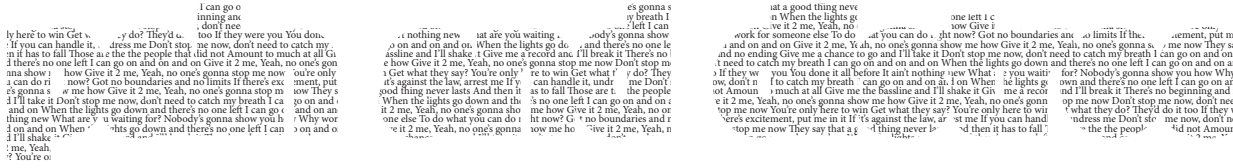

management of pain and distress in the adult icu patient

Management of Pain and Distress in the Adult ICU Patient

Management van pijn en onrust bij volwassen IC-patiënten

Proefschrift

ter verkrijging van de graad van doctor aan de Erasmus Universiteit Rotterdam op gezag van de rector magnificus Prof.dr S.W.J. Lamberts en volgens het besluit van het College voor Promoties

De openbare verdediging zal plaatsvinden op
donderdag 13 november 2008 om 11.00 uur

door

Fenna Jeannette Schoonderbeek
geboren te Utrecht

Promotiecommissie

Promotor
Prof.dr H.A. Bruining

Overige leden
Prof.dr D. Tibboel
Prof. J.H.P. Wilson
Prof.dr J. Kesecioglu

Copromotor
Dr M. van Dijk

Paranymfen
Drs M.M. Nooteboom
Jkvr.mr E.H.A. Sandberg

ISBN: 978-90-8559-442-0
Illustratie omslag: A. van Ommeren, 2005 (*bewerkt*)
Ontwerp en druk: Optima Grafische Communicatie, Rotterdam

Voor mijn ouders

contents

Chapter 1

Preface

The core business of doctors is to treat patients. And we like it. We like to base the treatment of our patients on evidence and preferably to follow the results by measurable parameters. At the same time, we stress that experience and clinical view (our so-called gut feeling) are very important assets to be obtained by young doctors.

In critical care, evidence based protocols are often not available and a measurable parameter not always obtainable. And so we continue to study new technologies and new strategies.

This thesis focuses on one of the more challenging and contentious areas of practice in intensive care: management of pain and distress in critically ill adult patients. Challenging and contentious for the following reasons: lack of a 'gold' standard of assessment, no consensus on a preferred regimen and contradictory results emerging from different studies comparing different technologies and approaches. Results of pharmacological studies in healthy subjects are unlikely to be applicable in critically ill patients. In addition, many studies in intensive care are still performed in stable postoperative patients, and not in those with multiple organ failure. Few studies have examined changes in drug metabolism and clearance during the course of critical illness, the significance of inter-individual differences in drug handling, the effect of changes in endothelial permeability or blood-brain barrier function, or the interplay between disease and drugs in influencing cerebral function. In part, this is a consequence of the heterogeneity of the intensive care population and the logistic difficulties of conducting research in an unpredictable clinical environment. The net result is wide diversity of clinical practice and the predominance of opinion over fact.

One way of encouraging a more uniform approach to manage pain and distress in critically ill patients would be to agree to a common terminology for describing the patient's apparent level of comfort. And what is important is not so much the precise method of measurement, as the fact that the measurement has been used to change the management in handling pain and distress.

The importance of good pain practice

Perhaps one of the most neglected issues in critical care practice is optimal pain treatment.
Pain may either result from the pre-existing illness or injury (e.g. recent surgery, inflammation or trauma) or from the very treatment of illness or injury, including invasive procedures and therapeutic interventions. [1,2]
Good pain practice and pain management have been shown to improve the patient's recovery. [3,4] Untreated pain, in contrast, may have several consequences. It may interfere with weaning from controlled ventilation. [5,6] It may also initiate a multifactorial cascade of complex physiologic responses – known collectively as the stress response – that has been associated with increased morbidity and length of stay. [5,7-9]
Poorly managed pain may have serious psychological impact as well. [10,11] It is associated with factors such as depression and anxiety, and is influenced by gender and race. [4,12-31] It increases the risk of posttraumatic stress disorders following intensive care unit discharge. [1,32]
In conclusion, pain is a significant problem for critically ill patients, because it is a major stressor associated with a variety of negative sequelae.[20,33-37]
Clinically important levels of pain and dissatisfaction with pain control are found in all disease categories, including chronic obstructive pulmonary disease and congestive heart failure, diseases that have not been traditionally associated with pain.[32] Pain experience and satisfaction with pain control vary significantly among hospital sites, even after adjustment for many potential confounders. [19,32,38]

These examples illustrate the problem of pain control in the critically ill. In this thesis the author wishes to emphasize the relevance of systematic and consistent assessment and documentation of pain.

Pain practice in the critically ill

Although pain management is receiving more and more attention, large multicenter studies indicate that good pain control still is a worldwide problem. [39-41] The results of the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT) show, in accordance with other studies, that pain is common among severely ill hospitalized patients.[32] Nearly fifty percent of the 5.176 interviewed patients reported pain, of whom 14.9% severe pain.
Twenty-one percent of patients who were asked about the location and perception of their pain, did not know the cause as they did not relate their pain to surgery, intravenous therapy or intramuscular injections. Similar results were reported in a large survey in the United Kingdom.[42] Routinely performed diagnostic and treatment related procedures were found to be considerably painful, but only less than 20% of patients received opiates before such interventions. [11,43]
A number of studies reveal the complexity of clinical decision making for pain interventions. Puntillo et al. developed the Pain Assessment and Intervention Notation (P.A.I.N.) tool [44] to determine which behavioural or physiological indicators of pain were most frequently used by nurses. These were grimacing, frowning, wincing, increased heart rate, increased

blood pressure and vocalization. Although pain intensity scores did not differ significantly between the patients and nurses, the nurses' ratings were consistently lower than the patients' ratings. Furthermore, the algorithm-based dose of opioids that nurses choose to administer correlated more often with the nurses' ratings of a patient's pain than with the patients' own self-reports.[44]

Physicians, too, significantly underestimate patients' pain compared to self-report of the patient. Discrepancies between nonverbal pain behaviour and the patients' verbal complaint of pain are often resolved by disregarding the patients' self-report, notwithstanding the fact that even in critically ill patients, self-report is probably the most valid indicator of pain. [4,45,46]

The moderate correlation between self-report and observational pain behaviour ratings increases during episodes of acute pain when both assessments are performed simultaneously.[47]

These studies also indicated that focussed attention to behavioural and physiological signs of pain may lead to more effective pain management, thus pain cannot be treated adequately unless it is adequately assessed. An improved awareness may lead to better identification and anticipation of a patient's need for analgesia. The frequency of pain assessment increases by lowering the threshold when, for example, a pre-printed area is provided on an assessment flow sheet.[48-50]

Although physicians frequently prescribe analgesics with wide dose ranges, pain in critically ill patients is often undertreated.[19] One major reason is reluctance to use potent analgesics, in view of their potential for masking diagnoses, producing side effects and adverse events, and their interaction with other drugs.[51-53] In addition, critical illness may affect the pharmacokinetics of analgesics.[54,55] The above mentioned drawbacks should be considered, but should not be used as an excuse to avoid adequate analgesia.[56]

For comparison, in other groups of patients, where objective documentation of pain is impossible (e.g. children less than 3 years of age), many pain assessment instruments have been developed and studied.[57,58]

The importance of good sedation practice

Most critically ill patients require sedation for at least a part of their stay in the intensive care unit. Sedation can minimize agitation, can promote synchrony with the ventilator, and can help to relieve the anxiety and discomfort associated with the high technology environment of the ICU. The presence of an endotracheal tube, the performance of various diagnostic tests and interventions, such as tracheal suctioning, mobilization and transportation may necessitate either intermittent or continuous administration of sedative drugs. Sedation is integral to the management of certain patients, including those with severe intracranial hypertension or severe respiratory failure.

Inappropriate administration of sedation has potentially serious consequences. Insufficient sedation may lead to life-threatening agitation precipitating myocardial ischemia or ventilator dysynchrony. Excessive sedation may create prolonged alteration of consciousness, which could lead to increased morbidity, increased costs, as well as a prolonged stay in the ICU. [59-65]

Sedation practice in the critically ill

In 1981, a survey of 34 ICU's in the United Kingdom and Ireland found considerable variation in sedative agents used; however, the common target level of sedation was reflected in the fact that 67% of the respondents believed that patients should ideally be "detached from the ICU environment".[66] A follow-up study in 1987 found that 69% of the respondents would prefer to have their patients "asleep, but easily arousable". [67] In a survey conducted in the United States in 1991, 84% of the ICU's reported frequent use (20-70% of the patients) or routine use (>70% of the patients) of sedatives for mechanically ventilated patients.[68] Written standard protocols for sedation were used in 33% of the 39 responding ICU's in a survey in 1999 of sedation practice in Denmark.[69] Either way, sedation practice and the use of scoring systems and guidelines is quite different between countries. [70]

Present views on pain management

Both the Society of Critical Care Medicine (in 2002) and the Dutch Society of Intensive Care (in 2001) have published guidelines on the use of analgesics and sedatives in adults. [71,72] They also investigated existing pain assessment instruments and recommended, by absence of a generally accepted assessment tool, to use an instrument targeted to the defined patient population, in combination with systematic documentation.

Self–report is regarded as the gold standard. In patients who cannot communicate, pain should be assessed through observation of pain-related behaviour and physiological indicators, and on the guidance of changes in these parameters following analgesic therapy. [71,72]

Although the use of behavioural and physiological indicators to infer the presence of pain has been advocated, their appropriateness or accuracy have not yet been properly studied.[44,73,74] Research-based assessment tools that use physiological and behavioural cues of pain are needed. [44,75]

In a large pain study in 1999, only 4 out of 13 hospitals had alternative tools available (in addition to verbal and visual numeric scales) for patients who did not speak English, or who had functional deficits (blind, deaf, intubated).[48] The alternative tools were based on physiological signs and symptoms, gestures etc. Although such signs may be of help in assessing the presence of pain, they may also be unreliable and result in underestimation of pain or be a measure of anxiety rather than pain. [44,76-78]

Restlessness, sweating, tachycardia, lacrimation, dilation of the pupils and hypertension, as well as particular eye signals, facial expressions or hand or leg motions, have been found to be signs of inadequate analgesia in critically ill patients requiring controlled ventilation. [19,79]

The problematic nature of pain assessment in critically ill adults who seemingly have no cause for discomfort, may partly explain the lack of adequate analgesic therapy. In this context, Puntillo et al. studied the understanding of behavioural responses to pain in procedural and non-procedural situations. [11,17,19,44,80-82] Educating health care practitioners on the awareness of pain-related behaviour definitely is a first step.

Present views on sedation management

Methods used to achieve and evaluate tolerance to the IC-therapy are often determined by tradition or by convenience. In part, this is a consequence of the heterogeneity of the intensive care population and the logistic difficulties of conducting research in an unpredictable clinical environment. The result is a wide diversity of clinical practice and the predominance of opinion over fact. One way of encouraging a more uniform approach to sedation for critically ill patients would be to agree to a common terminology for describing depth of sedation and the patient's apparent level of comfort.
The proliferation of different methods for measuring sedation is open to several interpretations. The most obvious is between simple but subjective clinical bedside methods and more complex systems using innovative techniques to improve objectivity, accuracy and reliability.[83-85] So far, none single method has found universal favour, and the more complex methods may lack reproducibility.

What is important is not so much the precise method of measurement as the fact that the method is valid and has been used to improve the management of sedation. It is the translation from measurement to effective action which counts, i.e. to increase, reduce or continue sedatives. This requires collaboration between medical and nursing staff using simple guidelines which become an integral part of clinical practice, e.g. in the same way that vasoactive drugs are individually adjusted. This approach has been shown to allow effective sedation even with long acting agents without a negative effect on weaning time.[86]
Recent advances with more controllable drugs, better ventilation techniques and sedation strategies, as well as the use of scoring systems and sedation protocols, enable optimalization of sedation. [62,87,88] Yet, the optimal sedation strategy still remains a controversial issue. Despite controversies, a shift from deeper to lighter sedation, thereby maintaining the normal circadian rhythm, is emerging within the literature. [87-89]

Aim of the thesis

This thesis addresses specifically ongoing clinical issues concerning pain and distress policy in adult intensive care and describes encountered obstacles.
It discusses existing methods for assessing pain in critically ill adult patients, and evaluates their applicability, usefulness and reliability **(chapter 2)**.
It describes the development, validation and the process of implementation of a new pain assessment tool, the Critically Ill Assessment scale (C.I.A.), for critically ill adult patients **(chapter 3 and 4)**. This new tool is based on behavioural items and is easy to use.
The efforts made in introducing this new instrument in daily practice and the barriers encountered are described. This process is put in perspective with general issues in implementation of new strategies and the many different barriers in physician adherence to clinical practice guidelines.

The use of clinical guidelines is an important issue. Evidence of effectiveness is limited, but their introduction into clinical practice is inevitable and supported by most.
It is interesting that in an area as difficult and controversial as analgosedation in the ICU, the use of clinical guidelines based on a simple scale seems to have a beneficial effect on clinical practice.
This thesis also describes the development and implementation of a new pain-distress treatment algorithm, based on assessment with the C.I.A., in clinical practice **(chapter 5)**. The attitude towards a new strategy is evaluated by means of a questionnaire before introduction. Behaviour towards the use of this standardized therapy is analyzed six months after the introduction.
Monitoring the depth of sedation in patients under intensive care is difficult, because an 'ideal tool' does not exist. A scientifically validated instrument that could represent an international 'gold standard' has not been established. During the last few years, many different methods, including scoring systems ('subjective' evaluation) and recent instrumental systems, such as bispectral index scoring (BIS) and auditory evoked potential (AEP) ('objective' evaluation), have been proposed. However, none of these instruments is supported by strong clinical evidence.
This thesis also evaluates the usefulness of the bispectral index **(chapter 6)**. In two different studies BIS-results are compared to generally used subjective scoring systems. The results of these two studies are discussed.
Finally, in **chapter 7** general considerations are presented, general conclusions are drawn and some directions for future management of pain and distress in adult intensive care are set.

References

1. Nasraway S. Use of sedative medications in the ICU. *Semin Resp Crit Care Med* 2001;**22:**165-174.
2. Lang J. Pain: a prelude. *Crit Care Clin* 1999;**15:**1-16.
3. Kaiser K. Assessment and management of pain in the critically ill trauma patient. *Crit Care Nurs Q* 1992;**15**(2)**:**14-34.
4. Puntillo K, Weiss S. Pain: its mediators and associated morbidity in critically ill cardiovascular surgical patients. *Nurs Res* 1994;**43**(1)**:**31-6.
5. McArdle P. Intravenous analgesia. *Crit Care Clin* 1999;**15:**89-104.
6. Desai P. Pain management and pulmonary dysfunction. *Crit Care Clin* 1999;**15:**151-166.
7. Epstein J, Breslow M. The stress response of critical illness. *Crit Care Clin* 1999;**15:**17-33.
8. Arbour R. Sedation and pain management in critically ill adults. *Crit Care Nurs* 2000;**20**(39-56).
9. Hamill-Ruth R, Marohn M. Evaluation of pain in the critically ill patient. *Crit Care Clin* 1999;**15**(1)**:**35-54, v-vi.
10. Stanik-Hutt J. Pain management in the critically ill. *Crit Care Nurse* 1998;**18**(5)**:**85-8.
11. Puntillo K, White C, Morris A, et al. Patients' perceptions and responses to procedural pain: results from Thunder Project II. *Am J Crit Care* 2001;**10**(4)**:**238-51.
12. Chyun D. Patients' perceptions of stressors in intensive care and coronary care units. *Focus Crit Care* 1989;**16**(3)**:**206-11.
13. Dracup K, Bryan-Brown CW. Pain in the ICU: fact or fiction? *Am J Crit Care* 1995;**4**(5)**:**337-9.
14. Pooler-Lunse C, Price P. Pain and the critically ill. *Canadian Nurse* 1992;**88**(7)**:**22-25.
15. Shannon K, Bucknall T. Pain assessment in critical care: what have we learnt from research. *Intensive Crit Care Nurs* 2003;**19**(3)**:**154-62.
16. Murray M. Pain problems in the ICU. *Crit Care Clin* 1990;**6**(2)**:**235-53.
17. Porter L. Procedural distress in critical care settings. *Crit Care Nurs Clin North Am* 1995;**7**(2)**:**307-14.
18. Puntillo K. The phenomenon of pain and critical care nursing. *Heart Lung* 1988;**17**(3)**:**262-73.
19. Puntillo K. Pain experiences of intensive care unit patients. *Heart Lung* 1990;**19**(5 Pt 1)**:**526-33.
20. Simpson T, Armstrong S, Mitchell P. American Association of Critical-Care Nurses demonstration project: patients' recollections of critical care. *Heart Lung* 1989;**18**(4)**:**325-32.
21. Stein-Parbury J, McKinley S. Patients' experiences of being in an intensive care unit: a select literature review. *Am J Crit Care* 2000; **9**(1)**:**20-27.
22. Hendler N. The anatomy and psychopharmacology of chronic pain. *J Clin Psychiatry* 1982;**43**(8 Pt 2)**:**15-21.
23. Garron D, Leavitt F. Chronic low back pain and depression. *J Clin Psychol* 1983;**39**(4)**:**486-93.
24. Williams A, Schulz R. Association of pain and physical dependency with depression in physically ill middle-aged and elderly persons. *Phys Ther* 1988;**68**(8)**:**1226-30.
25. Strang P. Emotional and social aspects of cancer pain. *Acta Oncol* 1992;**31**(3)**:**323-6.
26. Ahles TA, Ruckdeschel JC, Blanchard EB. Cancer-related pain--II. Assessment with visual analogue scales. *J Psychosom Res* 1984;**28**(2)**:**121-4.
27. Spiegel D, Bloom J. Pain in metastatic breast cancer. *Cancer* 1983; **52**(2)**:**341-5.
28. Kinder B, Curtiss G, Kalichman S. Anxiety and anger as predictors of MMPI elevations in chronic pain patients. *J Pers Assess* 1986; **50**(4)**:**651-61.

29. Rees W. Opioid needs of terminal care patients: Variations with age and primary site. *Clin Oncol* 1990;**2:**79-83.
30. Harkins S, Chapman C. Age and sex differences in pain perception. In: Pain in the Trigeminal Region. *Anderson DJ, Matthews B (eds)* 1977**:**435-444.
31. Kaiko R, Wallenstein S, Rogers A, Houde R. Sources of variation in analgesic responses in cancer patients with chronic pain receiving morphine. *Pain* 1983;**15**(2)**:**191-200.
32. Desbiens NA, Wu AW, Broste SK, et al. Pain and satisfaction with pain control in seriously ill hospitalized adults: findings from the SUPPORT research investigations. For the SUPPORT investigators. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment. *Crit Care Med* 1996;**24**(12)**:**1953-61.
33. Ballard K. Identification of environmental stressors for patients in a surgical intensive care unit. *Issues Ment Health Nurs* 1981(3)**:**89-108.
34. Baker CF. Sensory overload and noise in the ICU: sources of environmental stress. *Ccq* 1984;**6**(4)**:**66-80.
35. Jones J, Hoggart B, Withey J, Donaghue K, Ellis B. What the patients say: A study of reactions to an intensive care unit. *Intensive Care Med* 1979;**5**(2)**:**89-92.
36. Nadelson T. The psychiatrist in the surgical intensive care unit. *Arch Surg* 1976(111)**:**113-117.
37. Minckley B. A study of noise and its relationship to patient discomfort in the recovery room. *Nurs Res* 1968;**17**(3)**:**247-50.
38. Belville J, Forrest W, Miller E et al. Influence of age on pain relief from analgesics. *JAMA* 1971(171)**:**1835-1841.
39. Bertolini G, Minelli C, Latronico N, et al. The use of analgesic drugs in postoperative patients: the neglected problem of pain control in intensive care units. An observational, prospective, multicenter study in 128 Italian intensive care units. *Eur J Clin Pharmacol* 2002;**58**(1)**:** 73-7.
40. Sun X, Quinn T, Weissman C. Patterns of sedation and analgesia in the postoperative ICU patient. *Chest* 1992;**101:**1625-1632.
41. Dasta JF, Fuhrman TM, McCandles C. Patterns of prescribing and administering drugs for agitation and pain in patients in a surgical intensive care unit. *Crit Care Med* 1994;**22**(6)**:**974-80.
42. Bruster S, Jarman B, Bosanquet N, Weston D, Erens R, Delbanco TL. National survey of hospital patients. *Bmj* 1994;**309**(6968)**:**1542-6.
43. Thompson C, White C, Wild L, et al. Translating research into practice. Implications of the Thunder Project II. *Crit Care Nurs Clin North Am* 2001;**13**(4)**:**541-6.
44. Puntillo K, Miaskowski C, Kehrle K, Stannard D, Gleeson S, Nye P. Relationship between behavioral and physiological indicators of pain, critical care patients' self-reports of pain, and opioid administration. *Crit Care Med* 1997;**25**(7)**:**1159-66.
45. Melzack R, Katz J. Pain measurement in persons in pain. *in Wall PD, Melzack R (eds): Textbook of Pain, third edition. Churchill Livingstone 1994* 1994.
46. Melzack R, Torgerson W. On the language of pain. *Anesthesiology* 1971;**34**(1)**:**50-9.
47. Labus JS, Keefe F, Jensen M. Self-reports of pain intensity and direct observations of pain behavior: when are the correlated? *Pain* 2003(102)**:**109-124.
48. Carroll K, Atkins P, Herold G, et al. Pain assessment and management in critically ill postoperative and trauma patients: a multisite study. *Am J Crit Care* 1999;**8**(2)**:**105-117.
49. Voigt L, Paice JA, Pouliot J. Standardized pain flowsheet: impact on patient-reported pain experiences after cardiovascular surgery. *Am J Crit Care* 1995;**4**(4)**:**308-13.
50. Veselis R. Intravenous narcotics in the ICU. *Crit Care Clin* 1990; **6**(2)**:**295-313.
51. Allock N, Toft C. Student nurses' attitudes to pain relieving drugs. *Int J Nurs Studies* 2003;**40**(2)**:**125-131.

