.0946</td>
<td>0.1115</td>
<td>0.1760</td>
<td>0.5290</td>
<td>0.1500</td>
</tr>
<tr>
<td></td>
<td>(P = .003)</td>
<td></td>
<td>(P = .56)</td>
<td>(P = .49)</td>
<td>(P = .27)</td>
<td>(P &lt; .01)</td>
<td>(P = .35)</td>
</tr>
<tr>
<td>During</td>
<td></td>
<td>0.5724</td>
<td>0.4058</td>
<td>0.2067</td>
<td>0.3877</td>
<td>0.6134</td>
<td>0.4917</td>
</tr>
<tr>
<td></td>
<td>(P = .001)</td>
<td></td>
<td>(P = .009)</td>
<td>(P = .20)</td>
<td>(P = .01)</td>
<td>(P &lt; .01)</td>
<td>(P = .001)</td>
</tr>
<tr>
<td>Suctioning</td>
<td></td>
<td>0.2197</td>
<td>-0.1485</td>
<td>0.2050</td>
<td>0.3385</td>
<td>0.4607</td>
<td>0.1072</td>
</tr>
<tr>
<td></td>
<td>(P = .18)</td>
<td></td>
<td>(P = .35)</td>
<td>(P = .19)</td>
<td>(P = .03)</td>
<td>(P = .002)</td>
<td>(P = .50)</td>
</tr>
<tr>
<td>During</td>
<td></td>
<td>0.7613</td>
<td>0.5594</td>
<td>0.5557</td>
<td>0.6527</td>
<td>0.5288</td>
<td>0.6320</td>
</tr>
<tr>
<td></td>
<td>(P &lt; .001)</td>
<td></td>
<td>(P &lt; .001)</td>
<td>(P &lt; .001)</td>
<td>(P &lt; .001)</td>
<td>(P &lt; .001)</td>
<td>(P &lt; .001)</td>
</tr>
</tbody>
</table>

Abbreviations: ANVPS, Adult Nonverbal Pain Scale; BPS, Behavior Pain Scale; FACES-patient, use of FACES scale by the patient as a self-report measure by pointing to the corresponding image; FACES-nurse, use of FACES scale by the investigator to score patients’ pain level by selecting the corresponding image; FLACC, Face, Legs, Activity, Cry, and Consolability scale; PABS, Pain Assessment Behavioral Scale.

No one tool was superior to the other in capturing pain response during the noxious procedure.

3-8), with no difference in rating \( F_{39}^2 = 0.56, P = .46 \) between NRS and BPS.

Sensitivity, Noncommunicative Intubated Patients. The 6 pain scales (Figure 1) were all sensitive in capturing the patient’s pain response before and during the stimulus that was not noxious (routine physical examination) and before and during the noxious stimulus (endotracheal tube suctioning; \( P < .001 \)). However, overall sensitivity was higher during suctioning. Interestingly, during suctioning, investigators tended to rate pain higher on FACES-nurse (mean score, 6.48) than on similar tools with a 10-point rating scale (mean scores: ANVPS, 3.41; PABS, 3.41; FLACC, 3.06).

Discussion

Although pain assessment is difficult in sedated, critically ill patients, pain must be assessed in a valid and reliable manner to ensure adequate pain management by using a pain tool that is useful for such patients. The use of unidimensional pain scales such as the NRS is recommended for patients who are able to self-report pain intensity.\(^1\)\(^2\) However, when patients are unable to self-report their pain, valid and reliable behavioral pain scales such as the BPS and the CPOT are recommended in the clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the intensive care unit.\(^1\)

At the time of our study, BPS was more commonly used than CPOT because of its better psychometric properties and more frequent use in research studies.\(^6\) We used the BPS along with other behavioral pain tools (ANVPS, COMFORT, FACES, FLACC, and PABS) to compare the relationship with the patient’s self-report of pain via the NRS. However, no one tool was superior to the other in capturing pain response during the noxious procedure and showed moderate to high associations to the NRS. Even though patients tended to score higher on FACES-patient than a numeric value during suctioning, the investigators also rated pain higher in both the communicative and the noncommunicative group by using the FACES-nurse scale. Visual images such as FACES scales (Figure 2) may add subjectivity and bias versus selecting behavior descriptors in other tools. Further studies are warranted, as this subjectivity has implications for overtreatment or undertreatment of pain.

Furthermore, during the physical examination, all tools were associated with the NRS, except for the BPS. In a closer review of the BPS, the tool ranged from 3 to 12, with an assumption of 3 being no pain, whereas other tools assume zero as no pain. Chanques et al\(^29\) suggested that behavioral pain tools such as the BPS should not be used in communicative patients because correlation coefficients between BPS and self-reported pain scales are low (\( r = 0.40, P < .001 \)). Similarly, our study supports their finding, as there was a moderate correlation between BPS and NRS (\( r = 0.56, P < .001 \)) during the noxious procedure but no correlation during the procedure that was not noxious (\( r = 0.21, P = .20 \)). Therefore the validity of BPS should be further investigated in noncommunicative patients.

More recently, Keane\(^30\) also reported a weak nonsignificant association of 0.26 (\( r = .31 \)) between CPOT score and patient’s self-report of pain during repackaging after extubation. Positioning was used as a noxious procedure in that study. Even though the
Figure 1 Sensitivity of 6 pain scales in noncommunicative intubated patients during a procedure that was not noxious and a noxious procedure. Scores on the Face, Legs, Activity, Cry, and Consolability Scale are from 0 to 10; the score for cry was not included because it was inappropriate in this sample, resulting in a range of scores from 0 to 8. Scores on the Pain Assessment Behavioral Scale are from 0 to 10; the score for vocalization was not included because it was inappropriate in this sample of nonverbal patients, resulting in a range of scores from 0 to 8.
range of scores for the CPOT is 0 to 8, further analysis is needed to explore variation in score ranges in these tools during noxious procedures and procedures that are not noxious.

The clinical practice guidelines for management of pain recommend that observational pain scales that include vital signs alone not be used for pain assessment. Interestingly, 2 observational pain scales in our study (ANVPS and COMFORT) both use physiological data such as heart rate and blood pressure and showed moderate to high associations with the NRS as well as significant sensitivity in capturing the patient’s pain response during a noxious stimulus. It may be that the combination of physiological along with behavioral measures affected this relationship.

Limitations

This study was conducted in an intensive care unit in a single institution. Although the unit was fairly representative of general medical populations in a critical care setting, the findings may not be generalized to every type of medical population. An important limitation of this study was that we used 1 noxious condition, no stimulus control, and assumed absence of pain at baseline, although we did measure pain at this time and evaluated the change in pain over time. The use of suctioning may bias the investigators to rate higher assuming that suctioning causes pain. Even though we used endotracheal suctioning to elicit pain response, endotracheal suctioning is comparable to other common procedures that cause pain in critically ill patients. Use of 4 evaluators may have contributed some measurement error, but extensive training and education was done before implementation until reliability for each tool achieved a Cronbach α of 0.80 or better. In addition, completing all tools at one time may have created bias among the raters; however, we attempted to reduce that effect by random ordering of the tools, completing one tool before starting another, and enrolling no more than 2 patients at a time. In addition, interrater reliability was evaluated before study implementation and again during the midcycle of enrollment of patients. Since the goal of the study was to compare multiple pain tools, the use of 1 procedure was required so that all tools could be evaluated simultaneously.

