Pain Management and Patient-Controlled Analgesia: Improving Safety and Quality of Care

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Inter-Professional Conference on Pain Management and Sedation

The sixth invitational conference at the Center for Safety and Clinical Excellence in San Diego, held November 17-18, 2005, brought together a distinguished faculty from clinical practice, academia, organizations and government. Philip J. Schneider, MS, FASHP, Director of the Latiolais Leadership Program and Clinical Professor at The Ohio State University, chaired the conference. Nationally recognized experts from different health professions focused on current issues and opportunities in postoperative pain management and sedation in intensive care patients. This document summarizes the information presented on topics related to pain management and patient-controlled analgesia (PCA) with regard to assessment, risk factors for opioid-related adverse events, respiratory monitoring and clinical improvement of the PCA process. A second document summarizes the information presented on sedation therapy with regard to safety concerns, criteria for determining best practices, guidelines, assessment, nursing issues, and new administration and monitoring technologies that can help improve safety and quality of care.

Contents

EDITORIAL

Tolerance for Ambiguity

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Few would argue that these are times of change, in general, and within healthcare, in particular. It would also be a safe assumption that most people, including healthcare professionals, are more comfortable in circumstances that are predictable and where certainty exists. Most of us have been drawn to science-based careers because what we do is based on facts that have been proven. The current focus on evidence-based medicine is a reflection of this. It is nice to know what to do in a clinical situation and to know that the decision is based on scientific proof.

Unfortunately, this is not always the case in healthcare; uncertainty often exists. When there is uncertainty about what to do, healthcare providers are uncomfortable. In fact, healthcare professionals are not even comfortable about whether we can afford to wait for scientific proof before making healthcare decisions. This was particularly evident at this invitational conference during presentations and discussion on pain management and the safe use of patient-controlled analgesia (PCA). It is widely recognized that medication errors with PCA and adverse drug events resulting from these errors are common.[1-14] What is not widely recognized is how to improve the safe use of PCA in those patients for whom it is needed. One of the goals of this conference was to determine if consensus could be obtained about safe practices for the use of sedation therapy and PCA in the absence of a solid evidence base for practice. We did not get very far. Instead, there was lively discussion about the need for an evidence base to create a consensus about safe practices and a mandate for the adoption of these practices.

Several approaches were offered to improve the safety of PCA therapy. They included avoiding the use of opiates for analgesia, minimizing and standardizing the opiate medications and concentrations for PCA use, using pain teams, improving training, and using pulse oximetry and capnography to monitor patient response to self-administered analgesia. While all of these strategies have merit in improving patient safety, there was no consensus about which one or more should be mandated as a standard of practice.

As healthcare continues to change, each of us needs to become confident during times when uncertainty exists. An important dimension of the personal characteristics associated with being able to do this is called "tolerance for ambiguity." This refers to the extent to which individuals are threatened by or have difficulty coping with situations that are ambiguous, where change occurs rapidly or unpredictably, where information is inadequate or unclear, or where complexity exists.[15] Sound like your practice?

How does one improve one's tolerance for ambiguity? Persons with a high tolerance for ambiguity tend to be more cognitively complex, interpret more cues, and possess more sense-making categories and pay attention to more information than those who do not. Perhaps a good way to improve your tolerance for ambiguity is to find ways to become more comfortable in circumstances

of uncertainty. If PCA and sedation therapies are part of your practice, based on the discussion at this conference, these are good places to start. The presentations given at this conference will provide you with the information needed to do this.

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PROCEEDINGS

Pain Management and Patient-Controlled Analgesia

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Key Points

- *Pain management has improved in recent years because of an awareness of how to use analgesics more effectively.*
- *Standards of care now exist for pain management to guide clinicians in treating pain more effectively and safely.*
- *Technology, including the use of patient-controlled-analgesia, has the potential to further improve pain management.*

Over the last 40 years, numerous developments have improved clinical understanding, available medications, and patient outcomes related to pain management. This overview provides a brief history of such developments in pain management and patient-controlled analgesia (PCA), as well as a brief discussion of current issues from the perspective of a practicing clinician.

History of Pain Management

In the 1960s meperidine was the medication most commonly used to treat post-operative pain. Aspirin was the only pain medicine sold without a prescription, and there was a perception that strong pain medications such as morphine should be used only for dying patients. Melzack and Wall published the Gate Control Theory of pain.

The hospice movement began in the United States in the 1970s, and Kubler-Ross became well known for her publications on the stages of grief and death. Pain management became a part of healthcare discussions, but still was not a priority. The major focus of pain management was on changes in vital signs, and pain was seen as an experience that could be measured objectively. Lamaze and childbirth coaching became standard, offering yet another approach to managing pain, i.e., that of labor and delivery. The National Oncology Nursing Society was founded in 1975, and the National Hospice Organization was founded in 1978. These two organizations began a movement to improve outcomes in patient care and to enhance the quality of life, including the management of pain.

Advances in the 1980s included the NIH Consensus Conference on Pain in 1986, and the development of the Cancer Pain Initiatives based on the Wisconsin Pain Initiative Model. The World Health Organization published "Cancer Pain Relief," and the use of non-steroidal anti-inflammatory agents and PCA came to the forefront as options for pain relief. Research studies began to focus on pain assessment, sedation, the subjective nature and behaviors of pain, and quality of life.

The 1990s saw comparison studies of different medications and routes of administration (e.g., PCA delivery vs. intramuscular administration), and the enhanced quality of pain relief achieved for patients who were able to control their own analgesia. The Agency for Healthcare Policy and Research (now Agency for Health Research and Quality, AHRQ) published clinical practice guidelines in 1994 and set a national standard for pain management. Morphine became the "gold standard" for pain management, with less use of meperidine, and sustained-released opioids were developed. However, along with clinical advances, there was a heightened awareness and fear of addiction and concern about tolerance and physiologic dependence. Media reports about abuse of pain

medications raised fear and doubt among consumers.

More recently, the release of the Institute of Medicine report has heightened consumers' awareness of adverse drug events and increased fear and concern related to the use of opioids for pain management. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has published standards for pain management, requiring assessment and pain management to be appropriate and effective. Smart infusion pumps, bar-coding, computerized prescriber order entry and other safety initiatives have been developed in response to the need to create a safer healthcare environment with reduced risk of error and harm.

Despite the progress made in pain management since the 1960s, there is still a gap between what is known and what is done in practice. Evidence-based management of pain is still not part of many academic curricula for healthcare professionals. The major source of information about pain management becomes informal on-the-job training—a type of pain-management education that greatly needs improvement.

PCA

When did PCA really start? In theory PCA has been used for centuries, since people have always taken medications based on their needs using oral and sublingual doses. Studies in the 1970s and early 1980s showed significant lag time between a patient's request for pain medication and the actual administration of the pain medication. The lengthy period of time between request and administration resulted in increased anxiety and pain in patients. The hospice movement set the standard for allowing patients to establish or influence dosing regimes, which has now become an accepted practice.

In response to the need for consistent pain relief and an approach that would allow pain management without peaks and troughs of pain and sedation, Abbott introduced PCA infusion technology in the 1970s. With some limitations, the PCA pump allowed the patient to have a set dose available as needed and almost immediate delivery of the pain medication.

PCA's advantages are that it allows patient autonomy with safe, individualized dosing, improved analgesia with less sedation, and enhanced satisfaction. Provision of effective and appropriate pain relief allows patients to have earlier mobilization and better respiratory function, resulting in less risk of pneumonia and pulmonary emboli and a reduced length of stay. Reduced length of stay reduces healthcare costs and allows less time for patients to become subject to nosocomial infections. PCA is now being used postoperatively, including the use of patient-controlled epidural analgesia (PCEA).

Current Issues

Despite the enhancements in technology and the increasing scope of knowledge about pain management, societal issues and concerns remain. Consumer awareness of patient rights, specifically the right to effective and appropriate pain management, has increased. There is also a heightened concern among consumers about addiction, and a fear of medication errors and risks related to opioids. These societal concerns will undoubtedly continue, and healthcare agencies and professionals will need to determine appropriate mechanisms of communicating with consumers and develop more collaborative relationships with the media, so that consistent, accurate information can be delivered.

Healthcare professionals need to pursue accurate, evidenced-based knowledge related to pain management and the technology and interventions that can be used to enhance quality of life. More consistent academic curricula related to pain management need to be advocated for healthcare professionals. New technology for infusion and PCA will allow safer, more efficient mechanisms of pain relief.

Although much progress has been made in the last 40 years, pain management continues to be a major fear and concern of patients. There is an obligation to find better ways to manage pain effectively and safely.

PROCEEDINGS

Managing Pain in the ICU Patient

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Key Points

- *Advances in intensive care unit (ICU) technology, specialization, and clinical skills have increased the likelihood of patients surviving critical illness; however, ICU patients are still at risk for suffering unrelieved pain.*
- *No valid, reliable physiologic or biochemical measures of pain are currently appropriate for use in the ICU setting, but patient behaviors often can indicate the presence and causes of pain.*
- *Many studies have documented pain associated with common diagnostic and treatment procedures.*
- *Pre-emptive administration of analgesics can be used to help to reduce procedural pain and avoid the development of persistent pain.*
- *Balancing the positive and adverse effects of analgesia and sedation is essential but difficult; daily interruptions of sedative infusions may reduce the incidence of complications but can result in acute withdrawal syndrome following rapid discontinuation.*

Intensive care units (ICUs) have been developed to provide an environment for the care of critically ill patients. There have been tremendous advances in technology, specialization, and ICU professionals' skills, which have increased the likelihood of ICU patients surviving their serious illnesses. ICU patients are still at risk for suffering considerable pain from their diseases, injuries, and/or clinical procedures. Several studies have documented the physiological[1] and psychological[1-3] costs of ICU patients' unrelieved pain (Table 1).

Pain Assessment

One of the primary causes of inadequate pain management in the ICU is the lack of appropriate pain assessment (Table 2). The use of well validated pain assessment instruments[4,5,7] can be difficult in ICU patients. Professional practice standards and regulatory mandates[8] require that pain assessments be attempted for all patients. No valid or reliable physiologic or biochemical measures of pain are currently appropriate for use in the ICU setting, but pain-associated behaviors often indicate the presence and causes of pain.

Table 1. Challenges of Unrelieved Pain[1]

Physical suffering

- 40% of 80 post-ICU ARDS patients recalled having pain while in ICU[1]
- 40% higher frequency of chronic pain than in controls[1]
- 87% of 97 post-ventilation patients remembered being moderately to extremely bothered by pain[2]

Psychic suffering

- Significantly higher PSTD scores in post-ICU ARDS patients than in controls (28% vs. 12%)[1]
- Traumatic memories associated with pain after cardiac surgery (81.6% of 184 patients)[3]

Puntillo and colleagues[9] noted a significant relationship between behavioral indicators of pain observed by nurses and the nurses' ratings of postoperative patients' pain intensity. Payen and colleagues[10] reported validation of a pain behavior scale (PBS) in a sample of 30 intubated, sedated ICU patients. Using a model in which patients underwent common noxious and non-noxious procedures, they found that the percent of patients exhibiting no pain behaviors was significantly lower in the patient group that underwent a non-noxious procedure than in the group that underwent a noxious procedure. More recently a behavior observation scale was developed and tested in a large sample of patients undergoing common procedures such as wound care, wound drain removal, and turning.[11] By comparing behaviors exhibited before and during the procedure, and behaviors in patients with and without procedural pain (as noted on a 0-10 numeric rating scale), the researchers identified specific procedural pain behaviors that included grimacing, rigidity, wincing, shutting of eyes, verbalization, moaning, and clenching of fists. Patients with procedural pain were 2.8 times more likely to have increased facial responses, 4.1 times more likely to have increased body movement responses, and 10.3 times more likely to have increased verbal responses during the procedure than patients without procedural pain. Despite these studies, there is still a need for a valid, reliable, and feasible behavioral assessment methods for ICU patients.[12]

Pain Management

Pain assessment is an essential step before pain intervention, but pain intervention can be provided even before a pain stimulus. Preemptive analgesia is the administration of an analgesic agent before the patient experiences a noxious stimulus to prevent amplification and hyperexcitability of the central nervous system (CNS). Hyperexcitability may lead to CNS sensitization, which can result in persistent pain. Patients may not receive preemptive analgesia before procedures because health professionals are unaware of the degree of pain associated with various common procedures. Many studies have documented the pain associated with procedures such as arterial blood gas draws, nasogastric tube insertion, intravenous (IV) catheter insertion, mechanical ventilation,[13] turning, wound drain removal, wound care, tracheal suctioning,[14,15] and chest tube removal.[14,16,17] Planning for these procedures should include consideration of the optimal preemptive analgesic intervention. Analgesic administration should be timed so that the selected drug's peak effect is obtained at the time of the procedure. Puntillo and Ley[18] demonstrated that pain associated with chest tube removal was minimal when patients were given either IV ketorolac or IV morphine before the procedure at a time that would achieve a drug's peak effect during the procedure.

Opioid and Sedative Therapies

Opioid analgesic therapy remains the primary pharmacologic treatment modality for ICU patients. Based on a review of the most recent evidence, Jacobi and colleagues[4] have developed clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill. Organ dysfunction and hemodynamic abnormalities in critically ill patients can result in significant inter-individual variability in the pharmacokinetics and pharmacodynamics of drugs. For a given patient, a standard drug dose could be toxic, subtherapeutic, or effective.

It is not unusual for critically ill patients to receive a combination of opioid and sedative therapies, so proper use of multiple, potentially interacting medicines can be challenging (Table 3). One or both types of agents may adversely affect the

Table 2. Pain Assessment in Patients Who Cannot Self-report

- No valid or reliable physiological or biochemical measure of pain
- Pain behaviors have been validated in acutely/critically ill patients undergoing procedures
- Behavioral Pain Scale validated in critically ill, sedated patients[10]

Table 3. Balancing Analgesia and Sedation is Essential but Elusive

- Combination of analgesics and sedatives common in ICU
- Challenges:
  - Tools that differentiate pain from anxiety/agitation exist, with limitations
  - Choosing right type and combination of medications
  - Need new ways to assess pain and discomfort in all ICU patients

patient's hemodynamic or respiratory status. The use of both treatments may have synergetic adverse effects. The clinical challenge is to use the right type and combination of medications while avoiding adverse effects. Another challenge is to use tools that differentiate among pain, anxiety, and agitation, so that pharmacological interventions can be targeted to more clearly defined goals. Without the use of such tools, patients may be under-, over-, or "mis"-dosed.