52. Sun X, Weissman C. The use of analgesics and sedatives in critically ill patients: physicians' orders versus medications administered. *Heart Lung* 1994;**23**(2)**:**169-76.
53. Whipple J, Lewis K, Quebbeman E, et al. Analysis of pain management in critically ill patients. *Pharmacotherapy* 1995;**15**(5)**:**592-9.
54. Kato R, Takanaka A, Onoda K, Omori Y. Drug affecting the gastric emptying rate and drug absorption. *Jpn J Pharmacol* 1972;**22**(3)**:** 434-6.
55. Boldt J, Thaler E, Lehmann A, Papsdorf M, Isgro F. Pain management in cardiac surgery patients: comparison between standard therapy and patient-controlled analgesia regimen. *J Cardiothorac Vasc Anesth* 1998;**12**(6)**:**654-8.
56. Waheed U, Brett S. Pain management in the intensive care unit. *Neth J Crit Care* 2004;**8**(4)**:**302-305.
57. van Dijk M, de Boer J, Koot H, Tibboel D, Passchier J, Duivenvoorden H. The reliability and validity of the COMFORT scale as a postoperative pain instrument in 0 to 3-year-old infants. *Pain* 2000;**84**(2-3)**:** 367-77.
58. Terstegen C, Koot H, de Boer J, Tibboel D. Measuring pain in children with cognitive impairment: pain response to surgical procedures. *Pain* 2003;**103**(1-2)**:**187-98.
59. Kress J, Pohlman A, O'Connor M, Hall J. Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation. *N Engl J Med* 2000;**342**(20)**:**1471-7.
60. Freire A, Afessa B, Cawley P, Phelps S, Bridges L. Characteristics associated with analgesia ordering in the intensive care unit and relationships with outcome. *Crit Care Med.* 2002;**30**(11)**:**2468-72.
61. Riker R, Fraser GL. Adverse events associated with sedatives, analgesics, and other drugs that provide patient comfort in the intensive care unit. *Pharmacotherapy.* 2005;**25:**8S-18S.
62. Kollef M, Levy N, Ahrens T, Schaiff R, Prentice D, Sherman G. The use of continuous i.v. sedation is associated with prolongation of mechanical ventilation. *Chest* 1998;**114**(2)**:**541-8.
63. Cook D, Walter S, Cook R, Griffith L, Guyatt H, Leasa D, Jaeschke R, Brun-Buisson C. Incidence of and risk factors for ventilator-associated pneumonia in critically ill patients. *Ann Intern Med* 1998;**129**(6)**:**433-40.
64. Meade M, Cook D, Kernerman P, Bernard G. How to use articles about harm: the relationship between high tidal volumes, ventilating pressures, and ventilator-induced lung injury. *Crit Care Med* 1997; **25**(11)**:**1915-22.
65. De Jonghe B Cook D, Sharshar T, Lefaucheur JP, Carlet J, Outin H. Acquired neuromuscular disorders in critically ill patients: a systematic review. Groupe de Reflexion et d'Etude sur les Neuromyopathies En Reanimation. *Intensive Care Med* 1998;**24**(12)**:**1242-50.
66. Merriman H. The techniques used to sedate ventilated patients. A survey of methods used in 34 ICUs in Great Britain. *Intensive Care Med* 1981;**7**(5)**:**217-24.
67. Bion JF, Ledingham I. Sedation in intensive care--a postal survey. *Intensive Care Med* 1987;**13**(3)**:**215-6.
68. Hansen-Flaschen J, Brazinsky S, Basile C, Lanken PN. Use of sedating drugs and neuromuscular blocking agents in patients requiring mechanical ventilation for respiratory failure. A national survey. *JAMA* 1991;**266**(20)**:**2870-5.
69. Christensen B, Thunedborg L. Use of sedatives, analgesics and neuromuscular blocking agents in Danish ICUs 1996/97. A national survey. *Intensive Care Med* 1999;**25**(2)**:**186-91.
70. Soliman H, Melot C, Vincent J. Sedative and analgesic practice in the intensive care unit: the results of a European survey. *Br J Anaesth.* 2001;**87**(2)**:**186-92.

71. Jacobi J, Fraser GL, Coursin D, et al. Clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult. *Crit Care Med* 2002;**30**(1)**:**119-41.
72. Snellen F. Richtlijnen intraveneuze analgesie en sedatie voor volwassen patienten op de Intensive Care. *NVIC catern* 2001.
73. Christoph S. Pain assessment. The problem of pain in the critically ill patient. *Crit Care Nurs Clin North Am* 1991;**3**(1)**:**11-6.
74. Harrison M, Cotanch P. Pain: advances and issues in critical care. *Nurs Clin North Am* 1987;**22**(3)**:**691-7.
75. Webb M, Kennedy M. Behavioral responses and self-reported pain in postoperative patients. *J Post Anesth Nurs* 1994;**9**(2)**:**91-5.
76. Stannard D, Puntillo K, Miaskowski C, Gleeson S, Kehrle K, Nye P. Clinical judgment and management of postoperative pain in critical care patients. *Am J Crit Care* 1996;**5**(6)**:**433-41.
77. Stephenson N. A comparison of nurse and patient: perceptions of postsurgical pain. *J Intraven Nurs* 1994;**17**(5)**:**235-9.
78. Mateo O, Krenzischek D. A pilot study to assess the relationship between behavioral manifestations and self-report of pain in postanesthesia care unit patients. *J Post Anesth Nurs* 1992;**7**(1)**:**15-21.
79. Rawal N, Tandon B. Epidural and intrathecal morphine in intensive care units. *Intensive Care Med* 1985;**11**(3)**:**129-33.
80. Puntillo K. Dimensions of procedural pain and its analgesic management in critically ill surgical patients. *Am J Crit Care* 1994;**3**(2)**:**116-22.
81. Puntillo K. Effects of interpleural bupivacaine on pleural chest tube removal pain: a randomized controlled trial. *Am J Crit Care* 1996; **5**(2)**:**102-8.
82. Puntillo K, Morris A, Thompson C, Stanik-Hutt J, White C, Wild L. Pain behaviors observed during six common procedures: Results from Thunder Project II. *Crit Care Med* 2004;**32**(2)**:**421-7.
83. Veselis R, Reinsel R, Sommer S, Carlon G. Use of neural network analysis to classify electroencephalographic patterns against depth of midazolam sedation in intensive care unit patients. *J Clin Monit.* 1991; **7**(3)**:**259-67.
84. Wang D, Pomfrett C, Healy TE. Respiratory sinus arrhythmia: a new, objective sedation score. *Br J Anaesth.* 1993;**71**(3)**:**354-8.
85. De Deyne C, Struys M, Decruyenaere J, Creupelandt J, Hoste E, Colardyn F. Use of continuous bispectral EEG monitoring to assess depth of sedation in ICU patients. *Intensive Care Med* 1998;**24**(12)**:**1294-1298.
86. Devlin J, Holbrook A, Fuller H. The effect of ICU sedation guidelines and pharmacist interventions on clinical outcomes and drug cost. *Ann Pharmacother.* 1997;**31**(6)**:**689-95.
87. Kress J, Hall J. Sedation in the mechanically ventilated patient. *Crit Care Med* 2006;**34**(10)**:**2541-6.
88. Brattebø G, Hofoss D, Flaatten H, Muri AK, Gjerde S, Plsek PE. Effect of a scoring system and protocol for sedation on duration of patients' need for ventilator support in a surgical intensive care unit. *BMJ* 2002; **324:**1386-9.
89. Pochard F, Lanore J, Bellivier F, Ferrand I, Mira JP, Belghith M, Brunet F, Dhainaut JF. Subjective psychological status of severely ill patients discharged from mechanical ventilation. *Clin Intensive Care* 1995; **6**(2)**:**57-61.

Chapter 2

Pain assessment in the adult ICU patient

A critical appraisal

Systematic and accurate pain assessment is critical to optimal pain management. Generally it is accepted that a patient's self report is the most reliable indicator of pain. Most patients are indeed able to quantify the severity of their pain themselves, for instance by using the Visual Analogue Scale or the Numeric Rating Scale. [1]

However, significant groups of patients cannot reliably report their pain, such as seriously ill or injured patients, those with mental handicaps, and also patients who are comatose, are physically or "chemically" immobilized, sedated or disoriented. These patients are specifically at risk for inadequate pain treatment.

Only a few observational pain assessment instruments have been developed for use in adult patients in whom self-report is impossible. This article describes the present situation in daily pain practice and reviews these pain assessment instruments with regard to their applicability to the critically ill adult patient in the intensive care setting.

Pain assessment instruments for the critically ill adult patient

In general, pain assessment instruments are either unidimensional or multidimensional. Unidimensional pain assessment instruments, such as in the Visual Analogue Scale (VAS) or the Verbal Graphic Scale (VGS), focus on one type of indicator or on a unitary dimension of pain assessment. [1,2] Multidimensional instruments include both behavioural and physiologic indicators of pain.

Several assessment instruments have been developed for postoperative pain assessment in patients admitted to the recovery room or Post Anaesthesia Care Unit (PACU).[3-5] Designed for patients who are (almost) fully able to communicate, the emphasis lies on self-report based scales. Nevertheless, even in the postoperative period nurses tend to use the pain tool which is most easy for them to use, rather than the tool recommended for the specific population.[6]

We performed an extensive literature search in Pubmed and Google for articles and English abstracts (without date restriction) using the key words 'pain assessment' and 'pain assessment tool', combined with 'intensive care unit' and 'critical care'. Also, reference lists of retrieved articles were reviewed.

The literature search revealed that there is only a limited amount of literature that directly addresses pain assessment in the uncommunicative critically ill patient.

Only six pain assessment instruments which are potentially useful for critically ill adults were found, although not all of them have been validated for this population. Some of them originate from existing postoperative pain assessment instruments and some of them were tested on a self-report basis, but, as the authors state, can be used as non-selfreport. All include items referring to the different behavioural indicators of pain. The contents and psychometric characteristics are summarized in Table 1 and Table 2, respectively. Short descriptions are given below.

Pain Behaviour Observation Tool (PBOT)

A 30-item Pain Behaviour Observation Tool (PBOT) was developed especially for procedural pain in patients who are able to communicate and who can adequately rate their pain intensity on a numeric rating scale.[7] At present, it is not validated for uncommunicative critically ill patients. The items describe facial responses, verbal responses and body movements, which are observed before and during procedures. While patients rated their pain intensity, their behavioural responses were recorded as well. The findings in 5,957 adult patients are consistent with a strong relationship between self-reported procedural pain and behavioural responses.

Critical-care Pain Observation Tool (CPOT)

The Critical-care Pain Observation Tool (CPOT) was originally introduced as a pain assessment tool for conscious and unconscious intubated critically ill patients.[8] Recently it has been validated for postoperative cardiac surgery patients in the intensive care unit.[9] The tool is based on behavioural responses (facial expression, body movements, rigid posture

and compliance with mechanical ventilation or vocalization). The total score ranges from 0-8. Validation parameters varied, but were acceptable. In 2007 the reliability and validity of the CPOT was examined with physiological indicators.[10] It showed that behavioural indicators represent more valid information than physiological indicators.

Modified Pain Scoring Tool (MPST)

The Modified Pain Scoring Tool (MPST) is a linear 4-point scale, score range 0-3, used in an algorithm.[11] Part of the guideline Pain Assessment for Critically Ill Patients (PACIP), the MPST rates the presence or absence of characteristics such as hypertension, tachycardia, sweating, dilatation of the pupils, facial grimacing and writhing or distressed movements. Preliminary evaluation established its effectiveness as a means of systematic attention to pain levels in individual patients. However, it did not lead to altered pain management.

Behavioural Pain Scale (BPS)

The Behavioural Pain Scale (BPS) was designed and validated for the ventilated critically ill patient.[12] It is based on three behavioural items: facial expression, movement or posture of upper limbs, and compliance with mechanical ventilation, each with a score range of 1-4. The total BPS score is the sum of the scores for these three items, thus ranging from 3 (no pain) to 12 (worst possible pain).

The BPS was tested in a total of 269 assessments in 30 patients, more than 14 years of age, after trauma or after major surgery. All patients were mechanically ventilated, hemodynamically stabilized and needed analgesia and sedation. Ramsay sedation level scores ranged from 4-6. Both physiological and BPS items were scored before and during care procedures. The results indicate that the expression of pain can be scored validly and reliably by using the BPS in sedated, mechanically ventilated patients. The author states that further studies are warranted regarding the utility of the BPS in making clinical decisions about the use of analgesic drugs in the intensive care unit.

Faces scale

The Faces scale was originally designed for children.[13,14] However, this unidimensional 5-grade scale was also tested in 50 postoperative, extubated adult patients in a total of 518 assessments. While patients were asked to rate their pain intensity on a visual analogue (VAS) scale, nurses independently assessed the patients' facial expression as a measure of pain intensity on the Faces scale. Comparison of VAS and Faces scores showed only low to moderate agreement. The authors state that this tool may be useful for pain evaluation in the ICU.

Pain Assessment and Intervention Notation (PAIN) tool

The Pain Assessment and Intervention Notation (PAIN) tool is part of an algorithm and was tested in 3 ICUs and 2 PACUs.[15] Eleven nurse participants performed 114 assessments in 31 adult patients who underwent major surgery and were within the first 48 postoperative hours. They were mechanically ventilated or had been extubated less than 4 hours before assessment. All patients were able to use a numeric rating scale. The nurse first performed a numeric rating based on behavioural responses (body movement, facial expression, posturing/guarding), secondly a rating based on physiological indicators and finally a numeric rating (by NRS) as an overall assessment of pain intensity. Finally, the patient was asked to rate his or her pain on the numeric rating scale. The author concludes that the use of a detailed, standardized pain assessment and intervention notation algorithm, that incorporates behavioural and physiological indicators, may assist healthcare professionals in making relatively accurate assessments of a patient's pain intensity. Further research is needed to determine the specific decision-making processes and criteria that healthcare professionals use to choose doses of analgesics to administer to critically ill patients.

Nonverbal Pain Scale (NVPS)

The Nonverbal Pain Scale (NVPS) is based on the FLACC (Face, Legs, Activity, Cry, Consolability), a postoperative pain assessment scale for infants.[16,17] The NVPS is modified into three behavioural items and two physiological items. The total score ranges from 0 (no pain) to 10 (worst possible pain).
At present, the NVPS is of limited use in adult ICU patients. Measurement of the indicators is not standardized, nor do its psychometric properties provide enough evidence to support its reliability or validity.

Discussion

The literature presents vast amounts of evidence as to the significance of pain in the process of severe illness, yet evidence on the effectiveness of pain assessment and pain management for the adult critically ill patient is scarce. This is in contrast to the paediatric literature, where the effect of adequate pain management has been documented extensively. [18,19]
Nevertheless, in critically ill adult patients the process of clinical decision making for pain interventions remains very complex. Patients may have decreased levels of consciousness, can be cognitively impaired, sedated or otherwise nonverbal. These patients are not only vulnerable to the mere subjective experience of pain and suffering but also to the physiological effects of pain. Both are proven risk factors for increased morbidity and length of stay. [20-26]

Detailed analysis of the literature revealed only seven pain instruments for adults.

In general, each of these instruments has its limitations. As each of them is designed for a specific group or specific situation, they are not directly applicable for standard use on the average intensive care unit.
Facial expression is included in all seven instruments. Certain features of facial expression (e.g. brow lowering and eyelid squeezing) are considered to be the most specific indicators for pain. In adult critical care patients, though, it can be difficult to differentiate between the patient's normal facial expression, with wrinkling and frowning, and the altered expression in a painful situation.
Body movements and tone or posture are included in almost all instruments. Assessments of these items could be hampered, however, by the fact that patients may be unable to move due to their neurological status (e.g. paralysis), to their medication (e.g. neuromuscular blocking agents) or to their peripheral nerve status (e.g. peripheral polyneuropathy), and also in specific situations when the patients' hands are tied to secure vital therapy.
Both the PBOT and the PAIN tool include vocalization. Most of the critically ill patients will be unable, however, to produce sounds due to endotracheal intubation.

Physiological parameters are tested in five of the described instruments, but for lack of sensitivity were later removed from 2 of them (BPS, CPOT). Although physiological parameters have been found useful in pain assessment [27-29], their additional value is debatable, since they are not specific for pain. Fluctuations in heart rate and blood pressure, for example, may also be caused by blood loss, fluid intake, body temperature or medical interventions. [12]

Both the BPS, CPOT and the Faces scale have shown moderate to good interrater reliability. Internal consistency was tested in the BPS and the NVPS and proved sufficient. Concurrent validity, established by comparing the instrument with other instruments or with expert opinion, was found to be satisfactory in five instruments. It could not be tested for the BPS, as a similar instrument did not exist. Furthermore, for the CPOT, only content validity is documented through nurse and physicians surveys. Responsiveness to change was documented only in the PBOT and CPOT. Clinical utility is addressed in only the BPS and the CPOT. Observation periods, if mentioned, vary. Practical usefulness, in terms of providing cut-off scores to determine whether analgesics should be administered or not, and degree of efficacy remain underexposed.
The main conclusion is that none of the described instruments meets the requirements for an appropriate assessment tool for the evaluation of pain in the critically ill.

Self-report remains the most reliable guide. However, when patients are unable to report their pain, comprehensive assessment of behavioural indicators should be performed. Such behaviour, though, might be misinterpreted or affected by observer bias, leading to an underestimation of the degree of pain experienced by the patient.[30] It is important, therefore, to develop an effective pain assessment tool in which health care professionals may observe reproducible behaviour indicators objectively.
Another important objective of pain assessment is its use in the context of a treatment algorithm. A pain measurement instrument combining

assessment and treatment in an algorithm would improve nurses' commitment and consequently pain management. [11,31,32]

Extensive experience of pain research in our research group has shown that the assessment of pain without the possibility to respond to an algorithm by the application of analgesia is without any significance and will lead to a fast decrease of the willingness of the care-taker to continue assessments.

In conclusion, by increasing awareness of pain-related behaviour in relation to specific and common procedures, clinicians may be able to identify and anticipate the need for analgesia.

At present no instrument fulfils all the requirements for its use in daily clinical practice.

For critically ill patients, existing instruments should be further developed and vigorously tested for their clinical utility and feasibility.

Table 1. Contents of observational pain assessment instruments for critically ill adults

Instrument	Facial expression	Vocal expression	Body movement	Tone / posture	Physiological items	Additional items	Sample	Remarks
Pain Behaviour Observation Tool (PBOT) 7	√	√	√	-	-	-	n=5957 medical and surgical patients	communication obligatory procedural pain
Critical Care Pain Observation Tool (CPOT) 9	√	√ (when extubated)	√	√	excluded	ventilator compliance (when intubated)	n=105 cardiac surgery	3 testing moments: • intubated & unconscious • intubated & conscious extubated
Modified Pain Scoring Tool (MPST) 11	√	-	√	-	√	sweating dilatation of pupils	not specified	no validation study performed
Behavioral Pain Scale (BPS) 12	√	-	√	-	excluded	ventilator compliance	n=30 medical and surgical patients	all patients sedated and ventilated
Faces Scale14	√	-	-	-	-	-	n=50 postoperative and extubated patients	communication obligatory
Pain Assessment and Intervention Notation (PAIN)33	√	√	√	√	√	pallor perspiration	n=31 postoperative patients intubated or extubated up to 4 hours prior to assessment	measurements not standardized
Nonverbal Pain Scale (NVPS)16	√	-	√	√	√	skin colour warmth dilatation of pupils	n=59 medical and surgical patients	no differentiation between scores at rest and during painful procedures

Table 2. Characteristics of observational pain assessment instruments for critically ill adults

	Reliability		Validity			
Instrument	Interrater reliability	Internal consistency	Concurrent/ criterion	Construct/ Responsiveness to change		Score range
Pain Behaviour Observation Tool (PBOT) 7	-	-	NRS	before, after or during painful procedures	yes 33%	present or absent
Critical Care Pain Observation Tool (CPOT) 9	κ = 0,52-0,88	-	-	during procedure	P<0,001	0-8
Modified Pain Scoring Tool (MPST) 11	-	-	-	-		0-3
Behavioral Pain Scale (BPS) 12	κ = 0.74	α=0,6444-0,721	-	before and during procedures	P<0,01	3-12
Faces Scale 14	κ = 0.67 (30”) 0.62 (60”)	-	VAS	-		graphic
Pain Assessment and Intervention Notation (PAIN)33	-	-	NRS	consistent in common pain behaviours	yes 24-38%	-
Nonverbal Pain Scale (NVPS)16	-	α=0,78	FLACC	-		0-10

Abbreviations: NRS Numeric Rating Scale, VAS visual analogue scale, FLACC face, legs, activity, cry, consolability

References

1. Huskisson E. Measurement of pain. *Lancet* 1974;**2:**1127-1131.
2. Rucker KS, Metzler HM, Kregel J. Standardization of chronic pain assessment: a multiperspective approach. *Clin J Pain* 1996;**12**(2)**:**94-110.
3. Mateo OM, Krenzischek DA. A pilot study to assess the relationship between behavioral manifestations and self-report of pain in postanesthesia care unit patients. *J Post Anesth Nurs* 1992;**7**(1)**:**15-21.
4. Aubrun F, Valade N, Coriat P, Riou B. Predictive factors of severe postoperative pain in the postanesthesia care unit. *Anesth. Analg.* 2008; **106**(5)**:**1535-41.
5. Derrode N, Lebrun F, Levron J, Chauvin M, Debaene B. Influence of peroperative opioid on postoperative pain after major abdominal surgery: sufentanil TCI versus remifentanil TCI. A randomized, controlled study. *Br J Anaesth* 2003;**91**(6)**:**842-9.
6. Aubrun F, Paqueron X, Langeron O, Coriat P, Riou B. What pain scales do nurses use in the postanaesthesia care unit? *Eur J Anaesthesiol* 2003; **20**(9)**:**745-9.
7. Puntillo KA, Morris AB, Thompson CL, Stanik-Hutt J, White CA, Wild LR. Pain behaviors observed during six common procedures: Results from Thunder Project II. *Crit Care Med* 2004;**32**(2)**:**421-7.
8. Gelinas C, Fillion, L.,Viens, C.,Fortier, M., Puntillo, KA. Development of a Critical Care Pain Observation Tool (CCPOT). *J Pain* 2004; **5**(3)**:**S106.
9. Gélinas C FL, Puntillo KA, Viens C, Fortier M. Validation of the critical-care pain observation tool in adult patients. *Am J Crit Care* 2006; **15**(4)**:**420-7.
10. Gélinas C, Johnston C. Pain assessment in the critically ill ventilated adult: validation of the Critical-care Pain Observation Tool and physiologic indicators. *Clin J Pain* 2007;**23**(6)**:**497-505.
11. Blenkharn A, Faughnan S, Morgan A. Developing a pain assessment tool for use by nurses in an adult intensive care unit. *Intensive Crit Care Nurs* 2002;**18**(6)**:**332-41.
12. Payen JF, Bru O, Bosson J, et al. Assessing pain in critically ill sedated patients by using a behavioral pain scale. *Crit Care Med* 2001;**29**(12)**:**2258-63.
13. Terai T, Yukioka H. [Assessment of postoperative pain using face scale judged by nurses: comparison between hepatectomy and esophagectomy]. *Masui (abstract in english)* 1999;**48**(9)**:**981-5.
14. Terai T, Yukioka H, Asada A. Pain evaluation in the intensive care unit: observer-reported faces scale compared with self-reported visual analog scale. *Reg Anesth Pain Med* 1998;**23**(2)**:**147-51.
15. Puntillo KA, Miaskowski C, Kehrle K, Stannard D, Gleeson S, Nye P. Relationship between behavioral and physiological indicators of pain, critical care patients' self-reports of pain, and opioid administration. *Crit Care Med* 1997;**25**(7)**:**1159-66.
16. Odhner M, Wegman D, Freeland N, Steinmetz A, Ingersoll GL. Assessing pain control in nonverbal critically ill adults. *Dimens Crit Care Nurs* 2003;**22**(6)**:**260-7.
17. Merkel S, Voepel-Lewis T, Shayevitz J, Malviya S. The FLACC: a behavioral scale for scoring postoperative pain in young children. *Pediatr Nurs* 1997;**23**(3)**:**293-7.
18. van Dijk M, de Boer JB, Koot HM, Tibboel D, Passchier J, Duivenvoorden HJ. The reliability and validity of the COMFORT scale as a postoperative pain instrument in 0 to 3-year-old infants. *Pain* 2000; **84**(2-3)**:**367-77.
19. van Dijk M, Peters JW, Bouwmeester NJ, Tibboel D. Are postoperative pain instruments useful for specific groups of vulnerable infants? *Clin Perinatol* 2002;**29**(3)**:**469-91, x.
20. McArdle P. Intravenous analgesia. *Crit Care Clin* 1999;**15:**89-104.
21. Desai P. Pain management and pulmonary dysfunction. *Crit Care Clin* 1999;**15:**151-166.