Conclusion

Pain assessment remains a challenge in noncommunicative critically ill patients whose pain experience is inferred from observation of behaviors and physiological measures. In this study, we evaluated commonly used pain scales in noncommunicative critically ill adult patients. Our study aim was to evaluate and identify an effective scale for assessing pain in these patients. We found that all tools were valid and sensitive to capturing changes in pain response during a noxious procedure in critically ill communicative and noncommunicative patients. However, caution is necessary when using the FACES scale because its subjectivity may lead to overtreatment or undertreatment of pain. Further analysis is needed to define discrete behavior descriptors that are reliable and useful in measuring pain response.

ACKNOWLEDGMENTS

The authors thank the staff, patients, and patients’ families in the medical intensive care unit for participating in this study.

FINANCIAL DISCLOSURES

None reported.

eLetters

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To purchase electronic or print reprints, contact American Association of Critical-Care Nurses, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 899-1712 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.
CE Test  Test ID A1524062: Validity and Sensitivity of 6 Pain Scales in Critically Ill, Intubated Adults

Learning objectives: 1. Identify 6 pain assessment tools and their roles in pain assessment for noncommunicative intensive care unit (ICU) patients. 2. Compare and contrast the use of pain assessment tools in communicative and noncommunicative ICU patients. 3. Identify additional research needed to ensure pain assessment is further investigated in noncommunicative patients.

1. Which 2 procedures were identified as causing pain in critically ill patients?
   a. Suctioning and central-line placement
   b. Mobility and venous access device placement
   c. Blood draws and mobility
   d. Repositioning and suctioning

2. According to the authors, which of the following best aligns with the nurse’s ability to manage a patient’s pain?
   a. The family’s ability to interpret and express pain
   b. The physician’s ability to prescribe and manage pain
   c. The nurse’s ability to assess and document pain
   d. The patient’s ability to express level and location of pain

3. In some disease processes the expression of pain may not be typical. For that reason, which of the following diagnoses excluded a patient from the study?
   a. Head trauma and meningitis
   b. Neuromuscular blocking agents and Parkinson’s disease
   c. Intracranial hemorrhage and seizure disorders
   d. Multiple sclerosis and taking Avonex

4. Which of the following pain scales was developed for the pediatric population and then modified to meet the assessment needs of the adult population?
   a. Adult Nonverbal Pain Scale (ANVPS)
   b. Behavioral Pain Scale (BPS)
   c. Critical-Care Pain Observation Tool (CPOT)
   d. FACES Pain Scale

5. How was interrater reliability determined for this study?
   a. Internal rate of return was calculated for each measurement result.
   b. Study investigators reached consensus for interpretation of measurement results.
   c. Study investigators assessed the same patient at the same time.
   d. Each investigator was trained on every pain scale used for the study.

6. How long was the patient observed before the investigator implemented noxious stimulus and pain assessment?
   a. Two minutes
   b. Ten minutes
   c. Prior 2 shifts
   d. There was no observation period prior to pain assessment.

7. Which of the following is true for the assessment of pain on noncommunicative patients?
   a. Noncommunicative patients were excluded from the study.
   b. Noncommunicative patients were unable to use the Numeric Rating Scale (NRS).
   c. The sensitivity of the NRS was assessed during all 4 phases of the study.
   d. Because of their inability to communicate, there was not a 2-minute observation time prior to pain assessment.

8. Which scale was developed by pediatric ICU nurses and uses an 8-parameter assessment?
   a. ANVPS
   b. Pain Assessment Behavioral Scale
   c. Face, Legs, Activity, Cry, and Consolability
   d. COMFORT Scale

9. Which of the following best describes study participants’ characteristics?
   a. There were more females in the study than males.
   b. Most study participants were identified as black or African American.
   c. Most study participants were identified with neurological disorders.
   d. The mean number of intubation days for study participants was 2.8 days.

10. Which of the following pain assessment tools demonstrated the best results during noxious stimulus?
    a. There was no significant difference between behavior tools used.
    b. The ANVPS outperformed the other behavior tools with noncommunicative patients.
    c. The FACES tool performed better with the pediatric patient population.
    d. There was no correlation between the behavioral tools and the numeric rating scale.

11. Which of the following is considered a limitation of the study?
    a. There was inconsistency in the assumption of pain prior to noxious stimulus.
    b. The study population was not representative of a general medical population.
    c. Interrater reliability was not addressed at the beginning of the study.
    d. The study was conducted in a single ICU within 1 institution.

12. Which statement best describes the findings of the study?
    a. Pain assessment for pediatric and adult patients requires the use of different pain assessment tools.
    b. All tools evaluated offered some degree of creditable pain assessment during noxious stimulation.
    c. Communicative and noncommunicative patients require different pain assessment tools.
    d. The subjective validity of NRS scale excludes it from being used with communicative patients experiencing pain.

Test ID: A1524062 Contact hours:1.0; pharma 0.0  Form expires: November 1, 2018. Test Answers: Mark only one box for your answer to each question.

1. q 2. q 3. a 4. a 5. a 6. a 7. q 8. a 9. a 10. a 11. a 12. a
   d c b c q q q b d d d d d d d d d b q q q q q q q q q q q q q q

Fee: AACN members, $0; nonmembers, $10 Passing score: 9 correct (75%) Category: CERP A Test writer: Jean Shinners, PhD, RN-BC.

Program evaluation

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<th>Objective 1 was met</th>
<th>No</th>
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<tr>
<td>Objective 2 was met</td>
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<td>This method of CNE is effective for this content</td>
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<td>q</td>
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<tr>
<td>difficult</td>
<td>q</td>
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<tr>
<td>To complete this program, it took me ______ hours/minutes.</td>
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</tr>
</tbody>
</table>

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Verifying Placement of Small-Bore Feeding Tubes: Electromagnetic Device Images versus Abdominal Radiographs

By Vera Bryant, DNP, ARNP, ACNP-BC, CCRN, CNRN, SCRN, Jean Phang, RN, BSN, CNSN, and Kevin Abrams, MD

Background Clinicians are unsure if radiography is needed to confirm correct positioning of feeding tubes inserted with assistance from an electromagnetic system.

Objectives To compare radiographic reports of feeding tube placement with images generated by an electromagnetic feeding tube placement device.

Methods The medical records of 200 consecutive patients who had feeding tubes inserted with assistance from an electromagnetic feeding tube placement device were reviewed retrospectively. Radiographic reports of tube site were compared with images generated by the device.

Results Radiographic evidence of tube sites was available in 188 cases: 184 tubes were located in portions of the gastrointestinal tract. Ninety of the 188 tubes were situated in the optimal site (distal duodenum or jejunum) radiographically. Images generated by the electromagnetic device were available in 176 cases; of these, 52 tubes appeared to end in the expected left lower quadrant. Tubes shown on radiographs to be in other sites also occasionally appeared to end in the left lower quadrant. Nurses using the device did not recognize 4 of the 188 tubes (2.1%) that were inadvertently placed in the lung. No consistent pattern of quadrant distribution was found for tubes positioned in the stomach or proximal duodenum.

Conclusions Images generated by the electromagnetic tube placement device provided inconsistent results regarding tube location. A small percentage of seriously malpositioned tubes were not detected by using the electromagnetic device. These findings do not support eliminating radiographs to confirm correct tube placement following use of an electromagnetic tube placement device. (American Journal of Critical Care. 2015;24:525-531)
It is estimated that more than 1 million styleted feeding tubes are placed in the United States annually. Blindly inserted enteric feeding tubes are placed in the respiratory system in 1.2% to 1.8% of cases; further, about 1 in 3 tube misplacements result in a pneumothorax. Manufacturers of the commercially available Cortrak electromagnetic enteral access device (CEAS; Corpak Medsystems) for feeding tube placement assert that radiography may not be necessary when a feeding tube is placed by using their device. In contrast, a review of reports to the Food and Drug Administration’s Manufacturer and User Facility Device Experience (MAUDE) database lists cases in which operators using the device did not detect tubes inadvertently positioned in the lung or other inappropriate locations.