Daily interruptions of sedative infusions for the purpose of assessing the patient have become standard practice in many ICUs. Kress and colleagues[19] showed that in ICU patients daily interruptions of sedative infusions reduced the incidence of many complications and did not result in negative psychological outcomes.[20] Interruptions in sedative infusions should include pain and agitation assessments, and be minimized in patients who respond adversely to them. In patients who have been receiving opioids and benzodiazepines for more than a few days, interruptions can result in a withdrawal syndrome. Cammarano and colleagues[21] showed that some ICU patients who received analgesic and sedative medications for longer than seven days experienced acute withdrawal syndrome after rapid discontinuation of medication.

Summary

Although advances have been made in pain assessment and treatment for patients in the ICU, gaps remain. There are no comparative trials of opioids,[4] and the evidence for most recommendations made by the most current guideline panel[4] is based on observational studies rather than randomized clinical trials. Until more evidence-based practice tools and guidelines become available, clinicians will need to use available practice-based assessment tools to promote patient comfort and safety.

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PROCEEDINGS

Perioperative Management of Obstructive Sleep Apnea

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Key Points

- *The overall incidence of obstructive sleep apnea (OSA) is approximately 10%. Based on this estimate, 3 million patients are at risk of post-operative OSA.*
- *The risk of postoperative complications in OSA patients is related to three factors: the severity of the OSA, the invasiveness of the surgery, and the requirement for postoperative analgesics.*
- *The goal of the* ASA Practice Guidelines for the Perioperative Management of Patients with OSA *is to reduce the likelihood of adverse outcomes in patients judged to be at the greatest risk of OSA-related perioperative morbidity and mortality.*
- *Intraoperative management of patients with OSA is primarily an issue of airway management.*

Increasing age and obesity are important risk factors for obstructive sleep apnea (OSA). As surgical patients become older and larger, they are at greater risk for OSA in the perioperative period. It has been estimated that about 25% of men and 10% of women between 30 and 60 years of age have an apnea–hypopnea index (AHI), which is used to evaluate sleep disorders, of greater than 5 events per hour, and that approximately 10% of men and 5% of women in this age cohort have an AHI greater than 15.[1] In patients over 65 years of age, an AHI of greater than 10 has been reported in 70% of men and 55% of women.[2] The prevalence of OSA in children is estimated to be about 3%, but is likely much higher in those who are obese or undergoing tonsillectomy.

Assuming that the overall incidence of OSA is approximately 10% and that the number of operations performed annually in the U.S. is approximately 30 million, it could be estimated that approximately 3 million patients are at risk of perioperative OSA. It is likely that most of these patients have undiagnosed OSA. Despite this large number of patients at risk, relatively few patients suffer severe morbidity or mortality. OSA does significantly increase the risk of perioperative complications including hypoxemia, hypercapnia, and the need to be transferred to an intensive care unit (ICU).[3] OSA also predisposes patients to other medical conditions including hypertension, arrhythmias, and bronchospasm, which further increase the risk of surgery and anesthesia.

ASA Guidelines

In view of the magnitude of the problem, the American Society of Anesthesiologists (ASA) commissioned a Task Force to develop evidence-based perioperative guidelines for management of patients with OSA. There have been few well-controlled studies of the management of OSA patients in the perioperative period. Thus, some of the recommendations are based on meta-analyses of studies performed on OSA patients in non–perioperative settings, while others are based on the opinion of consultants drawn from medical specialties who treat patients with OSA, e.g., anesthesiology, sleep medicine, bariatric surgery, otolaryngology, pulmonary medicine, pediatrics, etc. The guidelines recognize "that it is not possible to determine with 100 percent accuracy whether a given patient will develop perioperative complications related

to OSA. Therefore, these guidelines should be used with the goal of reducing the likelihood of adverse outcomes in patients who are judged to be at the greatest risk, with the understanding that it may be impractical to completely eliminate OSA-related perioperative morbidity and mortality."

The risk of perioperative complications in OSA patients is related to three factors: the severity of the OSA, the invasiveness of the surgery, and the requirement for postoperative analgesic sedative medications. For example, a bunionectomy under local anesthesia poses a much lower risk than hemicolectomy under general anesthesia (with either neuraxial or systemic opioids for postoperative analgesia). In the latter case, patients may be at risk for airway obstruction and hypoxemia for several days, until their normal sleep patterns have been re-established.[4] (Airway obstruction is most likely to occur during REM sleep, when muscle tone is markedly diminished; REM rebound, an increase in the frequency and duration of REM sleep, typically occurs two to four days after major surgery.) To help clinicians assess which patients may be at increased risk of perioperative complications from OSA, the Task Force developed a scoring system which is shown in Table 2 of the ASA Guidelines.[5] It is important to understand that this scoring system was developed empirically and that there are no data available to establish its validity.

In order to appropriately manage patients with OSA in the perioperative period, it is essential to establish the diagnosis and assess the severity of the condition. If a sleep study has been performed, the diagnosis and severity have been determined, and many of these patients will have been started on therapy with nasal continuous positive airway pressure (CPAP). The majority of patients with OSA will be undiagnosed at the time of their preoperative evaluation. If the possibility of OSA is suspected on the basis of history and physical examination, the surgeon and anesthesiologist should work together to develop a management plan. Ideally, this would include obtaining a sleep study and, if time permits, instituting therapy, if indicated. In many instances this may prove to be impractical, in which case it may be appropriate to empirically treat the patient as though he or she has OSA even though the diagnosis has not been established.

To maximize patient safety, the clinical criteria suggested in the ASA guidelines are conservative; as a result, patients are likely to be treated more aggressively than might have been necessary had the patients completed a sleep study. Planning is important, particularly when determining where the surgery should be performed (stand-alone surgery center versus hospital-connected surgery center vs. inpatient facility) and whether a patient should be admitted to the hospital for a procedure that is typically performed on an outpatient basis. For inpatients, it is also necessary to plan postoperative analgesia and arrange for appropriate postoperative monitoring; in some cases this may require admission to an intensive care or step-down unit.

Preoperative Management

Preoperative initiation of CPAP or bi-level positive airway pressure (BIPAP) is likely to improve nocturnal oxygenation, decrease the incidence and severity of nighttime apneic episodes, decrease daytime hypersomnolence, and decrease both pulmonary[6] and systemic arterial pressures.[7] Although it seems reasonable to speculate that these hemodynamic changes would improve perioperative outcomes, there are no data to support this possibility. Another advantage of preoperative CPAP is that patients will have become accustomed to the equipment prior to surgery.

Intraoperative Management

The intraoperative management of patients with OSA is primarily an issue of airway management. The equipment and personnel necessary to make use of the ASA difficult–airway algorithm should be available, even if only moderate sedation is planned. Because of the propensity of these patients to develop airway obstruction during intravenous (IV) sedation, it may actually be safer to control the airway with a laryngeal mask airway or endotracheal tube. (If patients have been treated with nasal CPAP preoperatively, intraoperative use of the CPAP device is likely to reduce the risk of airway obstruction during IV sedation.[8]) Extubation is also potentially risky, and it is recommended that if possible these patients be extubated in the semi-upright or lateral position rather than supine to improve airway dynamics.

Postoperative Management

The postoperative period is fraught with danger for patients with OSA. Postoperative sedatives, analgesics, and an altered sleep pattern are likely to increase the incidence of airway obstruction and increase the risk that patients will not "self–resuscitate" from such episodes. How can patients be treated to minimize these risks? Postoperative analgesic modalities should be chosen to minimize the risk of respiratory depression. If patient-controlled analgesia is used, basal infusions should be avoided to minimize the risk of over-sedation. If neuraxial anesthesia is planned, the risks and benefits of using a local anesthetic-opioid mixture as opposed to local anesthetic alone must be weighed. Other analgesic modalities (local anesthetic infiltration, surface cooling, non-steroidal anti-inflammatory agents, etc.) may potentiate the analgesic effects of opioids without increasing the likelihood of respiratory complications.

The use of supplemental oxygen during the recovery period is also controversial. On the one hand, it reduces the risk of hypoxemia during periods of partial or complete airway obstruction by providing an oxygen reserve in the lungs. On the other hand, oxygen blunts the "arousal response," which may be necessary to cause OSA patients to self-resuscitate following airway obstruction. Supplemental oxygen will also delay detection of hypoventilation and atelectasis by pulse oximetry.

Monitoring

It is important to closely monitor OSA patients in the postoperative period so that potentially lethal episodes of apnea, hypoxemia, or hypoventilation can be detected or treated before morbidity occurs. This is not a simple task: many patients with OSA routinely develop multiple episodes of severe hypoxemia (oxygen saturation [SpO_2] < 80%) while asleep. It is difficult for a clinician to determine whether a patient will arouse himself and "self-resuscitate" from such an episode, or whether self-resuscitation will be ablated by the analgesics and sedatives the patient has received. Intermittent monitoring using a pulse oximeter at the patient's bedside will not suffice. Another possibility might be the use of a pulse oximeter that automatically pages the nurse if SpO_2 falls below a preset limit. However, such a device is likely to produce too many false alarms, leading to the "boy who cried 'wolf' syndrome." Similar problems are likely to occur with newly developed automated apnea detection devices, since patients with OSA always have apneic episodes during sleep, and it is difficult for a device to determine which of those episodes is severe and/or prolonged enough to require intervention. For the time being, observation in an intensive care or step-down unit, or continuous observation in a hospital room by a trained observer may be most appropriate. The observer needs to be trained to recognize that a problem is occurring, to call for help, and to attempt to arouse the patient if a significant episode of apnea and/or hypoxemia should occur; he or she does not need to be an expert in resuscitation or airway management.

If clinically significant apnea and/or hypoxemia occur during recovery, it has been suggested that nasal CPAP be instituted, even in patients who have not received this modality previously. Although there may be problems with patient acceptance, the newer, self-titrating units may alleviate some of these problems.

Outpatient Management

A similar problem arises regarding the postoperative management of outpatients who are at risk because of suspected or diagnosed OSA. Since one must assume that there will be no professional monitoring and no means for resuscitation (other than verbal or tactile arousal of the patient by a family member), criteria for discharge must minimize the risk of subsequent respiratory embarrassment. Important factors to be considered in determining OSA risk include the site of surgery (airway surgery may pose increased risks, particularly in children) and whether opioid analgesics will be required for postoperative pain control. Patients should also be monitored during recovery to verify that significant OSA-related events do not occur while the patient is resting undisturbed (and ideally is asleep) in the recovery area. Room-air oxygen saturation should remain at or above baseline levels, and any airway obstruction which occurs should be mild and self-limited. This is likely to require a longer recovery

room stay than in patients without OSA undergoing similar procedures.

Feasibility of Guidelines Implementation

More than 60% of the consultants who reviewed the OSA guidelines felt that implementing them would require formal protocols for management of patients and improved communication between surgeons and anesthesiologists. Almost 50% felt that patients would need to be asked more often about signs and symptoms of OSA. The costs of these changes were viewed as being relatively small and the potential benefits, significant.

The cost of preoperative evaluation and testing is more significant. For patients with clinical evidence of OSA, almost 40% of the consultants felt that they would order a sleep study rather than treating the patients empirically. For a medium-sized practice (5,000 cases/year) with 10% of patients at risk of OSA based on clinical criteria, sleep studies would cost at least $125,000 annually (assuming that half of the clinically-detected patients underwent sleep studies at a discounted cost [not patient charge] of $500 each). The consultants' median estimate of the annual cost associated with implementing the preoperative evaluation and preparation recommendations was $45,000/year. This may represent an underestimate of the extent of the problem or of the cost of obtaining the recommended studies. In addition to cost, other factors which may preclude obtaining preoperative sleep studies include difficulty in scheduling the studies within a reasonable time frame and distance, patient refusal, and surgeons' preference for proceeding on clinical grounds rather than delaying surgery to obtain a study

The cost of implementing the intraoperative management guidelines is negligible; only 15% of the consultants indicated a need to obtain new equipment to comply. This suggests that the ASA Difficult Airway Guidelines are being followed.

The consultants' median estimate of the cost for implementing the postoperative monitoring recommendations was only $25,000 per year. Assuming that only 1% of the patients in the medium-sized practice described above require postoperative monitoring for two nights at a cost of $500/night, the additional cost would be $50,000/year. The problem is determining which 1% of the patients to monitor. It would be unfortunate if a patient whose OSA was not felt to be severe enough to justify postoperative monitoring had a serious complication which could have been prevented had monitoring been prescribed.

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PROCEEDINGS

Perioperative Respiratory Depression and Monitoring

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Key Points

- *Opiate-related respiratory depression has not been eliminated by the use of patient-controlled analgesia (PCA).*
- *Respiratory depression may be caused by PCA pump programming errors and mechanical malfunction, and patient risk factors such as advanced age, obstructive sleep apnea and μ-receptor polymorphisms.*
- *Administration of the proper dose of opiate and the avoidance of drug interactions may reduce the risk of respiratory depression.*
- *Attempts to improve the safe use of opiates by better patient selection and limiting the use of these drugs to patients in high-intensity monitoring units are not practical.*
- *The safe use of opiates may be enhanced by incorporating respiratory pattern analysis into postoperative monitoring technology.*

Despite the introduction of closed-loop opiate self-administration (patient-controlled analgesia [PCA]) and careful monitoring of patients receiving spinal opiates, drug-induced respiratory depression continues to occur. Opiate-related drug-induced respiratory depression can be defined as impaired consciousness in a patient receiving opiates and one or more of the events listed in Table 1 that are not attributable to any co-morbid condition such as a stroke, pulmonary embolus, or primary cardiac arrest resulting from arrhythmia or infarction. The estimated incidence of respiratory depression in patients being treated with PCA ranges from 0.16% to 5.2%.[1-9] Epidural narcotics appear to have a lower risk of causing drug-induced respiratory depression.[8,10]

Reasons for opiate-related respiratory depression include errors related to pump malfunction, programming errors, and inadequate instruction of friends and relatives who push the demand button instead of the patient ("PCA by proxy") (Table 2). Patient-related factors (Table 3) include increased opiate-sensitivity associated with advanced age, gender, race, sleep apnea or specific surgical procedures that require high opiate doses or impair respiration (e.g., upper abdominal or thoracic procedures). The peak effect of the opiate could occur after the PCA pump lockout interval. Interactions may occur with other sedative drugs such as hypnotics or anti-emetics. Lung pathology could augment the respiratory depressant effects of the

Table 1. Events Related to Opiate-Related Respiratory Depression

Ventilatory support (ventilator, bag-valve-mask)
Hypercapnia ($PaCO_2 \geq 60$ mmHg)
Hypoxemia ($SpO_2 \leq 85\%$, $PaO_2 \leq 50$ mmHg)
Opiate antagonist (e.g. administration of an opiate antagonist (naloxone or nalmefene) other than for treatment of pruritus
Escalation of level of care secondary to respiratory event (e.g. transfer of a patient to a unit with increased level of care such as an ICU)

opiate and cause a disproportionate degree of hypoxemia. There could also be tolerance to the analgesic effects on a genetic basis.[11] Evidence suggests that people with μ-receptor polymorphisms may have an attenuated opiate-related analgesic effect combined with an intact respiratory depressant effect.[12]

Strategies for Reducing the Likelihood of Respiratory Depression

Appropriate Dosing

Respiratory depression may result from avoidable drug interactions or unnecessarily high doses of opiates. Progressive accumulation of pharmacologically active metabolites such as morphine-6-glucuronide may also augment respiratory depression. Short lockout times may allow the patient to self-administer multiple doses before each one has reached its peak effect. Whether particular drugs are inherently safer is as yet unknown.