22. Hamill-Ruth RJ, Marohn ML. Evaluation of pain in the critically ill patient. *Crit Care Clin* 1999;**15**(1)**:**35-54, v-vi.
23. Stanik-Hutt JA. Pain management in the critically ill. *Crit Care Nurse* 1998;**18**(5)**:**85-8.
24. Puntillo KA, White C, Morris AB, et al. Patients' perceptions and responses to procedural pain: results from Thunder Project II. *Am J Crit Care* 2001;**10**(4)**:**238-51.
25. Epstein J, Breslow M. The stress response of critical illness. *Crit Care Clin* 1999;**15:**17-33.
26. Arbour R. Sedation and pain management in critically ill adults. *Crit Care Nurs* 2000;**20**(39-56).
27. Sweet S, McGrath P. Physiological measures of pain. *In: Finley GA, McGrath PJ, editors. Measurement of pain in infants and children. Progress in pain research and management,* 1998;**10**(Seattle (WA):IASP Press)**:**59-81.
28. Franck LS, Greenberg CS, Stevens B. Pain assessment in infants and children. *Pediatr Clin North Am* 2000;**47**(3)**:**487-512.
29. Abu-Saad HH, Bours GJ, Stevens B, Hamers JP. Assessment of pain in the neonate. *Semin Perinatol* 1998;**22**(5)**:**402-16.
30. Ferguson J, Gilroy D, Puntillo K. Dimensions of pain and analgesic administration associated with coronary artery bypass grafting in an Australian intensive care unit. *J Adv Nurs* 1997;**26**(6)**:**1065-72.
31. Krulewitch H, London MR, Skakel VJ, Lundstedt GJ, Thomason H, Brummel-Smith K. Assessment of pain in cognitively impaired older adults: a comparison of pain assessment tools and their use by nonprofessional caregivers. *J Am Geriatr Soc* 2000;**48**(12)**:**1607-11.
32. Jensen D, Justic M. An algorithm to distinguish the need for sedative, anxiolytic, and analgesic agents. *Dimens Crit Care Nurs* 1995;**14**(2)**:** 58-65.
33. Puntillo KA, Stannard D, Miaskowski C, Kehrle K, Gleeson S. Use of a pain assessment and intervention notation (P.A.I.N.) tool in critical care nursing practice: nurses' evaluations. *Heart Lung* 2002;**31**(4)**:**303-14.

Chapter 3

Introduction of the Critically Ill Assessment (CIA) scale

A new assessment tool for pain and distress in critically ill patients

Pain is a major problem among critically ill patients. Acute disease, trauma and surgery can cause tissue damage. In addition, pain can be the result of discomfort associated with invasive procedures, change of position, or the administration of therapies. After discharge, patients refer to pain as their second greatest ICU stressor. [1-9] Therefore, effective pain management is a core principle for all members of the critical care team and fundamental in providing high-quality critical care. However, the literature suggests that ICU clinicians can still improve pain management. [10]

ICU stay also causes emotional distress next to pain. Pain and distress may be expressed in a similar fashion and therefore cannot always be distinguished. Moreover, the use of sedatives challenges the confounding effect on the objective indicators of pain.[11]

It is well accepted that a patient's self-report of pain intensity is the gold standard. [1,8,9,12] Patients in the ICU often are incapable of self-report, due to numerous communication barriers, e.g. endotracheal intubation, motor impairments, and altered levels of consciousness. They may therefore be at risk for poor pain management.

Physiologic responses to pain, resulting from activation of the autonomic nervous system, are not specific for pain in an ICU environment.[13,14] These responses are also influenced by medication and illness-related factors. [2] Therefore other indicators are required, for instance behavioural responses communicated through facial expression and body language.

Sedation scales are often used to assess distress in ICU patients. Several sedation scales have been developed since the first description of the Ramsay scale in 1974.[15-19] The Ramsay scale, although commonly used, has never been rigorously validated. A systematic review of other sedation scoring systems confirmed that some also lack formal validation.[20] This aspect of scoring systems raises questions about the reproducibility and validity of the results.

A systematic, comprehensive method for assessing pain is warranted for effective pain management.[3] Pain assessment should be performed regularly and consistently in the ICU setting. Furthermore, effect of pain-therapy should be evaluated periodically.[2,3,13,21]

Another important objective of pain assessment and discrimination from distress is the development of an algorithm. A pain algorithm combining assessment and treatment improves nurses commitment and thus pain management. [21-23]

At present, only two instruments are specifically designed and validated as pain scoring tool for the adult nonverbal ICU patient, i.e. the Behavioral Pain Scale (BPS) and the Critical-care Pain Observation Tool (CPOT).[2,24,25] Unfortunately, both instruments do not fulfil all the requirements for use in daily clinical practice.[26]

At our ICU we were not satisfied with the existing scoring tools. We developed a new pain-distress tool, based on behavioural responses. The aim of this study is to determine the reliability, validity and clinical usefulness of this tool for critically ill adult patients.

Materials and methods

Patients and setting

The study was conducted over a 9-month period (May 2004 to February 2005) in an 18-bed general surgery / trauma intensive care unit (ICU) that cares mainly for transplantation, trauma and oncology patients. All patients, ≥ 15 years of age, admitted to the ICU were eligible for the study.

Instruments

The "Critically Ill Assessment" (CIA) scale is loosely based on the Comfort scale.[17,27] The Comfort scale assesses six behavioural items (alertness, calmness, muscle tone, movement, facial tension and respiratory response) and two physical items (heart rate and mean arterial pressure).

These two physiological items were removed from the CIA-scale after a pilot study because they showed insufficient variability between pain and nonpain assessments. This was in line with findings in paediatric studies. [27-29]

A second pilot study with the remaining six behavioural items, included 38 patients and 100 scores. The results showed good internal consistency between all items (Cronbach's alpha 0.74). The item calmness proved redundant based on both reliability analyses and its overlap with alertness in adults, and was excluded (Cronbach's alpha increased to 0.78).

Table 1 presents the items of the CIA tool, each with four response categories of distinct behavioural descriptions. The total CIA score ranges from 5 to 20.

In this investigation a Numeric Rating Scale for pain (NRS pain) and a NRS for distress (NRS distress) were used to compare the CIA tool. The NRS pain is a numeric score ranging from 0 to 10 with the anchors 'no pain' (0) and 'worst possible pain' (10). The NRS distress is a similar scale, ranging from 0 to 10 with the anchors 'no distress' (0) and 'worst possible distress' (10). In pain research, the NRS is frequently used as an observational instrument. Construct and criterion validity as well as reliability of numeric rating scales have been previously established. [30] In this study NRS ≥ 4 indicates substantial pain or distress. When patients were able to communicate, verbally NRS scores were obtained by self-report.

Procedure

A motivated research group of personnel consisted of the research leader (senior medical staff member), a head nurse (senior nursing staff member), a qualified Research Nurse, a research nurse trainee and a psychologist, thus representing most sections of professionals on our ward.

The CIA score is rated after observing the patient for two minutes. This observation starts with addressing the patient to determine ability of self-report. The observation ends with assessing muscle tone by lifting the patient's arm or leg or by shaking hands. The NRS pain/distress was determined after completing the CIA score.

Table 1. The Critically Ill Assessment (CIA) scale

Critically Ill Assessment scale; observe the patients and rate after 2 minutes		
Item	Score	Response categorie
Alertness	1	Asleep
	2	Awake
	3	Exaggerated reaction (controlled)
	4	Exaggerated reaction (uncontrolled)
Facial tension	1	Decreased
	2	Relaxed
	3	Increased
	4	Continuous increased grimacing
Muscle tone	1	Polyneuropatic or decreased
	2	Normal
	3	Increased
	4	Contorted
Body movements	1	Incidental
	2	Relaxed
	3	Motor restlessness (controlled)
	4	Motor restlessness (uncontrolled)
Respiratory response	1	Controlled ventilation without resistance
	2	Normal breathing 10-30/min
	3	Tachypnoe > 30/min
	4	Use of accessory respiratory muscles
		Total score

For adequate use of the CIA score and the NRS, the nursing and medical staff attended a clinical training. A video presentation demonstrated the procedure and each item of the CIA score. Trainees completed ten CIA scores with one of the trainers or an experienced colleague. When interrater reliability was acceptable, i.e. a linearly weighted Cohen's Kappa >0.65, the trainee was allowed to score patients for the study.
The CIA score and the NRS were assessed every day at 8 am in all patients. All scores were recorded in the Patient Data Management System (PDMS).

Data Analysis

The weighted Cohen's Kappa test was calculated to estimate the interrater reliability agreement between the observing nurses and researchers.[31] Reliability analyses were used to determine the internal consistency between the items of the CIA score.
Pearson's product-moment correlation coefficient was used to examine relationships between CIA scores and NRS scores. To determine congruent validity, CIA scores of the researcher were compared with NRS scores of nurses.
Concurrent validity was tested by comparing CIA scores with patient self-report.
The Wilcoxon test was used to compare scores (before and during treatment) in the same patients. In this way sensitivity to change of the CIA score could be calculated.
The Mann-Whitney test was used to compare two groups of patients.
Cut-off scores were calculated based on the combined NRS. A Receiver Operator Characteristic (ROC) curve was made to show the 'best' cut-off point.

Results

During a nine-month period, 1792 CIA assessments were performed in 244 patients. Table 2 shows the background characteristics, including the primary diagnosis. The median age was 58 years and the median stay on the ICU was 61 hours. Most admissions (95.1%) related to major, non-cardiac surgery.
Interrater reliability. Forty-six ICU nurses, a research student and an ICU medical staff member were trained to use the CIA scale. The median linearly weighted Cohen's kappa was 0.86 (IQR 0.81 to 0.91).
Internal consistency. Cronbach's alpha of the five items was 0.76 and the corrected item-total correlation for individual items ranged from good for body movement (0.64), alertness (0.61), muscle tension (0.53), to acceptable for facial expression (0.49) and respiratory response (0.40).
The median CIA score was 9 (IQR 7 to 10). A NRS-pain score above or equal to 4 was scored in 13.2% and a NRS-distress score above or equal to 4 in 8.4% of all assessments. Table 4 shows the median CIA scores broken down into various combinations of NRS pain and NRS distress. In most cases (81.6%) both NRS pain and NRS distress scores were below 4 with a median CIA of 9 (IQR 7 to 10).
In 27 patients (11%) polyneuropathy was observed at least once.

Table 2. Background characteristics of the patients (n=244)

	N (%)	Median (p25 to p75)
Age in years		58 (46 to 70)
minimum and maximum		15 to 91
Sex (male/female)	159/85 (65.2/34.8)	
Duration of ICU stay in hours		61 (21 to 187)
minimum and maximum		3 to 3204
Reason ICU admission		
Postoperative (n=230)		
Digestive tract	127 (52.0)	
Circulatory	51 (20.9)	
Skeletal	22 (9.0)	
Urinary tract	10 (4.1)	
Respiratory tract	7 (2.9)	
Reproductive	5 (2.0)	
Endocrine	4 (1.6)	
Central Nervous System	4 (1.6)	
Trauma	7 (2.9)	
Other	7 (2.9)	

Concurrent validity. The Pearson's product moment correlation coefficient between CIA score and NRS pain was 0.39 (1721 observations), and 0.56 (1760 observations) between CIA and NRS distress.

Use of analgesics and sedatives. Table 3 gives an overview of the analgesics and sedatives administered to the patients, during the study period. In total 139 (57%) patients received one or more opioids and 120 patients one or more benzodiazepines. Ninety-one patients (37.3%) received both opioids and benzodiazepines and 76 patients (31.1%) neither of the two. Continuous propofol was administered to 119 patients. Fifty-three patients received haloperidol.

CIA score and NRS self-report

Fifty additional CIA observations were performed in 30 patients who were able to communicate. Pearsons product moment correlation coefficient between CIA score and NRS pain self report was 0.39. Median CIA score was 10 (IQR 10 to 11) and the median NRS pain was 2 (IQR 0 to 5).

Scoring of CIA scale and NRS by two different observers

NRS scores of the caregiving nurse were compared with CIA scores of an independent observer (PvL). Pearson's product moment correlation coefficient between the CIA score by the independent research-worker and the NRS-pain score by the nurse was 0.46 and 0.55 for NRS distress. The median CIA score was 9 (IQR 7 to 10), the median NRS pain was 1 (IQR 0 to 4) and the median NRS distress was 0 (IQR 0 to 0).

Sensitivity to change

Twenty patients were observed in daily care situations, such as washing or changing of position in bed. The patients were scored before and during care. Nine patients received a bolus medication of morphine or fentanyl before care. The median CIA scores for the 20 patients were 9 before care and 11 during care. The median CIA score for the patients without extra

Table 3. Analgesics and sedatives

Medication	C or B	Min and maximum	N of patients (%)
Analgesics			
Paracetamol 1000 mg	B	1 to 321 dosages	198 (81.1)
Fentanyl	C	1 to 900 mcg/h	100
Morphine	C/B*	1 to 100 mg	88
Tramadol	B	50 mg	7
Gabapentin	B	300 to 600 mg	4 (1.6)
Number of opioids			
None			105 (43)
One			83 (34)
Two			56 (23)
Sedatives			
Midazolam**	C/B	C 1 to 40 mg/h B 1 to 30 mg	71
Lorazepam	C	1 to 15 mg/h	70
Temazepam	B	10 to 40 mg	53
Bromazepam	B	1 to 3 mg	31
Oxazepam	B	5 to 10 mg	8
Clonazepam	C	1 to 8 mg/h	2
Number of benzodiazepines			
None			124 (50.8)
One type			52 (21.3)
Two or three			55 (22.6)
Four to five			13 (5.3)
Propofol	C	30 to 600 mg/h	119 (48.8)
Haloperidol	B***	1 to 10 mg	53 (21.7)

Abbreviations: C=continuous, B=bolus

* With the exclusion of 4 patients who received continuous morphine,

** Bolus only in n=26, both in n=35 and only continuous in n=11 patients

*** Patients who required haloperidol were not older but duration of stay was significantly different in the haloperidol vs. no haloperidol group (Mann-Whitney U-test, z=-7.88, 0.000)

Table 4. CIA scores (median and IQR) divided by Numeric Rating of Pain and Distress

	NRS pain ≥ 4 NRS distress ≥ 4	NRS pain ≥ 4 NRS distress < 4	NRS pain < 4 NRS distress ≥ 4	NRS pain < 4 NRS distress < 4
CIA assessments				
Number (%)	50 (2.9)	171(10.0)	94 (5.5)	1394 (81.6)
Median (IQR)	12 (10 to 14)	10 (9 to 11)	12 (10 to 14)	9 (7 to 10)

medication increased from 10 to 12; for the patients with extra medication from 9 to 10.

The scores during daily care were significantly higher than the scores before care (Wilcoxon, Z=-3.88, p<0.0001). CIA scores during care were significantly lower in the patients who received analgesics (Mann-Whitney U test, Z=-2.39, p=0.016).

Sensitivity and Specificity

The sensitivity and specificity of different cut-off points of the CIA scale were calculated using the NRS pain or distress ≥ 4 as 'gold standard'. Figure 1 gives the ROC curve. A cutoff of CIA 10 or higher corresponds with a sensitivity of 0.80 and a specificity of 0.67.

Discussion

Pain in critically ill patients may be expressed by facial features, body language and non-compliance to the ventilator. By designing a tool, based on

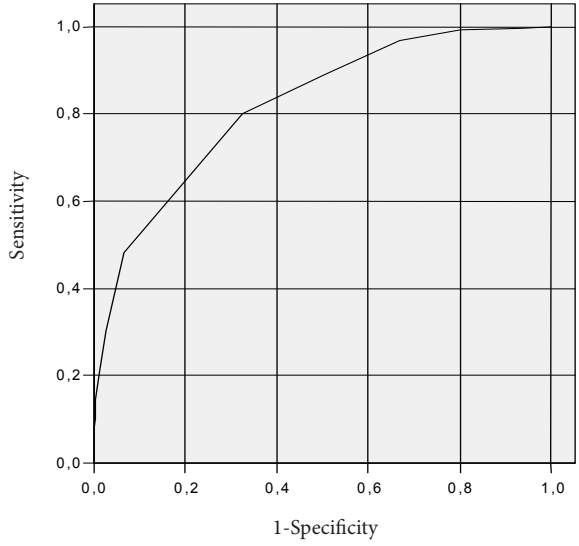

Figure 1. Receiver Operating Characteristic (ROC) curve

these behavioural responses, we tried to make a practical and reliable scale to assess discomfort and discriminate between pain and distress in critically ill patients. [3,32,33]

By stimulating awareness of pain- and distress-related behaviour in relation to specific and common procedures, clinicians may be able to better identify and anticipate the need for extra medication. It proved feasible to train nurses in observing the CIA pain/distress-related behaviour items in a reliable way. The implementation of the CIA scale on our ward indeed increased the staff alertness. An instrument combining assessment and treatment in an algorithm will further improve commitment and consequently pain/distress management. [21-23]

The CIA scale is evaluated on its psychometric properties: internal consistency, construct validity, criterion validity, interrater reliability, congruent validity and concurrent validity were analysed and adequate.

The two other objective pain instruments (i.e. BPS and CPOT) also show validity and reliability, but were not as vigorously tested. At present, they are not considered to be robust pain instruments for use in the nonverbal adult ICU patient.[26]

Because of the relatively low CIA scores, correlations may be deflated due to lack of variability in pain and distress scores. On the other hand, the CIA scale was sensitive to change during daily care, in the item facial tension most notably. This strongly suggests a component of pain during routine procedures.

Peripheral polyneuropathy can complicate the use of a scale based on behavioural items because of the lack of muscle tone and the inability to use the limbs. Therefore we added a category 'polyneuropatic' for the item muscle tone. This enabled us to identify patients who are unable to show their pain intensity through body language. A senior member of the medical staff diagnosed polyneuropathy.

In our population critical illness neuropathy was mentioned in medical letters in 11% of the patients. However, observation of polyneuropathy may be flawed and unreliable. For clinical practice it might be worthwhile to focus on it more precisely. The CIA scale might be scored with deletion of the item muscle tone and adjusting for this by multiplying the score with 5/4.

The CIA scores (range total score 5 to 20), were overall low (median 9 IQR 7 to 10). In 81,6% of all observations, both NRS pain and NRS distress were below 4. We propose two main explanations for the overall low scores. Firstly, our hospital is a tertiary referral centre, to which specific categories of severely injured patients are admitted. Our patients often have a history of severe illness and treatment difficulties on other ICU's. Extensive use of analgesics and sedatives and accumulation may therefore be responsible for the low scores.

Clinicians should not too easily accept a state of "oversedation". In the international literature more and more reports have been published discussing this issue of "oversedation", as well as attempts to objectively downregulate sedative and analgesic medication, e.g. by bispectral index monitoring (BIS) and new medication strategies.[34,35] We made an overview of used sedatives and analgesics during this study. Prescription patterns were too complex to identify scores influenced by medication. In addition, the amounts as recorded in the PDMS may be an underestimation of the real amounts given. Sometimes a 'little extra' is given without recording it in PDMS.

Secondly, adults are not inclined to express their pain openly. This explanation is confirmed by the low correlation between self reported NRS scores and CIA scores of the researcher. Adults (in our culture) have learned to control themselves and in expressing their pain they are relatively introverted. In this respect, it would be interesting to compare different cultures in future pain research.

After the development of the CIA scale, the final goal was to develop an algorithm on which we could adapt the pain-distress policy. Based on sensitivity and specificity and making a ROC curve, we found the 'best' cut-off point would be a score of ≥ 10 indicating pain, but the CIA algorithm needs a high sensitivity. However, false positive results are not acceptable and a moderate number of false negative results are acceptable. Therefore the best cut-off should be ≥ 10 or ≥ 11. But the choice of an algorithm is not only a statistical decision. In line with this, in principle, when a patient shows discomfort, an extra dose of an analgesic should be administered. When there is no improvement, as shown by CIA observation, an extra dose of a sedative should be prescribed.

In combination with an algorithm and a clear pain/sedation policy, the CIA scale is an easy to use assessment tool to monitor pain and reduce the level of sedation in critically ill patients.

Conclusion

The CIA scale is a valid and reliable pain/distress tool for critically ill patients, either ventilated or non-ventilated. It is easy to use and offers ICU-professionals a basis for developing a systematic and comprehensive method for the assessment of patients´ pain and distress and to act to both accordingly.

References

1. Ballard K. Identification of environmental stressors for patients in a surgical intensive care unit. *Issues Ment Health Nurs* 1981(3)**:**89-108.
2. Payen JF, Bru O, Bosson JL, et al. Assessing pain in critically ill sedated patients by using a behavioral pain scale. *Crit Care Med* 2001; **29**(12)**:**2258-63.
3. Puntillo KA, Morris AB, Thompson CL, Stanik-Hutt J, White CA, Wild LR. Pain behaviors observed during six common procedures: Results from Thunder Project II. *Crit Care Med* 2004;**32**(2)**:**421-7.
4. Gelinas C, Fortier M, Viens C, Fillion L, Puntillo K. Pain assessment and management in critically ill intubated patients: a retrospective study. *Am J Crit Care* 2004;**13**(2)**:**126-35.
5. Christoph SB. Pain assessment. The problem of pain in the critically ill patient. *Crit Care Nurs Clin North Am* 1991;**3**(1)**:**11-6.
6. Whipple JK, Lewis KS, Quebbeman EJ, et al. Analysis of pain management in critically ill patients. *Pharmacotherapy* 1995;**15**(5)**:**592-9.
7. Erdek MA, Pronovost P. Improving assessment and treatment of pain in the critically ill. *Int J Qual Health Care* 2004;**16**(1)**:**59-64.
8. Cheever KH. Reducing the effects of acute pain in critically ill patients. *Dimens Crit Care Nurs* 1999;**18**(3)**:**14-23.
9. Puntillo KA. The phenomenon of pain and critical care nursing. *Heart Lung* 1988;**17**(3)**:**262-73.
10. Nelson JE, Meier DE, Oei EJ, et al. Self-reported symptom experience of critically ill cancer patients receiving intensive care. *Crit Care Med* 2001;**29**(2)**:**449-450.
11. Li D, Puntillo K. What is the current evidence on pain and sedation assessment in nonresponsive patients in the intensive care unit? *Crit Care Nurse* 2004;**24**(5)**:**68, 70, 72-3.
12. Pasero C. Pain in the critically ill patient. *J Perianesth Nurs* 2003; **18**(6)**:**422-5.
13. Puntillo KA, Stannard D, Miaskowski C, Kehrle K, Gleeson S. Use of a pain assessment and intervention notation (P.A.I.N.) tool in critical care nursing practice: nurses' evaluations. *Heart Lung* 2002;**31**(4)**:**303-14.
14. Rawal N, Tandon B. Epidural and intrathecal morphine in intensive care units. *Intensive Care Med* 1985;**11**(3)**:**129-33.
15. Ramsay MA, Savege TM, Simpson BR, Goodwin R. Controlled sedation with alphaxalone-alphadolone. *Br Med J.* 1974;**22**(2)**:**656-659.
16. Devlin JW, Boleski G, Mlynarek M, et al. Motor Activity Assessment Scale: a valid and reliable sedation scale for use with mechanically ventilated patients in an adult surgical intensive care unit. *Crit Care Med* 1999;**27**(7)**:**1271-1275.
17. Ambuel B, Hamlett KW, Marx CM, Blumer JL. Assessing distress in pediatric intensive care environments: the COMFORT scale. *J Pediatr Psychol.* 1992;**17**(1)**:**95-109.
18. Riker RR, Picard JT, Fraser GL. Prospective evaluation of the Sedation-Agitation Scale for adult critically ill patients. *Crit Care Med* 1999;**27**(7)**:**1325-1329.
19. Sessler CN, Gosnell MS, Grap MJ, et al. The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care unit patients. *Am J Respir Crit Care Med* 2002;**166**(10)**:**1338-1344.
20. De Jonghe B, Cook D, Appere de Vecchi C, Guyatt G, Meade M, Outin H. Using and understanding sedation scoring systems: a systematic review. *Intensive Care Med.* 2000;**26**(3)**:**275-285.
21. Blenkharn A, Faughnan S, Morgan A. Developing a pain assessment tool for use by nurses in an adult intensive care unit. *Intensive Crit Care Nurs* 2002;**18**(6)**:**332-41.
22. Jensen D, Justic M. An algorithm to distinguish the need for sedative, anxiolytic, and analgesic agents. *Dimens Crit Care Nurs* 1995; **14**(2)**:**58-65.
23. Krulewitch H, London MR, Skakel VJ, Lundstedt GJ, Thomason H, Brummel-Smith K. Assessment of pain in cognitively impaired older

adults: a comparison of pain assessment tools and their use by non-professional caregivers. *J Am Geriatr Soc* 2000;**48**(12)**:**1607-11.
24. Gélinas C, Filion L, Puntillo KA, Viens C, Fortier M. Validation of the critical-care pain observation tool in adult patients. *Am J Crit Care* 2006;**15**(4)**:**420-7.
25. Gélinas C, Johnston C. Pain assessment in the critically ill ventilated adult: validation of the Critical-care Pain Observation Tool and physiologic indicators. *Clin J Pain* 2007;**23**(6)**:**497-505.
26. Li D, Puntillo K, Miaskowski C. A review of objective pain measures for use with critical care adult patients unable to self-report. *J Pain* 2008;**9**(1)**:**2-10.
27. Van Dijk M, de Boer JB, Koot HM, Tibboel D, Passchier J, Duivenvoorden HJ. The reliability and validity of the COMFORT scale as a postoperative pain instrument in 0 to 3-year-old infants. *Pain* 2000; **84**(2-3)**:**367-77.
28. Carnevale FA, Razack S. An item analysis of the COMFORT scale in a pediatric intensive care unit. *Pediatr Crit Care Med.* 2002;**3**(2)**:**177-180.
29. Ista E, van Dijk M, Tibboel D, de Hoog M. Assessment of sedation levels in pediatric intensive care patients can be improved by using the COMFORT "behavior" scale. *Pediatr Crit Care Med.* 2005;**6**(1)**:**58-63.
30. Bijur PE, Latimer CT, Gallagher EJ. Validation of a verbally administered numerical rating scale of acute pain for use in the emergency department. *Acad Emerg Med* 2003;**10**(4)**:**390-392.
31. Cohen J. Weighted kappa: Nominal scale agreement provision for scaled disagreement or partial credit. *Psychological Bulletin* 1968; **70**(4).
32. Carroll K, Atkins P, Herold GR, et al. Pain assessment and management in critically ill postoperative and trauma patients: a multisite study. *Am J Crit Care* 1999;**8**(2)**:**105-117.
33. Prkachin KM. The consistency of facial expressions of pain: a comparison across modalities. *Pain* 1992;**51**(3)**:**297-306.
34. Hogarth DK, Hall J. Management of sedation in mechanically ventilated patients. *Curr Opin Crit Care* 2004;**10**(1)**:**40-46.
35. De Deyne C, Struys M, Decruyenaere J, Creupelandt J, Hoste E, Colardyn F. Use of continuous bispectral EEG monitoring to assess depth of sedation in ICU patients. *Intensive Care Med* 1998;**24**(12)**:**1294-1298.