Reliable final placement of enteric feeding tubes is inherently important in the prevention of avoidable morbidity and mortality. The ability of operators of an electromagnetic enteral access device to detect unintended misplacement of feeding tubes is uncertain. Additional information is needed to help clinicians decide if a confirming radiograph is needed to assess tube position when such a device is used.

**Objectives**

The objectives of this retrospective review of medical records were as follows:
1. To compare images generated by an electromagnetic tube placement device with radiographic reports of tube location for agreement.
2. To describe the number of times that CEAS-assisted tube insertions result in inadvertent placement of tubes in the respiratory tract.
3. To describe the number of cases of pneumothoraces following CEAS placement of feeding tubes.
4. To describe the placement centimeter mark at the end of each tube insertion.
5. To describe the number of placement attempts per placement episode.
6. To review the educational experiences about use of the electromagnetic tube placement device provided to nurses at the data collection site between January 1, 2012, and December 31, 2012.

**Methods**

**Sample and Setting**

Following approval from the appropriate institutional review boards, medical records at a single-center, 680-bed, nonprofit community hospital where nurses place approximately 900 enteric tubes annually were retrospectively reviewed. The study population consisted of a convenience sample of the first 200 hospitalized patients to undergo enteric tube placements with the electromagnetic Cortrak 2 Enteral Access System (CEAS) in 2012. The majority (84%) of enteric tube placements in the study population occurred in the intensive care unit. The remainder of the placements (16%) were performed in patients in the medical and surgical step-down units as well as the general medical care areas. Inclusion criteria were as follows: admission between January 1, 2012, and December 31, 2012; a physician’s order for placement of a small-bowel feeding tube; and patient’s age 18 years or older. Patients with blindly placed enteric tubes were excluded from the study.

**Measurements**

Variables included in the medical record review were as follows: radiographic reports of tube site, radiographic images, images generated from the electromagnetic tracking device, centimeter marks on the enteric tubing recorded at the end of the placement procedure, number of placement attempts per episode, and educational experience of placement personnel.

**Radiographs.** Abdominal radiographs were required for all placements of small-bowel feeding tubes. All radiographs were interpreted by a radiologist, independent of information generated by the CEAS. Radiographic reports included the following tube sites: esophagus, gastroesophageal juncture, stomach, gastroduodenal juncture (duodenal bulb), duodenum first or second part, duodenum third or fourth part, jejunum (ligament of Treitz), right lung, and left lung.

**About the Authors**

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Images from the CEAS were reviewed independently by the 2 nurse members of the research team to determine where the tube tips were positioned in relation to the vertical and horizontal reference lines provided on the anterior view, default placement screen, accounts mode of the CEAS. Possible positions included above the horizontal axis to the left of the vertical axis, below the horizontal axis to the left of the vertical axis, above the horizontal axis to the right of the vertical axis, and below the horizontal axis to the right of the vertical axis. These axes portrayed the patient’s midsagittal line (vertical) and the patient’s diaphragm (horizontal) according to the CEAS operator’s manual. Possible quadrant positions included the left upper quadrant, left lower quadrant, right upper quadrant, and the right lower quadrant. During independent assessments of the location of tube tips on the CEAS images, agreement was reached in 100% of the cases by the 2 nurse members of the research team.

Centimeter Mark on Tube. The centimeter mark indicating the length of tube inserted into the patient was recorded in the medical record by the registered nurse who inserted the feeding tube at the time of placement. These markings were recorded to determine the extent to which they compare with radiographic evidence of the tube site. Using information published by Gatt and MacFie, centimeter marks are associated with anatomic tube position. For example, esophageal placement was associated with the 35- to 40-cm mark, gastric placement was associated with the 55- to 65-cm mark, and distal small-bowel placement was associated with the 115-cm mark.

Placement Attempts. Data on the number of insertion attempts (number of Cortrak tracing events) per placement episode were also retrieved from the medical records. If multiple attempts were made to place the enteric tube, only the last tracing was included in the sample.

Training of Personnel. All of the tubes were placed by registered nurses employed at the study site. All placement nurses received training in using the CEAS. It was not possible to track the amount of training given to each nurse in past years. However, a review was conducted of recorded educational programs provided by the hospital on use of the electromagnetic feeding tube placement device during the data collection period (January 2012 through December 31, 2012). Training emphasized placement of the feeding tube’s tip into the distal small bowel because this is the site that physicians at the data collection site prefer.

Data Analysis

The quadrant in which each feeding tube tip ended on the CEAS image was recorded for each of the radiographically identified feeding tube sites. Data were analyzed with SPSS statistical software (version 22, SPSS Inc). Descriptive statistics (frequencies, percentages, means and standard deviations) were used to report the findings. Other statistical comparisons were not possible because of the relatively small numbers in some of the anatomic tube placement sites.

Results

Two hundred patients were reviewed in the study; 49.5% (n = 99) were female and 50.5% (n = 101) were male. The mean age of the patients was 69.7 years. Most patients in the study population (84%) were in the intensive care unit. All patients represented cases that met criteria for small-bowel nutrition as evaluated by a physician. Although 200 cases were initially examined, 12 cases had missing radiographic reports and 11 had missing CEAS images; in addition, 1 of the 200 cases failed to meet the inclusion criteria and was deleted from the sample. A sample of 188 cases with radiographic data remained. Table 1 shows the placement locations of the tip of the feeding tube.

<table>
<thead>
<tr>
<th>Tube site</th>
<th>Number</th>
<th>Level of success</th>
<th>Anatomic site</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esophagus</td>
<td>1</td>
<td>Unacceptable</td>
<td>4/188</td>
<td>2.1</td>
</tr>
<tr>
<td>Gastroesophageal juncture</td>
<td>3</td>
<td>Unacceptable</td>
<td>60/188</td>
<td>31.9</td>
</tr>
<tr>
<td>Stomach</td>
<td>40</td>
<td>Variably acceptable</td>
<td>30/188</td>
<td>16.0</td>
</tr>
<tr>
<td>Gastroduodenal juncture</td>
<td>20</td>
<td>Variably acceptable</td>
<td>90/188</td>
<td>47.9</td>
</tr>
<tr>
<td>Proximal duodenum</td>
<td>30</td>
<td>Satisfactory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal duodenum</td>
<td>47</td>
<td>Optimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jejunum</td>
<td>43</td>
<td>Optimal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right lung</td>
<td>3</td>
<td>Potentially lethal</td>
<td>4/188</td>
<td>2.1</td>
</tr>
<tr>
<td>Left lung</td>
<td>1</td>
<td>Potentially lethal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Only the last tracing was included if multiple attempts were made.
within the gastrointestinal tract and respiratory tract. The extent to which feeding tubes were placed into acceptable locations also was described.

Of the 188 tubes with radiographic reports, only 176 had recorded images generated by the CEAS. Table 2 shows the CEAS image quadrants in which the feeding tube tips were located when the confirmatory radiographs were obtained to determine the final position of the feeding tube. When compared with confirmatory radiographs of tubes situated at the optimal site (distal duodenum or jejunum), the electromagnetically generated images indicated that only 52 tubes ended in the expected left lower quadrant. Additionally, tubes demonstrated by radiography to be in other sites (such as the esophagus, gastroesophageal juncture, stomach, proximal small bowel, and right lung) were also shown in CEAS images to be in the left lower quadrant (n = 32). No consistent pattern of quadrant distribution was found for tubes positioned in the stomach or proximal duodenum.

Four of the 188 tubes with radiographic reports (2.1%) were situated in the respiratory tract; 2 of the 4 tubes with lung misplacements (1.1%) resulted in a pneumothorax that required insertion of a chest tube. A tube placed in the lung would be expected to be situated in an upper quadrant on the CEAS image (above the diaphragm); however, 2 of the tubes placed in the right lung were shown in CEAS images to end in the left lower quadrant (Table 2).