Patient Selection

Triage of patients who are at risk of respiratory depression and transferring them to high-intensity monitoring units or intensive care units could be part of preoperative screening. Examples of patients at risk include those of advanced age or with obstructive sleep apnea (OSA). Only a minority of patients with these risk factors will experience respiratory depression. In an evaluation of 102 consecutive opiate-induced respiratory events at Duke University Medical Center, it was found that only 5% of patients were older than 80 years. Cepeda reports that only 3.2% of octogenarians experienced respiratory depression after surgery.[7] Only a minority of patients with OSA develop complications,[13] and many patients with OSA are undiagnosed. Triage of patients and transfer to high-intensity monitor beds based on age or indeed any specific risk factor is unlikely to be cost-effective or practical.

Bedside Identification of Respiratory Depression

Since only a small proportion of high-risk patients actually develop respiratory problems and many patients who are actually at high risk may not be identifiable preoperatively, an effective strategy must include an enhanced ability to detect respiratory events or their premonitory signs as they occur. Possible

Table 2: Possible Reasons for Opiate-Related Respiratory Depression in Patients Receiving Opiates Via PCA

Provider Errors

Incorrect pump programming

Design Errors or Mechanical/Electrical Failure

Pump malfunction

Inadequate Instruction

Someone other than the patient pushing the demand button

Patient Factors

- Increased opiate susceptibility: age, gender, race, genetic susceptibility, obesity, anxiety or depression, alcoholism, sleep apnea, surgical procedure
- Peak respiratory depression of narcotic occurring after PCA lockout interval
- Metabolically active metabolites of parent drug (e.g., morphine-6-glucuronide)
- Interactions of opiates with other drugs, e.g. anti-emetics, hypnotics
- Lung pathology, e.g., atelectasis, pulmonary edema, causing disproportionate hypoxemia
- Tolerance to analgesic effects of opiates with intact respiratory depressant effects
- Interaction of opiates and sleep and their combined effects on respiratory control

Monitoring Techniques Inadequate to Detect Respiratory Depression

Table 3. Patient Factors Associated With Opiate-Related Respiratory Depression[9]

Age >70 years
Basal infusion
Renal, hepatic, pulmonary or cardiac impairment
Sleep apnea (suspected or diagnosed)
Concurrent CNS depressants
Obesity
Upper abdominal or thoracic surgery
IV PCA bolus >1 mg morphine

monitoring techniques include the following:

Level of consciousness. Respiratory depression is accompanied by depressed level of consciousness, and it is possible that the respiratory depressant effects of opiates are greater during sleep. Oversedation due to narcotics may be difficult to distinguish from normal sleep. Therefore, some respiratory parameters are needed as well. Conceivably, respiratory depression may be identifiable during sleep by analysis of respiratory pattern.

Respiratory minute volume. Respiratory minute volume can be measured in experimental settings but requires use of a body plethysmograph or a rigid head tent.[14] Thus, it is not practical for a routine clinical use.

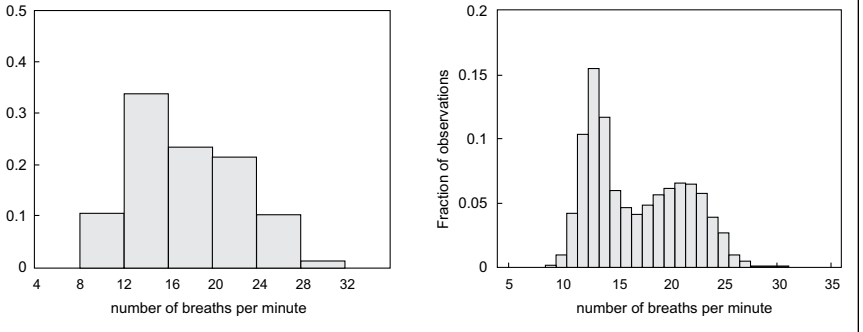
Pulse oximetry. Pulse oximetry is widely available and inexpensive. The use of pulse oximetry to detect respiratory depression has been fraught with difficulty. Mild hypoxemia in the postoperative period can occur for several reasons that are not associated with major respiratory depression. The ready availability of pulse oximetry, and the frequency with which low SpO_2 is observed have resulted in routine administration of oxygen. When oxygen is administered, desaturation is a very late sign of respiratory depression.

PCO_2 monitoring. As an estimate of arterial PCO_2, end-tidal CO_2 ($EtCO_2$) monitors are now portable and relatively inexpensive. Newer sampling ports allow more accurate exhaled gas sampling during mouth-breathing.[15] While a high $EtCO_2$ indicates a problem, the measured value may be artifactually low due to shallow respiration or displacement of the capnograph sampling probe. Transcutaneous PCO_2 ($PTCCO_2$) monitors are also available and are reported to correlate well with arterial CO_2 tension.[16]

Respiratory rate. Opiate-induced respiratory depression is believed to be earmarked by a low respiratory rate with apneic pauses. Respiratory rate monitoring is a routine bedside measurement that is easy to perform. The short sample times in which breaths are counted (e.g., 15 to 30 seconds) create uncertainty in defining normal respiratory rates and renders this method relatively unsatisfactory. Simple environmental influences can affect the measurement of respiration. The awareness that respiratory measurement is occurring tends to decrease respiratory rate[17] and pain tends to increase it.[18-20]

Figure 1 shows an example of a 20-year-old male during the three days following liver resection. In this case breaths were detected objectively using diaphragm EMG and the histograms generated by a computer. When breaths are counted for a full minute there are very few instances of a respiratory rate less of 10. When using the more common time frame

Figure 1



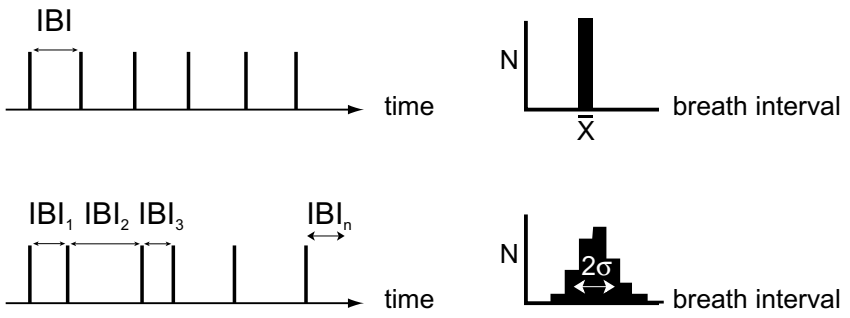
Histograms of respiratory rates obtained by continuous monitoring of breaths using diaphragm EMG in a 20 year old male during the first 3 days following liver resection. Left panel: breaths counted during 15 second intervals. Right panel: breaths counted during 60 second intervals.

of 15 seconds, a greater proportion of respiratory rate values is evident at the tails of the distribution.

It has been assumed that respiratory depression is associated with low respiratory rate and that high or normal respiratory rate indicates the absence of significant respiratory depression. This may not always be true. Severe respiratory depression can occur even with a normal respiratory rate.[21-23] The relationship between the regularity of breathing and the degree of respiratory depression may be poorly correlated.[24] In a 55-year-old male after liver resection receiving morphine via PCA, a higher, more regular respiratory rate was associated with a $PETCO_2$ of 106 mmHg, while a slower, irregular breathing pattern was associated with a $PETCO_2$ of 52 mmHg. These findings suggest that there is an incomplete understanding of opiates pharmacology and respiratory physiology in the postoperative period.

Respiratory pattern. Despite the problems with determining the respiratory rate clinically, there are several other methods of detecting respiratory problems non-invasively such as using capnography, chest wall movement detectors. A more sophisticated analysis of breathing pattern may enable the detection or prediction of respiratory depression. Periodic physiological events can be characterized by their statistical pattern, most commonly the mean. Because the physiological events rarely occur regularly, additional information can be obtained by calculating how much variation there is in the occurrence of these events using standard deviation (σ) (Figure 2).

Figure 2



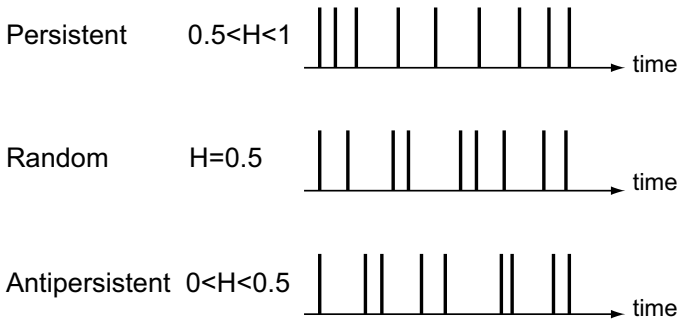
Conventional statistical parameters for a periodic process such as breathing. Inter-breath intervals (IBI) are shown. Top panel: completely regular rhythm, for which the only parameter is the mean. Bottom panel: Irregular rhythm, for which a distribution of IBI can be estimated and its mean and standard deviation (σ) can be calculated.

Further insight may be obtainable by Hurst analysis, which assesses the connectedness of one event to another. Persistence is the tendency for events to correlate positively with subsequent events and antipersistence is the tendency for events to correlate negatively with subsequent events. If a breathing pattern is persistent, a short inter-breath interval is usually followed by another short inter-breath interval. If a breathing pattern is antipersistent, a short inter-breath interval is usually followed by a longer one, or vice versa (Figure 3).

The connectedness of periodic events such as inter-breath interval can span more than one breath. That is, any particular inter-breath interval may influence more than one subsequent interval. On the other hand, if the breathing pattern is random, then there is no relationship between any two inter-breath intervals.

Respiratory depression might be predictable from breathing pattern using Hurst analysis of inter-breath interval. Volatility (Vo) is the absolute value of the difference between successive inter-breath intervals.[25] The

Figure 3

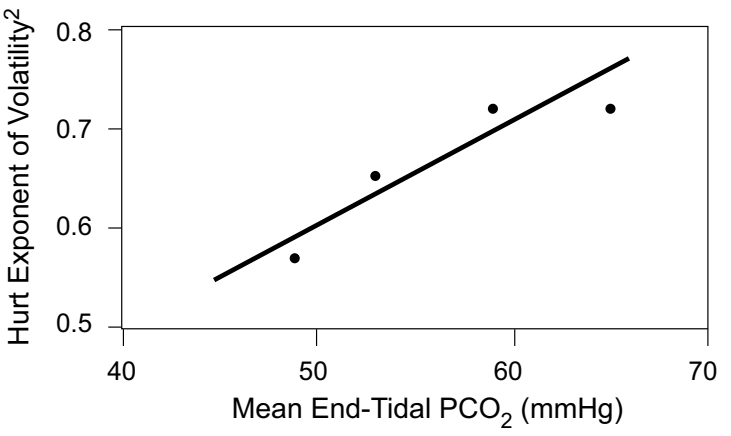


Hurst analysis of a periodic process. Hurst analysis provides an additional parameter, the Hurst exponent (H), which provides information regarding the connectedness or long range correlation of the duration of one event to another.

square of volatility (Vo_2) may be a more useful parameter to evaluate respiration.

In a preliminary series of four patients monitored after major upper abdominal surgery it appears that Hurst exponent of Vo_2 is directly related to the average $PETCO_2$ over the 2-3 day postoperative period (Figure 4). This preliminary series of observations indicates the possible effectiveness of new monitoring technology incorporating on-line Hurst analysis of respiratory pattern.

Figure 4



Postoperative Hurst exponent (H) in a preliminary series of 4 patients monitored for 3 days postoperatively. H is correlated with mean $PETCO_2$ for the postoperative period, suggesting that Hurst analysis of this breathing pattern may be a useful predictor of respiratory depression.

Conclusions

Respiratory depression caused by opiates in hospitalized patients has not been eliminated by computer-controlled self-administration of opioid analgesics such as PCA. There are several possible reasons for this, including programming errors and mechanical malfunction. In addition, there are patient risk factors that include advanced age, obstructive sleep apnea and perhaps μ-receptor polymorphisms. Careful dosing and avoidance of specific drug interactions may reduce the risk. Patient selection and providing care in high-intensity monitoring units is unlikely to be practical. Preliminary data obtained by longitudinal monitoring of respiration for the first three postoperative days support the utility of incorporating respiratory pattern analysis into postoperative monitoring technology.

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PROCEEDINGS

PCA by Proxy: Issues Related to Authorized and Unauthorized Use of PCA Pumps

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Key Points

- *The Joint Commission on Accreditation of Healthcare Organizations issued a sentinel event alert about the unauthorized use of PCA and recommendations for preventing potentially life-threatening "PCA by proxy."*
- *When patients are unable or unwilling to use PCA, authorized individuals including family members and nurses may do so.*
- *"Family-controlled" analgesia can be a safe alternative to PCA, when a family member is carefully selected and trained to act as primary pain manager.*
- *In nurse-activated dosing for critically ill patients, a PCA pump can be used to administer a continuous infusion, with a nurse pressing the button to administer supplemental doses.*
- *Patient control of PCA should be initiated as soon as the patient is well enough to use it effectively.*

Since its introduction, patient-controlled analgesia (PCA) has been proved to be safe and effective for managing all types of moderate to severe pain.[1-3] An appropriate candidate for PCA therapy is any adult or child who is cognitively and physically able to use the equipment and who understands the relationships between pain, pressing a button, and pain relief.[3] Important principles underlying PCA use are that only the patient knows how much pain he or she is experiencing and when the pain has been relieved.[4] PCA is generally considered safe, because opioids, the primary analgesic administered by the modality, cause sedation before they cause respiratory depression, and a sedated patient would most likely drop the PCA button, thereby preventing delivery of more opioid and subsequent respiratory depression. This safeguard can be circumvented when someone else, intending to help, administers PCA for the patient. This is called "PCA by proxy."