Chapter 4

Implementation of a new pain and distress assessment tool for critical care medicine

Efforts and results

Clinical practice guidelines encourage the standardization of strategies and can improve the quality, safety and efficiency of patient care.
Still, the introduction of new guidelines, despite wide promulgation, often has limited effect on changing the behaviour of health care professionals.[1-3]
In recent years we developed the CIA (Critically Ill Assessment) scale, a new instrument for management of pain and distress in adult critically ill patients.
In this report we describe the process with all its difficulties of implementation of this new tool. General considerations on implementation issues are shared, as well as recommendations for future use.

Implementation of the CIA scale

During daily practice we noticed that the subjective observation of discomfort in the critically ill patient was often treated by ad hoc interventions of the physicians and nurses. Although it is well accepted to sedate patients in order to secure vital therapy, we also suspected a tendency to oversedate, which we considered a source of concern. [4-6]

We studied the usefulness of existing pain and distress instruments and the incorporation in daily practice. All of them had limitations and were not directly applicable for daily use.

On the paediatric intensive care of our University Hospital, the COMFORT behaviour scale was validated and implemented.[7,8] Remarkable success was reported on the commitment by the paediatric health care workers since the introduction of the instrument, and therefore we considered adaptation of the scale for use in the adult ward. In the following period a behavioural pain and distress instrument was developed, tested and validated. The next step was implementing the tool.

At first, a group of interested and motivated personnel was formed representing all sections of professionals on our ward, including a research leader (FJS), the unit coordinating qualified research nurse (WV) and a research nurse trainee (WM). This group followed a 2-day program of structured introduction and training concerning pain assessment implementation.

All personnel attended visually attractive clinical lessons (multimedia presentations). During these sessions, given by the research leader, the general subject of pain and distress, as well as the specific advantages of scoring them were pointed out. Also the possibilities for use in the adult Intensive Care were discussed. These lessons were received enthusiastically and led to lively discussions.

Successively, the synthesis of this presentation was summarized in a letter which was handed out to all members of the ward.

After that, the first bedside pilot with the adapted instrument was performed in pairs by members of the research group. This seemed to intensify the motivation of the remaining staff members. When the first pilot was completed and analysed, the results and also the alterations in the assessment tool, following from the results, were presented to all the professionals of the ward.

In the same period a medical student, interested in clinical research projects, was introduced on our unit. He also successfully completed the structured training and joined our research group.

We then started to train all medical and nursing staff members in independently using the assessment tool. Since the CIA scale is a behavioural instrument for which the patient is observed for 2 minutes, we purchased small alarm clocks for each of the 18 patients' rooms to facilitate the training.

This training included an introduction by a member of the research team by showing a video presentation that demonstrated the procedure and also demonstrated each item of the CIA score. As part of the training program each trainee completed ten CIA scores (at the surgical ICU) with one of the trainers or an experienced colleague. When interrater reliability was acceptable, according to a linearly weighted Cohen's Kappa >0.65, the trainee received an official certificate from our hospital and was allowed to score patients for the study.[9]

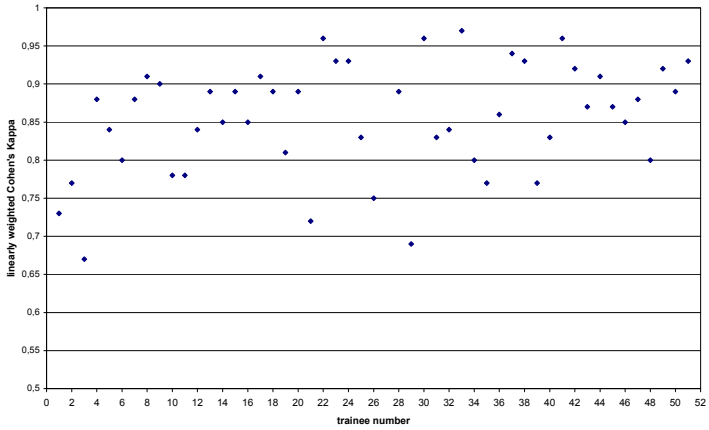

Figure 1. Interrater reliability, linearly weighted Cohen's Kappa

In this way we had 51 qualified and certified nurses and doctors, as shown in figure 1.

After completion of the second pilot and assessing the results, we finally designed the definitive form of the instrument and incorporated it in our Patient Data Management System (PDMS).[10]

We decided to secure commitment to this new tool by scheduling the CIA-observation in daily care routine by a standard order at 8 a.m. We also provided the possibility to insert assessment results on any moment during 24 hours, when the care giver thought it necessary. The assessments became standard part of our daily multidisciplinary meeting, routinely reporting the results and discussing whether or not they were satisfactory and if steps should be taken considering the results.

Before 'going live' with recording the assessment tool in our PDMS, we, again, offered multiple sessions of clinical presentations of the results of the second pilot and the adaptations made.

We announced that, as a next logical step, an algorithm would be developed based on the CIA-assessments. The nurses would thereby be given a means to take the first necessary steps when a patient was suspected to be uncomfortable.

Again, we summarized the principles in a letter which was distributed to all workers in the unit, attracting as much attention as possible.

On the first day of recording the tool in PDMS, the research leader hung up posters with the announcement of 'going live' and presented the ward with sweets and liquorice.

Practical outcome

We put extensive effort in trying to get all co-workers on our ward familiar with the new instrument and tried to emphasize the importance of a more structured approach to sedative and analgesic regimens.

Despite the fact that we were under the impression that this was successful, we were confronted with a disappointing commitment.

The assessments at the standard order times were performed flawlessly on every patient. Assessments at other moments were rarely performed, the most of them by the same small group of interested caregivers.

The fact that the standard time assessments were performed is probably due to the fact that a red alert stays on in the PDMS when an order is not carried out.
In daily practice the old routine of giving 'a little extra' medication without assessing the CIA scale continued. In this way the real amount of administered analgosedative medication stays unclear, with the potential risk of oversedation.
When asked at our daily meeting why the CIA score was not assessed the most heard answer was that it was just simply forgotten.
As a reaction to this reminder, there always was a slight increase of assessments, but in the evening and night shifts, a disappointing number of assessments were performed. During a nine-months period, 93,7% of 1792 scores were performed between 8.00 and 9.00 AM.

General considerations

Patient quality of life related research traditionally has been focussed on analysing data to identify problems and on demonstrating that a new practice will lead to improved quality or safety. Peer review journals pay little attention to the actual implementation of a new practice, despite the notorious fact that there are many different barriers to physician adherence to clinical practice guidelines.[11]
Implementation of a new practice appears to be a huge challenge, because changing a culture is at stake, culture being defined as "how we are used to do things over here".[12]
Since implementation of a new practice almost invariably requires changing of old habits, it affects many individuals with different backgrounds. Experiencing pushback and resistance is not something that we encountered exclusively.[12-15]
Everyone who describes the process of changing daily practice is challenged to change human behaviour. The complexity of changing behaviour is well recognised and comprises a wide range of factors, including organisational, economic and environmental issues.[16] And so there are many hurdles to overcome.
A few themes emerge. First, there is the difficulty of convincing physicians into a new practice. Many lessons have already been learned on that subject, like involving physicians early in the planning of the new process and emphasizing the saving of time and workload. Even when evidence of effectiveness is substantial and recommendations are clear, huge effort is still required to persuade physicians to follow a new practice. This conservative attitude towards change is not seen in any industry outside the health care system. In a review on physicians' guideline adherence, 293 potential barriers were investigated.[11] Three major themes were formulated: barriers in knowledge, attitude and behaviour, ranging from lack of awareness, to lack of motivation, to external barriers. Although behaviour can be modified without affecting knowledge or attitude, change based on influencing knowledge and attitude is likely to be more sustainable than indirect manipulation of behaviour alone.[17] Maybe by using this rational approach, progress can be made.
Second, there is complexity. Changes in health care practice are confronted with an extended system of issues and, primarily, relationships, which are

more difficult to deal with than straight-on technology. Maybe this can be overcome by means of simplification of the internal organizational structure.

Third, there is the important subject of commitment by the organization's top leadership. Without leadership support, even a brilliant plan executed by a talented and dedicated staff will rarely succeed.

In a recently published report of the Dutch Society of Intensive Care an overview is given of the implementation problems of some novel treatments and breakthrough studies.[13]

One of the conditions for a relatively easy implementation seems to be that the new practice is not subject to strong sentiments and emotions and not subject to preconceived perceptions. But even then it remains unclear why there still is such a discrepancy in the success of implementation. In our situation maybe more emphasis could have been put on the fact that structured pain assessment is one of the quality indicators set up by the Netherlands Health Care Inspectorate, reluctance to use the instrument therefore not being an example of good clinical practice.

In general, barriers based on cognitive components are considered to affect knowledge, barriers based on affective components to affect attitude and through a restriction of physicians ability to affect behaviour. In this way 76 articles were reviewed examining barriers to adherence.[11] Seven general categories of barriers were defined. Lack of awareness, or lack of familiarity (affecting physician knowledge), lack of agreement, lack of self-efficacy, lack of outcome expectancy or inertia of previous practice (affecting attitude) and external barriers (patient-, guideline- or environmental-related, affecting behaviour) were discriminated.

Successful strategies for improving physician adherence in one setting, may be less useful in a setting where barriers differ. This framework presents a differential diagnosis for why practice guidelines are not followed, and therefore offers possibilities to improve adherence by guided interventions.

For the future we recommend that physicians take the issues of implementation seriously.

Implementation issues are, in a certain way, 'where it's at' for patient safety. By putting research results into practice, care can be made safer. However, it turns out to be very difficult. But it is necessary to change some aspects of the culture in health care to make patient care safer.

It will be necessary to investigate what is needed to do the right thing all of the time. And also what is required to ensure full compliance of all parties, every time, without fail.

In this respect, we plead in favour of the development of a new specialized professional in healthcare: the implementologist. This new ambitious colleague will not only supervise the initial implementation of a new strategy, but also the maintenance of the commitment. In this was, maybe the implementation issue will be less of a problem in modern health care.

References

1. Lomas J, Anderson G, Domnick-Pierre K, Vayda E, Enkin MW, Hannah WJ. Do practice guidelines guide practice? The effect of a consensus statement on the practice of physicians. N Engl J Med 1989; **321**(19)**:**1306-11.
2. Greco P, Eisenberg J. Changing physicians' practices. N Engl J Med 1993;**329**(17)**:**1271-3.
3. Goldman L. Changing physicians' behavior. The pot and the kettle. N Engl J Med 1990;**322**(21)**:**1524-5.
4. Feeley K, Gardner A. Sedation and analgesia management for mechanically ventilated adults: literature review, case study and recommendations for practice. Aust Crit Care 2006;**19**(2)**:**73-7.
5. Pun B, Dunn J. The sedation of critically ill adults: part 2: management. Am J Nurse 2007;**107**(8)**:**40-9.
6. Devlin J, Nasraway jr. S. Reversing oversedation in the intensive care unit: the role of pharmacists in energizing guideline efforts and overcoming protocol fatigue. Crit Care Med 2008;**36**(2)**:**626-8.
7. Ambuel B, Hamlett KW, Marx CM, Blumer JL. Assessing distress in pediatric intensive care environments: the COMFORT scale. J Pediatr Psychol. 1992;**17**(1)**:**95-109.
8. van Dijk M, de Boer JB, Koot HM, Tibboel D, Passchier J, Duivenvoorden HJ. The reliability and validity of the COMFORT scale as a postoperative pain instrument in 0 to 3-year-old infants. Pain 2000; **84**(2-3)**:**367-77.
9. Cohen J. Weighted kappa: Nominal scale agreement provision for scaled disagreement or partial credit. Psychological Bulletin 1968; **70**(4).
10. Schoonderbeek J, Van Leeuwen P, Van der Hoven B, Bruining H, Tibboel D, Van Dijk M. The CIA scale; a new pain assessment scale for critically ill patients. Critical Care 2005;**9(suppl 1):**P143.
11. Cabana MD, Rand CS, Powe NR, et al. Why don't physicians follow clinical practice guidelines? A framework for improvement. Jama 1999;**282**(15)**:**1458-65.
12. Leape LL. Where the rubber meets the road. In: Advances in Patient Safety: From Research to Implementation 2005;**3:**http://www.ahrq.gov/qual/advances/.
13. Polderman KJ, Girbes ARJ. Introduction of novel therapies in the ICU: the bittersweet experience of implementation. Neth J Crit Care 2005;**9**(5)**:**271-274.
14. Pronovost PJ, Angus DC, Dorman T, Robinson KA, Dremsizov TT, Young TL. Physician staffing patterns and clinical outcomes in critically ill patients: a systematic review. Jama 2002;**288**(17)**:**2151-62.
15. Rubenfeld GD. Implementing effective ventilator practice at the bedside. Curr Opin Crit Care 2004;**10**(1)**:**33-9.
16. Lomas J. Retailing research: increasing the role of evidence in clinical services for child birth. Milbank Q 1993;**71:**439-75.
17. Woolf SH. Practice guidelines: a new reality in medicine. III. Impact on patient care. Arch Intern Med 1993;**153**(23)**:**2646-55.

Chapter 5

Introduction of a pain-distress treatment algorithm

Attitude versus behaviour

The evaluation of levels of pain and agitation and the titration of sedative and analgesic drugs in critically ill patients, is generally recommended by medical societies in accordance with the Joint Commission on Accreditation of Healthcare Organization's standards. [1-3]

In an European survey it became clear that only 43% of the ICU's use a sedation scale. The majority of them, 74 %, used the Ramsay scale, a scale that is not properly validated and that is not appropriate for agitation states, because it reflects the level of consciousness.[4,5]

Assessment and management of pain also seems to be hard to implement. Only a minority of the ICU's (<20-40%) perform painful procedures after administration of analgesic medication. [6,7]

There also seems to be a barrier for ICU professionals, who are hesitant in treating pain appropriately, because of organ system dysfunction, impaired mental status and altered pharmacodynamics and –kinetics. The critically ill population is also more susceptible to side effects of sedative and analgesic medication.[8,9]

On our ward we conducted an investigation by questionnaire to see whether it was desired to protocolize our pain and distress therapy.

After that, we introduced an algorithm, based on the Critically Ill Assessment scale.[10]

In the following chapter the results of the questionnaire, as well as the results of standardized therapy on our ward six months after implementation of the algorithm will be discussed.

Materials and Methods

We investigated attitude versus behaviour towards a new clinical strategy. Attitude was studied by a questionnaire, where behaviour was analyzed as compliance to the algorithm.

Attitude

We designed a questionnaire to evaluate the opinion on the current state of pain-distress assessment and management on our ward. We performed this investigation (January 2006) as a quality indicator for our patient policy, as well as an indicator to evaluate the commitment or attitude of the nursing staff to comply to another, more engaged method of pain policy. A comprised, but complete example of the questionnaire is presented at the end of this thesis (appendices).
We formulated 5 general questions, 2 numeric questions, 2 open space questions and 21 questions put as statements. Compliance to the statements could be expressed in four response categories, varying from "absolutely" to "definitely not".
Important for the researcher was the open space question about the atmosphere on the ward, to see if there was a fundament to change policy.

Behaviour

After presenting the results of the survey to the nursing and medical staff, we introduced a new, standardized approach to pain and distress assessment and management.
This approach contained a regular assessment, every 4 hours, of the Critically Ill Assessment scale and a treatment algorithm in case of high (CIA>9) or low (CIA<7) scores.[10]
Our general Intensive Care comprises a 10-bed unit in a university affiliated teaching hospital. In April 2006 we introduced the Paindistress treatment algorithm on the ICU and incorporated it into daily practice. The algorithm is shown in figure 1.

The CIA scale is based on the Comfort scale [11,12] and is designed as a pain assessment tool for the adult critically ill patient.
Table 1 presents the items of the CIA tool. The CIA-score comprises five items. These items are alertness, muscle tone, facial tension, body movements and respiratory response (for both ventilated patients and non ventilated patients).
All items have four response categories with distinct behavioural descriptions, resulting in a CIA score range from 5 to 20.

Compliance to the algorithm was assessed for both high scores and low scores.
For CIA high scores (> 9) according to the algorithm the following actions were recorded:

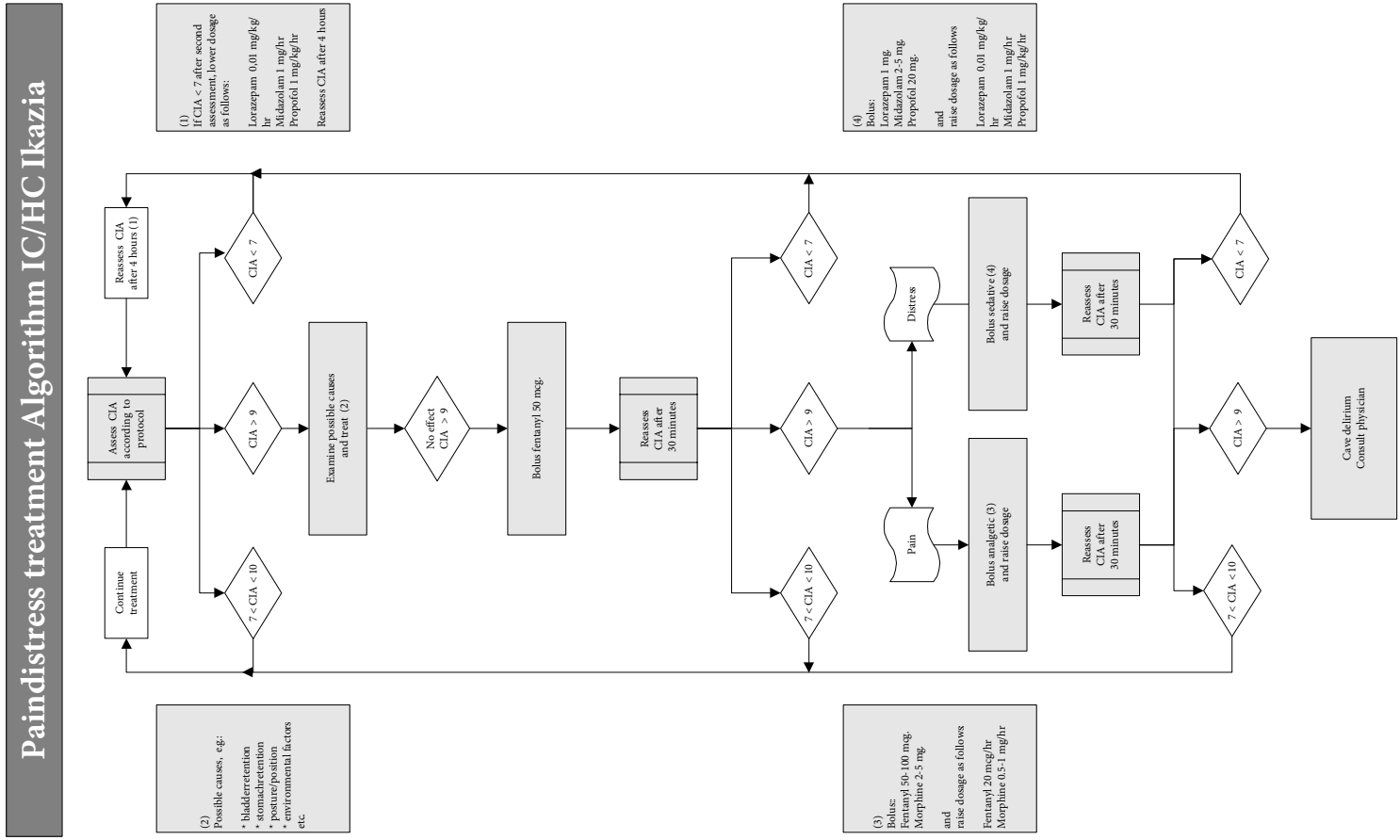

Figure 1. Paindistress treatment algorithm

Table 1. The Critically Ill Assessment (CIA) scale

Critically Ill Assessment scale; observe the patients and rate after 2 minutes		
Item	Score	Response categorie
Alertness	1	Asleep
	2	Awake
	3	Exaggerated reaction (controlled)
	4	Exaggerated reaction (uncontrolled)
Facial tension	1	Decreased
	2	Relaxed
	3	Increased
	4	Continuous increased grimacing
Muscle tone	1	Polyneuropatic or decreased
	2	Normal
	3	Increased
	4	Contorted
Body movements	1	Incidental
	2	Relaxed
	3	Motor restlessness (controlled)
	4	Motor restlessness (uncontrolled)
Respiratory response	1	Controlled ventilation without resistance
	2	Normal breathing 10-30/min
	3	Tachypnoe > 30/min
	4	Use of accessory respiratory muscles
		Total score

- repeated assessment within one hour (the protocol indicates 30 minutes after treatment but lenience seems fair);
- whether or not treatment was adjusted and how (opioids and/or sedatives).

For CIA low scores (< 7) according to this algorithm the following actions were recorded:

- repeated assessment within 4 hours after initial low score;
- weaning of medication performed if score was <7 again.

For both situations potential reasons for non compliance were addressed.
The results of this new approach, both of compliance to the algorithm, as well as patient related results, are reported below.
All patients admitted to the ICU requiring opioids and/or sedatives were eligible.
Since pain and distress assessment is part of daily care, IRB approval was waived because the non-invasive and observational character of the study.