Table 3 lists the various tube insertion lengths (as indicated by centimeter marks on the tubes). Although mean insertion lengths were greater for tubes positioned in the small bowel than for tubes placed in the upper portions of the gastrointestinal tract, there was considerable overlap in the centimeter markings according to the various tube sites.
The number of attempts made by the nurses who used the CEAS to place tubes varied from 1 to 30 per episode (mean, 5.2; SD, 4.2).

Description of the training provided to the specific registered nurses who placed the feeding tubes with the CEAS was not entirely available. All nurses who placed feeding tubes did have documentation of some degree of initial training using the CEAS; however, no documented evidence of standardized training or competency was found. During the data collection period (January 1, 2012 through December 31, 2012), didactic training classes for using the CEAS ranged from 30 minutes to 2 hours long, and clinical training varied from 0 to 10 supervised placements. Training was provided by the manufacturer and/or hospital educators; no provision for annual revalidation of clinical or written competencies was available.

**Discussion**

Nurses were able to place 64.8% (114/176) of CEAS-guided tubes in the postpyloric position, but were successful in placing only 48.3% (85/176) of the tubes into the preferred site of the distal duodenum or jejunum. Additionally, the nurses did not detect 4.5% (8/176) of the tubes that were placed in unacceptable and potentially lethal locations. The 4 most serious incidents involved placements into the lung (2 of which resulted in pneumothoraces), which resulted in an incidence of pulmonary placement and pneumothorax similar to the rate observed when feeding tubes are placed blindly. Fortunately, none of the enteric tubes placed in the lung during the study were used to provide nutrition to the patients.

Failure to detect malpositioned tubes when using an electromagnetic enteral access device can lead to serious complications. Altered mental status, preexisting endotracheal tube, and critical illness place patients at higher risk for malposition.7 The seemingly small percentage of complications from malpositioned tubes (1%-2%) affects an underappreciated number of patients, bearing in mind that 1.2 million small-bowel feeding tubes are placed annually in the United States alone.1 Unusual anatomy, monitoring equipment, movement of the patient, malposition of the receiver unit, and variability in clinical skill may account for the low success rate of feeding tube placement in the preferred site of the distal small bowel.

Use of the centimeter mark to determine location of enteric tubes was an unpredictable measure of correct anatomic position (Table 3). Overlap and variability between the various sites in the gastrointestinal tract and in the lung were considerable (Table 3). Instructions provided by Gatt and MacFie,6 Mosby’s Nursing Skills Quick Sheet for small-bore feeding tube insertion: electromagnetic guidance system (Cortrak),8 and the AACN Procedure Manual for Critical Care for small-bore feeding tube insertion using an electromagnetic guidance system (Cortrak)9 all use conflicting centimeter markings associated with anatomic position6,8,9 (Table 4). Findings from this review generate serious uncertainty about the reliability of centimeter marks for predicting tube tip location accurately.

The mean number of placement attempts reported in this review was 5 (range, 1-30). A placement attempt was defined as each time the placement procedure was reinitiated and retraced by using the CEAS device during a placement episode. With a mean of 5 attempts per placement procedure, one could surmise that the training may not have been adequate. The level of training established in this study was thought to be far less than reported in a large study by Koopmann et al,1 in which the CEAS device used by a dedicated team was effective in eliminating cases of pneumothorax associated with tube placements, or in the study by Rivera et al,10 where 1 designated nurse placed feeding tubes with the use of the CEAS device, resulting in greater accuracy in distal small-bowel placement.

**Table 4**

<table>
<thead>
<tr>
<th>Tube site</th>
<th>Gatt and MacFie</th>
<th>Mosby's Nursing Skills</th>
<th>AACN Procedure Manual (6th ed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterior pharynx</td>
<td>—</td>
<td>10-20</td>
<td>10-15</td>
</tr>
<tr>
<td>Esophagus</td>
<td>35-40</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Gastroesophageal juncture</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Stomach</td>
<td>55-65</td>
<td>65-70</td>
<td>55-70</td>
</tr>
<tr>
<td>Proximal small bowel</td>
<td>—</td>
<td>90</td>
<td>—</td>
</tr>
<tr>
<td>Distal small bowel</td>
<td>115</td>
<td>—</td>
<td>90-110</td>
</tr>
<tr>
<td>Lung</td>
<td>—</td>
<td>—</td>
<td>25-40</td>
</tr>
</tbody>
</table>

a Dash indicates not reported.
Strengths and Limitations

The major strength of this study was that it evaluated the ability of nurses in a community hospital setting to use the CEAS device to place feeding tubes for 1 year. The retrospective review of medical records used in the study is recognized as a limitation by design. Another important limitation of the study was the lack of specific information about the training, competencies, and experience levels of all the nurses who inserted tubes with assistance from the CEAS.

Conclusions

Nurses in this study who used the CEAS to place feeding tubes were successful in placing tubes into the optimal site (jejunum or distal duodenum) in slightly less than half of the patients (90/188 of the radiographically identified cases or 85/176 by CEAS imaging). More importantly, they did not detect 4 of the tubes that entered the lung, or 4 tubes that were positioned in the esophagus or gastroesophageal juncture. The study setting was thought to be fairly representative of hospitals across the nation that do not employ a dedicated nurse or teams to place enteric feeding tubes. Training and competency were also thought to be similar to those in hospitals without a designated placement nurse or teams. The images generated by the electromagnetic feeding tube placement device provided inconsistent results regarding tube location. This finding, combined with a varied clinical skill mix, could very well increase risk of an adverse event.

These results do not support eliminating obtaining radiographs to confirm correct tube placement following use of an electromagnetic tube placement device. In addition, this study uncovered an opportunity for improvement at the study site. A process review at the institution was initiated that included clinical retraining, updating of institutional policies, and a standardization of process according to national standards. Future research is planned to replicate, readdress, review, and expand on these study results.

ACKNOWLEDGMENT

This was a Capstone Project performed as a partial requirement for completion of a doctorate in nursing practice degree from Saint Louis University School of Nursing, St Louis, Missouri.
CE Test  
Test ID A152406: Verifying Placement of Small-Bore Feeding Tubes: Electromagnetic Device Images Versus Abdominal Radiographs

<table>
<thead>
<tr>
<th>Learning objectives: 1. Identify the potential complications of feeding tube placement. 2. Explain the results of the study. 3. Discuss the implications to practice as a result of this study.</th>
</tr>
</thead>
</table>

1. Roughly, how many placements of styleted feeding tubes are done annually in the United States?  
   a. More than 1 million  
   b. More than 2 million  
   c. More than 5 million  
   d. More than 8 million

2. What percent of blindly inserted feeding tubes are accidentally placed in the respiratory system?  
   a. 0.6% to 1.2%  
   b. 1.2% to 1.8%  
   c. 1.6% to 2.2%  
   d. 1.8% to 2.4%

3. Most feeding tube placements in the study population occurred in which unit?  
   a. Medical unit  
   b. Surgical unit  
   c. Burn unit  
   d. Intensive care unit

4. Which of the following was required for all placements of small-bowel feeding tubes?  
   a. Positive auscultation  
   b. PH testing  
   c. Abdominal radiographs  
   d. Cortrak Enteral Access System (CEAS) verification

5. Which of the following centimeter marks is associated with placement in the distal small bowel?  
   a. 35 cm  
   b. 55 cm  
   c. 65 cm  
   d. 115 cm

6. Physicians at the data collection site preferred placement of feeding tubes into which site?  
   a. Esophageal placement  
   b. Gastric placement  
   c. Gastroesophageal junction placement  
   d. Distal small bowel placement