Adapted from Pasero C, McCaffery M: Authorized and unauthorized use of PCA pumps. *American Journal of Nursing* 2005;105(7):30,31,33. Reprinted with permission.

Safety Issues

There have been many reports in the literature of the dangers of unauthorized family members administering PCA.[1,2,5-8] In 1994 Ashburn and colleagues observed almost 4,000 patients who received IV PCA and reported 14 critical events, three of which involved unauthorized family members pressing the PCA button.[5] A later review of more than 6,000 patients revealed unauthorized PCA administration by relatives in two of the 14 observed cases of respiratory depression.[2]

Late in 2004 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a "sentinel event alert" on unauthorized PCA administration. Of 460 reports of PCA-related errors resulting in death or serious injury in a five-year period, 15 were the direct result of unauthorized family members or clinical staff pressing the PCA button.[9] The alert suggested ways that facilities can prevent this unauthorized use of PCA, including teaching patients, family, visitors, staff, and physicians that PCA is for patient-only use. The Institute for Safe Medication Practices has issued similar precautions.[10]

Although the JCAHO alert stated specifically that its warning concerned unauthorized people pressing the PCA button on behalf of patients, some confusion has arisen among clinicians as to when authorized individuals—family members and nurses—may do so.

Family-Controlled Analgesia

When patients are unable or unwilling to use PCA, one safe alternative that has been used for many years in institutions and home settings is "family-controlled" analgesia (administered by a parent or significant other).[11-14] For example, many children are too young, and some simply may not want to manage their pain by PCA. In such cases, a parent would do so. A spouse may want to manage the pain in a terminally ill patient who is unable to manage his or her own pain.

Use of family-controlled analgesia is safest when there is strict designation of one person as the patient's primary pain manager; only that person can press the button for the patient. The primary pain manager must be chosen carefully and taught to assess for pain and adverse effects of opioids (see Table). It may be necessary to designate a secondary pain manager, who can manage the patient's pain when the primary pain manager needs respite.[11,12] A secondary or even tertiary pain manager is helpful in preventing exhaustion of one family member when family-controlled analgesia is used in a terminally ill patient.

Nurse-activated Dosing

When nurse-activated dosing is used, the patient's primary nurse has the responsibility of using the PCA technology to manage the patient's pain.[14] Nurse-activated dosing is appropriate for patients who have no family member or significant other who can manage their pain. It is also useful in the ICU, where most patients are too ill to administer PCA. Critically ill patients of all ages experience significant, continuous pain from surgery or underlying pathology and are subjected to numerous repetitive, painful procedures during their care.[16-18] PCA is rarely appropriate in these patients.[19] But a PCA pump can be used to administer a continuous infusion, and the nurse can press the button to administer supplemental doses for breakthrough pain and to prepare for painful procedures.[14,19] PCA should be initiated as soon as the patient is well enough to use it effectively.

Table. Education of the Pain Manager[15]

- Select the appropriate method for assessing the patient's pain, such as the 0-to-10 numerical pain rating scale or a faces scale.
- Teach the pain manager to look for adverse effects, such as nausea, sedation, and respiratory depression, before administering a bolus dose and to notify staff if adverse effects are detected.
- Explain that sedation precedes opioid-induced respiratory depression and that the patient's sedation level should be assessed using a sedation scale, such as the following:

S =	Sleep, easy to arouse (awaken patient to determine arousability before administering a bolus)
1 =	Awake and alert (acceptable; may administer bolus)
2 =	Slightly drowsy, easily aroused (acceptable; may administer bolus)
3 =	Frequently drowsy, arousable, drifts off during conversation (unacceptable; do not administer a bolus; notify staff immediately)
4 =	Somnolent, minimal or no response to physical stimulation (unacceptable; do not administer a bolus; notify staff immediately)

- Provide a form on which the pain manager may document assessment.

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PROCEEDINGS

Physiology of Oxygen and Carbon Dioxide Monitoring

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Key Points

- *Oxygenation is vitally important in the management of postoperative patients and those being sedated for procedures.*
- *Pulse oximetry does not give enough forewarning of hypoxia to implement timely corrective action.*
- *Capnography is a reliable monitor of ventilation that can be used to monitor pain management in postoperative patients and sedation for procedures.*
- *The use of pulse oximetry and capnograpy should allow patients to be treated with opiate analgesics and sedatives with less risk of undetected catastrophic respiratory events.*

Among many complications that are of concern in the postoperative period, oxygenation assumes a vitally important place in the management of any postoperative patient. This becomes all the more important when pain relief medications are used to control postoperative pain. Many pain relief medications result in respiratory depression and consequent hypoxia (Figure 1). Hypoxia, if unrecognized, leads to unexpected postoperative disaster with medicolegal implications. Therefore, postoperative monitoring becomes mandatory for patients who are receiving pain medications that can depress cardio-respiratory systems.

Clinical Determination of Oxygenation

A pulse oximeter is an excellent and reliable device that monitors oxygenation and detects hypoxia. However, it does not give enough forewarning to implement corrective measures to prevent hypoxic consequences. This is easily understood based on the relationship between arterial oxygen tension (PaO_2) and oxygen saturation (SpO_2) (Figure 2).

The SpO_2 does not begin to decrease from 98-100% until PaO_2 decreases below 100 mmHg. Decreases in PaO_2 below 80 mmHg are associated with dramatic decreases in SpO_2. This is because of 'S'-shaped relationship between SpO_2 and PaO_2. The decreases in SpO_2 can be exaggerated with clinical conditions associated with a reduction

Figure 1. Potential Post-Operative Complications

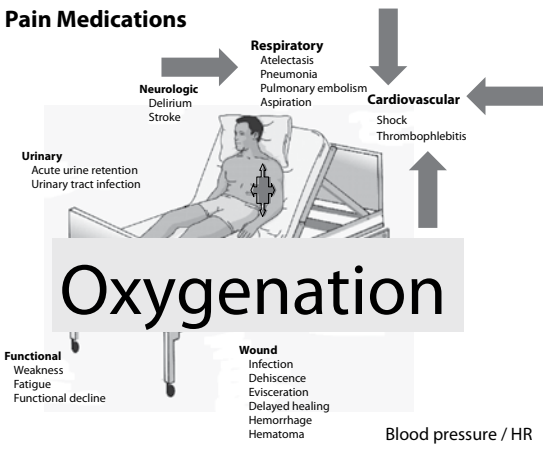
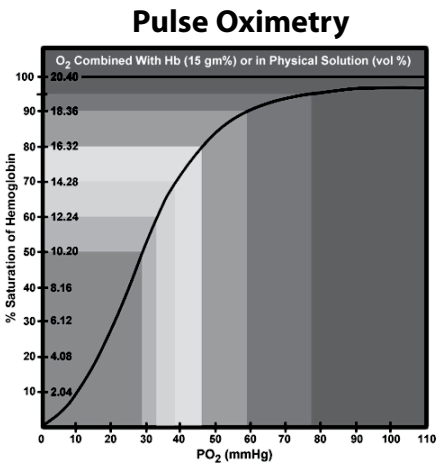


Figure 2. Relationship Between PaO_2 and SpO_2



in functional residual capacity (FRC) that acts as the oxygen reserve buffer in the lungs. Obesity is a classic example, and FRC is known to decrease following abdominal surgeries even in normal-weight individuals.

The time interval from impending hypoxia to actual hypoxia is decreased with decreased FRC, and this decreased time may not be sufficient to call and initiate corrective measures to prevent hypoxia from occurring. Apart from stable homodynamics, ventilation is a major determinant of oxygenation. Hence, it is necessary to monitor ventilation to detect episodes of inadequate or decreased ventilation that may result in hypoxia, if uncorrected. This way, one could avoid potentially life-threatening episodes in the postoperative period, when the monitoring of vital signs is not as frequent as in the operating room or in the postoperative anesthesia care unit (PACU).

Capnography has been shown to be a reliable monitor of ventilation in the operating room. Its use is being extended into many areas outside of operating rooms to monitor ventilation in patients undergoing a variety of invasive and non-invasive surgical and medical procedures. These areas include intensive care units, emergency rooms, interventional radiology suites, gastroenterology suites, interventional cardiology units, and pre-hospital settings such as air and emergency ambulance services. It is only a question of time before capnography in association with pulse oximetry will be used to monitor postoperative patients receiving postoperative pain medications via intravenous route.

Overview of Physiology of Capnography

Carbon dioxide (CO_2) is produced in the tissues and diffuses into the venous blood, which reaches the right side of the heart and reaches the lungs via pulmonary circulation. Here oxygen (O_2) enters the blood and carbon dioxide (CO_2) is eliminated during expiration. CO_2 is typically measured at the mouth, nose, or at the junction between the endotracheal tube and ventilator circuit.

At the end of inspiration, assuming that there is no rebreathing, the airway and the lungs are filled with CO_2-free gases. Carbon dioxide diffuses into the alveoli and equilibrates with the end-alveolar capillary blood ($PaCO_2$ = $PcCO_2$ = 40 mm Hg). The actual concentration of CO_2 in the alveoli is determined by the extent of ventilation and perfusion into the alveoli (V/Q ratio). The alveoli with higher ventilation in relation to perfusion (high V/Q alveoli) have lower CO_2 compared to alveoli with low V/Q ratio that would have higher CO_2. As one moves proximally in the respiratory tract, the concentration of CO_2 decreases gradually to zero. The volume of CO_2-free gas is termed "respiratory dead space" and here there is no exchange of O_2 and CO_2 between the inspired gases and the blood. As the patient exhales, a CO_2 sensor at the mouth will detect no CO_2 as the initial gas sampled will be the CO_2-free gas from the dead space. As exhalation continues, CO_2 concentration rises gradually and reaches a peak as the CO_2-rich gases from the alveoli make their way to the CO_2 sensing point at the mouth. At the end of exhalation, the CO_2 concentration decreases to zero (base line) as the patient commences inhalation of CO_2-free gases. The evolution of CO_2 from the alveoli to the mouth during exhalation, and inhalation of CO_2-free gases during inspiration gives the characteristic shape to the CO_2 curve, which is identical in all humans with healthy lungs. Any deviation from this identical shape should be investigated to

determine a physiological or a pathological cause producing the abnormality.

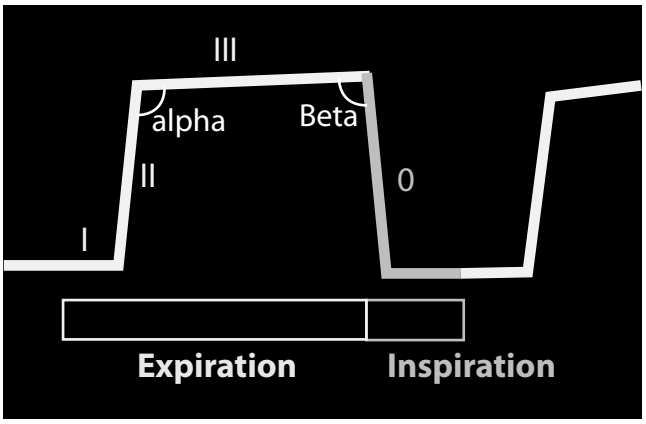
Time Capnograms

A time capnogram can be divided into inspiratory (phase 0) and expiratory segments (Figure 3). The expiratory segment, similar to a single breath nitrogen curve or single breath CO_2 curve, is divided into phases I, II and III, and occasionally, phase IV, which represents the terminal rise in CO_2 concentration. The angle between phase II and phase III is the alpha angle. The nearly 90-degree angle between phase III and the descending limb is the beta angle. For more details on this section: please refer to www.capnography.com terminology section.

The CO_2 concentration reaches a maximum at the end of exhalation. This maximum concentration is called end-tidal carbon dioxide concentration or tension depending on whether it is expressed in fractional concentration or mm Hg. End-tidal carbon dioxide reflects CO_2 concentration of alveoli emptying last. The normal values of EtCO2 are around 5% or 35-37 mm Hg. The gradient between the blood CO2 ($PaCO_2$) and exhaled CO_2 (end tidal CO_2 or $PetCO_2$) is usually 5-6 mm Hg. $PetCO_2$ can be used to estimate $PaCO_2$ in patients with essentially normal lungs.

The three major determinants of CO_2 waveform are cardiac output, ventilation, and CO_2 production. Hypermetabolic states such as thyrotoxicosis or malignant hyperpyrexia are associated with increased CO_2 production and therefore with higher end-tidal CO_2.

Figure 3. Time Capnogram

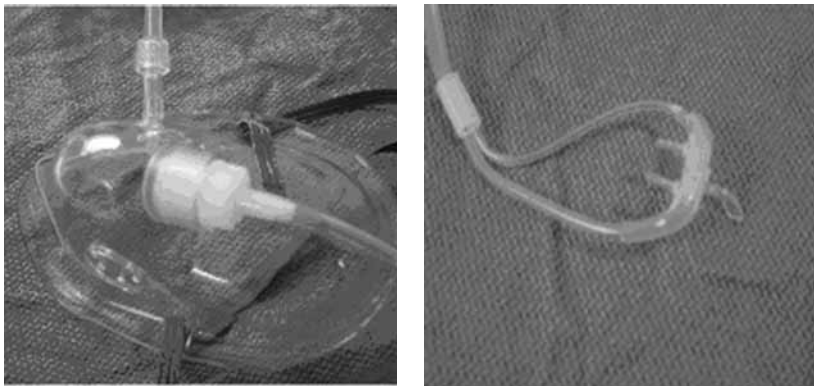


Capnography Sampling Devices

Capnography not only detects abnormalities in ventilation perfusion, such as those resulting from COPD or bronchial asthma, but also monitors $PaCO_2$ indirectly. If the sampling of end-tidal gas is adequate, hypercarbia can be detected from capnography monitoring. In addition, capnography displays abnormal respiratory patterns that may suggest inadequate or depressed ventilation. Adequate sampling can be ensured by several methods and sampling devices (Figure 4).

The capnograms from good sampling devices appear similar to conventional capnograms obtained via endotrachal intubation. However, dilution of expired gases is unavoidable in certain circumstances. Under these conditions, a change from baseline should forewarn of respiratory depression or at least should encourage a clinician to investigate the change in capnograms.