Results

Attitude; results of the questionnaire

We distributed 45 copies between 36 nurses and 9 doctors. We received 36 completed copies back (overall response rate 80%), of which 29 nurses (response rate 81%) and 7 doctors (response rate 78%).
Median age of the responders was 30 years (22 to 54 years). Gender distribution (male/female) in the nursing staff was 6/23, and in the medical staff 4/3.
On the question on atmosphere, generally all responders answered positively. Overall descriptions varied from "good and loyal to professional".

Three responders mentioned that feedback and assertive behaviour could be improved. One responder mentioned that discussions are avoided.
Every nurse felt that nurses in general are important in assessing pain; also every nurse (except one) felt that the underlying disease had influence on the assessment.
Every responder felt the need for a good assessment instrument.
Ninety-four percent of the responders found that the need for analgesics increased with the number of endured operations.
Although it is clear that all patients on the ICU suffer from pain, this knowledge is not yet shared by everyone. Nineteen percent of the responders (29% of the medical staff and 17% of the nursing staff) considered pain assessment not necessary in all ICU patients.
"Giving a little extra" of analgosedative medication (on individual initiative and without specific protocolization) is daily practice in most ICU's, although it is not documented.
Still, 11 nurses (38%) and 2 doctors (29%) thought that it did not happen in our department.
The usefulness of pain assessment without integration in medication strategies is doubted by 24% of the nurses and 29% of the doctors.
Almost all responders (83%) agreed that medication can be administered independently by nurses, when an algorithm is available.
Only 14% of the responders (all nurses) is of the opinion that overdosage of analgesic medication in critically ill patients occurs. On sedative medication, 59% of the nurses and 43% of the doctors think that oversedation occurs.
Eighty-six percent of the nurses think that records of behaviour, especially in situations when the patient is clearly not comfortable, are written down in the nursing reports.
Forty-three percent of the doctors think that similar reports of behaviour are noted in the medical status.
In general the idea exists that the analgesic strategy is better outlined than the sedative strategy.
When asked how many patients are thought to be in pain on the ICU, varying answers were given. Half of the responders think that this is less than 50% of the patients.
Analgesic management is rated from 4 to 8, with a median of 7 (on a scale of 0 to10).
We also left room for suggestions to improve our analgosedative strategies. Ninety-seven percent of the responders gave suggestions, with a general preference for structured assessments and protocolization of medication strategies.

Behaviour; compliance to the algorithm

After an initial period of getting used to work with the algorithm, we collected all data related to the algorithm during six months.
Table 2 gives the background characteristics of the 73 patients whose data were analysed. All patients were intubated and received mechanical ventilation. All patients were deemed by the intensive care unit team to require analgosedation by continuous intravenous infusion. Two patients were readmitted in this period and one patient underwent two operations.

Table 2. Patient characteristics (N=73)

Variables	
Age in years	
median	69
minimum and maximum	20 to 86
Gender (Male/Female)	42/31
Primary diagnosis	
postoperative	32 (43.9%)
respiratory problems	25 (34.2%)
heart failure	6 (8.2%)
infection	6 (8.2%)
other	4 (5.5%)
ICU stay in days	
median	10
range	3 to 43
Duration ventilation in days	
median	6
range	1 to 26 days
Deceased on ICU	12 (16.4%)
APACHE	
median	22
range	11 to 38

Patients were between 20 and 85 years with a median of 69 years. Respiratory insufficiency and postoperative ventilation were the main reasons for admittance. Apache II scores varied from 11 to 38 with a median of 22. All deceased patients died within 26 days after admittance.

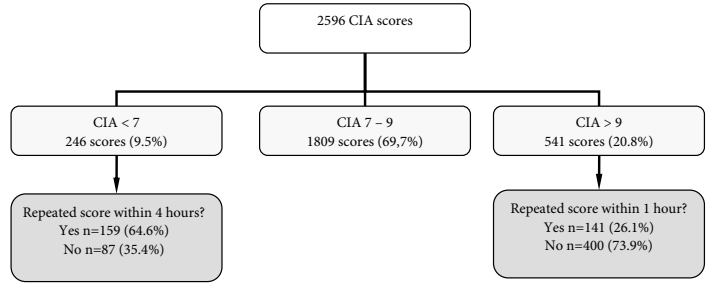

Figure 2. Compliance to the algorithm

This sample of assessments comprised 866 ICU days during which 2596 CIA scores were assessed. This results in a median number of 4 assessments per day per patient. ICU stay varied between 3 to 43 days; the number of assessments per patient vary from 3 to 170.

Figure 2 gives the results for the CIA assessments and the compliance to the algorithm in terms of pain assessment.

In 69.7% of the assessments, the scores are adequate (CIA 7-9). In 9.5% CIA scores are below 7. According to the algorithm reassessment should be performed within 4 hours for low scores. This is done in 64.6% of the scores. The low scores were scored during night time (23.00 to 7.00) in 38.6%. Reassessment within 4 hours was not significantly different for day or night time (Chi-square test, p=0.51).

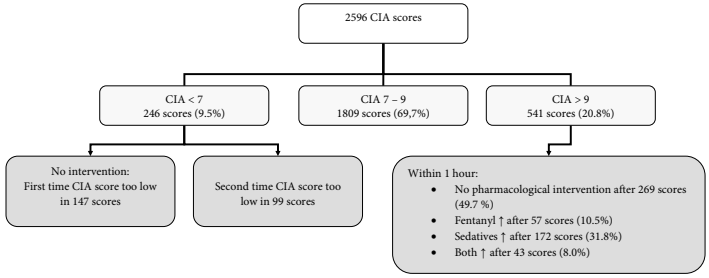

Figure 3. Treatment according to the algorithm

In 20.8% of all assessments (541 scores), CIA was > 9 and reassessment within one hour according the algorithm was done in only 26.1% of the cases. The high CIA scores were seen during night time in 31.8% of the 541 scores and more often repeated during night time than during day time (32.0% vs. 23.6% respectively, Chi-square test, p=0.04).

Figure 3 relates to treatment according to the algorithm. Scores below 7 indicate a high probability for oversedation, but to prevent too quick weaning, treatment is only indicated when a repeated CIA score (within 4 hours) is too low. Of the 246 CIA scores < 7 it was a first score in 147 assessments. The remaining 99 scores resulted in weaning in 14 scores and no weaning in 85 scores.

For the high CIA scores almost half of the assessments (49.7%) did not result in a medical intervention within an hour. If an intervention was performed, this was more often adaptation of the sedative medication (31.8%), than of the analgesic medication (10.5%).

Medication and assessment

Table 3 summarizes the doses of the used analgosedative drugs and antipsychotics.

The preferred analgetic drug was fentanyl and the preferred sedative drug was midazolam, both by continuous intravenous infusion.

Figure 4 shows the different interventions related to CIA assessments>9. Sixty-seven patients (92%) received fentanyl by continuous intravenous infusion, 52 patients of whom also received bolusdosages of fentanyl. These patients had CIA assessments between 10 and 16.

Table 3. Doseranges of analgetic and sedative medication

Medication	Method of administration	Number and dose range
Midazolam	continuous	n=69
	dose range	50-600 mg/24hr
	bolus	n=60
	dose range	2 – 5 mg
Fentanyl	continuous	n=67
	dose range	500-1500 µg/24hr
	bolus	n=52
	dose range	50-100 µg
Propofol	continuous	n=56
	dose range	20-80 mg
	bolus	N=40
	dose	20 mg
Haloperidol	bolus	n=9
	dose range	1-5 mg
	frequency	1-38x

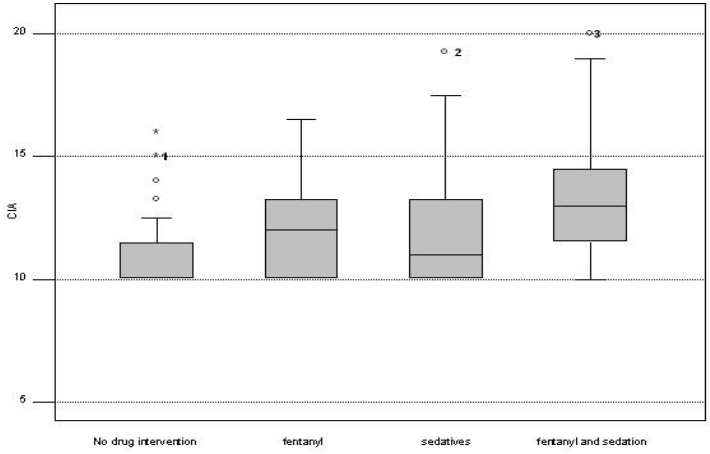

Figure 4. Boxplot showing the different interventions related to CIA assessments > 9
* extremes (p99); ° outlier; [1] extubation; [2] 30 minutes after extubation; [3] haloperidol as well

Sixty-nine patients (95%) were given midazolam by continuous intravenous infusion, 60 patients of whom also received boluses of midazolam. This group of patients had CIA assessments between 10 and 17.
Fifty-six patients (77%) received propofol by continuous intravenous infusion, 40 patients of whom also received boluses of propofol. Propofol is reserved for patients in which a short period of ventilation is expected or for patients whose awakening towards extubation is uncomfortable.
Nine patients were suspected of developing a delirium and also received haloperidol.

Discussion

Clinical practice guidelines encourage the standardization of strategies and can improve the quality, safety and efficiency of patient care.
Still, the introduction of new guidelines, despite wide promulgation, often has limited effect on changing the behaviour of health care professionals.[13-15]

Despite this, we had high hopes on the introduction of the CIA based algorithm. The results of the questionnaire showed that there was enough basis for starting a new strategy in this specific area. Most of the responders (83%) felt qualified to independently treat discomfort according to approved guidelines.
And more important, the appraisal of the existing policy in analgosedation varied from 4 to 8 (on a scale of 10). Thus, the time seemed right to introduce this new strategy.
First of all, it springs to attention that in 70% of all assessments the CIA score is between 7 and 10, thus indicating that in 70% of our patients the analgosedative strategy is according department-guidelines.
Still, in the remaining 30%, when the patient does not seem to be in a comfortable state or seems to be oversedated, compliance to the algorithm seems to be mediocre. A few patients were in a end of life situation or just waking up to be extubated, but still it seems fair to say that in many of these cases compliance to the algorithm is incomplete.
We did not analyse if compliance increased during the study period, but reports that that can be the case exist.[16] On the other hand, we especially

introduced the algorithm 4 months in advance of the study period to get used to it and avoid adaptation problems.

In general, the use of detailed protocols to manage clinical problems is becoming more common in the ICU. [17] Protocols promote a multidisciplinary approach to patient care, and enhance efficiency by making the clinical plan explicit to all care providers. A level of uniformity of approach and goals for the patient can be achieved, reducing within-patient variability of decision-making.

In addition, protocols enhance efficiency by allowing non-physician care providers to proceed with clinical decision-making without the need for continuous physician input. In this regard, protocolized strategies directed by nurses has been shown to be more effective than physician directed strategies, as well as significant in cost saving.[18]

Sedation protocols are algorithms by which nurses adjust sedative and analgesic doses based upon written guidelines and assessment of the patient's level of sedation. Use of sedation protocols has been shown to decrease the duration of mechanical ventilation, promote the judicious use of therapeutic agents, reduce variability in prescribing, and decrease sedative costs in critically ill patients.[19-22]

Despite compelling evidence that use of sedation protocols improves outcome and reduces costs, only a minority of ICU's have adopted their use. A multicenter survey of critical care pharmacists found that sedation, pain and paralysis protocols were used in only 26% of respondents' practices, and health professional-generated Painsedation scores were used to assess dosing needs in only 25% of the practices.[23]

In summary, guidelines that minimize unnecessary variability in practice, prevent excessive medication, and emphasize individual patient management. In that way effective utilization of sedatives and analgesics is improved.

Use of standardized protocols may also increase the satisfaction of clinicians. The potential impact of guidelines and protocols on nursing satisfaction was emphasized by a survey that was recently completed. [24] In this survey 51% of the nursing staff was satisfied with current practice, and cited physician inconsistency in choice and dosing of analgosedative medication. Almost all respondents thought a nursing-directed protocol combined with a scoring system would be valuable to patient care (91%), by reducing inconsistency in practice, and allowing individualized dosing based on the nursing assessment. Finally, 94% of the respondents reported that a protocol would enhance professional practice, by providing greater nursing autonomy, promoting consistency and serving as a valuable communication and assessment tool.

In conclusion, it is clear that the manner in which sedatives are used in the ICU is important, in terms of meaningful clinical and cost-related outcomes such as duration of mechanical ventilation and lengths of hospital and ICU stay. The management of sedation in critically ill patients may be equally or more important than the choice of which sedative drug to use. Because there is no risk-free medication, recent efforts to improve outcomes for patients in the ICU have shifted towards investigations of the manner in which the medication is administered.

Many important questions regarding analgosedation in the ICU remain unanswered. It is clear that intensivists need better methods of ensuring that the lowest effective doses of the most appreciated sedative, analgesic and tranquilizing drugs are given for the shortest time to critically ill patients receiving mechanical ventilation.

References

1. Jacobi J, Fraser GL, Coursin DB, et al. Clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult. *Crit Care Med* 2002;**30**(1)**:**119-41.
2. JCAHO. Standards for the assessment and management of pain. http://www.jcaho.org 2002.
3. Fraser G, Riker R. Monitoring sedation, agitation, analgesia, and delirium in critically ill adult patients. *Crit Care Clin.* 2001;**17**(4)**:**967-87.
4. Soliman H, Melot, C, Vincent, JL. Sedative and analgesic practice in the intensive care unit: the results of a European survey. *Br J Anaesth.* 2001;**87**(2)**:**186-92.
5. Ramsay MA, Savege TM, Simpson BR, Goodwin R. Controlled sedation with alphaxalone-alphadolone. *Br Med J.* 1974;**22**(2)**:**656-659.
6. Kinney M, Kirchhoff K, Puntillo K. Chest tube removal practices in critical care units in the United States. *Am J Crit Care.* 1995;**4**(6)**:** 419-24.
7. Puntillo K, Wild L, Morris AB, Stanik-Hutt J, Thompson CL, White C. Practices and predictors of analgesic interventions for adults undergoing painful procedures. *Am J Crit Care.* 2002;**11**(5)**:**415-29.
8. Hamill-Ruth R. Use of analgesics in the intensive care unit: who says it hurts? *Crit Care Med.* 2002;**30**(11)**:**2597-8.
9. Freire A, Afessa B, Cawley P, Phelps S, Bridges L. Characteristics associated with analgesia ordering in the intensive care unit and relationships with outcome. *Crit Care Med.* 2002;**30**(11)**:**2468-72.
10. Schoonderbeek J, Van Leeuwen P, Van der Hoven B, Bruining H, Tibboel D, Van Dijk M. The CIA scale; a new pain assessment scale for critically ill patients. *Critical Care* 2005;**9(suppl 1):**P143.
11. Ambuel B, Hamlett KW, Marx CM, Blumer JL. Assessing distress in pediatric intensive care environments: the COMFORT scale. *J Pediatr Psychol.* 1992;**17**(1)**:**95-109.
12. van Dijk M, de Boer JB, Koot HM, Tibboel D, Passchier J, Duivenvoorden HJ. The reliability and validity of the COMFORT scale as a postoperative pain instrument in 0 to 3-year-old infants. *Pain* 2000; **84**(2-3)**:**367-77.
13. Goldman L. Changing physicians' behavior. The pot and the kettle. *N Engl J Med* 1990;**322**(21)**:**1524-5.
14. Greco P, Eisenberg J. Changing physicians' practices. *N Engl J Med* 1993;**329**(17)**:**1271-3.
15. Lomas J, Anderson G, Domnick-Pierre K, Vayda E, Enkin MW, Hannah WJ. Do practice guidelines guide practice? The effect of a consensus statement on the practice of physicians. *N Engl J Med* 1989; **321**(19)**:**1306-11.
16. Elliott R, McKinley S, Aitken LM, Hendrikz J. The effect of an algorithm-based sedation guideline on the duration of mechanical ventilation in an Australian intensive care unit. *Intensive Care Med* 2006; **32**(10)**:**1506-14.
17. Morris AH. Developing and implementing computerized protocols for standardization of clinical decisions. *Ann Intern Med* 2000;**7**(132)**:** 373-83.
18. Kollef M, Shapiro S, Silver P, St John RE, Prentice D, Sauer S, Ahrens TS, Shannon W, Baker-Clinkscale D. A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation. *Crit Care Med* 1997;**25**(4)**:**567-74.
19. Brook A, Ahrens T, Schaiff R, Prentice D, Sherman G, Shannon W, Kollef MH. Effect of a nursing-implemented sedation protocol on the duration of mechanical ventilation. *Crit Care Med* 1999;**27**(12)**:**2609-15.
20. Devlin J, Holbrook A, Fuller H. The effect of ICU sedation guidelines and pharmacist interventions on clinical outcomes and drug cost. *Ann Pharmacother.* 1997;**31**(6)**:**689-95.

21. MacLaren R, Plamondon J, Ramsay KB, Rocker GM, Patrick WD, Hall RI. A prospective evaluation of empiric versus protocol-based sedation and analgesia. *Pharmacotherapy* 2000;**20**(6)**:**662-72.
22. Watling S, Johnson M, Yanos J. A method to produce sedation in critically ill patients. *Ann Pharmacother.* 1996;**30**(11)**:**1227-31.
23. Watling S, Dasta J, Seidl EC. Sedatives, analgesics, and paralytics in the ICU. *Ann Pharmacother.* 1997;**31**(2)**:**148-53.
24. Burry L, Hynes-Gay P, Cook D, Meade M, Gibson J, Mehta S. A survey of ICU nurses regarding the use of sedatives and analgesics in mechanically ventilated adults. *Am J Respir Crit Care Med* 2003; **167:**A659(abst).

Chapter 6

The use of bispectral index (BIS) in the ICU

More than 70% of the ICU patients experience anxiety, pain or agitation. This feeling of discomfort is aggravated when patients are mechanically ventilated. [1]

Systemic titration and evaluation of analgosedative medication is important in controlling discomfort and is associated with a decrease in incidence of pain and agitation, as well as a decrease in the duration of mechanical ventilation and nosocomial infections. [2] Routine assessment of sedation levels therefore should be a part of total care for critically ill patients.

An ideal level of 'standard sedation', optimal for every patient, does not exist. A survey conducted in 1981 recorded that 67% of ICUs preferred a deep sedation for critically ill patients and more than 90% used neuromuscular blockers to facilitate mechanical ventilation. [3] A similar survey conducted in 1987 revealed that the aim of sedation in the ICUs changed over time; 69% of responders preferred to maintain asleep but easily arousable patients, and only 16% of them used neuromuscular blockers. [4]

Nowadays, with new sedative strategies and medication, daily interruptions of sedative infusions in ventilated patients are propagated. [5-7]

Current consensus is goal-directed therapy in each individual patient on the basis of systematic evaluation and management of the clinical features of analgosedation. Any patient under sedation deserves continuous monitoring from physicians and/or nurses. But subjective assessment is only useful when it is promoted in educational programs and is embedded in protocols.[8,9]

Another matter that should be considered is the quantity of sedation. Both oversedation and undersedation cause problems. Undersedation leads to inadequate ventilation, hypertension, tachycardia, and discomfort, which negatively interfere with the outcome of ICU patients.

On the other hand, oversedation, as a result of accumulation of sedative and analgesic drugs, leads to many complications, among which delayed arousal, prolonged ventilator dependence, difficulty of weaning and a considerable increase in costs.
However, monitoring the depth of sedation in intensive care patients is difficult, because an "ideal tool" does not exist. A validated instrument that could be considered an international "gold standard" has not been established. [10] During the last few years, many different methods, including scoring systems ("subjective" evaluation) and monitoring, such as bispectral index scoring (BIS) and auditory evoked potential (AEP) ("objective" evaluation) [11], have been proposed. However, none of these instruments is supported by strong clinical evidence.
Processed EEG algorithms, such as the bispectral index (BIS), were initially introduced into clinical practice as a tool to assess the depth of anaesthesia objectively in the operating room. Although the method by which the BIS is derived has been partially published, the complete algorithm is not yet available.[12] Furthermore, it is currently not supported by strong evidence that the BIS monitor could be a reliable parameter in assessing the depth of sedation in critically ill patients.

Accountability and aim

We performed two studies, study A and study B, in different clinical settings, to investigate the usefulness of the BIS to determine the level of sedation on the ICU. In both studies we used the BIS-XP monitor, model A-2000.
Although the designs of the studies differ, the results of both are discussed in this chapter because the final remarks are in unison and derived from both studies.
The first study (study A) was conducted on a general surgery/trauma ICU in a university hospital, and the second (study B) on the general ICU of a university affiliated teaching hospital, both in Rotterdam, the Netherlands.

Study A

The aim of the study was (1) to analyze if the use of sedatives could be minimized to a level where a patient can undergo therapy comfortably, using the BIS method, (2) to analyze the correlation between the subjective assessment scales used and the BIS and (3) to determine the level of consciousness measured by BIS-values in these patients.
In general anesthesia a BIS value of 40 to 60 is desirable, but in critical care no general values are recommended, other than the suggestion that amnesia reliably occurs at BIS-values between 64 and 80.[13-15]

Study A: Material and methods

After internal medical ethics review board consent, we performed a prospective, double-blind, controlled clinical trial.

In a cohort of 23 patients the level of consciousness was monitored with BIS simultaneously with a two-hourly assessment of distress with three different clinical assessments instruments: the Numeric Rating Scale (for distress, range 0-10), the Ramsay-score (range 1-6) and the Critically Ill Assessment scale (range 5-20). [16-18] The goal values for the different assessment instruments are < 4 in NRS, 2 or 3 in Ramsay en between 7 and 10 for the CIA.

All assessments were recorded in a separate file; also the display of the BIS monitor was shielded from sight to aim for objectivity in applying the assessment instruments.

All patients were over eighteen years of age, required mechanical ventilation and received analgesic and sedative medication. All patients were admitted to the intensive care unit after major surgery or because of the onset of critical illness.

Exclusion criteria were patients under the age of 18, patients with head trauma and possible or apparent neurological dysfunction, patients with pre-existent neurological dysfunction and patients receiving neuromuscular blocking agents.

BIS value measurements started immediately upon admission and were performed during the first 24 hours of ICU stay. The BIS values were automatically generated and stored in our Patient Data Management System (PDMS).

The assessments were performed by the attending nurse (AN) and an independent researcher (IR) every two hours, independently of each other, and blind for the accompanying BIS values. Measurements were only performed when no stimulus had occurred for 10 minutes, such as turning the patient or tracheal suctioning.

During the study-period the amounts of hourly given sedatives were stored in the PDMS. Only in consultation with the attending physician these amounts were adjusted, without his or hers knowledge of the current assessment results.

Study A: Results

Patient and study characteristics are shown in Table 1.

A total of 552 values of BIS and a total of 1656 simultaneous assessments of NRS, Ramsay and CIA were analyzed.

All patients received lorazepam (range 0-2,6 mg/hr), midazolam (range 0-15 mg/hr) or propofol (range 0-200 mg/hr).

Median NRS-AN and median NRS-IR were 0, median Ramsay-AN and median Ramsay-IR were 5, whereas the median CIA-AN and CIA-IR were 7 and 8 respectively. The CIA score was below 10 in 92% of the assessments. The Ramsay score was 5 in 47% of the time and 6 in 32% of the time.

BIS scores varied greatly, between patients as well as individually in time (figure 1 and figure 2).

The median BIS value was 55 (IQR 42-73). Mean BIS value was 57 +/- 21. BIS values were between 61 and 80 in 28% of the measurements, between 40 and 60 in 34 % and in 22% below 40. Fourteen out of 23 patients had a median BIS value below 60 (figure 2).