7. Where were 2 tubes actually located when the CEAS images showed them to be in the left lower quadrant?  
   a. Esophagus  
   b. Distal small bowel  
   c. Right lung  
   d. Left lung

8. Which of the following was a limitation of the study?  
   a. Lack of information about training, competency, and experience  
   b. Small sample size  
   c. Lack of CEAS training  
   d. Short time of study

9. All of the following place patients at higher risk for tube malposition except which?  
   a. Altered mental status  
   b. Preexisting endotracheal tube  
   c. Surgery  
   d. Critical illness

10. Findings from this review generate uncertainty about the reliability of which of the following?  
    a. Centimeter marks for predicting tube tip location  
    b. Auscultation of tube location  
    c. Aspirating gastric contents  
    d. Using the CEAS device to reduce insertion attempts

11. The success rate of placing tubes into the optimal site using the CEAS was slightly less than which of the following?  
    a. 25%  
    b. 50%  
    c. 75%  
    d. 100%

12. The results from this study support which of the following?  
    a. Eliminating radiographs to confirm correct tube placement  
    b. Using radiographs to confirm correct tube placement  
    c. Using an electromagnetic tube placement device to prevent malposition of tubes  
    d. No further research is necessary

Test ID: A152406 Contact hours: 1.0; pharma 0.0 Form expires: November 1, 2018. Test Answers: Mark only one box for your answer to each question.

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<thead>
<tr>
<th>1.</th>
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<th>8.</th>
<th>9.</th>
<th>10.</th>
<th>11.</th>
<th>12.</th>
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<td>c</td>
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Fee: AACN members, $0; nonmembers, $10  Passing score: 9 correct (75%)  Category: CERP A Test writer: Daniel N. Storzer, RN, DNP, ACNPC, ACNP-BC, CNRN, CCRN, CCEMT-P

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Increasing Parental Participation During Rounds in a Pediatric Cardiac Intensive Care Unit

By Angela Blankenship, APN, Sheilah Harrison, CPHQ, Sarah Brandt, BSN, Brian Joy, MD, and Janet M. Simsic, MD

Background Inviting parents of sick children to participate during the rounding process may reduce parents’ anxiety and improve communication between the parents and the health care team.

Objectives To increase the percentage of available parents invited to participate in morning rounds in a pediatric cardiothoracic intensive care unit (CTICU).

Methods Invitations to parents to participate in morning CTICU rounds were randomly audited from June 2012 to April 2014 (mean, 15 audits per month). From June 2012 to February 2013 (before intervention), 73% of parents available during morning rounds received an invitation to participate. From April 2013 to May 2013, the following interventions (family participation bundle) were implemented: (1) staff education, (2) “Invitation to Rounds” handout added to the parent welcome packet with verbal explanation, (3) bedside tool provided for parents to communicate desire to participate with the team, (4) reminder to invite parents added to nursing rounding sheet. Following interventions, family feedback was obtained by 1-on-1 (physician-parent) open-ended conversation.

Results From April 2013 to April 2014, 94% of parents available during morning rounds received an invitation to participate. Reasons for not participating: chose not to participate (63%), sleeping—staff reluctant to wake (25%), not English speaking (7%), breastfeeding (5%).

Conclusion Implementation of a family participation bundle was successful in increasing invitations to parents to participate during morning rounds in the CTICU. Engagement of staff and addressing specific staff concerns was instrumental in the project’s success. (American Journal of Critical Care. 2015;24:532-538)

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doi: http://dx.doi.org/10.4037/ajcc2015153
Family-centered care has been endorsed by several health care organizations, including the American Academy of Pediatrics.\textsuperscript{1-3} It has been suggested that parental participation during rounds is an important component of family-centered care and offers a consistent, timely way to discuss the child’s care and keep the family informed.

Having parents participate in rounds minimizes parental anxiety, builds trust, and improves communication and team building between the family and the medical team.\textsuperscript{4-7} Rounds have several purposes: decision making regarding clinical management, communication among the team members, and serving as a venue for teaching and discussion. Some concerns voiced by staff regarding inclusion of parents during rounds include privacy issues, increasing parents’ anxiety, increasing duration of rounds, decreasing teaching during rounds, and concerns for parents’ understanding of complex discussions.\textsuperscript{8-11}

Phipps et al,\textsuperscript{10} in an observational study, showed that parental presence during rounds did not inhibit teaching during rounds, although admittedly the data on this topic are controversial. Cameron et al,\textsuperscript{12} in a prospective, observational, and survey-based study, showed that 40\% of attending physicians limited their teaching during rounds to avoid exposing the knowledge gaps among house staff.\textsuperscript{12} This same study showed that 88\% of parents believed that parents should be invited to participate during rounds and 81\% reported that participation during rounds increased their overall satisfaction with their child’s care.\textsuperscript{12} Only 19\% stated that rounds increased their anxiety.\textsuperscript{12} In a prospective study via parental surveys, Kuo et al\textsuperscript{13} found that family participation during rounds was associated with higher parental satisfaction, improved and consistent transfer of medical information, discussion of care plan, and participation in decision making. Parents in the family-centered rounding group also thought that the physicians spent more time with their child than did parents in the rounding group that was not family centered.\textsuperscript{13}

Parental participation during rounds offers a venue to meet the Accreditation Council for Graduate Medical Education’s core competencies of professionalism, interpersonal and communication skills, direct observation, and feedback.\textsuperscript{1,14-16} Physician trainees reported that family-centered rounds enhanced their medical education by increasing the number of encounters with patients and observations of direct patient care, providing an opportunity for real-time feedback and role modeling by attending physicians, and enhancing communication and interpersonal skills.\textsuperscript{16}

Parental participation during rounds has been embraced as a measure of quality and as standard practice recommended by the American Academy of Pediatrics.\textsuperscript{3} The purpose of this quality improvement project was to increase the percentage of invitations to participate in morning rounds on the pediatric cardiothoracic intensive care unit (CTICU) that were extended to the parents available.

**Methods**

**Ethical Issues**

This quality improvement work involved development of practices designed to increase parental participation when parents were present during morning rounds. No interventions involved comparison of therapies, and there was no randomization. Patients’ medical records were not accessed. No personal health information was shared. Therefore, this study did not require approval by the institutional review board at our institution.

**Setting**

The CTICU is a 20-bed unit with approximately 540 admissions per year. The CTICU staff includes a multidisciplinary team of critical care and cardiology physicians, advanced nurse practitioners, a dedicated clinical pharmacist, nurses, respiratory therapists, physicians in training in critical care and cardiology, a clinical dietician, a physical therapist,
The rounding process takes approximately 15 minutes per patient. The CTICU is staffed 24 hours per day with in-house physician and advanced nurse practitioner coverage.

**Rounding Process**

The rounding process takes approximately 15 minutes per patient. The multidisciplinary rounding team consists of an attending intensive care physician, a consulting physician as appropriate (ie, cardiologist, transplant physician, perfusionist, neonatologist), 2 or 3 CTICU advanced nurse practitioners, fellows (cardiology and PICU), a clinical pharmacist, a dietician, a bedside nurse, a respiratory therapist if the patient is intubated, and the patient’s parents if available. If the patient is to be transferred to the cardiology step-down unit, that team (attending physician, charge nurse, resident, advanced nurse practitioner or cardiology fellow) also participate. Rounds begin promptly at 8 AM with the bedside nurse reading the rounding sheet. The rounding sheet begins with the diagnosis and reason for admission, followed by the events of overnight, then a review by systems including vital signs, medications, laboratory values, and nursing concerns. Following the bedside nurse’s presentation, the fellow or advanced nurse practitioner reviews with data and presents the plan for the day by systems. Next, the family is asked if all of their concerns were addressed and if they have any additional questions or comments that they would like to share. The bedside nurse then summarizes the plans for the day by using a daily goals worksheet and new orders are reviewed.