Figure 4. Capnograph Sampling Devices



Summary

An understanding the physiology of oxygenation and ventilation should make it apparent that it is quite logical to monitor not only oxygenation but also ventilation in postoperative patients receiving narcotics for pain relief. Capnography has been used successfully in gastroenterology sedation procedures to detect inadequate respiratory events well before the changes in oxygenation. Using combined technology should allow patients to recover safely in the potentially turbulent postoperative period, without being subjected to the risk of undetected catastrophic respiratory events.

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PROCEEDINGS

Respiratory Depression in PCA Patients: What Continuous Respiratory Monitoring Has Revealed

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Key Points

- *The incidence of respiratory depression in postoperative patients on patient-controlled analgesia (PCA) may be much greater than commonly thought.*
- *The prevalence of respiratory depression with PCA is probably underestimated because of a lack of standard or consistent definitions for respiratory depression, the use of surrogate measures that do not comparably reflect the degree of respiratory depression, and reliance on chart review.*
- *A pilot study of the use of continuous pulse oximetry and capnography to monitor patients with PCA revealed higher rates of clinically significant episodes of respiratory depression and bradypnea than reported in published studies.*
- *Analyzing trends in physiologic responses that precede respiratory depression, such as pain or respiratory depression, may allow the development of heuristic algorithms to aid clinicians in identifying or preventing complications of PCA.*

Patient-controlled analgesia (PCA) is a popular, effective, and widely used method of administrating postoperative analgesia.[1,2] Although the literature suggests the incidence of respiratory depression with PCA is low, e.g., 0.25%,[3] there is circumstantial evidence that PCA presents more frequent and serious risks to patients receiving pain therapy by this modality. The FDA's MAUDE Database for 2004, a voluntary database of problems with devices, includes 22 deaths associated with PCA pumps compared to 16 deaths associated with conventional infusion pumps.[4] The risk of patient harm resulting from a medication error with PCA pumps is 8%, which is 3.5 times higher than the risk of patient harm associated with any other type of medication error.[5] Preliminary data from a study using continuous pulse oximetry and capnometry to monitor postoperative patients on PCA suggest that the incidence of respiratory depression is much greater than commonly thought.

The objectives of this preliminary study were twofold. The first was to measure a true incidence of desaturation and bradypnea in postoperative patients with PCA pain therapy. The second objective was to observe trends in physiologic data obtained (oxygen saturation, respiratory rate, heart rate and end–tidal carbon dioxide [$EtCO_2$]) that preceded clinically relevant respiratory depression and model them to provide predictive and diagnostic information.

After Institutional Review Board approval, 96 adult, post-surgical patients at St. Josephs/Candler Health System in Savannah, Georgia were monitored with oximetry (n=26; Alaris® SpO_2 Module, Model # 8210), capnography (n=53 Alaris® $EtCO_2$ Module, Model # 8300) or both modules (n=28) while receiving PCA (Alaris® PCA Module, Model # 8120). An episode of respiratory depression was defined as an average oxygen saturation (O_2Sat) of less than 90% or a respiratory rate (RR) of less than 8 breaths per minute (bpm) for two or more consecutive minutes, and distinguished from a subsequent episode by an O_2Sat ≥ 90% and a RR ≥ 8 bpm for three or more consecutive minutes. All doses of PCA opioids were automatically

recorded within the same electronic database. The monitors transmitted average, maximum, and minimum values, per minute, to a data server via secure wireless protocol.

Incidence of Respiratory Depression

Analysis of pulse oximetry data revealed that 7% of all individual saturations values were below 90%. As shown in the Table, clinically significant episodes of respiratory depression as measured by oxygen desaturation lasting more than 2 minutes were found in 31% of the patients, with an average of 19 episodes per patient. This is about three times the incidence of 11% found in a meta-analysis of 163 studies on respiratory depression by Cashman.[6] The episodes-per-patient data are of the same magnitude as the 14 episodes per patient reported by Curry.[7] Capnometry data revealed that 7.5% of all individual respiratory rate values were below 8 breaths per minute, and 21% of the patients had clinically significant episodes of bradypnea, which is almost 20-fold higher than reported by Cashman.[6]

The disparities between the results of this pilot study and those of Cashman can be explained by a combination of the shortcomings of our pilot study and flaws in previous studies of respiratory depression. The data from our pilot study were obtained from our data server without clinical correlation between the data and the clinical status of the patients. The exception to this was synchronous data from the infusion device indicating when the patient self-administered a bolus of pain medication. Although our monitor data may suggest respiratory depression, we lack verification of the clinical status of the patient at that time. It is possible that the pulse oximetry probe became partially displaced or the patient repositioned the nasal cannula to eat more comfortably. We made several accommodations to try to minimize this 'artifact.' We imposed an additional requirement for a desaturation or bradypnea to be maintained for greater than two minutes before being counted as respiratory depression, and we employed an averaging filter that would reject spurious single values. In our ongoing study, we do obtain bedside correlations during monitor-alarm conditions, including a sedation scale, since sedation invariably accompanies opioid-induced respiratory depression. Another factor which may influence our results is the presence of two separate audible alarms, one on each monitor, which may arouse the patient. This, however, would bias our data toward underestimation of the incidence of respiratory depression.

Close review of published studies documenting the incidence of respiratory depression with PCA reveals several flaws that may contribute to an underestimation of the prevalence of respiratory depression with PCA. There are no standard or consistent definitions for respiratory depression. Although most studies use desaturation and bradypnea (low respiratory rate) as surrogate measures for respiratory depression, thresholds for the degree of desaturation and bradypnea that constitutes respiratory depression vary and many studies ignore important qualifiers of the degree of respiratory depression such as duration, depth, and outcome. Studies examining the incidence of respiratory depression also combine surrogate measures that perhaps should not be combined because they are not comparable in terms of the degree of respiratory depression. For example, many patients may experience brief periods of desaturation or apnea, which are of little clinical consequence when not persistent or recurrent. The use of naloxone, an opioid-reversal agent, or positive pressure ventilation, which are also used as surrogate measures

Table. Pilot Data December 2004 - January 2005

	Patients on each monitor	Hours	Patients with respiratory depression	Mean episodes/pt	Cashman data
Oximetry $SpO_2 < 90\%$ >2min	58	4420	**18 (31%)**	19	11.5%
Capnometry RR<8bpm >2min	91	4425	**19 (21%)**	11	1.2%

of respiratory depression, portend a much greater degree of respiratory compromise, and should not be combined with desaturation and bradypnea data.

The most glaring deficiency in studies of respiratory depression, however, is the reliance on chart review (mostly retrospective) for acquiring the respiratory rate of patients on PCA who experience respiratory depression. Respiratory rate is typically measured and documented no more than every two hours on patients receiving PCA, introducing a large sampling error to the data. Pulse oximetry, which provides continuous data when in use, is also documented only sporadically. Curry found that only 9 of 493 desaturation events below 88% measured by continuous oximetry were documented on the patient record.[8] It has also been demonstrated that in the setting of patients receiving conscious sedation for procedures, manual assessment of respiratory rate, as commonly done by nurses on the hospital ward, is woefully inaccurate when compared to capnometry or impedance plethysmography.[9, 10]

It appears that the incidence of desaturation and bradypnea is much greater than reported. The significance of these data with regard to adverse patient outcomes will be unclear until we complete the study using clinical correlation.

Predicting and Diagnosing Respiratory Depression

Pain is often characterized by an increase in heart and respiratory rate. Oxygen saturation may or may not change, and $EtCO_2$ often decreases as patients become tachypneic and take shallower breaths, which are less representative of alveolar $EtCO_2$ concentration. A 24-hour graph of the condensed physiologic data of a patient with PCA therapy (Figure 1) shows a remarkable correlation between dramatic increases in their heart rate (spikes) and their self-administration of a pain bolus (upward arrows). In one such event (Figure 2), the expected physiologic response to pain monitored precedes the use of the pain button (bottom graph). Thus, it seems likely that analyzing the trends in physiologic responses that precede significant clinical events, such as pain or respiratory depres-

Figure 1. 24-Hour Condensed PCA Record

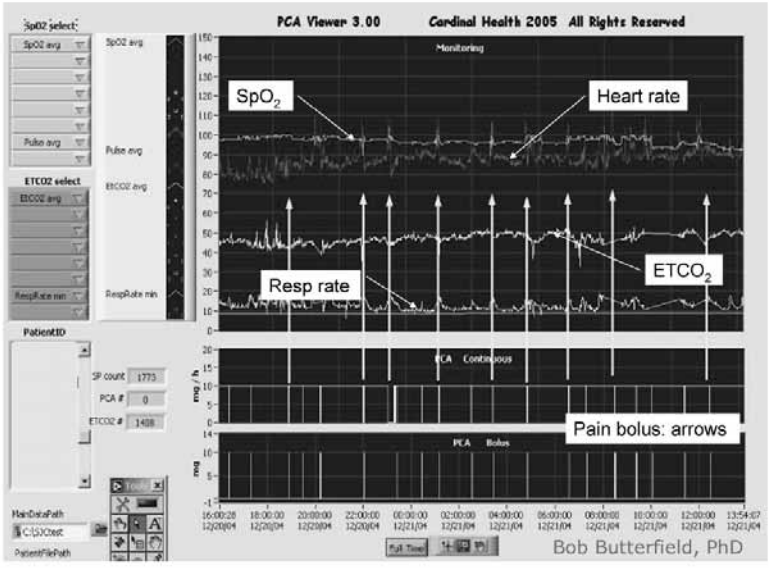
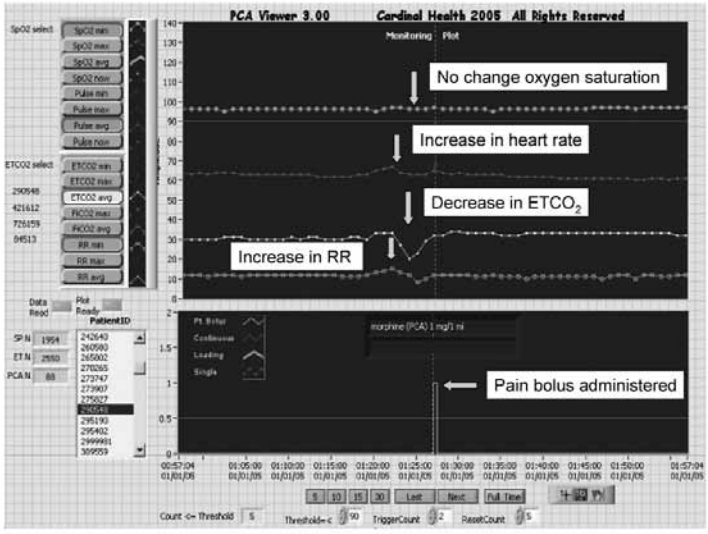


Figure 2. Close-Up: Single Pain Event



sion, may allow us to devise heuristic algorithms that have prognostic value in predicting the occurrence of these events. Integrating these algorithms into the monitor alarms will aid clinicians in preventing and diagnosing complications of PCA.

Summary

Recent literature suggests that more aggressive and appropriate of treatment of pain resulting from the JCAHO mandate to include pain as a fifth vital sign (http://www.jcaho.org) may have further increased the incidence of opioid-induced respiratory depression. There is a need to accurately quantify the risks of PCA and improve the monitoring of these patients to increase the safety of this popular pain therapy modality.

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PROCEEDINGS

PCA Administration: Failure Modes and Effects Analysis Identifies Opportunities to Improve Best Practice and Prevent Adverse Drug Events

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Key Points

- *An analysis of adverse events reported in Stanford's new electronic Patient Safety Network revealed a previously unrecognized pattern of widely distributed, low-frequency, intravenous patient-controlled analgesia (IV PCA) problems.*
- *A Failure Modes and Effects Analysis (FMEA) was used to identify and rank probable causes, and a multidisciplinary team developed and implemented solutions that significantly reduced the number and frequency of adverse events.*
- *The experience reinforced the value of electronic adverse event reporting and tracking, the use of a FMEA problem-solving approach, and the importance of multidisciplinary teams in solving problems and implementing solutions.*

Introduction

Intravenous patient-controlled analgesia (IV PCA) for opioid administration allows patients in pain to self-administer smaller, more frequent doses of an analgesic as needed with preset control limits.[1] Studies have shown that patients using PCA have improved pain control and reduced total opiate consumption.[2,3] At Stanford Hospital and Clinics, IV PCA is the standard for parenteral opioid administration for pain control after many types of surgery. In 2004 over 40% of patients used IV PCA. Despite the effectiveness of PCA, significant hazards are associated with this method of opioid administration.[1,4-13]

Stanford Hospital and Clinics use of the online adverse event reporting system, Patient Safety Net (PSN), provides a shared database that allows trend analyses and comparisons across the hospital and within the aggregate data from 90 academic health centers. In only three months of PSN implementation, data analyses performed by Stanford's quality managers suggested a small but widespread problem with IV PCA. To confirm the problem, the quality manager conducted chart reviews and an in-depth, retrospective analysis of an entire year's data, which included nine months of pre-PSN data collected on paper forms.

PCA Programming Errors: The Missing Decimal

The analysis revealed 56 incidents involving IV PCA over 12 months. The drugs most frequently involved were morphine sulfate (40%), fentanyl (20%) and hydromorphone (16%). The most frequent cause of these incidents was programming errors (71%).[14]

A typical programming error was a missing decimal: an order was written for a 0.5 mg/mL bolus dose of morphine, but the PCA device was inadvertently programmed for 5 mg/mL. Depending on the location of an incorrect decimal, in the 56 incidents the result of such errors was either overmedication (75%) or undermedication (25%).[14]

Improving PCA Medication Safety

To improve IV PCA medication safety, Stanford's Quality Improvement and Patient Safety Department initiated a performance improvement project, which was approved by Stanford's Quality Improvement and Patient Safety Committee (QIPSC) and Medical Board. Led by a quality manager, the interdisciplinary project team included pharmacists, nurse managers, staff nurses, a physician, a

clinical nurse specialist, and a representative from clinical engineering. After reviewing the 12-month report, the team conducted a failure modes and effects analysis (FMEA) to examine every step of the PCA process and identify possible failure modes, causes, and effects. The FMEA identified four areas as being in need of change to reduce the occurrence of IV PCA-related ADEs.