Table 1. Study A: patient and study characteristics and results

Patients	Male	n = 15
	Female	n = 8
Age (yrs)	Median	68
	IQR	58-73
BIS score	Median	55
	IQR	42-73
Ventilation	CPAP	n = 13
	BiPAP	n = 9
	SIMV	n = 3
	CPPV	n = 1
Sedatives	Lorazepam	n = 11
		0-2,6 mg/hr
	Midazolam	n = 6
		0-15 mg/hr
	Propofol	n = 6
		0-200 mg/hr
Diagnosis on admission	Peritonitis	n = 6
	Neo-esophagus	n = 5
	Respiratory insufficiency	n = 5
	Abdominal aneurysm	n = 2
	Severe trauma	n = 2
	Haemorrhagic shock	n = 1
Sedation scores median and (range)	CIA-IR	8 (7-9)
	CIA-AN	7 (6-9)
	NRS-IR	0 (0-0)
	NRS-AN	0 (0-0)
	Ramsay-IR	5 (5-6)
	Ramsay-AN	5 (4-5)

IQR = Inter Quartile Range
CIA = Critically Ill Assessment scale
NRS = Numeric Rating Scale
IR = independent researcher
AN = attending nurse

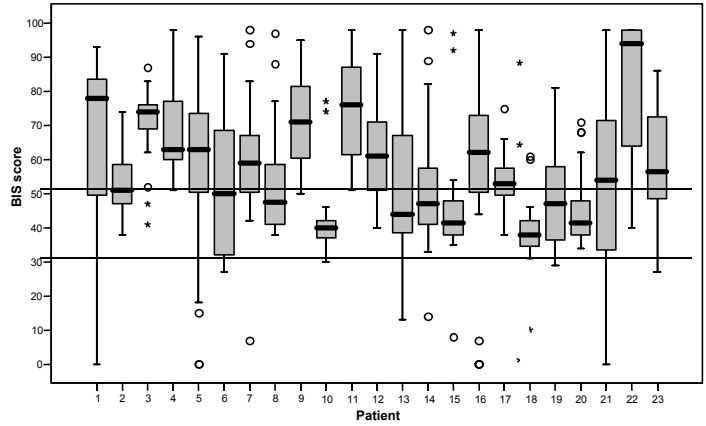

Figure 1. Study A: Boxplot showing median BIS scores with IQR of 23 individual patients
*extremes (p99, p1); ° outlier

Study A: Conclusion

BIS values in this heterogeneous population vary widely and sometimes the monitor produces data inconsistent with the clinical situation.
The very first thing that comes to attention is a trend to oversedation in this group of critically ill patients, with a Ramsay of 5, a median NRS of 0 and a median CIA of 7 and 8 respectively.
Although the median BIS value was 55, which seems to be in accordance with these observations, sometimes the data are clinically unreliable and randomly fluctuating. Therefore, a role for the BIS monitor as a helpful tool on the spot diagnosis situation seems to be too farfetched.

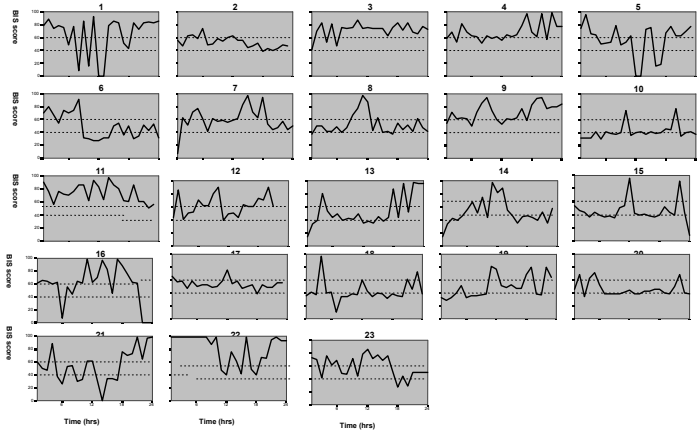

Figure 2. Study A: Individual BIS scores in time of 23 patients

The eventual usefulness of BIS monitoring requires a beneficial effect on relevant clinical or economic outcomes. A potential outcome, such as decreased sedative requirements, cannot be achieved by BIS monitoring alone, when the individual variation according to the results in study A are taken into account.

Study B

Study B was performed on the general ICU of a university affiliated teaching hospital.

In this study we compared BIS values in sedated patients with two validated subjective scores, the Ramsay score and the Critically Ill Assessment (CIA) score.

Study B: Material and methods

A total of 622 observations were collected in twenty patients during a period of minimal 12 to maximal 64 hours on a general ICU (498 Ramsay and 124 CIA).

All patients were mechanically ventilated and received sedative and/or analgesic medication.

The level of consciousness was prospectively evaluated using the Ramsay and CIA scores.

BIS measurements were continuously monitored and together with Ramsay and CIA scores recorded every hour.

All assessments were recorded in a separate file; also the display of the BIS monitor was shielded from sight to aim for objectivity in applying the assessment instruments.

Median BIS values were analyzed for different Ramsay scores and the overall and intra-individual correlations between BIS and CIA scores were calculated.

Study B: Results

The patient and study characteristics are listed in Table 2.

Table 2. Study B: patient and study characteristics and results

Patients		n = 20
Gender	Male	n = 8
	Female	n = 12
Age (yrs)	Median	74
	Range	24-86
BIS score	Median daytime	50
	IQR	40-65
	Median night-time	47
	IQR	40-63
Sedatives	Midazolam	n = 7
		2-16 mg/hr
	Propofol	n = 3
		32-150 mg/hr
	Combination	n = 10
	Additional opiates	n = 14
	morphine	1-4 mg/hr
Diagnosis on admission	Sepsis	n = 1
	Neo-esophagus	n = 1
	Respiratory insufficiency	n = 9
	Abdominal aneurysm	n = 1
	Cardiac failure	n = 3
	Haemorrhagic shock	n = 1
	Major abdominal surg.	n = 3
	Other	n = 1
Sedationscores (n/%)	CIA ≤ 9	119/96
	CIA > 9	5/4
	Ramsay 1-2	15/3
	Ramsay 3-4	92/18
	Ramsay 5-6	391/79

IQR = Inter Quartile Range
CIA = Critically Ill Assessment

The median age of patients was 74 (range 24-86 years). Seven patients were sedated using only midazolam, three patients using both midazolam and propofol and 3 patients using propofol only. In addition, fourteen patients received opiates.
Median BIS value during daytime was 50 (IQR 40-65) and during night time 47 (IQR 40-63).

Study B: Results - BIS versus Ramsay

Almost 80% of the Ramsay assessments ranged from a score of 5 (sluggish response to glabellar tap) to 6 (no response). Median BIS values when Ramsay was scored 5 or 6 was 42 (IQR 39 to 53) (n=391, 79%). Median BIS values when Ramsay was scored 3 or 4 was 72 (IQR 51 to 82) (n=92, 18%). Ramsay 1-2 was scored 15 times (3%). Figure 3 shows the abovementioned results, again indicating the difficulty in the interpretation of these results.

Study B: Results - BIS versus CIA

In 96% (n=119) CIA-scores were 10 or lower. The CIA-scale has a range from 5-20, with cut-off points 7 as suspect for deep sedation, above 10 as suspect for a state of discomfort and in between (7-10) as optimal sedation.
BIS measurements ranged from 0 to 75 when a minimal CIA of 5 was scored. When a state of optimal sedation was scored, according to a CIA assessment of 7-10, BIS values varied from 26 to 94. When CIA was scored above 10, BIS values ranged from 44 to 96.
Overall Pearson's product moment correlation between BIS and CIA was 0.55 (n=124) with intra-individual correlations ranging from -0.36 to 0.85.

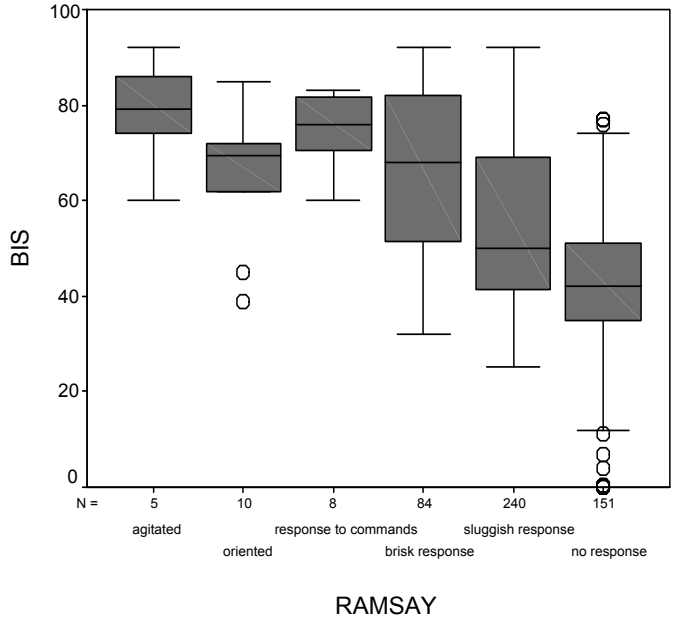

Figure 3. Boxplot showing the range of BIS scores for different Ramsay scores (Study B)
º outlier

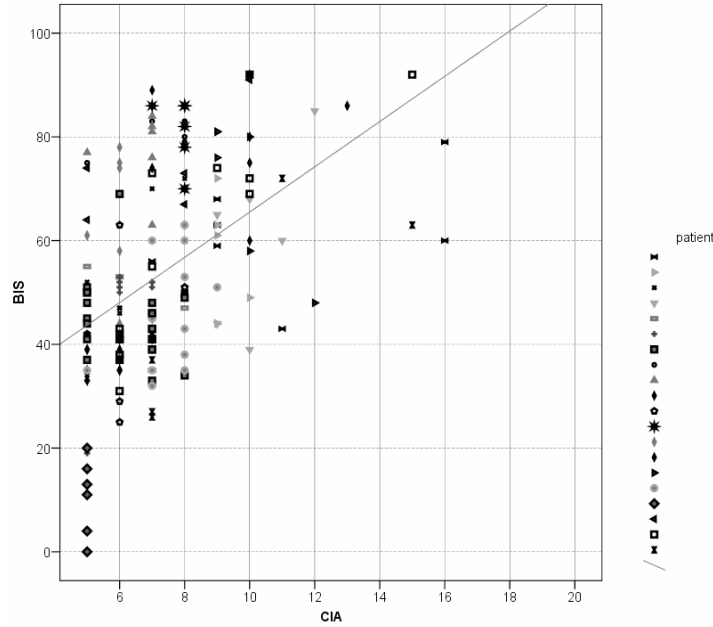

Figure 4. Scatterplot showing the association between BIS and CIA scores (Study B)

One male patient with ischaemic bowel and sepsis received 4.1 mg morphine/hr and had BIS values ranging from 0 to 20 (figure 4).

Study B: Results - Sensitivity to change

We also observed the sensitivity to change of the BIS values. In 13 assessments we focussed on the change of BIS value after addressing the patient. BIS values increased after addressing the patient from 0 to a maximum of 36, with a median of 31.

Study B: Conclusion

Individual Ramsay and CIA scores were reflected by a broad range of BIS scores. Especially in patients with CIA scores above 10 or Ramsay scores above 4, BIS scores varied widely.

General remarks

Sedation and analgesia are important components of care for critically ill patients. However, all sedation scales are to a certain degree subjective, and determining the depth of sedation may vary depending on the person evaluating a patient. Many intensivists feel strongly that an objective monitor of sedation is crucial for adequately assessing the status of a patient.
Processed EEG algorithms were initially introduced into clinical practice as a tool to assess depth of anaesthesia objectively in the operating room. In this setting it has been shown that BIS monitoring allowed an adequate administration of hypnotics, resulting in improved recovery times and reduced awareness under general anaesthesia.[12,19,20] Although recently a report has been published, in which these previous advantageous results could not be reproduced.[21] Anaesthesia awareness occurred even when BIS values were within target ranges.
Although the BIS scoring was developed from a large database of patients under general anaesthesia, its use was also extended to ICU sedation.[22]
There are however differences between patients under general anaesthesia and those in ICU. Most importantly, ICU patients do not require a level of sedation that is as deep as surgical anaesthesia. In contrast to general anaesthesia, recent sedation strategies try to keep patients as cooperative as possible.[23] Consequently, these patients show a higher level of muscular activity, often resulting in an increased number of EEG artefacts. [24]
Accordingly, results from studies evaluating the performance of processed EEG parameters in critically ill patients have not been satisfactory.[14,25,26]
The index has not been validated in critically ill patients, and it is currently not clear to what degree the BIS-reading is influenced by underlying disease, encephalopaties and other (patho-)physiological factors, for example age, temperature, glucose level, electrolyte balance, hepatic or renal failure or endocrine disorders, as well as artefacts induced by other electrical equipment, patient movement and activities and manipulation of the patient (e.g. electromyographic activity).[12,27-30]

A few studies have been performed correlating the BIS with clinical scores of sedation, such as the Ramsay Sedation Scale or the Sedation Agitation Scale.[31] In a prospective, single blind study, 20 patients were evaluated using the Sedation Agitation Scale and the BIS.
A wide variability in BIS readings was found for any given level of consciousness, and the correlation between the two parameters was deemed to be less than satisfactory. In a subgroup of patients who did not show excessive muscle movement, the correlation was improved because there were fewer artefacts. [25]
Similar results were found when the BIS was compared with the Ramsay score. In 44 ventilated patients following major surgery, BIS, Ramsay score, body temperature and EMG activity were recorded.[26]

Although a correlation was found between the BIS and Ramsay score in deeply sedated patients, temperature instability and EMG activity inappropriately increased BIS values. In order to improve the correlation between the two parameters, it had to be ensured that patients had low muscular activity and that body temperature was not changing rapidly.
In a recently published review, 19 articles comparing BIS with sedation scales, including case series, letters and editorials, were evaluated.[32] They found that correlations between BIS and subjective scales were low in most studies (r^2 0.21-0.93). Additionally, there was poor correlation between drug dosage and the BIS.
It is evident from these studies that the correlation between the two parameters is modest at best.

The influence of EMG activity on BIS is implied by the method of measurement and calculation of the BIS algorithm. The EEG signal analysed by the BIS monitor ranges up to 47 Hz. Contamination of the EEG signal can occur because EMG activity is considered to arise at overlapping frequencies of 30-300 Hz.[33] This relationship of frequencies ranges partly accounts for the vulnerability of BIS monitoring. The BIS algorithm was frequently updated in order to improve the signal-to-noise ratio as well as to improve the assessment of sedation and hypnosis under different anaesthetics.
In our two clinical studies we used the improved version of the BIS (BIS XP), with a supposedly better correction for EMG activity.
This version is based on a four-electrode sensor and a filtering system that is supposed to render BIS XP less vulnerable to EMG artefacts. Although there was an initial report that BIS XP performed better than a previous version of BIS in the intensive care setting, these data were not confirmed in a later study.[34]
Four studies have been performed comparing BIS XP with earlier versions of the BIS and simultaneously with subjective scoring systems for sedation, specifically testing for increased precision and reliability.[34-37] Deogaonkar et al. compared the BIS XP with the earlier BIS and three sedation agitation scales in patients with primary brain injury.[35]
As before, the older BIS demonstrated weak correlation, but the newer BIS XP excelled with an r^2 of 0.81, 0.725 and 0.655 when tested against the RASS, the Riker Sedation-Agitation Scale and the Glasgow Coma Scale, respectively. The correlations were maintained even in patients who received sedative medication.
However, three other studies in which patients with head trauma were excluded have not confirmed these favourable findings and demonstrated quite poor correlation with subjective measures of sedation.[34,36,37]
The reason for this better correlation in a subgroup of patients with brain injury remains unclear at this point. Other studies in patients without brain injury did not find a similar high degree of correlation.[37,38]

In a recent study, BIS XP and the previous version were compared with a clinical sedation scale in mechanically ventilated patients requiring postoperative sedation on an ICU in order to evaluate performance and reliability under routine clinical conditions.
It was found that BIS and BIS XP values correlated to a high degree. Both parameters however showed great variation, especially in deeply sedated patients, indicating that neither parameter appears to be a reliable tool for

assessing the level of consciousness of patients requiring postoperative sedation in the ICU.[37]
Overall, it would appear that BIS XP may be an improvement over earlier versions of the BIS, but seems not to have fully overcome the barriers imposed by muscle artefacts. The exception may be in critically ill patients receiving neuromuscular blockade or with primary brain injury.

The variety of correlation between clinical sedation scales and processed EEG parameters is not surprising as it has recently been pointed out that there are several reasons why a direct comparison of clinical scales is problematic.
First, clinical scales are typically ordinal scales and may be compared with continuous scales only by employing special statistics. Thus, any comparison of sedation scales with a continuous measure needs to be performed with a non-parametric test; many studies however, incorrectly involved linear correlations.
Second, clinical scales such as the Ramsay scale and BIS are not interchangeable.[23] The scales overlap only at higher levels of consciousness, but when sedation is increased to a level of 6 on the Ramsay scale, this state of consciousness is somewhat comparable to surgical anaesthesia, which occurs at a BIS level of approximately 50-60.
It has been suggested that BIS monitoring may be of a special benefit when oversedation has to be avoided because clinical scales do not allow a discrimination of deep sedation. A deeper degree of sedation cannot be differentiated by clinical scales, whereas the BIS can discriminate the level of sedation even down to a burst-suppression EEG.

The correlation between clinical sedation scales and the BIS is modest. Ultimately, a high level of correlation may not be achievable between clinical sedation scales and EEG methods because the two methods work best at different levels of sedation.
At present, monitoring sedation with processed EEG parameters cannot generally be recommended. The BIS has failed to demonstrate consistent reproducibility as a monitor of sedation in heterogeneous populations of ICU patients. However, in special situations such as deep sedation and neuromuscular blockade, in which clinical sedation scales are prone to failure, the bispectral index may help to assess the level of sedation.

References

1. Crippen D. Comfortably numb in the intensive care unit. *Crit Care Med* 2006;**34**(5)**:**1558-9.
2. Chanques G, Jaber S, Barbotte E, Violet S, Sebbane M, Perrigault PF, Mann C, Lefrant JY, Eledjam JJ. Impact of systematic evaluation of pain and agitation in an intensive care unit. *Crit Care Med* 2006; **34**(6)**:**1691-9.
3. Merriman H. The techniques used to sedate ventilated patients. A survey of methods used in 34 ICUs in Great Britain. *Intensive Care Med* 1981;**7**(5)**:**217-24.
4. Bion J, Ledingham I. Sedation in intensive care--a postal survey. *Intensive Care Med* 1987;**13**(3)**:**215-6.
5. Kress J, Pohlman A, O'Connor MF, Hall JB. Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation. *N Engl J Med* 2000;**342**(20)**:**1471-7.
6. Carson S, Kress JP, Rodgers JE, Vinayak A, Campbell-Bright S, Levitt J, Bourdet S, Ivanova A, Henderson AG, Pohlman A, Chang L, Rich PB, Hall J. A randomized trial of intermittent lorazepam versus propofol with daily interruption in mechanically ventilated patients. *Crit Care Med* 2006;**34**(5)**:**1326-32.
7. Schweickert W, Gehlbach B, Pohlman A, Hall J, Kress J. Daily interruption of sedative infusions and complications of critical illness in mechanically ventilated patients. *Crit Care Med* 2004;**32**(6)**:**1272-6.
8. Fraser G, Riker RR. Monitoring sedation, agitation, analgesia, and delirium in critically ill adult patients. *Crit Care Clin.* 2001;**17**(4)**:** 967-87.
9. Payen J, Chanques G, Mantz J, et al. Current practices in sedation and analgesia for mechanically ventilated critically ill patients: a prospective multicenter patient-based study. *Anesthesiology* 2007;**106**(4)**:** 687-95.
10. Carrasco G. Instruments for monitoring intensive care unit sedation. *Crit Care* 2000;**4**(4)**:**217-25.
11. Schulte-Tamburen A, Scheier J, Briegel J, Schwender D, Peter K. Comparison of five sedation scoring systems by means of auditory evoked potentials. *Intensive Care Med* 1999;**25**(4)**:**377-82.
12. Rampil I. A primer for EEG signal processing in anesthesia. *Anesthesiology* 1998;**89**(4)**:**980-1002.
13. Liu J, Singh H, White PF. Electroencephalographic bispectral index correlates with intraoperative recall and depth of propofol-induced sedation. *Anest Analg* 1997;**84**(1)**:**185-9.
14. De Deyne C, Struys M, Decruyenaere J, Creupelandt J, Hoste E, Colardyn F. Use of continuous bispectral EEG monitoring to assess depth of sedation in ICU patients. *Intensive Care Med* 1998;**24**(12)**:**1294-1298.
15. Berkenbosch J, Fichter CR, Tobias JD. The correlation of the bispectral index monitor with clinical sedation scores during mechanical ventilation in the pediatric intensive care unit. *Anesth Analg.* 2002; **94**(3)**:**506-11.
16. Ramsay M, Savege T, Simpson B, Goodwin R. Controlled sedation with alphaxalone-alphadolone. *Br Med J.* 1974;**22**(2)**:**656-659.
17. Huskisson E. Measurement of pain. *Lancet* 1974;**2:**1127-1131.
18. Schoonderbeek J, Van Leeuwen P, Van der Hoven B, Bruining H, Tibboel D, Van Dijk M. The CIA scale; a new pain assessment scale for critically ill patients. *Critical Care* 2005;**9**((suppl 1))**:**P143.
19. Gan T, Glass P, Windsor A, et al. Bispectral index monitoring allows faster emergence and improved recovery from propofol, alfentanil, and nitrous oxide anesthesia. BIS Utility Study Group. *Anesthesiology* 1997;**87**(4)**:**808-15.
20. Song D, Joshi G, White P. Titration of volatile anesthetics using bispectral index facilitates recovery after ambulatory anesthesia. *Anesthesiology* 1997;**87**(4)**:**842-8.
21. Avidan M, Zhang L, Burnside BA, Finkel KJ, Searleman AC, Selvidge JA, Saager L, Turner MS, Rao S, Bottros M, Hantler C, Jacobsohn E,

Evers AS. Anesthesia awareness and the bispectral index. *N Engl J Med* 2008;**358**(11)**:**1097-108.
22. Shapiro B. Bispectral Index: better information for sedation in the intensive care unit? *Crit Care Med* 1999;**27**(8)**:**1663-4.
23. Tonner P, Weiler N, Paris A, Scholz J. Sedation and analgesia in the intensive care unit. *Curr Opin Anaesthesiol.* 2003;**16**(2)**:**113-21.
24. Bruhn J, Bouillon TW, Shafer SL. Electromyographic activity falsely elevates the bispectral index. *Anesthesiology* 2000;**92**(5)**:**1485-7.
25. Nasraway Jr. S, Wu E, Kelleher R, Yasuda C, Donnelly A. How reliable is the Bispectral Index in critically ill patients? A prospective, comparative, single-blinded observer study. *Crit Care Med* 2002;**30**(7)**:**1483-7.
26. Riess M, Graefe U, Goeters C, Van Aken H, Bone H. Sedation assessment in critically ill patients with bispectral index. *Eur J Anaesthesiol.* 2002;**19**(1)**:**18-22.
27. Fodale V, Praticò C, Santamaria L. Coadministration of propofol and midazolam decreases bispectral index value as a result of synergic muscle relaxant action on the motor system. *Anesthesiology* 2004; **101**(3)**:**799-801.
28. Bonhomme V, Hans P. Monitoring depth of anaesthesia: is it worth the effort? *Eur J Anaesthesiol.* 2004;**21**(6)**:**423-8.
29. Vivien B, Di Maria S, Ouattara A, Langeron O, Coriat P, Riou B. Overestimation of Bispectral Index in sedated intensive care unit patients revealed by administration of muscle relaxant. *Anesthesiology* 2003; **99**(1)**:**9-17.
30. Fodale V, Santamaria L. Is overestimation of bispectral index in sedated intensive care unit patients only related to electromyographic activity? *Anesthesiology* 2004;**100**(3)**:**746-7.
31. Riker R, Picard J, Fraser G. Prospective evaluation of the Sedation-Agitation Scale for adult critically ill patients. *Crit Care Med* 1999; **27**(7)**:**1325-1329.
32. LeBlanc J, Dasta J, Kane-Gill SL. Role of the bispectral index in sedation monitoring in the ICU. *Ann Pharmacother.* 2006;**40**(3)**:**490-500.
33. Johansen J, Sebel P. Development and clinical application of electroencephalographic bispectrum monitoring. *Seminars in Cardiothoracic and Vascular Anesthesia* 2004;**8** (1)**:**9-12.
34. Coluzzi F, Di Filippo C, Rossetti E, Summonti D, Mattia C. BIS monitoring in ICU: Advantages of the new XP generation (abstract). *Crit Care* 2002;**6**(Suppl 1)**:**P68.
35. Deogaonkar A, Gupta R, DeGeorgia M, Sabharwal V, Gopakumaran B, Schubert A, Provencio JJ. Bispectral Index monitoring correlates with sedation scales in brain-injured patients. *Crit Care Med* 2004; **32**(12)**:**2403-6.
36. Ely E, Truman B, Manzi DJ, Sigl JC, Shintani A, Bernard GR. Consciousness monitoring in ventilated patients: bispectral EEG monitors arousal not delirium. *Intensive Care Med* 2004;**30**(8)**:**1537-43.
37. Tonner P, Wei C, Bein B, Weiler N, Paris A, Scholz J. Comparison of two bispectral index algorithms in monitoring sedation in postoperative intensive care patients. *Crit Care Med* 2005;**33**(3)**:**580-4.
38. Nasraway S. The Bispectral Index: expanded performance for everyday use in the intensive care unit? *Crit Care Med* 2005;**33**(3)**:**685-7.