**Planning the Intervention**

The project began with a retrospective review of hospital random audits performed by the hospital’s quality department via direct observation of invitations to participate in morning CTICU rounds extended to the parents who were available. The quality representative was present during rounds and observed if the parent was present in the room and if present, if the rounding team invited the parent to participate during rounds. From June 2012 to February 2013 (before the intervention), only 73% of parents available during morning rounds received an invitation to participate.

A multidisciplinary team, including a CTICU attending physician, advanced nurse practitioner, nursing leadership representative, bedside nurse, and quality improvement services representative, was recruited to explore reasons for not inviting an available parent to participate during morning rounds. Based on this information, a SMART (specific, measurable, achievable, realistic, timely) specific aim statement and key driver diagram were created (Figure 1).

**Intervention**

Staff education was planned on the basis of the issues discovered during the root-cause analysis. A large component of this education included reassurance that education and teaching would not be reduced, reassurance that rounds would not last longer than necessary, and reassurance that information would be presented to the parents at an appropriate level. Education was in the form of e-mails, individual and small-group discussions, as well as staff meetings, review of the published literature, and making it personal—“what would you want if it were your child?” Throughout the process,
real-time feedback from the staff was also entertained regarding the concerns just listed.

The first intervention was to place a formal “invitation to rounds” (Figure 2) in the CTICU parent welcome packet. The invitation to rounds was intended to share the desire, importance, and goal of family participation during rounds. The formal invitation was accompanied by a verbal explanation of the rounding process, what to expect during rounds, and the desire and importance of family participation by the nursing staff. The welcome packet already contained photos, job descriptions, and names of the multidisciplinary team members for the month.

Additionally, a method that parents could use to communicate whether they desired to participate in morning rounds was developed. The first attempt was a process where a member of the night-shift team (physician, advanced nurse practitioner, bedside nurse) asked the parents, if present, if they wished to participate during morning rounds the following morning. Their response was then written on the glass door to the patient’s room where the morning rounding team could read it. The staff and parents enjoyed writing on the doors, which enhanced buy-in for the project. This intervention was the first plan-do-study-act (PDSA) cycle. This method of communication improved staff engagement and was effective in communicating parents’ desire to participate, but it did not address the communication needs for our patients in our open bay rooms (without doors). Therefore, the hang tag was introduced (Figure 2). The hang tag was given to the parents on admission with the instructions to hang it on the hook outside each room (even in the open bay rooms) on the appropriate side. One side of the hang tag stated “Yes, I want to join rounds” and the other side stated “No, I do not wish to join rounds.”

A third intervention was to place a reminder on the nurse’s morning rounding sheet to remind the rounding team to invite the parent to participate. This nursing reminder, the hang tag, and the invitation to rounds were the 3 components that made up the CTICU family participation bundle.

Method of Evaluation and Analysis

A retrospective review of random audits performed by our hospital’s quality information services department via direct observation of invitations to participate in morning CTICU rounds was analyzed to obtain preintervention baseline data. During the initial months following the implementation of the family participation bundle, audits were performed more frequently by the CTICU staff to encourage staff buy-in, to obtain real-time feedback, and to address any ongoing concerns (mean, 7 audits per month June 2012-Feb 2013 vs 24 audits per month April 2013-April 2014). During implementation of the family participation bundle, use of the hang tag was audited for the first 2 months after implementation (May and June 2013).

Five weeks after implementation of the family participation bundle, 1-on-1 open interviews were undertaken between a single attending physician and 5 parents in the CTICU to solicit feedback regarding family participation during morning rounds.

Results

The multidisciplinary initial root-cause analysis revealed several issues and concerns, including (1) the perception that the parents did not desire to participate, (2) reluctance to wake the parent if the parent was asleep during rounds, (3) concern that education or teaching during rounds would be reduced, (4) concern that rounds would take longer, (5) concern that rounds were too technical, and (6) concerns that differing opinions in management would lead to parental anxiety or confusion.

From June 2012 to February 2013 (before the intervention), only 73% (n = 66 audits) of parents who were present during morning rounds received an invitation to participate. From April 2013 to April 2014 (after the intervention), 94% (n = 309 audits) of parents present during morning rounds received an invitation to participate (P < .001; Figure 3). Monthly use of the hang tag was 80% in May 2013 and 77% in June 2013. The percentage of families who were present to whom invitations were extended was 90% in May 2013 and 94% in June 2013. Monthly hang tag audits were stopped because
of the sustained improvement in extending invitations to available parents to participate during rounds.

Of the 5 parents interviewed for parental feedback, 4 of the 5 thought that participation during rounds was beneficial and enhanced the understanding of their child’s medical condition and management plan. Only 1 parent did not think that participating in morning rounds was beneficial. This parent’s child had been in the CTICU for several months and the parent was not interested in hearing all of the data presented. He preferred for the physician or nurse practitioner to provide a brief update and plan for the day following rounds.

During the random audits between April 2013 and April 2014, parents were physically present in the room at the time of morning rounds only 57% of the time. Unfortunately, these data were not collected before the family participation bundle was instituted. Reasons for available parents not participating during rounds included the following: parent chose not to participate (63%), parent was asleep and staff was reluctant to wake (25%), parent was not English speaking (7%), and the mother was breastfeeding and staff did not want to intrude (5%).

**Discussion**

Parental participation during rounds is an important component of family-centered care and offers a consistent, timely way to discuss the child’s care and keep the family informed. Implementation of a multidisciplinary collaborative bundle to increase the percentage of available parents invited to participate in morning CTICU rounds resulted in an increase in parental participation in rounds from 73% to 94%.

Quality methods were useful tools in analysis, organization, and communication of information to direct this initiative. The first step in this project was to use cause and effect analysis to provide a way of considering all possible factors contributing to parental participation during rounds. These factors include systems, equipment, materials, external forces, and people. For each of the factors identified, possible causes of the problem that may be related to the particular factor were discussed. Addressing staff concerns and perceptions through brainstorming discussions and cause and effect analysis led to the development of the specific aim statement, key driver diagram, and family participation bundle.

**Figure 3** Run chart from June 2012 to April 2014 of parents available during morning rounds who received an invitation to participate.
The specific aim statement answers the question: “What are we trying to accomplish?” An aim statement provides a clear focus for the improvement goal that is specific, measurable, achievable, realistic, and timely. The key driver diagram helps recognize relationships and organize work. It includes “key drivers” (elements, factors, or influences) contributing directly to the aims statement and interventions (in this case, family participation bundle) describing “how” to address the key drivers contributing directly to the aims statement includes “key drivers” (elements, factors, or influences) contributing directly to the aims statement.

Interventions are evaluated by using PDSA cycles to test success of the intervention, identify potential problems, note unexpected observations, and compare results with predictions. The result of the PDSA cycle is to adopt the intervention, abandon it or try again after modification. This was a useful tool in development of the components of the family participation bundle.

In regard to the components of the CTICU’s family participation bundle, the invitation to rounds served as an introduction for the staff to discuss the benefits and goals of parent participation during rounds with the parents. Currently we use a combination of communication tools including writing on the door, hang tags, and verbal inclusion during the nursing hand-off, as we discovered that communication of the desire to participate in morning rounds, in general, was more important than the specific communication tool (writing on the door vs hang tag). The reminder on the nurse’s rounding sheet that is read during rounds also helped avoid failing to extend an invitation to the parents to participate during rounds, especially when a float nurse was working in the CTICU. Most importantly, staff buy-in to the importance of parents’ participating during rounds and engaging in the process was a key element of our success.