Prescribing. Causes of wrong-dose prescribing errors (loading, PCA constant infusion, lockout interval, route, frequency) included knowledge deficits, wrong selection from drug list, drug information not available, and no standard protocol for IV PCA dosage or concentration. Another cause was the failure to include a patient's age on the computerized prescriber order entry (CPOE) system medication order screen. Errors could result in an overdose, underdose, or ADE.[14]

Dispensing. Errors in dispensing resulted from misunderstandings due to illegibility, ambiguous abbreviations, trailing zeroes, naked decimals, verbal orders, look-alike drug names or unclear order copies.[14]

Administration. PCA pump misprogrammings could result from equipment flaws, lack of standard concentrations, unnecessary variability in products used, knowledge deficit, confusion between units of measure (e.g., mg vs. mcg), and mechanical failure.[14]

Monitoring. Insufficient monitoring of the effects of PCA could result from excessive workload, knowledge deficit, lack of consistent monitoring parameters or standard protocol, or ineffective communication between clinicians.[14]

After identifying that these four areas needed improvement, the team identified specific actions to be taken to reduce failure modes related to IV PCA (Table).

Implementation

After the best practice improvement plan was developed by the team, the stakeholders needed to approve and sign off on each new change before its implementation. Clinician education and training were important. The proposed changes and the rationale were present both to the Stanford Nursing Education Council and to educators on the nursing units. Trainers then communicated the new protocols and double-check policy to all staff. Physicians and pharmacists were introduced to the new order sets and protocols through a published CPOE update, articles in the pharmacy and medical staff newsletters. Flyers describing all the changes also were posted in the physician workrooms on each nursing unit.[14]

Results

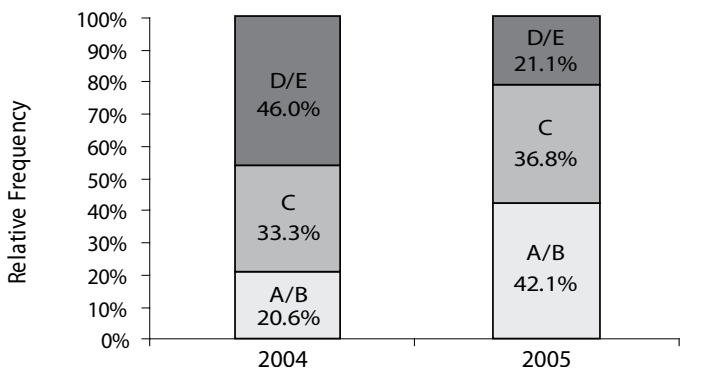
With the exception of acquiring new PCA pumps, all recommended actions were implemented within one year of discovering the problem of medication errors related to PCA.[14]

After implementing the performance improvement plan, PCA programming errors were reduced. Administration errors decreased by 43%, and programming errors decreased by 64%.

Harm severity was also reduced (Figure). Administration errors were most frequently Harm Scores D and monitoring errors, most frequently A/B.

Monitoring of all PSN/PCA events by the Quality Improvement and Patient Safety Department continues. PSN events that contain the word "PCA" are automatically flagged. Data are reviewed with nurse managers and the pharmacy manager, and quarterly reports are made to the Nursing Quality Council and the Quality Improvement and Patient Safety Committee.

Figure. PCA Incident Report Harm Scores*



* University Health System Consortium Patient Safety Net Harm Scores: Category A: Unsafe Conditions/ Potential Harm; Category B: Near Miss/No Harm; Category C: Reached Pt/No Harm; Category D: Reached Pt/Monitor/No Harm; Category E: Temporary Harm.

Lessons Learned

- Online data collection and reporting improves data access, cross-unit data aggregation, and cross-institution comparisons, all of which are crucial for identifying low-frequency, hospital-wide events and trends.
- FMEA provides an excellent model to analyze steps in the medication use process and rank-order action steps to address problem identified.
- Implementation of a best-practice improvement plan such as that described in this article can result in a significant reduction in PCA-related errors.
- Key components in the PCA medication safety plan developed and implemented by Stanford Hospital and Clinics included the establishment of policies and procedures that provided a standardized dosage protocol, preprinted order sets for PCA patients, a double-check process for drug administration, documentation of respiratory rates every 2 hours, and continuous oxygen saturation monitoring.
- For general problem-solving, incorporate stakeholders and communicate!

Conclusions

IV medication errors are associated with a high risk of harm,[15] and PCA-related errors have even greater harm potential than those related to large-volume infusion pumps.[13] Thus, PCA-related medication errors need to be given a high priority in safety improvement efforts. At Stanford Hospital and Clinics, the use of an online adverse event reporting system and FMEA identified low-frequency problems related to PCA administration of opioids. Within one year of problem identification, a multidisciplinary team developed and implemented a process improvement plan that led to a significant reduction in PCA-related medication errors, thus improving patient safety and quality of care.

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Table. FMEA Action Steps for Best Practice Improvements: Develop and Implement[14]

Prescribing. A standardized hospital-wide PCA dosage-prescribing protocol that allows for physician- or pharmacy-requested exceptions. Add patient's age to CPOE order screens.

Dispensing. Standardized PCA order sets–preprinted sets for paper-based nursing units and CPOE order sets–to address problems related to illegibility and ambiguous abbreviations.

Administration. Double-check policy that follows JCAHO National Patient Safety Goal 3 for improving the safety of high-alert medications: a second nurse must independently check and sign off on every IV PCA pump change, including all programming, syringe changes, changes in rate or dose, and at shift change.

Assessment and Monitoring. A hospital-wide nursing protocol that requires continuous monitoring of oxygen saturation and documentation of IV PCA patients' respiratory rates every 2 hours and that includes standing orders for nurses to administer opiate antagonists in cases of respiratory depression or somnolence.

New Technology. Determine the feasibility of acquiring "smart" IV PCA pumps to provide safety alerts when infusion parameters exceed pre-established limits, easier programming, clearer display, and CQI logs to provide data for best practice and quality improvement efforts.

PROCEEDINGS

Using Smart Pumps and Continuous Respiratory Monitoring to Reengineer the PCA Process

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Key Points

- *Opioid-related respiratory depression from patient-controlled analgesia (PCA) can be fatal, and identifying patients at increased risk is difficult.*
- *Causes of over-sedation include pump misprogramming and inadequate patient monitoring.*
- *Reengineering the PCA process to include the use of smart pumps and continuous respiratory monitoring, particularly non-invasive capnography, can help to improve the safety of PCA therapy.*
- *Respiratory therapists are an essential member of the multidisciplinary team to set standards, provide education to physicians, nurses and pharmacists, and be the "first responder" for patients receiving PCA therapy.*

A critical issue with the use of patient-controlled analgesia (PCA) is the potential for respiratory depression that can result from over-sedation. Identifying patients at increased risk related to PCA therapy is difficult: individuals vary greatly in their response to opioids, and patient status can change quickly.[1-8] If detected early, most cases of opioid-induced respiratory depression can be treated with naloxone. Severe cases, however, can be fatal.[9,10] FDA data suggest that the risk of death from an adverse event with a PCA pump is at least 10-times greater than with large-volume pumps.[8,9]

Causes of over-sedation include "PCA by proxy," inadequate patient and clinician education, improper patient selection, prescribing errors, pump misprogramming, and inadequate patient monitoring.[1-4] St. Joseph's/Candler Health System (SJCHS) sought to address all these causes as part of our continuing patient safety improvement efforts. In particular, to improve the safety of PCA pump programming and patient monitoring, we reengineered our PCA process through the implementation of smart pumps and continuous respiratory monitoring of both SpO_2 and $EtCO_2$. Until recently the use of continuous capnography has been limited mostly to critical care settings, since such monitoring required that a patient be intubated. The availability of modified cannulas (Figure 1) now expands capnography use beyond the previous settings to include non-intubated patients in general-care units.

SJCHS was the first health system in the United States to implement non-invasive capnography to monitor patients receiving PCA therapy.[7] In this article we describe the PCA process before and after the implementation of smart pumps and continuous oxygenation (SpO_2) and ventilation ($EtCO_2$) monitoring, the benefits of using these technologies, and the new role of the respiratory therapist in the PCA process.

Implementation

SJCHS is a 644-bed, tertiary-care health system with patient volume of 32,942 discharges annually. Patients requiring PCA pain management include oncology and sickle cell patients, post-anesthesia patients, and those with acute pain. A modular "smart" intravenous (IV) medication-safety system for large-volume and syringe pumps was implemented

hospital-wide in October 2002. The IV safety system helped avert significant IV medication errors with severe harm potential;[11] however, additional technology was needed to help protect patients receiving PCA therapy.

SJCHS became a beta site to evaluate the new PCA, SpO_2 and $EtCO_2$ monitoring modules. Safety software was customized so that the respiratory monitors alert whenever pre-established limits are exceeded.[7] Based on six months' evaluation, continuous respiratory monitoring of each PCA patient was made the standard of care. PCA and respiratory monitoring modules were implemented hospital-wide in June 2004.

Pharmacy and Nursing originally planned to purchase a pulse oximetry module for each PCA module. However, during our initial beta trial of PCA monitoring, when a trained respiratory clinician viewed a patient's trend data, it was noted that the patient's $EtCO_2$ would trend upward; however, the SpO_2 would remain the same or demonstrate a slow trend downward.

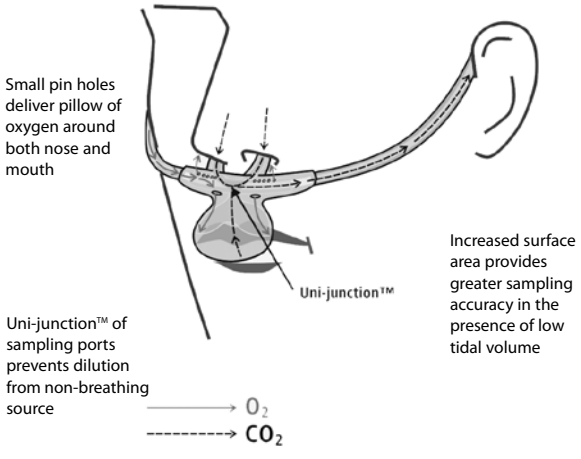
Our beta test experience showed that $EtCO_2$ monitoring was the earlier indicator of respiratory depression in patient's receiving pain management via a PCA device. This experience underscored the difficulty of predicting patient response to opioids and showed capnography to be the "first indicator" of opioid-related respiratory depression. A capnography module was purchased for each PCA module, and pulse oximetry modules for use with selected patients.[7]

Impact on the Medication Use Process

All steps in the medication use processes (procurement, prescribing, dispensing, administering, and monitoring) were affected by the introduction of PCA technology with continuous monitoring. The issues related to procurement were minimal and are not discussed in this paper.

Figure 1.

Non-Invasive Capnography:
CO_2 Sampling/O_2 Delivery for Non-Intubated Patients



Prescribing

Before implementing PCA with respiratory monitoring on the same platform, an order for PCA was generated by an anesthesiologist, surgeon, or internal medicine physician. Anesthesia services managed the PCA for a large number of the post operative patients and provided a pain management nurse specialist who assessed patients managed by the anesthesia service. This nurse supported the unit-based nurses who routinely monitored PCA patients managed by anesthesia and other physicians. Standardized order forms were used to communicate most of the orders, including parameters for administering the PCA and intermittent monitoring of vital signs. Interventions for managing overdose were also outlined on the form. At SJCHS the concentrations are standardized to a single concentration for each PCA medication.

After implementing PCA with continuous monitoring, an unexpected change in process occurred almost simultaneously: the anesthesiologist stopped ordering and managing PCA. Several factors contributed to this decision, including the recognition of the value of continuous respiratory monitoring to reduce adverse drug events. Based on findings from continuous $EtCO_2$ and SpO_2 monitoring, order sets were revised with additional guidelines for the nurse. Respiratory therapists were added to the order set as a resource. The same standardized medication concentrations were maintained.

Dispensing

There was minimal impact on the dispensing phase of the process. The only change was to adjust the pocket size of the automated dispensing cabinet to accommodate larger packaging of syringes after implementing the new technology.

Administration

During programming of the PCA pump, safety software in the smart infusion system verifies that the concentration is the one that is available in our institution. The software also verifies that the PCA dose, continuous dose, clinician bolus, loading dose, and 4-hour maximum dose are within the pre-established safe limits in the drug library. Programming that exceeds institution-established limits results in an alert that must be addressed before infusion can begin. The nurse reviews the order and may proceed with programming or correct the programming if an error has occurred. In this way, the infusion safety system provides another "check" of all programming of PCA pumps.

Safety software logs capture data on alerts (when dosing exceeds established parameters) and averted errors (when an alert results in reprogramming or cancellation of an infusion). Review of continuous quality improvement data collected demonstrated a reduction of eleven programming errors each month. The Table shows examples of prevented programming errors.[7]

Monitoring

The addition of continuous monitoring of $EtCO_2$ and SpO_2 adds valuable clinical information to the vitals signs and intermittent oxygen saturation monitoring assessed prior to implementation of the technology. Having both infusion and monitoring on the same platform provides up to 24 hours of PCA dosing history with corresponding monitoring values from either SpO_2 and/or $EtCO_2$ (Figure 2). This aids in review of a patient's physiological response to PCA therapy and helps provide an early warning to potential respiratory depression for a patient.

New Role of Respiratory Therapist

Early during the implementation of continuous respiratory monitoring for patients receiving PCA we realized the need to incorporate respiratory therapy as part of the multidisciplinary team for PCA medication safety. As part of the decision-making process, respiratory care was asked which parameter, SpO_2 or $EtCO_2$, would be the better indicator of respiratory depression in patient's receiving pain management. Based on experience and published reports,[12-15] respiratory care believed that the breath-to-breath detection of $EtCO_2$ would give the staff the earliest sign of respiratory dysfunction. SpO_2 was thought to be a late indicator of respiratory depression, because changes in oxygenation may be delayed, especially in patients receiving supplemental oxygen.