Chapter 7

General discussion

Efforts to improve pain assessment and treatment in critically ill patients represent an opportunity to improve quality of care.

Historically, pain has been inadequately managed in critically ill patients. [1,2] During the past decade, the awareness of poor pain management and its liabilities has matured.[3,4] Increased risks and costs associated with inadequate treatment have been identified, including unplanned extubations and line removals, longer stay on the ICU and duration of mechanical ventilation, and development of posttraumatic stress disorder. [5-7]

Pain can also increase agitation and these conditions are difficult to differentiate in noncommunicative patients.[8] Multiple effective therapies are available to manage pain and agitation. The term 'multimodal therapies' is to be understood in the broadest possible sense: oral and intravenous medication, topical agents, music etcetera. All have been shown to provide potential benefit. The availability of a wide range of treatment options together with the recognized importance of adequate management provides a mandate to better understand, evaluate and manage pain in the critically ill patient.

Pain assessment

Practically all patients in the ICU will require some form of sedation or analgesia, because they experience pain, anxiety or discomfort. Survivors of intensive care have reported distressing memories about fear and pain and the presence of various catheters and procedures such as physiotherapy and airway suctioning. [9,10]

Failure by caregivers to recognise that the patient may be experiencing pain, may result in the patient receiving unnecessary sedatives, since pain may present itself as agitation or anxiety. Usually the source of pain is self evident: for example post-operative or procedural pain. However, pain can also be caused by prolonged immobility, indwelling catheters and other not so obvious reasons.[10-12]

Until recently, we have used vital signs to assess the level of analgosedation in critically ill patients. However, this simplistic approach does not seem to be adequate to achieve optimal patient care. Pain is a common and negative experience for most medical, surgical and trauma patients.[11] Everyone working in the ICU understands the challenge of achieving an adequate level of analgosedation in an anxious and agitated patient. And again, patient outcome is improved with successful pain management.[13,14]

The ideal analgosedative regimen should control pain, anxiety, agitation and delirium while avoiding withdrawal symptoms and minimizing respiratory and cardiac depression, yet preserving communication.

Failure to recognize that pain frequently leads to agitation may result in excessive daily administration of sedatives thus delaying ICU discharge.[15]

Pain must be recognized in order to permit a treatment adapted to patient needs.

Pain assessment needs to be performed regularly and consistently in the ICU setting. It is used to assess the initial onset and severity of pain as well as the response to interventions. If patients are unable to understandably communicate about their pain, alternative methods of gaining the information, like observing defined behavioural parameters, can be used.

This thesis shows that applying a relatively simple scoring scale, embedded in an algorithm, has remarkably raised the pain-awareness by the caregivers.

There are also indications that perhaps relatives may be able to assist ICU providers in establishing the severity of pain and the response to analgesia. One multicenter study demonstrates that relatives are moderately successful in estimating the presence of pain in their seriously ill loved ones. In 73.5 % of all 2645 paired assessments, relatives were able to estimate absence or presence of pain but were less successful to assess the exact level of pain (in approximately 50% of the time).[16]

Challenges to pain management

Many patients in the ICU are dissatisfied with the pain control they receive.[12] Dramatic improvements in the methods of relieving pain have been achieved over the last 50 years. These include the development of new analgesics, such as synthetic narcotics and adjuvant medications, that act in conjunction with opioid and nonopioid analgesics agents including

nonsteroidal anti-inflammatory drugs, and an increased knowledge base of alternative medical options such as meditation, hypnosis, relaxation, and acupuncture. A framework for addressing the full range of potential opportunities in relieving pain should be considered.

Sedatives should never be given as a substitute for analgesia. A strategy focusing initially on adequate analgesia will often reduce the need for other sedatives in many critically ill patients. Whereas some analgesics have sedative properties, the reverse is not true and adequate analgesia should be achieved before any sedation is given. There is now growing evidence indicating that if mechanically ventilated patients receive good analgesia, they can remain conscious, aware and cooperative, all of which lead to a more positive patient experience.[17] This consummation is devoutly wished by many colleagues in the field. In order to achieve this, we have to manage and control stress and pain.

Since effective medications and interventions to manage pain already exist, providers must have a tool to adequately provide pain control for critically ill patients. The answer lies in standardizing pain control. This thesis shows that healthcare professionals do realize this and support the introduction of guidelines. Adherence to guidelines though, even when they are evidence-based and adapted to local practices, is generally poor.[18,19] Despite practice guidelines, there is a considerable variability in the ways providers address pain control, due to patient-specific factors, resident guideline learning curve, and physician medication preferences.[19]

One major limitation in effectively managing pain in the critically ill is the inability to appropriately assess the quality and intensity of the pain. A thorough pain history is often not possible in the critically ill patient due to numerous communication barriers. First, in the patient who is unable to effectively communicate either because of an altered level of consciousness or endotracheal tube, this detailed information can simply not be captured.

Secondly, patients may not have an adequate understanding of the symptoms of discomfort and as a result may not be fully able to characterize their experiences.[12,20] Finally, language barriers and cultural issues in the communicative patient can affect the patient's ability to provide this information to the caregiver. This is why careful observation of behavioural changes is the key.

Some considerations

In the sixties the term 'quality' first emerged in healthcare circles as a topic for discussion.[21-23] In the following years, the meaning of the term 'quality' has been modified considerably.

However, the definition by Juran in1989, which includes "meeting the needs of customers," still has relevance in this modern era of healthcare.[24,25] Following the lead of industry, the healthcare system in America started to focus on quality assurance and quality management techniques to improve the delivery of healthcare.[26] In the eighties, there was a shift from the more traditional 'quality assurance' to 'quality improvement'. This was especially important for healthcare. Where 'quality assurance' focuses on production and seeks to identify faults within the production process, 'quality improvement' considers the patient or family in the healthcare experience.

Over the past 20 years, increasing attention has been paid to the issues of quality improvement in healthcare.
In 2001 the Institute of Medicine (IOM) published a report entitled 'Crossing the Quality Chasm' that defined quality healthcare as: "doing the right thing, at the right time, in the right way, for the right person - and having the best possible results".[27] This definition comprises four aspects, which are internationally acknowledged as the four core-components of quality: effectiveness, safety, timeliness and patient-centeredness.[28]
Together with efficiency and equity they represent the recommended 'Six Aims for Improvement'. These 'Aims' are intended to frame the fundamental changes that need to be incorporated to improve the healthcare services delivered to individuals and populations. [27]
Patient-centeredness as an IOM Aim helps to characterize the interactions between practitioners and their patients, and places the patient and family in a central role as the recipients of services during the episode of illness. Healthcare personnel should possess traits that comprise service quality, including empathy, compassion and respect. Actions that demonstrate appropriate service quality include the provision of information, communication, education, attention to physical comfort, emotional support, and the involvement of family and friends in care. The attention to both physical and emotional comfort is of considerable importance for the ICU patient and reflects one dimension of healthcare quality.
Beyond being a compassionate and empathetic intervention, managing acute pain in the critically ill patient has beneficial physiological and economic effects.[18] Adequate analgesia can promote good respiratory function and pulmonary toilet, modulate the stress response, and promote hemodynamic stability, thereby preventing complications and reducing the utilization of resources. Patients treated appropriately for their pain can be mobilized quicker and discharged earlier than those who are not.[13] These considerations highlight how pain control impacts other domains of quality beyond patient-centeredness, including efficiency, timeliness and effectiveness.

Delirium

Delirium is something that should not go unmentioned, but its impact and management goes beyond the scope of this thesis.
Delirium is characterized by an acutely changing or fluctuating mental status, inattention, disorientation and an altered level of consciousness that may or may not be accompanied by agitation. Although agitation may be part of delirium, it frequently follows drug withdrawal after a long-term weaning period. This must be anticipated and recognized early to avoid the inherent complication of this extreme condition, which is unfortunately frequent in ICU's.
The development of delirium is associated with increased mortality, prolonged hospital stay and increased costs.[29,30] The etiology for delirium is multifactorial, but iatrogenic risk factors include sedative and analgesic medications, although the exact relationship remains largely undetermined.[31] Until recently, little was known concerning the scale of the problem in the ICU because of the lack of a sensitive and specific monitoring and diagnostic tool. The development of the Confusion Assessment

Method for the ICU (CAM-ICU) with a sensitivity and specificity of 95% has increased the understanding of delirium, and research has been initiated to minimize this problem.[32]

Final remarks

Pain management is an essential component of quality care delivery for the critically ill patient and their families.
Regular pain assessments result in optimizing medications doses, both increases and decreases. This leads to clinically important outcome effects, such as a substantial decrease in nosocomial infection rates as well as hours of ventilation. [33] It takes little imagination to realize that this is an potentially economic blockbuster.
The key is in the education!
By training nurses to recognize significant behaviour, educating physicians about evaluation and management of pain and defining a systematic method for assessment and subsequent response, the incidence of severe pain can be significantly decreased.
We can no longer afford to continue to manage pain in the critically ill patient in a random manner. The incorporation of systematic education, evaluation and management protocols for pain should be standard in all ICU's.
High quality pain management should be a goal for every patient. Success in improving this important component of ICU care is to be realized, opportunities to improve its measurement, standardize its control, and linking to quality outcomes need to be achieved.

References

1. Freire A, Afessa B, Cawley P, Phelps S, Bridges L. Characteristics associated with analgesia ordering in the intensive care unit and relationships with outcome. *Crit Care Med.* 2002;**30**(11)**:**2468-72.
2. Bertolini G, Minelli C, Latronico N, et al. The use of analgesic drugs in postoperative patients: the neglected problem of pain control in intensive care units. An observational, prospective, multicenter study in 128 Italian intensive care units. *Eur J Clin Pharmacol* 2002;**58**(1)**:** 73-7.
3. Swinamer D, Phang P, Jones RL, Grace M, King EG. Effect of routine administration of analgesia on energy expenditure in critically ill patients. *Chest* 1988;**93**(1)**:**4-10.
4. Kehlet H. Does analgesia benefit postinjury outcome? *in: Parker MM, Shapiro MJ, Porembka DT (eds.):Critical Care: State of the Art. Anaheim, CA 1995* 1995;**15:**213-229.
5. Jaber S, Chanques G, Altairac C, Sebbane M, Vergne C, Perrigault PF, Eledjam JJ. A prospective study of agitation in a medical-surgical ICU: incidence, risk factors, and outcomes. *Chest* 2005;**128**(4)**:**2749-57.
6. Marcin J, Rutan E, Rapetti PM, Brown JP, Rahnamayi R, Pretzlaff RK. Nurse staffing and unplanned extubation in the pediatric intensive care unit. *Pediatr Crit Care Med* 2005;**6**(3)**:**367-8.
7. Woods J, Mion L, Connor JT, Viray F, Jahan L, Huber C, McHugh R, Gonzales JP, Stoller JK, Arroliga AC. Severe agitation among ventilated medical intensive care unit patients: frequency, characteristics and outcomes. *Intensive Care Med* 2004;**30**(6)**:**1066-72.
8. Hogarth DK, Hall J. Management of sedation in mechanically ventilated patients. *Curr Opin Crit Care* 2004;**10**(1)**:**40-46.
9. Jones J, Hoggart B, Withey J, Donaghue K, Ellis BW. What the patients say: A study of reactions to an intensive care unit. *Intensive Care Med* 1979;**5**(2)**:**89-92.
10. Stein-Parbury J, McKinley S. Patients' experiences of being in an intensive care unit: a select literature review. *Am J Crit Care* 2000; **9**(1)**:**20-27.
11. Novaes M, Knobel E, Bork AM, Pavão OF, Nogueira-Martins LA, Ferraz MB. Stressors in ICU: perception of the patient, relatives and health care team. *Intensive Care Med* 1999;**25**(12)**:**1421-6.
12. Desbiens NA, Wu AW, Broste SK, et al. Pain and satisfaction with pain control in seriously ill hospitalized adults: findings from the SUPPORT research investigations. For the SUPPORT investigators. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment. *Crit Care Med* 1996;**24**(12)**:**1953-61.
13. Stevens D, Edwards W. Management of pain in the critically ill In Irwin RS, Cerra FB, Rippe JM, eds. Intensive Care Medicine 4th Edition. *Lippincott Philadelphia* 1999;**2:**1929-49.
14. Anand K, Barton B, McIntosh N, Lagercrantz H, Pelausa E, Young TE, Vasa R. Analgesia and sedation in preterm neonates who require ventilatory support: results from the NOPAIN trial. Neonatal Outcome and Prolonged Analgesia in Neonates. *Arch Pediatr Adolesc Med.* 1999;**153**(4)**:**331-8.
15. Kollef MH, Levy N, Ahrens TS, Schaiff R, Prentice D, Sherman G. The use of continuous i.v. sedation is associated with prolongation of mechanical ventilation. *Chest* 1998;**114**(2)**:**541-8.
16. Desbiens NA, Mueller-Rizner N. How well do surrogates assess the pain of seriously ill patients? *Crit Care Med* 2000;**28**(5)**:**1347-52.
17. Carlon G, Combs A. Role of sedation and analgesia in mechanical ventilation. *Crit Care Med* 2008;**36**(4)**:**1366-7.
18. Jacobi J, Fraser GL, Coursin DB, et al. Clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult. *Crit Care Med* 2002;**30**(1)**:**119-41.
19. Bair N, Bobek M, Hoffman-Hogg L, Mion LC, Slomka J, Arroliga AC. Introduction of sedative, analgesic, and neuromuscular blocking

agent guidelines in a medical intensive care unit: physician and nurse adherence. *Crit Care Med* 2000;**28**(3)**:**707-13.
20. Nelson JE, Meier DE, Oei EJ, et al. Self-reported symptom experience of critically ill cancer patients receiving intensive care. *Crit Care Med* 2001;**29**(2)**:**449-450.
21. Donabedian A. Evaluating the quality of medical care. *Milbank Mem Fund Q.* 1966;**44**(3)**:**Suppl:166-206.
22. Donabedian A. The evaluation of medical care programs. *Bull N Y Acad Med.* 1968;**44**(2)**:**117-24.
23. Donabedian A. Measuring and evaluating hospital and medical care. *Bull N Y Acad Med.* 1976;**52**(1)**:**51-9.
24. Juran J. Juran's Quality Control Handbook. *McGraw Hill, New York* 1989.
25. Juran J. Juran on Leadership for quality. *The Free Press, New York* 1989.
26. Philips L. Ìn the name of the patient. Consumer advocacy in healthcare. *American Hospital Association, Chicago, Illinois* 1995.
27. IOM. Crossing the Quality Chasm: A New Health System for the 21st Century. *Washington DC: National Academies Press* 2001.
28. Arah O. Performance Reexamined. Concepts, Content and Practice of Measuring Health System Performance *thesis* 2005;Amsterdam: UvA.
29. Pandharipande P, Jackson J, Ely EW. Delirium: acute cognitive dysfunction in the critically ill. *Curr Opin Crit Care* 2005;**11**(4)**:**360-8.
30. Pandharipande P, Ely E. Sedative and analgesic medications: risk factors for delirium and sleep disturbances in the critically ill. *Crit Care Clin* 2006;**22**(2)**:**313-27.
31. Girard T, Shintani A, Jackson JC, Gordon SM, Pun BT, Henderson MS, Dittus RS, Bernard GR, Ely EW. Risk factors for post-traumatic stress disorder symptoms following critical illness requiring mechanical ventilation: a prospective cohort study. *Crit Care* 2007;**11**(1)**:**R28.
32. Ely EW, Inouye S, Bernard GR, Gordon S, Francis J, May L, Truman B, Speroff T, Gautam S, Margolin R, Hart RP, Dittus R. Delirium in mechanically ventilated patients: validity and reliability of the confusion assessment method for the intensive care unit (CAM-ICU). *JAMA* 2001;**286**(21)**:**2703-10.
33. Chanques G, Jaber S, Barbotte E, Violet S, Sebbane M, Perrigault PF, Mann C, Lefrant JY, Eledjam JJ. Impact of systematic evaluation of pain and agitation in an intensive care unit. *Crit Care Med* 2006; **34**(6)**:**1691-9.

Chapter 8

Summary

Chapter 1 is the general introduction of this thesis and gives an overview of the historical and current attitude and literature towards pain assessment and pain management in the critically ill adult intensive care patient.

In **Chapter 2** a critical appraisal is presented on the existing pain assessment instruments for in the critically ill adult intensive care patient.
The literature presents vast amounts of scientific evidence as to the significance of pain in the process of severe illness, yet evidence on the effectiveness of pain assessment and pain management for the adult critically ill patient is scarce. Nevertheless, in critically ill adult patients the process of clinical decision making for pain interventions remains very complex. Patients may have a decreased level of consciousness, can be cognitively impaired, sedated or otherwise nonverbal. These patients are not only vulnerable to the mere subjective experience of pain and suffering but also to the physiological effects of pain. Both are proven risk factors for the increase of morbidity and length of stay.
Detailed analysis of the literature revealed only seven pain assessment instruments for adults.
This review provides a summary of the contents and the psychometric properties of these pain assessment instruments, and discusses their applicability to measure pain in critically ill adult patients.
In general, each of these instruments has its limitations. As each of them is designed for a specific group or specific situation, they are not directly applicable for standard use on the average intensive care unit.
The main conclusion is that none of the described instruments meets the requirements for an appropriate assessment tool for the evaluation of pain in the critically ill.

In **Chapter 3** the Critically Ill Assessment (CIA) scale is introduced. This is a new pain-distress observational tool for critically ill adult patients, either ventilated or non-ventilated. The results of the prospectively evaluated validity, reliability and applicability of the CIA-scale are discussed.
The CIA scale was developed during 2 pilot studies, performed by a trained research group. The final version was implemented and compared to Numeric Rating Scales (NRS) for pain and distress. Thereupon CIA-assessments were performed before and during routine care procedures to evaluate the sensitivity to change. 1792 Assessments were completed in 244 patients. Interrater reliability was established by a median linearly weighted Cohen's kappa of 0.86 (IQR 0.81 to 0.91) Internal consistency of the five items was 0.76 (Cronbach's alpha). Concurrent validity between CIA and NRS-pain was 0.39 (self-report and non self-report). Between CIA and NRS-distress concurrent validity was 0.56 (Pearsons correlation coefficient). The median CIA score in our population was 9 (IQR 7 to 10). The CIA was sensitive to change especially with respect to body movement and facial tension and scores increased significantly during daily care ($p<0.0001$). In conclusion, the CIA scale proved to be a reliable and valid assessment tool for uncomfortable adult critically ill patients.

In **Chapter 4** the difficulties of implementing a new practice guideline is demonstrated by describing the process of implementing the CIA scale in daily practice. Extensive effort was put in trying to get all co-workers familiar with the new instrument and in trying to emphasize the importance of a more structured attention to sedative and analgesic regimens. Despite the fact that we were under the impression that this was successful, we were confronted with a disappointing commitment. Implementation of a new practice appears to be a huge challenge and almost invariably requires changing of old habits. Experiencing pushback and resistance is not encountered exclusively. The complexity of adherence to clinical guidelines is discussed. The authors plead that in the future physicians take issues of implementation seriously, as well as for the introduction of a new health care professional: the implementologist.

Assessment and management of pain also seems to be hard to implement. Only a minority of the ICU's (<20-40%) perform painful procedures after administration of analgesic medication. There also seems to be a barrier for ICU professionals who are hesitant in treating pain appropriately, because of organ system dysfunction, impaired mental status and altered pharmacodynamics and -kinetics. **Chapter 5** describes the development and implementation of a new pain-distress treatment algorithm, based on assessment with the C.I.A., in clinical practice. We conducted an investigation by questionnaire to see whether it was desired to protocolize our pain and sedation therapy.
After that, we introduced an algorithm, based on the Critically Ill Assessment scale. We investigated attitude versus behaviour towards a new clinical strategy. Attitude was analyzed by the results of the questionnaire, where behaviour was analyzed as compliance to the algorithm.
The results of the questionnaire showed that there was enough basis for starting a new strategy in this specific area. Most of the responders (83%) felt qualified to independently treat discomfort according to approved guidelines.

And more important, the appraisal of the existing policy in analgosedation varied from 4 to 8 (on a scale of 10). Thus, the time seemed right to introduce this new strategy.
The results of the analysis towards behaviour were disappointing. In thirty percent of the cases, the patient did not seem to be in a comfortable state or seemed to be oversedated, but compliance to the algorithm was mediocre or incomplete.

In **Chapter 6** we describe the results of two studies to investigate the usefulness of the Bispectral Index (BIS) to determine the level of sedation on the ICU. In both studies we used the BIS-XP monitor, model A-2000. The first study was performed on the ICU of a university hospital as a prospective, double-blind, controlled clinical trial.
In a cohort of 23 patients the level of consciousness was monitored with BIS simultaneously with a two-hourly assessment of distress with three different clinical assessments instruments: the Numeric Rating Scale (for distress, range 0-10), the Ramsay-score (range 1-6) and the Critically Ill Assessment scale (range 5-20)(16)(17)(18). The goal values for the different assessment instruments are 4 in NRS, 2 or 3 in Ramsay en between 7 and 10 for the CIA.
The aim of the first study was (1) to reduce the use of sedatives to a level where a patient can undergo therapy comfortably, using the BIS method, (2) to analyze the correlation between the subjective assessment scales used and the BIS and (3) to determine the level of consciousness measured by BIS-values in these patients. A total of 552 values of BIS and a total of 1656 simultaneous assessments of NRS, Ramsay and CIA were analyzed.
The results show that BIS values in this heterogeneous population vary widely between patients, as well as individually in time. Sometimes even the monitor produces data inconsistent with the clinical situation.
The second study was performed on the general ICU of a university affiliated teaching hospital. In this study we compared BIS values in sedated patients with two validated subjective scores, the Ramsay score and the Critically Ill Assessment (CIA) score. A total of 622 observations were collected in twenty patients during a period of minimal 12 to maximal 64 hours on a general ICU (498 Ramsay and 124 CIA).
Median BIS values were analyzed for different Ramsay scores and the overall and intra-individual correlations between BIS and CIA scores were calculated.
Median BIS values when Ramsay was scored 5 or 6 was 42 (IQR 39 to 53) (n=391, 79%). Median BIS values when Ramsay was scored 3 or 4 was 72 (IQR 51 to 82) (n=92, 18%). Ramsay 1-2 was scored 15 times (3%).
BIS measurements ranged from 0 to 75 when a minimal CIA of 5 was scored. When a state of optimal sedation was scored, according to a CIA assessment of 7-10, BIS values varied from 26 to 94. When CIA was scored above 10, BIS values ranged from 44 to 96.
Analysis showed that the correlation between Ramsay or CIA scores and BIS values was suboptimal and inconsistent. Individual Ramsay and CIA scores were reflected by a broad range of BIS scores. Especially in patients with CIA scores above 10 or Ramsay scores above 4, BIS scores varied widely.
We conclude that the correlation between clinical sedation scales and the BIS is modest. At present, monitoring sedation with processed EEG

parameters cannot generally be recommended. The BIS has failed to demonstrate consistent reproducibility as a monitor of sedation in heterogeneous populations of ICU patients.