The initial concerns voiced by our CTICU staff, as well as in published reports, regarding privacy issues, increasing parental anxiety, increasing duration of rounds, decreasing teaching during rounds, and concerns for parents’ understanding of complex discussions were not found to be true in our experience. Our findings are more consistent with those of Kuo et al, who reported that family participation during rounds was associated with higher parental satisfaction.

Conclusions
Implementation of a family participation bundle was successful in increasing parent participation during morning rounds in the CTICU. Engagement of staff and addressing specific concerns were instrumental in project success.

Acknowledgments
We thank the CTICU staff for embracing this quality project and contributing to its success. We also acknowledge Dr Ben Braun for development of the invitation to rounds.

Financial Disclosures
None reported.

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In the past, tradition has not supported family presence during resuscitation efforts or during performance of invasive procedures. However, there is very little hard evidence to support this tradition. Research and evidence now tell us that including families, when appropriate, and providing them with the proper support during these experiences can have positive outcomes for the patient, family, and health care in general. This is not to say that all family members should be present during every situation. These decisions must be based on patient and family preference and availability of personnel to support the family.

Here’s what you can do:
- Evaluate the unit and hospital policy for family presence during resuscitation and invasive procedures.
- Survey the interprofessional staff regarding attitudes toward family presence.
- Discuss barriers and concerns about family presence during staff meetings.
- Include chaplaincy, risk management, and other disciplines in the conversation.
- Identify a champion for family presence on your unit.
- If feasible, bring family members back to the unit to talk about their experience of being included.
- Evaluate options for providing family presence on your unit: who, what, when, where, why, and how.
- Determine how family support during resuscitation or invasive procedures will be provided.
- Train appropriate staff on how to provide family support.
- Debrief staff after experiences where families have been included or excluded from being present.

Other helpful resources:

Based on material from and published as a supplement to the article by Twibell and colleagues, “Being There: Inpatients’ Perceptions of Family Presence During Resuscitation and Invasive Cardiac Procedures” (American Journal of Critical Care. 2015;24:e108-e115).
National news and medical journals shined the spotlight on cooling in spinal cord injury (SCI) when Buffalo Bills tight end Kevin Everett suffered the devastating effects from a head-on tackle in front of thousands of spectators in 2007. Within minutes, he was “iced” and transported to a medical center, where he underwent emergency surgery to repair damage to his cervical spine. With a potential paralysis prognosis, he was able to walk just 3 months after his injury. In 2011, another young athlete, a 20-year-old gymnast named Jorge Valdes, walked out of the hospital 7 days after receiving systemic cooling and surgery for a cervical spine injury. Although much media attention has been placed on these 2 captivating cases, where are we now and what does the research indicate for therapeutic hypothermia in patients with SCI?

Spinal cord injuries in the United States affect roughly 240,000 to 340,000 people, with approximately 12,500 additional cases each year.1 Eighty percent of those affected are male, with a mean age of 42 years, up from age 29 in the 1970s.1 The mechanism of SCI is multifaceted and includes motor vehicle collisions, sporting events, acts of violence, explosions, recreational activities, and increasingly falls in older adults.2,3 The goal of acute SCI treatment is preservation of function, limitation of secondary injury, and prevention of subsequent complications.4 Therapeutic hypothermia is described as a reduction of core body temperature to improve medical outcomes.5,6 The neuroprotective benefit of therapeutic hypothermia is considered to be wide ranging and complex; one theory is that it may reduce the metabolism within the central nervous system to maintain or improve functional outcomes and prevent secondary neuronal injury.5

Historically, lowering body temperature has captured the interest of many scientists. One of the earliest physicians to study the effects of cooling, originally termed as hibernation or refrigeration, was Dr Temple Fay, a neurosurgeon from Philadelphia. In 1919, he began to perform studies on lower temperature and the effects on cellular growth.5,7 This eventually guided further studies of cooling in areas such as cardiac surgery and other neurological conditions.8 As experiments advanced, attention paid to use of body temperature modulation to limit the effects of injuries sustained to the neurological system emerged in the 1950s and 1960s.2,8 Several reports and clinical examples were published in the 1970s, providing some indication of a possible benefit of localized cooling in patients with SCI.9-13 However, use of cord cooling began to decline in the mid 1970s to 1980s because of the unreliable outcomes and with the emergence of drug therapies such as administration of methylprednisolone.8 Unfortunately, drug therapy studies revealed an increase in complications and limited proven outcomes, leading to a decline in steroid use over time.8 Mild hypothermia again started to show promise in animal models with improved outcomes since 2000.14,15 Moreover, with the positive neurological outcomes seen after cardiac arrest and in neonates with hypoxia-ischemia,16,17 it makes sense to take a closer look at therapeutic hypothermia in neurologically injured patients. In this review, we summarize current evidence on therapeutic hypothermia in SCI patients.

Search Methods
A search was conducted in CINAHL and MEDLINE by using the following search terms: hypothermia, cooling, and spinal cord injury.

Results
Seventy-six references were identified, with a vast majority consisting of review articles, animal studies, and some case reports from the 1970s. Of the research studies completed, a total of 5 were retrieved (Table 1): 1 prospective
case series, a combined prospective and retrospective study, retrospective case series of the same patient population in a phase 1 feasibility study reviewing complications then outcomes after 1 year, and 1 case report.

Patients’ Background

Patients included in the 5 studies all had a score of 15 on the Glasgow Coma Scale and a grade of A on the American Spinal Injury Association Impairment Scale (AIS; Table 2) on admission. All were 16 to 65 years old, and all had been taken to the operating room for surgical decompression following their traumatic injury. All patients sustained cervical fractures, and 1 patient had fractures of both the cervical and the thoracic spine.

Initiation, Method, and Duration of Cooling

Cappuccino et al used an Alsius cooling catheter in the femoral vein started at postinjury hour 16 and cooled to 33.5°C for a total of 36 hours. Before the initiation of intravascular cooling, this patient also received external placement of chilled saline bags and an ambient room temperature of 55°F. Levi et al and Dididze et al also used an Alsius CoolGard catheter initiated at postinjury hour 7.76 (SD, 1.09 hours) for 46.77 hours (SD, 1.71 hours). Hansebout and Hansebout used a spinal cord cooling saddle and initiated cooling at 7.1 hours (mean) for 3.7 hours (mean).

Outcomes and Timing of Follow-up

Cappuccino et al reported that 4 months after receiving surgical decompression, steroids, and therapeutic hypothermia, the patient had an AIS grade of D. The patient sustained no medical complications. Dididze et al also used an Alsius CoolGard catheter initiated at postinjury hour 7.76 (SD, 1.09 hours) for 46.77 hours (SD, 1.71 hours). Hansebout and Hansebout used a spinal cord cooling saddle and initiated cooling at 7.1 hours (mean) for 3.7 hours (mean).