The respiratory care team was also involved in developing a patient-selection algorithm to determine which

Figure 2. PCA, SpO_2 and $EtCO_2$ Trending Data: Representative Examples

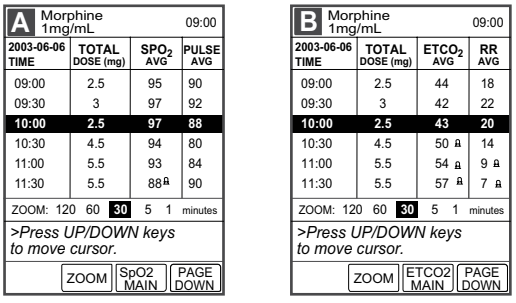


Table. "Smart" Alerts Result in Programming Changes to Avoid Errors: Representative Examples[17]

Location	Drug	Parameter	Initial	Reprogrammed
Med/Surg	Hydromorphone	PCA Dose	3mg	1mg
Med/Surg	Hydromorphone	Continuous Dose	30mg	1mg
Crit. Care	Morphine	Lock Out (time)	30 min	15 mins

patients would require $EtCO_2$, SpO_2, or both types of monitoring. The algorithm was based on patient's body mass index (BMI), medical history, and current disease process. Patient suffering from obstructive sleep apnea (OSA) and those with a high BMI were thought to be at increased risk of respiratory depression because of their tendency to experience apnea. The respiratory therapist also worked as part of the PCA monitoring team to revise our health system's PCA policy, which now requires that respiratory therapy staff evaluate every PCA patient at least once per 12-hour shift.

Education was an important element in the success of the program, because the new technology was being introduced to general care areas where the nursing staff was unfamiliar with monitoring $EtCO_2$. The Respiratory Care education coordinator worked with a Clinical Nurse Specialist to educate the nursing, pharmacy, and respiratory staffs. The education sessions successfully provided the basics. Additional education occurred at the patient's bedside when the respiratory therapist would evaluate PCA patients. This evaluation includes respiratory rate, respiratory effort, $EtCO_2$ trend, SpO_2 trend, alarm limits, and any changes in the patient's status.

During continuous respiratory monitoring, if an $EtCO_2$ module alarms only rarely, a nurse will respond by arousing and stimulating the patient to take some deep breaths. If the alarms are frequent, the nurse will arouse and stimulate the patient, verify that the monitoring unit is operational, and, if so, contact respiratory therapy. The respiratory therapist and the nurse decide the best course of action. If the situation is not readily corrected and a patient continues towards respiratory failure, a physician is consulted regarding further treatment and possible transfer to an ICU. Adding Respiratory Care to the team thus introduced a bedside $EtCO_2$ monitoring expert to our PCA safety program.

Using this technology allows Respiratory Therapy to care for patients more efficiently, so that existing staff can oversee more patients. Earlier identification of respiratory distress allows Respiratory Therapy to intervene before a patient's condition becomes serious, which saves time and increases the likelihood of a positive outcome.

Conclusions

Early intervention to avert respiratory depression is critically important to improving patient safety, quality of care, and optimal use of resources. The combination of PCA, SpO_2 and $EtCO_2$ monitoring modules on a single platform at the point of care provides accurate, non-invasive continuous respiratory monitoring for patients receiving PCA therapy. Implementing this system helps clinicians make more informed decisions about the care of patients receiving PCA.

Respiratory Therapy's role is an important factor in creating a successful PCA-respiratory monitoring program. At SJCHS we included respiratory therapists to help set standards; provide education to physicians, nurses, and pharmacists; and to become the "first responder" to improve the safety of pain management using PCA. Nurses and respiratory therapists see continuous $EtCO_2$ and SpO_2 monitoring as valuable assessment tools. Continuous respiratory monitoring allows early intervention and reduction in untoward outcomes.

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Philip J. Schneider
MS, FASHP, Moderator

The roundtable discussion brought together the speakers and invited guests to discuss the content of the presentations to determine if consensus could be reached on new practices for sedation and the use of patient-controlled analgesia (PCA). It was agreed that, if not properly used, both of these therapies can result in patient harm, and that new drugs and technologies are needed and have the potential to improve efficiency, effectiveness and safety. Beyond these broad principles, there was lively discussion on several topics that affect the use of sedatives and PCA – topics where consensus was not reached. These included the ability to standardize sedation and pain management treatments, methods for and the importance of patient monitoring, the impact of the process of care on patient outcome, the need for evidenced-based medicine to define practice, healthcare workforce issues, and the impact of new technologies.

Pain Management

Let's start the discussion by sharing experiences with some of the newer approaches to pain management – both the drugs and the technology. Are there ways to improve pain management and safety at the same time?

"I am bit concerned by what I hear about opiates. We use a multimodal approach to pain management in the standards of care for PCA, and it starts in the OR. We start with paracetamol, then for Step 2 use NSAIDS, and then go to Step 3 with PCA. A scheme is needed for the use of PCA where you cover all these steps in a multimodal approach. Fewer opiates are used in our institution compared to what I heard at this conference. Perhaps the multimodal approach is the way to go."

Michel M.R.F. Struys, *MD, PhD*

"I agree with the multimodal approach toward pain management. JCAHO, with their fifth vital sign for pain has got the snowball rolling down the hill, and it's rapidly turning into an avalanche. Recent published reports suggest side effects with opioids are increasing. Our opioid use is increasing and will be increasing, and in this conference, we need to address this issue. The Europeans are more advanced in the use of multimodal therapy. In this country, the emphasis on proper pain management and the consequences of using opiates is so well-established and so effective, that I think that's going to be where we're going to be in the short-term. This conference needs to address the short-term. Addressing a long-term objective is also, of course, the right thing to do."

Frank Overdyk, *MSEE, MD*

"With multimodal pain management, everything from clonidine to gabapentin is used. The question is why should we spend $12.00 on an NSAID instead of spending $0.46 on an opioid to get equipotent analgesia? Because of the cost difference there is often a tendency in the community to just give more opioids to get to the same level of pain control. However, we know that limiting the amount of opioids one gives both limits the well known side effects(eg puritis, illeus, respiratory depression) and the lesser known side effects such as opioid hyperalgesia and depressed immune function. In general, most of the discussion of pain management has been about parenteral PCA administering opioids, but we use a lot of PCEA and PCA peripheral nerve pumps, as well. These are key components to successful multi modal therapy, sometimes we mix these modalities though we try to refrain from our patients' having two buttons. If you address PCA, you also have to address all types of patient administered routes and drugs, whether administration is neuraxial or perineural. I'm a little surprised that no one has mentioned ketamine in a PCA format. We use ketamine as a constant infusion and for all sorts of procedural indications."

Ian H. Black, *MD, MAJ, MC*

"I'm not a fan of mixing different analgesics together and I think it's a dangerous thing to do. There are not only issues of pharmacological compatibility and stability in solution, there's lots of other issues. It would be very rare for two drugs that are mixed to have a similar time course, and the positive

effects that you are looking for and their adverse effects will all be slightly different and have a slightly different time course. Remifentanil and propofol are often mixed in a syringe, but I worry about it. If the patient needs to get a bolus dose, the propofol dose will be adequate, but the remifentanil will be too high. From my understanding, if you put two drugs together into a syringe, you've created a new drug, and so there are liability issues that you have to think about."

A. R. Absalom, *MBChB, MD, FRCA, ILTM*

"The argument that opioids are better than NSAIDs based on costs is not the most important one. With NSAIDS, the adverse effect profile is worse than opioids, including problems with renal failure. We were very aggressive in using NSAIDs in our cardiovascular surgical patients, and saw an inappropriately high incidence of post-operative renal failure. When we moved away from NSAID use, that went away. Now, that's not a controlled trial, but that was our observation. I also think NSAIDS are as not as universally efficacious as opioids."

John Englebert, *PharmD*

Patient Monitoring and Safety

Do we think that an envisioned future would involve having end-tidal CO_2 monitoring for patients who receive PCA with opiates? I'm hearing from the nurses that there's a need to monitor patients receiving opiates more closely and in the med-surg areas opiates aren't going away.

"My practice is part of a pain management team and we tend to see the more difficult-to-treat pain patients. I still don't know if we have a tool that's going to help us use opioids more safely. I have no arguments at all with the use of the multimodal approach and trying to use less opioids. But the reality is they still remain a mainstay of pain management. I also think one of the things that we are compromising is pain control. Because we are hesitant to escalate opioid doses, we do a very poor job of treating pain, primarily because of the fear of respiratory depression.

"If we have a tool that can allow us to detect respiratory depression and provide an alert when the patient is getting into trouble, it will be tremendously useful. I'm excited about it, if we can find the technology. I will say after listening yesterday, though, I don't know if we're there. It looks like we have a tool, but I'm just not convinced that the current technology can clearly discern issues with opioid use compared to other respiratory issues."

John Englebert, *PharmD*

"In today's legal climate, some of our anesthesiology colleagues are not willing to do some of these things because there are legal and reimbursement issues. In the last four years we've created an environment where we were told, 'There is no opioid ceiling, the only way you know what you need is by giving what you need.' Opioid use is now being encouraged for pain management in primary care settings. These patients are now receiving much higher doses of opiates. As a result, they have tolerance, dependence, addiction issues, and need higher opiate doses. Although we can't get away from using opioids in these types of patients now, my concern is using them safely.

"Two concepts that I have been fascinated about at this meeting are

targeted-concentration infusion (TCI) technology and capnography with PCA pumps. Something that I see in my hospital is a significant use of Narcan to reverse opiate toxicity. The use was different in our orthopedic hospital population vs. the non-orthopedic population. We've always pushed better pain control for the orthopedic patients, because many of them are on opioids. They become sedated, then they awake and the pain team gets called. There was a significant use of Narcan. It was being administered to patients when the respiratory rate was 8 per minute. Maybe these patients were well-narcotized and sleeping well. Narcan should not be routinely used for a respiratory rate of 8. What was the oxygen saturation in these patients? No one knows because we don't have enough continuous pulse oximetry devices to monitor these patients. The pain committee recommended that patients on PCA pumps, especially those people on a continuous dose, must have pulse oximetry. I also think that it's important to consider the use of capnography for these patients."

Gladstone C. McDowell II, *MD*

"Clearly, capnography has value. Its use is a standard in the operating room. It's not the value of capnography, *per se,* but the value of capnography under the conditions of PCA that's the question. How many patients, in the middle of the night, will pull it off, and you'll have spent your $350,000, have your disaster, and still pay up? We don't know whether capnography with the type of technology that is presently available is going to make a difference. Clearly it gives you information, but if you don't use that information, it has no value and may cause harm. ASA has now mandated that monitors be provided with alarms that cannot be switched off. Don't just ask, is capnography valuable and should it be mandated? Is capnography valuable with the technology you have under the set of circumstances you have with PCA? If we can answer that question, 'Yes,' then it should be a standard of care. We are nowhere close to that yet, in my opinion."

Peter Glass, *MD*

"Five years ago, there was no monitoring for procedural sedation cases because they did have pulse oximetry available. Even with pulse oximetry, patients would develop respiratory depression in procedure areas like gastroenterology. There have been studies of procedural sedation showing that capnography was able to detect hypoxia early. So it should also follow that there would be a similar pattern for the treatment of postoperative pain.

"We need to look for end points that are likely to produce a disaster if uncorrected: for example, a pulse oximetry measurement of less than a certain number, or an end-tidal CO_2 greater than a certain number, or a critical number of apneic attacks. Is there any reliable method of monitoring these patients? Probably, but it is not yet proven. End-tidal CO_2 monitoring is available but it has not been proven in any studies. We must have a multi-center trial to determine the end points that are likely to result in hypoxia, if uncorrected. Without that, I simply say you probably will have to wait for a few more years before this thing gets finalized."

Bhavani Shankar Kodali, *MD*

Process of Care

Do we need to have pain services? There are many people here who probably would advocate them, because they're running them. Or is the technology going to make it possible for us to take care of patients without specially trained clinicians? Are we putting too much emphasis on technology and forgetting common things like clinical symptoms of toxicity?

"Most of our experience with PCA is in med-surg and orthopedic patients. We have very little PCA experience in the ICU. We're using the end-tidal CO_2 in med-surg and orthopedics, not very much in OB, because OB patients don't typically have a PCA device. We have not done clinical trials. We do plan to look at the incidence of respiratory depression with PCA. Our experience has shown that we are identifying people with respiratory depression earlier, we are treating them with much less aggressive intervention, stimulation, re-positioning, minor dosage adjustments, and being able to maintain effective pain control in this patients. There is a void in education of physicians and nurses related to end-tidal CO_2. That's why we have respiratory therapists on our team. They are already experienced and already very knowledgeable."

Carolyn Williams, *BSPharm*

"Just a few years ago in Oregon, based in large part on the medical community's failure to treat pain effectively, the citizens passed a 'death with dignity' statute, physician-assisted suicide. I think the medical community looked at that and began to treat pain better, at least in some areas. But as we treat pain better, the unintended sedation becomes a side effect of that. At least in our facility, we looked at that rather aggressively, and we have protocols now that require specific monitoring and specific credentials if you're going to be sedating patients. Anybody who transports or cares for a patient that is getting pain medication has to have basic sedation credentials. Every year, they are trained in basic airway management, how to give help if needed, and how to assess their patients. That even includes the radiology transport staff. If you're going to be sedating a patient procedurally, you need advanced sedation credentials, and the training for that is a bit more intensive. The people who are monitoring procedural sedation patients have to have advanced sedation credentials. The people who are administering the sedation also have to have the credentials. To maintain those credentials, they have to do so many procedures every year. That has worked very well for us.

"Since we have begun monitoring more closely, our incidence of adverse events has decreased and our monitoring criteria also improved. The monitoring criteria are based on the patient's ASA scores and their level of sedation. For example, if a patient is at our score of level 3 sedation and they are an ASA of 3, they would need significantly more monitoring than if they started with an ASA score of 1. In the cardiac catheterization lab, where sedation procedures are used for prone patients over a significant period of time, end-tidal CO_2 monitoring is used as a part of the sedation procedure. In more than one case, an event has been detected before it escalated."

Pam Almandinger, *RN*

"Twenty years ago pain teams were taking care of everything: PCA, epidurals, peripheral nerve blocks. Because of the huge numbers of PCA patients and the apparent safety of PCA, a slightly different model has emerged. We thought we had the answer, but at this meeting and elsewhere we're hearing that respiratory depression is extraordinarily common among patients who are receiving PCA. So we've got two standards of care: In the operating room, where the incidence of respiratory depression and unintended hypoxemia is infinitesimally small, we mandate pulse oximetry and end-tidal CO_2 monitoring. On the ward, where adverse events are apparently more common, we don't have any such rules.

"I think that we can improve pain management by using multimodal pain management, but PCA is not going to go away. In fact, there are several forces promoting PCA over multimodal therapy. In our institution, because of the increased use of anticoagulants, we probably will never use a parenteral COX-2 inhibitor, and a large number of patients will have to rely on opiates."

Richard E. Moon, *MD, FRCPC, FACP, FCCP*

"Because of the way pain services were in the 90s, we would order close monitoring of sedation and respiratory status for patients with epidural analgesia. However, today with PCA, after four hours or so of close monitoring, vital signs and sedation levels are checked infrequently, perhaps every 4 hours. I've always said we need closer monitoring, and people fight me on that everywhere I go. I don't know why. But the first 24 hours when patients have anesthesia on board and are adjusting to the opioid and use of PCA, they need to be monitored more closely.