In **Chapter 7** we describe the challenges to pain management and take it to a broader perspective in making it part of the multimodality approach, as well as indicating it as an essential component of quality care.
Since effective medications and interventions to manage pain already exist, providers must have a tool to adequately provide pain control for critically ill patients. The answer lies in standardizing pain control. This thesis shows that healthcare professionals do realize this and support the introduction of guidelines. Adherence to guidelines though, is generally poor.
The key is in the education!
Training nurses in recognizing significant behaviour, educating physicians about evaluation and management of pain and defining a systematic method for assessment and subsequent response, the incidence of severe pain can be significantly decreased.
High quality pain management should be a goal for every patient. Success in improving this important component of ICU care is to be realized, opportunities to improve its measurement, standardize its control, and linking to quality outcomes need to be achieved.

Appendices

Samenvatting voor de leek

Questionnaire

Glossary

Abbreviations

Nawoord

Curriculum vitae

Stellingen

Samenvatting voor de leek

Algemeen

Het verblijf en de behandeling op de intensive care (IC) is voor patiënten een stressvolle ervaring. Om de behandeling zo comfortabel mogelijk te maken, worden patiënten vaak in slaap gehouden met sederende (kalmerende) middelen. De laatste jaren echter wordt duidelijk dat juist pijn een rol speelt in het ziektebeloop en in de beleving van stress. Dit geldt voor alle patiënten op de IC en niet alleen voor degenen waarbij de oorzaak van pijn zichtbaar is, bijvoorbeeld door een operatiewond. Toch wordt slechts in 20-40% van de gevallen op de IC's extra pijnstilling gegeven voor de uitvoering van pijnlijke procedures.
Over de kwalijke effecten van pijn is inmiddels veel bekend. Het verlengt de ziekteduur, kan complicaties veroorzaken en kan zelfs leiden tot het posttraumatisch stresssyndroom. Bij IC-patiënten is de situatie extra complex omdat het voor hen vaak niet mogelijk is om zelf aan te geven dat ze pijn hebben, bijvoorbeeld doordat ze een beademingsbuisje in de keel hebben en zich zodoende niet verstaanbaar kunnen maken, of ten gevolge van de slaaptoestand waarin ze verkeren. IC-patiënten lopen dus een extra risico op de kwalijke effecten van pijn.
Het lijkt dus logisch om pijn bij niet-communicatieve patiënten te meten en adequaat te bestrijden volgens een (erkende) standaardmethode. Hiervoor en voor het effect hiervan is, verrassenderwijs, van oudsher echter weinig aandacht geweest.
In dit proefschrift wordt gekeken naar de huidige stand van zaken in het meten en behandelen van pijn en onrust bij volwassen IC-patiënten. De ontwikkeling en het testen van een nieuwe pijn-onrust score, de Critically Ill Assessment (CIA) schaal, voor volwassen IC-patiënten die niet kunnen communiceren, wordt beschreven.
De introductie en uitvoering van een nieuwe meet- en behandelstrategie is vaak niet onmiddellijk succesvol. Dit heeft te maken met het veranderen van een cultuur, met "hoe we het hier gewend zijn om te doen". Het proces rondom de implementatie van de CIA schaal op de IC-afdeling, gekoppeld aan een behandelalgoritme, inclusief de obstakels onderweg, wordt beschreven. Tot slot wordt gekeken of de bispectrale index (BIS) een objectieve bijdrage levert aan de beoordeling van onrust bij de IC-patiënt.

Bestaande pijnmeetscores

Na uitgebreide literatuur studie, blijkt er niet één pijnmeetscore voor volwassenen te bestaan die direct gebruikt kan worden op de IC. Er worden zeven verschillende scores gevonden. Deze worden geanalyseerd en beoordeeld op hun inhoud, psychometrische kenmerken (mathematische analyse) en directe toepasbaarheid.
Het blijkt dat al deze zeven scores hun inhoudelijke beperkingen hebben. Ook zijn ze ontwikkeld voor een specifieke groep en als zodanig dus niet inzetbaar voor de gehele populatie op de IC.
De conclusie is dat geen van de bestaande pijnmeetscores voldoet aan alle voorwaarden voor een passend meetinstrument als standaard voor het meten van pijn bij de volwassen IC-patiënt.

De Critically Ill Assessment (CIA) schaal

De CIA-schaal is een pijn-onrust score voor alle niet-communicatieve volwassen IC-patiënten. Het is een observatieschaal waarin 5 gedragselementen worden beoordeeld (alertheid, gelaatsspanning, spiertonus, bewegingspatroon en ademhalingspatroon). Op elk van deze items kunnen 1 t/m 4 punten worden gescoord, zodat de totaalscore tussen 5 en 20 ligt. De optimale score is van 7 t/m 9. Daaronder is er sprake van (te) diepe sedatie, daarboven is sprake van (teveel) onrust.
De schaal zoals hij uiteindelijk definitief is vormgegeven, komt voort uit een aantal voorstudies. De schaal is inhoudelijk en psychometrisch uitvoerig geanalyseerd. Deze analyse wordt beschreven in dit proefschrift. De uitkomst is dat de CIA-schaal een betrouwbaar en valide meetinstrument is voor de niet-communicatieve volwassen IC-patiënt.
De invoering van de CIA-schaal in de dagelijkse praktijk op de IC leek eenvoudiger dan het in werkelijkheid was. Hoewel de werkvloer gemotiveerd was om ermee aan de slag te gaan, bleek een blijvend commitment tegen te vallen. Deze ervaring geldt voor de invoering van veel nieuwe strategieën. Implementatie en blijvend commitment aan richtlijnen in het algemeen is een complex traject, welk onveranderd tot tegenslagen leidt.
In dit proefschrift wordt dit traject beschreven en worden mogelijke verklaringen hiervoor gegeven. Een mogelijke oplossing voor de toekomst zou het aanstellen van een nieuwe professional kunnen zijn: de implementoloog.

Het behandelalgoritme

Een nieuwe strategie kan alleen succesvol worden ingevoerd, als het effect daarvan zichtbaar (of meetbaar) is voor degenen die ermee werken.
Een pijn-onrust behandelalgoritme op basis van de CIA-schaal werd ontworpen en geïntroduceerd.
Het algoritme houdt in dat de verpleegkundige naar aanleiding van de uitkomst van de score zelf de pijn- of kalmerende medicatie van de patiënt kan aanpassen. Het effect daarvan wordt binnen dertig minuten geëvalueerd, waarna deze handeling nog éénmaal mag worden herhaald, zonder overleg met de zaalarts.

Tevoren werd de motivatie (attitude) voor deze nieuwe strategie gepeild in een enquête. Van de geënquêteerden voelde 91% zich gemotiveerd en gekwalificeerd om deze nieuwe, geaccordeerde strategie uit te voeren. De resultaten werden gemeten als handelen in overeenkomst met het algoritme, zes maanden na invoering. De resultaten hiervan waren niet helemaal in overeenstemming met de attitude. In 30% van de patiënten was de CIA-score zodanig dat volgens algoritme de medicatie zou moeten worden aangepast. In meer dan de helft van deze gevallen gebeurde dit echter niet.

Een objectieve maat?

Een observationele schaal blijft een subjectieve maat. Als mogelijke objectieve maat voor de diepte van sedatie wordt de bispectral index (BIS) gepropageerd. De BIS is afgeleid van het electro-encephalogram (EEG of hersenfilmpje) en geeft een getalswaarde van 0 (geen activiteit) tot 100 (volledige activiteit) voor het niveau van bewustzijn. In de anesthesiologie wordt bijvoorbeeld een waarde van 40 tot 60 aangehouden. Voor de IC-populatie is de toepasbaarheid van de BIS niet eenduidig bewezen.
In dit proefschrift worden twee studies beschreven waarin de BIS-waarden worden vergeleken met andere meetinstrumenten, waaronder de CIA.
Het blijkt dat de BIS-waarden sterk varieerden, zowel tussen vergelijkbare patiënten, als ook individueel gedurende een bepaalde tijdperiode. Dit was niet in overeenstemming met de uitkomsten van de andere scores.
De conclusie is dan ook dat de BIS niet kan worden aanbevolen als objectieve maat voor de diepte van sedatie bij de volwassen IC-patiënt.

Conclusie

Het geprotocolleerd meten, behandelen en evalueren van pijn en onrust bij volwassen IC-patiënten is een nog redelijk onontgonnen terrein. Goed pijnmanagement is een essentieel onderdeel van kwaliteit in de zorg. Dit besef wordt door velen gedeeld. Op het vlak van de uitvoering is nog veel te winnen. De sleutel ligt in de uitvoering en voortdurende educatie.
Hoge kwaliteit pijn- en onrustmanagement voor elke patiënt is het doel!

Questionnaire

Kick off

January 2006 Questionnaire Pain Assessment

Dear colleagues,

Hereby you receive a questionnaire to evaluate our current pain policy on the IC/HC.
Standardized and repeated pain assessment in postoperative patients already is a quality indicator, and we expect it soon to be one for all critically ill patients.
This questionnaire refers to the actual situation. Basically, it is a meant as a starting point before implementation of structured assessments of pain and distress on our ward. Also, it is meant as a starting point before going life with the Paindistress algorithm.
In the future we will assess the results of this new strategy and analyse if it has lead to quality improvement.
Please answer the questions without consulting others and deliver the completed questionnaire to the pick-up box.
A few tips:
Please tick the answer which resembles your opinion best. Please use the reverse side for your special remarks.
The answering options should be interpreted as follows:

Absolutely!	= that is definitely true, (or) that is right
Yes	= that is true, (or) that is mostly right
No	= that is not true, (or) that is mostly untrue
Definitely not	= that is absolutely not true, (or) that is untrue

Thank you!
We will share the results with you in due time.

Background

1. I am a:
   - ☐ nurse
   - ☐ doctor
2. Sex:
   - ☐ male
   - ☐ female
3. My age (in years) is:

4. Working experience in years:

5. Nurses
   Qualification:
   - ☐ Dutch A-certification
   - ☐ Dutch HBO-certification
   - ☐ Dutch Specialization adult IC
   - ☐ Other, specify:

   Doctors
   Specialization:
   - ☐ Anesthesiology
   - ☐ Internal med.
   - ☐ Surgery
   - ☐ Fellow
   - ☐ Other, specify:

6. The atmosphere on our ward can be described as follows:

The following questions represent the current situation and patients on the IC/HC

		Absolutely!	Yes	No	Definitely not!
7.	Nurses are important for pain assessment.	☐	☐	☐	☐
8.	The underlying condition plays a role in pain assessment.	☐	☐	☐	☐
9.	Patients who underwent several operations need more analgesics.	☐	☐	☐	☐
10.	Pain assessment is necessary in all ICU patients.	☐	☐	☐	☐
11.	Doctors can discriminate pain from distress.	☐	☐	☐	☐
12.	Doctors have enough knowledge and skills to treat pain.	☐	☐	☐	☐
13.	Doctors are opinionated.	☐	☐	☐	☐
14.	Nurses can discriminate pain from distress.	☐	☐	☐	☐
15.	Nurses have enough knowledge and skills to treat pain.	☐	☐	☐	☐
16.	Nurses usually have enough attention for the patients' comfort.	☐	☐	☐	☐
17.	Nurses are opinionated.	☐	☐	☐	☐
18.	A pain-distress measurement instrument is necessary.	☐	☐	☐	☐
19.	"Giving a little extra" to treat pain quickly happens often on our ward.	☐	☐	☐	☐
20.	Pain-distress assessment is only useful when applied in daily care policy	☐	☐	☐	☐
21.	Nurses can administer analgosedative medication indepently, providing an algorithm is available	☐	☐	☐	☐
22.	Patients receive more analgesics than necessary.	☐	☐	☐	☐
23.	Patients receive more sedatives than necessary.	☐	☐	☐	☐

The following questions represent the current situation and patients on the IC/HC

	Absolutely!	Yes	No	Definitely not!
Question 24 only for nurses				
24. Patient behaviour, signaling pain or distress is described in the nurses report.	☐	☐	☐	☐
Question 25 only for doctors				
25. Patient behaviour, signaling pain or distress is described in the medical report.	☐	☐	☐	☐
26. When a patient seems not comfortable, action is undertaken within 30 minutes (e.g. extra medication)	☐	☐	☐	☐
27. When a patient reports pain, action is undertaken within 30 minutes (e.g. extra medication)	☐	☐	☐	☐

28. How many patients do you think are in pain on our ward (percentage)?

29. Please rate the quality of the current pain management on our ward (from 1 very bad to 10 very good)

30. Do you have suggestions how to improve the pain management and strategy on our ward?

Thank you very much!

Please use the open space for additional remarks.

Glossary

boxplot	graphical representation of a probability distribution through five-number summaries (i.e. smallest observation, lower quartile, median, upper quartile and largest observation)
chi square distribution	theoretical probability distribution in statistical significance tests
coefficient of determination	proportion of variability; the square of a correlation coefficient
Interquartile range	interpercentile range, equal to the difference between the third and first quartiles; used to build boxplots
Mann-Whitney U test	non-parametric test for assessing whether two samples of observations come from the same distribution; also known as Wilcoxon rank sum test
median	number separating the higher half from the lower half of a sample
outlier	observation that is numerically distant from the rest of the data
ROC curve	graphical plot of the sensitivity versus the (1-specificity); determination of best cut off point
scatterplot	collection of points, display of the values for a set of data
sensitivity	proportion of actual positives
specificity	proportion of actual negatives
Wilcoxon rank sum test	see Mann-Whitney U test

Reliability	
interrater reliability (Cohen's kappa)	the extent to which two or more individuals agree; addresses the consistency of the implementation of a rating system.
internal consistency (Crohnbach's alpha)	the extent to which tests or procedures assess the same characteristic, skill or quality.
Validity	
content validity	assesses the degree to which an indicator represents the universe of content entailed in the systematized concept being measured. An expert panel should determine if all aspects of the construct under study are represented in the instrument
criterion(-related) validity	predictability of an instrument
concurrent validity	comparability of instrument with criterion
construct validity	*convergent* correlation between measures of the same construct using different methods; e.g. behavioural vs. physiological parameters *discriminant* correlation between measures of different constructs using the same method; e.g. pain and distress scored by the same instrument
congruent validity	refers to a test's congruency or relationship with a known valid and reliable measure of the same construct. Comparable with and interchangeable to concurrent validity.
responsiveness or 'sensitivity to change'	a responsive instrument should detect meaningful change when it has occurred and remain stable when no change has occurred.

Abbreviations

BiPAP	Bilevel Positive Airway Pressure
BIS	Bispectral Index
BPS	Behavioral Pain Scale
CIA scale	Critically Ill Assessment scale
CPAP	Continuous Positive Airway Pressure
CPOT	Critical-care Pain Observation Tool
CPPV	Continuous Positive Pressure Ventilation
FLACC	Face, Legs, Activity, Cry, Consolability
ICU	Intensive care Unit
IQR	Interquartile range
IRB	Institutional Review Board
MPST	Modified Pain Scoring Tool
NRS	Numeric Rating Scale
NVPS	Nonverbal Pain Scale
PAIN	Pain Assessment and Intervention Notation
PBOT	Pain Behaviour Observation Tool
PDMS	Patient Data Management System
ROC	Receiver Operating Characteristic
Rsq, R^2	coefficient of determination
SIMV	Synchronized Mandatory Intermittent Ventilation
VAS	Visual Analogue Scale

Nawoord

Applaus voor mezelf!
Het blijkt heel leuk om een promotietraject af te ronden. Dat had ik eerder moeten weten! Al heeft het absoluut wel wat om het te beleven als midlife-doctor.
Hoewel ik heb geprobeerd om dit proefschrift zo geruisloos mogelijk af te leveren, is het maar de vraag of ik dit ook had kunnen zeggen zonder de support, interesse en het uithoudingsvermogen van de harde kern. Gelukkig bestaat er een nawoord.
En hoe bedank je dan?
Wat mij betreft het liefst persoonlijk en niet in oplage. Daar bent u misschien niet bij aanwezig. En saillante details zult u dus hier niet aantreffen. Wel volgt een poging u te laten weten aan wie ik veel te danken heb in dit meerjaren project.

Professor dr H.A. Bruining, beste Kieje, groot voorbeeld. Je kent me goed en dat is mooi! Ik zou zeggen, houden zo. Dank je wel voor je recht-door-zee mentaliteit en je onvoorwaardelijke eerlijkheid.
Dr M. van Dijk, beste Monique. Tsja, zo'n copromotor wil iedereen wel hebben. Vooral je sixties-achtige benadering maakte de klik. Ik ben blij dat je van mij was de afgelopen jaren.
De overige leden van mijn promotiecommissie, Prof.dr D. Tibboel, Prof.dr J. Kesecioglu, Prof. J.H.P. Wilson, Prof.dr H.W. Tilanus, Prof.dr G.J. Bruining en Prof.dr J. Bakker dank ik allen van harte voor de kritische beoordeling van het manuscript en voor hun bereidheid vandaag zitting te nemen achter de tafel. Ik ben er trots op deze verzameling van eminente namen in levende lijve tegenover mij te zien. Huug, Jan en Dick, jullie blijven altijd een beetje mijn baas. Dat persoonlijke tintje vind ik extra leuk aan tafel.
E en Noot, best friends forever! Ik vind het bijzonder, maar vooral heel prettig dat jullie mijn paranymfen zijn. Met een beetje geluk praten jullie het uur vol. Objection, your honor!

Pijn-leiders van het eerste uur: de research groep van de IC van het Erasmus MC (Ben van der Hoven, Wilma in 't Veld, Wil Mol, Rene van Engen), Pim van Leeuwen, oud-collega's en alle 'plegen' van het oude 10Zuid. Bij jullie lag de start van het onderzoek. Pijn is fijn, thanx!
Pijn-leiders van het laatste uur: 'mijn' verpleegkundigen van de IC van het Ikazia. Wat een topteam! Dank voor jullie betrokkenheid en accuratesse. Margriet, bedankt voor de eindeloze dataverwerking. Collega's Matthieu Middelkoop, Martha de Bruin en de IC-commissie van het Ikazia, dank voor jullie interesse en medewerking. Ik vind ons level 3!
CIA-congresgangers Diederik Bijdevaate, Anna Schut en Hien Nguyen: memorabele uren hebben wij beleefd. What happens …. Ook mooie posters, trouwens.

Dit proefschrift draag ik op aan mijn ouders, die mij altijd liefde, vertrouwen en vooral ruimte hebben gegeven, ook als ik weer zo nodig autonoom moest doen.

Zo, en nu ga ik dit boekje loslaten….

Curriculum vitae

De auteur van dit proefschrift werd geboren op een zonnige donderdagmiddag, 22 juni 1961, in de Emmakliniek te Utrecht. Zij groeide zorgeloos op in Bilthoven. In 1979 behaalde zij haar gymnasium α diploma aan het College Blaucapel te Utrecht. Hierna behaalde zij de staatsexamens chemie en fysica en studeerde een blauwe maandag rechten. In 1988 behaalde zij het artsexamen aan de Rijksuniversiteit Utrecht. In 1989 vertrok zij naar Heemstede voor haar eerste assistentschap Heelkunde (Diaconessenhuis, nu Spaarneziekenhuis; opleider Dr H.W.R. Siebbeles). Van 1992 tot 1998 volgde zij de opleiding tot chirurg in Rotterdam (Zuiderziekenhuis, nu Maasstad Ziekenhuis; opleider Dr K.J. Brouwer; AZR Dijkzigt, nu Erasmus MC; opleider Prof.dr H.A. Bruining). In deze periode, van 1994 tot 1996, had zij zitting in het bestuur van de Vereniging van Assistent-Geneeskundigen in de Heelkunde (VAGH), en was zij afgevaardigd in het bestuur van de Nederlandse Vereniging voor Heelkunde. (NVvH). Geïnspireerd door Bruining en zijn vrouw Drs G.L. Ong, koos zij voor de combinatie van Heelkunde en Intensive Care geneeskunde. Na inschrijving in het Specialistenregister bleef zij in de academie als staflid Heelkunde, en later staflid Intensive Care. Op de IC van het huidige Erasmus MC werd de basis gelegd voor het onderzoek dat in dit proefschrift wordt beschreven. In 2005 vertrok zij naar de periferie als medisch hoofd van de afdeling Intensive Care in het Ikazia Ziekenhuis te Rotterdam, de functie die zij thans nog vervult. Op deze afdeling werden de vervolgstudies uitgevoerd. In 2007 voltooide zij de Leergang Management voor Medici (Universiteit van Tilburg/Tranzo en SWOOG; Prof.dr J. Moen en Prof.dr A. de Roo). Zij vervult en vervulde verschillende, al dan niet aan haar vak gerelateerde, functies op lokaal, regionaal en nationaal niveau. Thans maakt zij o.m. deel uit van de landelijke Expertgroep Sepsis van het Veiligheidsprogramma (VMS) van de NVZ, Orde, LEVV en de V&VN. Ook heeft zij recent geparticipeerd in het formuleren van de Consensus Volumetherapie op de IC. Zij is medeoprichter van het Expert Institute for Clinical Relevance (EICR). Zij is getrouwd met Hajo Vis en heeft twee kinderen, Pieta en Hajo.

Stellingen

1. Pijn is niet fijn. *(dit proefschrift)*

2. De ontwikkeling van het subspecialisme Implementologie is van waarde voor nieuwe richtlijnen en werkwijzen. *(dit proefschrift)*

3. De *Critically Ill Assessment (CIA)* scale is een betrouwbaar en valide meetinstrument voor pijn en onrust bij volwassen intensive care patiënten. *(dit proefschrift)*

4. Op de werkvloer bestaat de behoefte aan gestructureerd beleid door middel van behandelalgoritmes. *(dit proefschrift)*

5. Pijnbeleid bij volwassen intensive care patiënten is een belangrijke kwaliteitskwestie. *(dit proefschrift)*

6. Het ondeskundig oordeel is aan een opmars bezig. *(M. Februari, 2008)*

7. De minister is niet in staat beslissingen die een wetenschappelijke basis behoeven, voldoende te depolitiseren.

8. Loslaten is de remedie tegen vastlopen.

9. Pijn op de vierde dag postoperatief is slecht voor de nachtrust van de patiënt èn van de chirurg.

10. De wetenschappelijke beoordeling van klinische relevantie wordt bemoeilijkt door farmafobie.

11. Voor het terugdringen van oplopende stress bij jonge ouders die beiden volledig zijn ingeschakeld in het arbeidsproces, is het een voorwaarde, dat de grootouders kerngezond zijn zodat zij op geregelde tijden kunnen assisteren in het jonge gezin. *(J. Schoonderbeek, 2006)*

The publication of this thesis was financially supported by:

Fresenius Kabi Nederland B.V., GlaxoSmithKline, Goodlife Healthcare B.V., Jansen-Cilag BV, Pfizer B.V., Fresenius Medical Care Nederland BV, KCI Medical B.V., B.R.A.H.M.S. Aktiengesellschaft, Hamilton Medical Nederland B.V., LAMEPRO B.V., Novartis Pharma B.V., Itémedical B.V., Pulsion Medical Systems, Drager Medical Netherlands B.V.