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Table 1

<table>
<thead>
<tr>
<th>Reference</th>
<th>Population</th>
<th>Design and interventions</th>
<th>Follow-up time after AIS</th>
<th>Steroids, time (if recorded)</th>
<th>Complications (frequency/difference)</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cappuccino et al, 2010</td>
<td>1 cervical</td>
<td>Case report; surgical decompression, intravascular cooling</td>
<td>4 months: AIS D = 1</td>
<td>Yes, 3 hours</td>
<td>None</td>
<td>E</td>
</tr>
<tr>
<td>Dididze et al, 2013</td>
<td>35 cervical</td>
<td>Retrospective (n = 14) and prospective (n = 21) case controlled study; surgical decompression and intravascular cooling</td>
<td>11 months: 15 of 35 improved at least 1 AIS class</td>
<td>None</td>
<td>Atelectasis (29), pneumonia (21), pleural effusion (19), pulmonary edema (15)</td>
<td>C</td>
</tr>
<tr>
<td>Hansebout and Hansebout, 2014</td>
<td>20 (14 cervical, 6 thoracic)</td>
<td>Prospective case series; dural cooling, surgical decompression, steroids</td>
<td>4.9 years: AIS A = 7, AIS B = 6, AIS C = 5, AIS D = 2</td>
<td>Yes, 11 days</td>
<td>Atelectasis (9), pneumonia (7), decubitus ulcers (6)</td>
<td>C</td>
</tr>
</tbody>
</table>

Initiation, Method, and Duration of Cooling

Cappuccino et al used an Alsius cooling catheter in the femoral vein started at postinjury hour 16 and cooled to 33.5°C for a total of 36 hours. Before the initiation of intravascular cooling, this patient also received external placement of chilled saline bags and an ambient room temperature of 55°F. Levi et al and Dididze et al also used an Alsius CoolGard catheter initiated at postinjury hour 7.76 (SD, 1.09 hours) for 46.77 hours (SD, 1.71 hours). Hansebout and Hansebout used a spinal cord cooling saddle and initiated cooling at 7.1 hours (mean) for 3.7 hours (mean).

Outcomes and Timing of Follow-up

Cappuccino et al reported that 4 months after receiving surgical decompression, steroids, and therapeutic hypothermia, the patient had an AIS grade of D. The patient sustained no medical complications. Dididze et al reported that 4 patients had converted to AIS grade B within 24 hours, and 15 of 35 patients had improved by at least 1 grade by 10.07 months (SD, 1.03 months). Most complications were pulmonary, and both prospectively and retrospectively analyzed patients had comparable odds of complications developing. Study was 14.2%. Levi et al reported that atelectasis...
developed in 12 of 14 patients, pneumonia in 8, acute respiratory distress syndrome in 2, atrial fibrillation in 1, and thrombocytopenia in 1. None of the patients sustained venous thromboembolism, myocardial infarction, or death.

Levi et al20 used the same population of patients as in the 2009 study and reported that at 1 year follow-up, 43% showed an improvement of 1 or more AIS grades. Specifically, 3 improved to AIS grade B, 2 improved to grade C, and 1 improved to grade D. Furthermore, comparing the complications noted in the 2009 study by Levi et al with the complications in a control group in the 2010 study, only the incidence of pleural effusions and anemia differed significantly. Hansebout and Hansebout4 followed up patients at 4.9 years and reported that 35% remained AIS grade A, 30% improved to grade B, 25% improved to grade C, and 10% improved to grade D. Early complications noted were largely pulmonary, followed by decubitus ulcers and urinary tract infections.

Recommendations for Practice

Although the research reviewed is encouraging, the level of evidence (Table 3) to support or recommend therapeutic hypothermia in SCI for protocol development is not high (grade C).24 The 5 studies reviewed suggest that use of therapeutic hypothermia (32ºC-34ºC) for 6 to 48 hours may be neuroprotective and lead to improved outcomes rather than just using surgical decompression and steroids alone. Therapeutic hypothermia is a relatively safe intervention that has been possibly associated with an improvement in AIS grade. Most complications identified are respiratory and are no more common in controls than in patients with SCI. Additionally, none of the selected studies had to stop their interventions because of the negative sequelae of therapeutic hypothermia. Regarding systemic (intravascular) cooling, it is a readily available and reproducible means to offer an improvement in functional neurological status. Regional (dural) cooling has side effects similar to those of systemic cooling, and if regional cooling can be initiated within hours of injury, may be an alternative to therapeutic hypothermia.

The current phase 1 study and the pending phase 2 clinical trials at the University of Miami...
and The Miami Project to Cure Paralysis should give future direction and strength to the body of research on use of therapeutic hypothermia in patients with SCI. Ideally, additional clinical trials at multiple centers would be most beneficial to define the ideal SCI candidate and determine how long therapeutic hypothermia should be administered while continuing to assess the safety of this intervention. Although promising study results have been reported and attention-grabbing case examples have been shared by the media, many questions remain to be answered. For such a sudden, catastrophic, and debilitating injury, it does create a vulnerable patient population; however, the sense is that many potential subjects may reasonably weigh the risks and benefits of therapeutic hypothermia to prevent a future life of uncertain disabilities.

FINANCIAL DISCLOSURES
No reported.

REFERENCES

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So do we.
**Scenario:** The Figure below is a screen shot of a bedside monitor in the emergency department from an 85-year-old man who complained of dizziness, weakness, and a “fuzzy” memory. The nurse was challenged managing the numerous false asystole alarms generated, particularly because she could see indications of a QRS complex. The patient was alert and oriented, and his vital signs were within normal limits. Why is there an asystole alarm despite the obvious QRS complexes?

**Interpretation Questions:**

1. Is the ECG properly calibrated (10 mm) and are leads properly placed? □ Yes □ No □ NA
   
2. Is this a sinus rhythm (one P wave preceding every QRS complex)? □ Yes □ No □ NA
   
3. Is the heart rate (R-R interval) normal (60-100 beats/min)? □ Yes □ No □ NA
   
4. Is the QRS complex narrow (duration < 110 milliseconds [ms] in V1)? □ Yes □ No □ NA
   
5. Is the ST segment deviated (> 2 mm in V2-V3, or > 1 mm in other leads)? □ Yes □ No □ NA
   
6. Is the QT interval lengthened (> 450 ms [women] or > 470 ms [men])? □ Yes □ No □ NA
   
7. Is R- or S-wave amplitude enlarged (S wave V1 + R wave V5 > 35 mm)? □ Yes □ No □ NA

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Answers:
1. Unable to assess calibration
2. Yes, P waves are visible before every QRS complex
3. No, a heart rate is not provided from the ECG signal, but the heart rate calculated by the \( \text{SPO}_2 \) is 54, which meets criteria for bradycardia
4. Unable to measure, V1 not shown
5. No, the ST segment is not deviated
6. No, the T wave is not inverted
7. Unable to determine from this bedside monitor view and measurements are not provided by the software
8. Unable to measure, V1 and V5 not shown

Interpretation
Sinus bradycardia at 54 beats/min, appears to have a first degree AV block (verify using printed ECG), with false positive asystole alarms

Rationale
The American National Standard for cardiac monitors states that ECG devices should not label a QRS complex if the waveform is lower than 0.15 mV (1.5 mm) in amplitude to avoid mislabeling P waves or baseline noise as QRS complexes during critical arrhythmias such as complete heart block or asystole. Whereas this is the stated standard, manufacturers of ECG devices use an even more conservative QRS threshold, in some cases greater than 5 mm in more than 1 ECG lead. The result of this more conservative amplitude requirement is an increase in the number of false positive asystole alarms in patients who have low amplitude QRS complexes, as is seen in this example. There are P waves, QRS complexes, and T waves visible on the Figure, however, the QRS complex does not meet the manufacturer’s amplitude requirement and results

Management
Bedside ECG monitoring is a valuable tool for surveillance of hospitalized patients, but these devices are often plagued with false alarms. Asystole is typically configured as a “latching” alarm, which means that once activated, it requires deliberate action to be deactivated. Low amplitude QRS complexes can be due to patient factors (eg, prior myocardial infarction, bundle branch block, and obesity). Two ways to optimize the ECG signal is to select an ECG lead with a tall QRS complex that meets the manufacturer’s detection threshold; this can be done by choosing a different monitoring lead on the bedside monitor, or increasing the gain of the QRS complex until it’s at least 5 mm. Optimizing the ECG signal on the bedside monitor may reduce false alarms and prevent alarm fatigue.
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