"I want to say one other thing on behalf of nursing. Part of the problem is also that nurses are not empowered to make decisions when a patient is sedated on PCA on the med-surg floor, for example, to back off on the dose. I don't have a problem calling a physician; however, I'm going to do everything else I can in the middle of the night first to avoid calling him or her. So there have to be options for the nurse to keep these patients safe. Nurses are capable of making decisions to back off on the dose before patients get into trouble."

Chris Pasero, *RN, MS, FAAN*

Evidence-Based Medicine

Dr. Stoelting discussed thinking about ways to define practice without relying on scientific evidence. This approach has been suggested for patient safety practices. There are some ways that we can generate expert opinion about practices without scientific evidence. The NIH does this through consensus development conferences, for example. Dr. Stolting described a four-step process to establishing best practices in the absence of double-blind, randomized, control studies. One was a mandate, second was consensus, third was advocacy, and the fourth was the establishment of standards. Is there agreement on this?

"I respectfully disagree. If you think about medicine, there are a lot of interventions that make sense. You can know the pharmacology, physiology, and imagine what could or should be an effective treatment. Consider the area of cardiology, which has a good history of evidence-based medicine. Drugs like calcium channel blockers, magnesium, nitrates: all make sense to use in an acute myocardial infarction. When you do a controlled trial with thousands of patients, they don't work. You might even imagine, it makes such utter sense to monitor people when you're giving them aggressive sedation or PCA. I spend most of my clinical time monitoring patients and I feel very confident that they're safe, because I'm there monitoring them. So I believe strongly that monitoring is good. But, at the same time, I also have an open mind, because the devil is in the details.

"You don't just put a monitor on and think everything's good, because a monitor by itself doesn't improve patient outcome. Someone has to do something with the monitor. Someone has to respond to it. Now, of course, the pump can have a pause protocol, but what is the best respiratory rate to use to initiate the pause? What's the effective limit? If you don't do a study, and you just advocate something because it makes sense, you have the potential to do harm. You have the potential to spend a great deal of resources buying new monitors and then not knowing the right way to use them. You need nursing education, policy and procedures. How do you respond to these monitors? If you just say, 'This is what we should do,' without investigating it, without doing studies, you have the potential to waste resources, where they could be spent otherwise to benefit patients. So, I think the idea of advocating this is the right thing to do; doing so without a study is premature."
James Paul, *MD*

"I'm responding to two issues which you've both brought up. First, I am going to take an in-between view in terms of evidence-based medicine. I take the model of a predilection for bombs. We don't explode atomic bombs anymore, but we understand what the impact is. You don't have to deal in outcomes that are very rare. You can't always have evidence-based medicine based on simple clinical trials, but you can do a variety of things to understand what the outcomes may be. I believe we need an evidence base, but it doesn't have to come from large, randomized clinical trials. We do need to test the hypothesis, and there are various ways to do this. So, it's a little modification of what both sides have said.

"The second issue is sedation and PCA and poor outcomes. First of all, you're going to take on a giant gorilla. The political issues involved in that within the United States around who owns sedation is enormous. This group of 40 to 50 people is not going to resolve these issues. If we look at the deaths that occur, they are probably far greater in the field of sedation than they are in the field of PCA. If you want to tackle an issue of patient safety, tackle sedation before PCA. Yesterday, when talking about PCA and deaths, everybody was talking about opiates, opiates, opiates and analgesia. We really need to get away from opiates. I was a great proponent that opiates are the mainstay of acute pain management; I think that thought process is going away. Although they are clearly a component of pain management, the amount of opiates we use needs to be minimized. It will be of far greater value in patient safety when we can markedly reduce opiate requirements by using alternatives like multimodal therapy and other techniques. We need to educate practitioners about it and really move away from centralizing post-op pain management with PCA. I believe that will save many more lives than trying to monitor these patients."

Peter Glass, *MD*

"I agree with what Peter said. I think there are two points that probably weren't explicitly stated by Dr. Stolting, but as a person who comes up with ideas for designing clinical trials, you have to do an analysis of your outcome and the incidence. As he said, but maybe not explicitly, when the incidence is extremely low, the sample size needed to generate the outcome with a statistical significance is extraordinary. So, it's not practical, because of the low outcome. And the second issue, which we didn't talk about, is that it is also hard to design a clinical trial in humans and get through the IRB because of the ethical concerns. You could argue scientifically whether that's rational or not, but the ethical concerns will limit the ability to answer these questions. So I think a middle ground is going to have to be the way that you look at studies for these rare and serious outcomes. If the outcome is rare, but not serious, it's a different issue, but when it's rare and serious, numbers and ethics really limit your ability to do a randomized, double-blind trial."

Frank Overdyk, *MSEE, MD*

"I was thinking about a clinical trial that addresses the question: 'Does monitoring of PCA patients with continuous oximetry and capnography with a pause protocol reduce the incidence of respiratory depression?' It might be difficult but it certainly is not impossible. I manage three Acute Pain Services in one city that serve a total of 4,000 patients per year, and we have managed to collect data on over 20,000 of these patients using a clinical database tool. Based on these data we found that severe respiratory depression occurs between 0.25% and 1.5% of the time. The proposed study would involve at least two arms, one with continuous monitoring and a control group. The primary outcome would be the incidence of respiratory depression. Considering the baseline risk of respiratory depression and a projected reduction in events by 50% using continuous monitoring, the sample size would likely be between 4,000 and 8,000 patients. So, even in

one city, this study is possible. If you include other centers, the study could be done within a year.

"So, it's not only a good question to ask, it is quite feasible. I would argue that in terms of ethics, there's no question it would get through an IRB because the standard of practice is to do without right now. Does continuous monitoring of every patient make a difference? It's not being done now, and until you test it and until you study it, you don't know the right answer."

James Paul, *MD*

"I'm also a strong advocate for evidence-based practices when I have evidence that is available, but I do think decisions often need to be made without it. I am currently deploying rapid response teams in all of our hospitals. I have never seen a double-blind, controlled, prospective study of the effectiveness of rapid response teams. What I have seen are data from hospitals that know their baseline code status rate and their failure-to-resuscitate rate, put in a rapid response team, and measured the relative effectiveness of those two variables in reducing mortality. There was enough evidence for me to make the decision to implement rapid response teams in my organization because it made sense.

"When I consider our current experience with PCA, it is my perception that we are having bad outcomes, particularly in orthopedic patients – they come in fast, they have very minimal preoperative evaluation, have what is considered a minor procedure, they go through surgery, they are sent to a med-surg floor where the nursing ratio is not 1:1 or 1:2, as in ICU, but actually 1:6. There might be six admissions to the unit that afternoon. The data are imperfect, but what I am seeing is complications that are occurring eight to 10 hours later. Some of those complications are very severe.

"To put an end-tidal CO_2 monitor on every PCA in my organization is going to cost about $350,000.00. One adverse outcome in one of those patients may cost many millions of dollars. The added cost of care in treating all those complications for each of those cases and one that goes to the ICU and ends up on a ventilator for a 21-day stay with further complications is going to take a very big toll on my organization. I'm not comfortable waiting for a double-blind, randomized, controlled, prospective trial, and I think that we have enough baseline information in most of our organizations to see essentially what the behavior was beforehand, and what the behavior is after the intervention."

Tom McCarter, Jr., *MD*

"Just from the preliminary data we have right now from the sites that are actually using sedation and PCA, it's probably easier than we actually think to do the study because the incidence of complications is much greater. If the incidence is greater, a study is even more feasible. If we were implementing a new drug treatment, no one would argue, no one would even dream of mandating it without a study – it would be against the law. The FDA would never approve it. Think about multimodal pain management and the use of COX-2 inhibitors. It makes a lot of sense. If we use multimodal pain management, the amount of narcotic PCA is reduced but unexpected harm might be dis-

covered in a large randomized trial. So, there are unanswered questions, and it is ill-advised to mandate something without a randomized trial, which is not only feasible and possible, but should be done and is probably much easier than we actually think."

James Paul, *MD*

Healthcare Workforce Issues

Much has been said about the shortage of healthcare professionals, particularly nurses. New developments in sedation and pain management may require additional skills that not all healthcare professionals have. Some institutions employ pain management services. On the other hand, perhaps some of the new technologies may make it possible to monitor sedation and pain management more easily. How will workforce issues in healthcare affect these treatments?

"We have a lot of new, novice RNs who have been working with us in our workforce. There's a nursing shortage. So the struggle then becomes, 'How do you get the skill set to these practitioners at the bedside who do not have experience, who are missing very subtle cues, which may be there but only the expert will recognize, and how do we protect the patients, bringing the same quality to all areas of practice, not just to ICU?'"

Regina Izu, *RN, PHN, MSN*

"I'm an ICU nurse, so when I see a patient come in after a PCA event, it's because something's happened on the floor. It is usually respiratory depression, and maybe other things going on with the patient. What I notice is that when these events are reviewed, there is not a formal root/cause analysis, but discussion that the nurse did a poor job. I don't hear people saying the physician over-prescribed the drug. It always sounds to the med-surg nurses like, if you had paid attention, if you had monitored more, this would not have happened. I feel sorry for the med-surg nurses who then get told off. You know something will be reported to the manager, and even if it's a supportive manager, he or she will have to discipline that nurse. People wonder why there is a turnover in med-surg nurses. A lot of it has to do with what seems an almost impossible task in med-surg: you have to see through walls when you're without any help. The onus always seems to be on 'the nurse didn't do a good job.' Anything that could support a nurse without too many nuisance alarms would be extraordinarily helpful."

Mary E. Lough, *RN, MS CNS, CCRN, CNRN*

"The nursing shortage is reality. A good nurse at the bedside could supplant the need for technology to help monitor the patient. We don't have the reality of a nurse being able to be at the bedside in the ratios that it takes to monitor PCA patients, and we need something else there.

"We recently had a patient who came from surgery, received nothing for pain in the PACU, and within two hours went into significant respiratory depression. We know he hadn't received any PCA.

"It's very difficult to guess who's going to need what dose of pain medications postoperatively. I understand limited resources, but it's important to realize that if you are trying to predict, it's going to be very difficult."

Carolyn K. Williams, *BSPharm*

"What resources do we need to take good care of patients? Let's not be satisfied with current nursing-to-patient ratios. I think the #1 thing we should recommend is better ratios. We know that improves patient safety across the board. So I think there should be a mandate about nursing ratios, that it's not safe to have too many patients for one nurse. There's a cost issue as well. I think the second aspect of a mandate would be to empower nurses with defined assessment skills, such as assessing respiratory function for patient on a PCA who should be monitored for the following things, period. The third aspect of a mandate is defining the type of monitoring technology that can be put in place to help us in this system.

"So I would recommend a three-tiered, three-step approach, three levels of saying better ratios at the bedside, better personnel, better monitoring, empowering nurses with standards of how much and what should these patients be monitored for, and using and empowering them with an understanding of how to use the technology."

Brenda T. Pun, *RN, MSN, ACNP*

"No mandated nurse ratio is going to solve this problem, so I want to put that on the table, and this group shouldn't be deciding. You've talked about empowerment. We're talking about patient safety, and that's the focus I would want us to take in this. We're talking about a nursing shortage for a long time, so there's a short-term discussion and a much longer term. If monitoring is what's going to help, I think we should do that."

Pam Almandinger, *RN*

"As far as nursing staffing and ratios go, working with novices and new graduates without experience, and patients with co-morbidities and complexities such as obesity, I think 'Yes, we have ratio concerns; yes, we have skill limitations; but can we identify the patients in med-surg and ortho who are at higher risk, who need a more experienced practitioner?'

"Joint Commission standards now require matching the needs of the patient with the skills of the practitioner. Do we look at changing the variance of staffing for those patients, for a limited amount of time, so that they can get the care that they need? Can we clarify and indicate exactly what caregivers should look for, so even the novice can recognize the signs and the symptoms of clinical problems?"

Regina Izu, *RN, PHN, MSN*

Improving Care with New Technology

Would you look to monitoring based on applying technology, or to having individuals who have better qualifications to perform that function, or both?

"I think there are two issues. One is the sedation that is occurring in cardiac catheterization and other procedure areas where there is a qualification issue. For the patient who is alone in a room for many hours at a time with his or her PCA machine, clearly it's technology that's going to be a factor in improving patient safety."

Richard E. Moon, *MD, FRCPC, FACP, FCCP*

"With PCA there are two problems. One is an inherent problem in PCA: something related to the feedback loop not working properly, even if it's implemented appropriately. We found that this was a problem in some of our patients, and what we did to avoid this was to eliminate the use of continuous infusions with PCA. According to some studies, that may result in decreased pain control efficacy, but there is an increase in safety because the patients will not self-administer doses of an opiate when sedated to the point where they are not pushing the button.

"The other systemic problem with PCA is operator errors. These include programming the pump incorrectly and attaching a syringe with the wrong dose in it. The way we resolved these problems was to use only single, equipotent concentrations of a limited number of opiates for PCA pumps: 1 mg/mL of morphine, 0.2 mg/mL of Dilaudid, and 10 mg/mL of meperidine. The program is always an incremental dose of 1 mL per push button. If the syringe gets swapped, the patient will still get the correct dose. Our complication rate has decreased appreciably. We're a very small hospital, only a couple of hundred beds, and we were seeing one or two respiratory arrests a year, and now we don't have that problem."

Jeffrey B. Gross, *MD*

"I wanted to expand on the value of having dose limits and the data that I saw. You are averaging 11 alerts per month, or one alert every three days of programming errors that are caught by having a drug library with standardized dosing limits."

Tim Vanderveen, *MS, PharmD*

"The dose-limit protections that we have in the devices are wonderful. I do like your idea of each concentration delivering the 1 mL dose being an appropriate dose, that's really an important thing, particularly if you don't have the safety limits. But with the safety limits five elements are protected: loading dose, bolus dose, PCA dose, continuous dose and lockout interval. The 11 alerts per month result from either grossly over or grossly under programming errors that are detected by the devices, and the nurse makes a decision to change the programmed dose based on what's in the orders. For example, on two different cases in one day, the nurse programmed a dose for Demerol, although she had a morphine syringe in the PCA pump. The PCA pump alerted the nurse to the programming error. These dose limit alerts have been invaluable in preventing programming errors."

Carolyn K. Williams, *BSPharm*

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